Analysis of the socio-economic impacts of a harmonised classification of Carcinogen Category 2 for titanium dioxide (TiO_2)

Updated Final Report

prepared for

Titanium Dioxide Industry Consortium

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RPA
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Executive Summary

Introduction

Titanium dioxide (TiO_2) is by far the highest volume and most versatile globally-used white pigment which is also widely used as a brightener for colours other than white. No other pigment comes close to matching its exceptionally high opacity (a result of TiO_2 having the highest refractive index among all known white pigments), bright whiteness and UV absorbing, protective properties. It is manufactured in 18 plants in the European Economic Area (EEA) with an annual production volume of ca. 1,100 ktonnes and an estimated market value of ca. €3 billion. Most TiO_2 is used in paints and coatings (architectural: 36%; industrial: 17%; inks: 4%), followed by plastics (25%), paper (12%) and specialty applications (6%) (based on Cefic data for 2013). Approximately 1-2% of all TiO_2 is made in non-pigmentary forms for use in many high-value-added applications including cosmetic sunscreens and clean air environmental technologies.

The French authorities proposed the classification of TiO_2 as a Carcinogen Category 1B substance in May 2016. Whilst ECHA's Risk Assessment Committee (RAC) has concluded that a Carc Cat 1B classification cannot be scientifically justified, it has also asserted in its opinion dated 14 September 2017 that TiO_2 meets the criteria to be classified as suspected of causing cancer (Carcinogen Category 2) specifically through the inhalation route. Although, a Carc Cat 2 harmonised classification is less severe than that proposed by the French authorities, this classification would still have severe adverse consequences as a result of (a) the absence of technically feasible alternatives for TiO_2; (b) the triggering of a series of changes in how the marketing and use of TiO_2 is treated under a variety of chemical safety regimes in the EEA; and (c) the negative perceptions that would develop among users and consumers over the safety of the substance. These changes would disregard the importance of the TiO_2 exposure pathway specified by RAC in their opinion: in a mixture or matrix of any form, there can be no or extremely low levels of human exposure by inhalation; nevertheless, regulatory changes would simply apply the classification as a carcinogen in all cases, so irrespective of the specificity of the inhalation route, and negative perceptions would develop due to consumers being largely oblivious to this critical parameter.

Impacts on downstream users of titanium dioxide

The Carc Cat 2 harmonised classification would impact upon a multitude of downstream user sectors with a combined Gross Added Value of hundreds of billions of Euros; paints and plastics alone, the most important uses for TiO_2, account for over €120 billion per annum. Downstream users might consider the reformulation of their products, however, in the vast majority of cases this could not be successful due to the lack of alternative pigments that match TiO_2's performance in technical and economic terms; in any case, substitution of TiO_2 would be costly (example estimates: €0.05-60 million per company), take considerable time (2-20 years) and invariably be a case of regrettable substitution. Additional workplace safety measures could have an investment cost of up to €0.1 million, if not more, per plant, while waste regulations would impact upon the recycling and reuse of waste that contains over 1.0% TiO_2 and might impose an additional cost ranging from a few thousand Euros to millions of Euros per site for the disposal of packaging and manufacturing waste classified that would be newly classified as hazardous.

The Carc Cat 2 harmonised classification could lead to the removal from the market of a multitude of consumer formulations and products such as toys, cosmetics, foodstuff, food contact materials, pharmaceuticals, tobacco products and ecolabelled products (including textiles); in some cases exemptions could be secured following an evaluation of risks by relevant scientific bodies, however, the cost of obtaining them could be high (possibly up to millions of Euros to demonstrate low bioavailability).

Importantly, the labelling of TiO_2-containing mixtures as suspected carcinogens (CLP requires the label to read "suspected of causing cancer") and the stigmatisation of the substance would drive negative consumer and industrial/professional user perceptions thus leading to market losses for manufacturers of TiO_2-containing products and their downstream supply chains.

Impacts on titanium dioxide manufacturers and their suppliers

It is estimated that a Carc Cat 2 classification would lead to 10-15% of current demand for TiO_2 being lost due to adverse effects on the downstream uses of the substance. This would in turn lead to the shrinking of EEA's TiO_2 manufacturing base and the likely shutdown of an uncertain number of production lines. The consequence of this would be a significant knock-on effect on the manufacture of titanium chemicals and iron-based co-products, the sales of which underpin the profitability of TiO_2 manufacturing plants. Adverse impacts would not be limited to those driven by effects on downstream users; the Carc Cat 2 harmonised classification would impact upon the sales of co-products (iron filter salts) that contain TiO_2 impurities at concentrations above 0.1% and would also have the potential to precipitate severe repercussions on the waste management of large volumes of manufacturing waste (neutralisation solids and red gypsum) which (a) could require disposal as hazardous materials and (b) would prevent sale of such materials for reuse in a range of industry sectors. Loss of sales and severely increased waste management costs could lead to the ultimate collapse of EEA's TiO_2 manufacturing base.

Looking only at TiO_2 manufacture, in the context of an EEA market value of ca. €3 billion, its Gross Added Value to the EEA economy is estimated at ca. €560 million per annum, excluding other socio-economically important co-products and by-products; the industry employs ca. 8,150 workers and is responsible for the creation of a further 22,800 directly related support jobs. The adverse impacts from the Carc Cat 2 harmonised classification could result in the loss of thousands of jobs across the EEA. Decimation of EEA's TiO_2 manufacturing base would impact upon both EEA-based and non-EEA supply chains as exports account for one-third of EEA manufacture while some TiO_2 grades are only produced by European plants.

Finally, a Carc Cat 2 harmonised classification would also cause market losses for two Norwegian feedstock manufacturers and would affect the trade of ca. 4 million tonnes of raw materials used in the manufacture of TiO_2.

Impacts on EEA competitiveness

EEA businesses would become less competitive both domestically and overseas and, over time, some parts of the value chains might consider relocating outside the EEA, unless a similar hazard classification was also adopted by non-EEA jurisdictions. For TiO_2 manufacture, production of the pigment outside the EEA would likely significantly increase in order to supply global demand. Downstream SMEs in the EEA would be particularly vulnerable to the loss of a critical raw material or articles that depend on it.

Impacts on EEA workers

TiO_2 formulations and articles are used by millions of workers; by way of example, 1 million workers apply paints/coatings and 4.5 million workers are involved in the use of plastics. Even if the Carc Cat 2 harmonised classification caused the loss of jobs for only a modest percentage of this workforce, the total number of jobs lost across all EEA would be significantly high. Impacts would not be limited to industries that use TiO_2 as a raw material; the re-classification of TiO_2-containing products such as coatings would also affect employment in downstream industries that use these products.

Impacts on the marketing and use of other minerals

The handling, processing and use of minerals that contain TiO_2 impurities at up to 4% by weight (e.g. kaolin, a mineral often referred to as a potential partial replacement for TiO_2, bentonite, mica, ball clays and refractory materials) would be affected. Combined, these minerals are used in the EEA in a volume of over 20 million tonnes per year and have a market value of over €3.3 billion. The volumes and market value of downstream products of these minerals are even larger.

In its September 2017 opinion, RAC acknowledges that the carcinogenicity profile described for TiO_2 is not exclusively characteristic of TiO_2 but applies to a group of chemicals with similar toxicity profile addressed as "poorly soluble low toxicity particles". Thus, adoption of this proposed Carc Cat 2 harmonised classification could open the pathway for the classification of other poorly soluble powders, including many minerals that might be considered potential (partial) substitutes for TiO_2.

Impacts on consumers

Consumers would face a reduction in product availability and choice, increased market prices, significantly increased costs for redecoration and maintenance tasks if these can as a result of the classification only be undertaken by professionals (thus impacting, in particular, consumers on low incomes), loss of performance, poorer aesthetics and also loss of a safe, effective UV filter in sunscreens and other cosmetics if use of TiO_2 was banned. More broadly, the hazard classification of a substance used so widely (including in food and medicines) for suspected carcinogenicity arising through an improbable, if not impossible, exposure pathway (inhalation) for the products concerned, could cause uncertainty and confusion which could damage the confidence consumers have in health protection rules and government decision-making and damage consumer confidence in the reliability and accuracy of label information. Paints, coatings, adhesives, sealants and generally consumer mixtures which typically contain TiO_2 in excess of 1.0% by weight (NB. detergent formulations may not) will be required to be labelled with "*suspected of causing cancer (through inhalation)*", but the meaning of this to a consumer would be unclear. It is not explicit, nor can it be made explicit on the label under CLP, that this refers to inhalation of TiO_2 dust particles and not to inhalation of the paint/coating/mixture more generally.

Conclusion

This high-level impact analysis demonstrates that the Carc Cat 2 harmonised classification for TiO_2 proposed by the RAC, similar to the original French proposal for a more severe Carc Cat 1B classification, would result in severe social and economic cost impacts, firstly for the manufacturers of the substance, secondly for the multitude of downstream users of TiO_2 in a diverse range of industry sectors, thirdly on the marketing and use of a vast array of industrial, professional and consumer products and finally on the employment of a very significant number of workers. Whilst quantification of these impacts has generally not been possible (due to, among other reasons, the impacts partly being driven by negative user and consumer perceptions; studies show that consumers read labels and do not understand them. There has been no research into how consumers, or indeed retailers, would respond to a label which says: "*suspected of causing cancer via inhalation*" which would be the required label wording under the CLP Regulation), the sheer volume and range of uses and products that would be affected points to a very significant adverse effect on EEA society as a whole.

This report gives particular emphasis on impacts arising from the labelling of mixtures that contain TiO_2, potential restrictions arising for the marketing and use of the substance in products such as toys, cosmetics, food contact materials, foodstuff and pharmaceuticals as well as products that are currently awarded an ecolabel. It also highlights the waste management impacts of a Carc Cat 2 classification of TiO_2. While some regulatory impacts of a Cat 2 harmonised classification could be considered less severe than a Cat 1B classification, this is not true for waste and its management in the EEA. Waste management impacts for both manufacturers and downstream users are considered in detail in this report and available information indicates significant cost increases for the management of waste which would be classified as hazardous if it contains above 1.0% TiO_2. Whilst Cefic has estimated that the price for treatment of waste classified as hazardous can be 2 to 3 times the price for the same material classified as non-hazardous, information from consultation would suggest a much higher price differential of 10-30 times (by way of example, the UK landfill tax for one tonne of hazardous waste is ca. 31 times higher than the respective tax rate for non-hazardous waste).

Impacts on waste management need to be seen in a wider policy context. One of the current major policy issues of the EU is the Circular Economy, where two of the objectives are: to reduce use of the earth's natural resources (which are by definition limited) and to encourage recovery from articles/products already in use via, for example, recycling, reuse, remake and energy recovery. Waste legislation and waste management are currently in the spotlight as their role in contributing to Circular Economy objectives is critical. In any event, objectives clearly aim to reduce landfill and incineration as ways of dealing with waste. In the context of the Circular Economy, the concepts underlying the current debates include the objectives to: (a) encourage and increase the volume of waste recovery (with multiple initiatives to do so including significant investment in relevant innovation research) and thereby reduce the volume of wastes that are incinerated and (b) aim to ensure that waste streams available for recycling and reuse do not contain hazardous waste and by extension, thereby reduce the amount of non-hazardous waste incinerated. The implications of a Carc Cat 2 harmonised classification would be three-fold:

- Many applications of TiO_2 generate waste streams which will or could become classified as hazardous waste under the Waste Framework Directive. Given the very wide spread of applications of TiO_2 in industrial and consumer products, the sheer volume of waste potentially reclassified as hazardous could in itself have a significant impact on waste management;

- Classification of several TiO_2-containing waste streams as hazardous would have a very detrimental effect on their recycling and reuse. An important example in this regard is plastic packaging waste where the value chain would be severely impacted by any adverse effect on recycling activities; and

- TiO_2-containing waste classified as hazardous would require specialist disposal. If incineration is selected as the appropriate waste management option, such waste would have to be shipped to special incineration plants. It is reported that there are currently insufficient hazardous waste incineration plants in the EU to deal with increasing volumes of waste classified as hazardous and that in some cases it is difficult to get planning permission to build them.

In conclusion, the classification of TiO_2 as Carc Cat 2 would have significant impacts in terms of non-industrial waste management and negative impacts on the EU's Circular Economy objectives.

On the other hand, it must be emphasised that the proposed classification as Carc Cat 2 would bring little, if any, gain with respect to the safe use of TiO_2 and thus it would fail to contribute to the improvement of the protection of worker and consumer health. Comprehensive in-depth analysis of available epidemiological data from TiO_2 production workers exposed via inhalation demonstrate no correlation between long-term exposures to TiO_2 and lung tumours or other chronic lung disorders. TiO_2 as a respirable powder is a representative of poorly soluble particles with low toxicity (PSLTs). The relevant mode of action of PSLTs by chronic inhalation are particle-induced inflammatory reactions in the lung as a result of overburdened natural cleaning processes ("lung overload"). Such inflammatory reactions are accompanied by an effect threshold below which no effects occur (NB. RAC considers it plausible to assume a practical threshold). Inhalation exposure of workers during industrial use of TiO_2 in its powder form can be feasibly kept below the effect threshold through adherence to an appropriate Occupational Exposure Limit for workers. On the other hand, inhalation exposure to TiO_2 dust during professional and consumer use of TiO_2-containing products is impossible or highly improbable, at extremely low levels and infrequent.

Finally, since the Carc Cat 2 harmonised classification is based on studies on the loading of rat alveolar macrophages where the mode of action for lung carcinogenicity cannot be considered "intrinsic toxicity" in a classical sense, it would be relevant for all potential alternatives which are also PSLT particles (including minerals such as kaolin, chalk, talc, etc.). The use of such alternatives, which in the vast majority cases is technically infeasible anyway, would therefore not lead to an overall reduction in exposure to poorly soluble particles of low toxicity.

Overall, classification of the substance as a suspected carcinogen fails to meet the requirement for proportionality; harmonised classification as a Carc Cat 2 is not necessary to achieve the objective of protecting the health of workers and consumers while it leads to highly disproportionate costs for society and stigmatisation of the substance irrespective of its form or route of potential exposure.

1 Introduction to the analysis

1.1 Background to this report

The French authorities submitted a proposal for a new harmonised classification (CLH) for titanium dioxide (TiO_2). The proposal was to classify the substance as a carcinogen category 1B by inhalation and it was made available for public consultation on the ECHA website on 31 May 2016 with a deadline of 15 July 2016 for submission of comments. During this period, the Titanium Dioxide Manufacturers Association (TDMA) submitted extensive comments as did numerous other stakeholders, the vast majority of whom have expressed severe reservations over the validity of the scientific arguments made in the French proposal but have also highlighted the potential adverse effects from the proposed classification across the TiO_2 supply chains.

Indeed, a harmonised classification of Carc Cat 1B would clearly have significant repercussions on the manufacture and use of the substance in the EEA. Furthermore, the presence of TiO_2 in several minerals placed on the market at discernible concentrations and the commonality of the key principles on which carcinogenicity is claimed in the French proposal between TiO_2 and other poorly soluble powders could mean that the proposed harmonised classification might have significant direct and indirect adverse impacts on other supply chains.

Risk & Policy Analysts Ltd (RPA), an independent consultancy, was contracted by the Titanium Dioxide REACH Industry Consortium (TDIC) to prepare a review of the regulatory impacts and an analysis of socio-economic impacts from the proposed harmonised classification. A final report was submitted to the TDIC on 15 March 2017.

Following deliberations with ECHA's Risk Assessment Committee (RAC), RAC adopted an opinion on 14 September 2017[1] in which the proposal for a Carc Cat 1B harmonised classification is rejected. However, the RAC believes that the available scientific evidence meets the criteria in the CLP Regulation to classify TiO_2 as a substance suspected of causing cancer through the inhalation route (Carc Cat 2, through the inhalation route).

The definitions of the two hazard classifications as prescribed in Annex I, Part 2, Section 3.6 of the CLP Regulation (EC) No 1272/2008:

- **Carcinogenicity Category 1B**: a substance classified as Carc Cat 1B is presumed to have carcinogenic potential for humans and its classification is largely based on animal evidence; and
- **Carcinogenicity Category 2**: a substance classified as Carc Cat 2 is suspected to be a human carcinogen. The placing of a substance in Category 2 is done on the basis of evidence obtained from human and/or animal studies, but which is not sufficiently convincing to place the substance in Category 1A or 1B, based on strength of evidence together with additional considerations (described in Section 3.6.2.2 of Annex I to the CLP Regulation).

It has thus been deemed appropriate to review and revise RPA's report from March 2017 to take into account the RAC's conclusion, i.e. to assess what the socio-economic impacts of a Carc Cat 2 (as opposed to a Carc Cat 1B) classification would be.

[1] Available at https://echa.europa.eu/documents/10162/6cf0942a-6e18-5ce9-fc95-5cd7fd2fbdad (accessed on 19 October 2017).

1.2 Consultation activities

The analysis presented herein is based to a large degree on information collected from numerous actors along the TiO_2 supply chain; information was also collected from concerned stakeholders outside of the supply chain. Consultation was undertaken in three phases:

- **First round of consultation on a Carc Cat 1B classification**: the first phase was conducted between mid-May 2016 and end of June 2016 and consisted of the circulation of a short initial questionnaire. 165 completed questionnaires were submitted by trade associations and individual companies. As had been expected, paints and plastics accounted for the majority of applications (over 80%). Printing inks and cosmetics also appeared to be widespread applications among the sample of respondents. Information collected included details of the TiO_2 concentration in products (0.01% wt. to 80% and even close to 100% in pigment formulations), the presence of SMEs in key industry sectors and the availability of alternatives (two out of three downstream users (or their representatives) had no knowledge of alternatives and the minority of respondents who have identified specific alternatives for TiO_2 indicated obsolescence, technical disadvantages and lower cost-effectiveness than TiO_2). The vast majority of respondents (over 80%) indicated that the proposed classification would have significant socio-economic impacts;

- **Second round of consultation on a Carc Cat 1B classification**: the second phase of consultation was conducted in the period between August 2016 and October 2016. A large number of trade associations and individual companies-downstream users of TiO_2 were contacted with a more detailed questionnaire. In addition, trade associations representing the producers of other poorly soluble powders were contacted with a separate questionnaire. As of 4 October 2016, 116 completed questionnaires had been submitted by 31 trade associations and 85 individual companies. Again, paints accounted for the majority of responses. Information collected included details of the tonnages of TiO_2 used and the value of the products containing it, the availability of alternatives and the potential impacts from the proposed classification. The information collected has been used in the preparation of this report. Information submitted by individual companies is generally used anonymously for reasons of confidentiality; and

- **Consultation on impacts from a Carc Cat 2 classification**: following the announcement by ECHA that RAC is looking into a Carc Cat 2 harmonised classification, RPA was tasked with revising its earlier written output. Part of this process was a targeted consultation with selected trade associations and industry experts on the impacts of the hazard classification on the management of waste that contains or consists of TiO_2. Consultation was undertaken during the period September-November 2017.

2 Properties of titanium dioxide

TiO_2 consists of four-valent titanium and two-valent oxygen ions. It is a solid under normal conditions and it first begins to melt at over 1800 °C. Its stability, even at high temperatures, and its pronounced slowness of reaction are worthy of note. A peculiarity of TiO_2 is its ability to lose relatively easily a small part of its oxygen from the crystal lattice. These very small oxygen losses cause great changes to the optical and electrical behaviour of TiO_2. On the one hand, it makes itself apparent in colour-shifts towards blue-grey and, on the other hand, the dielectric properties and the electrical conductivity are influenced to an unexpectedly high degree. This peculiarity is partly the reason for the striking photoelectric properties of TiO_2 (Kronos, 1968).

TiO_2 is insoluble in water, in organic solvents, in all alkalis and acids with the exception of sulphuric and hydrofluoric acids and it is polymorphous. Its three modifications, rutile, anatase and brookite, are all found in nature. Rutile and anatase are the technically important ones.

TiO_2 has a range of very significant properties that drive its usability in a wide range of applications. These are summarised below but are also frequently referred to in the rest of this report.

1. **It possesses the highest light scattering among known white pigments, which is responsible for the good hiding power, opacity and ability to lighten coloured media.**
2. **It acts as a base for the development of a very wide range of colours.**
3. **It is characterised by high efficiency, as only small additions can deliver the desired pigmentation.**
4. **It confers exceptional stability to heat, light and weathering.**
5. **It demonstrates high absorptive power in the UV region, which prevents the ageing of materials, the spoilage of packaging contents and the adverse effects of UV radiation on human skin.**
6. **It is approved as safe for use in foodstuff, pet foods, packaging, pharmaceuticals and cosmetics.**
7. **Its photocatalytic activity allows its use in many novel products, such as self-cleaning surfaces and air cleaning materials.**
8. **It shows favourable processing characteristics as TiO_2 pigments can be readily dispersed, achieve rapid wetting at low viscosities and remain inert in the presence of other formulation components.**
9. **Its capability to reflect light also enables heat to be reflected thus allowing lower energy use in the cooling of buildings or other infrastructure.**
10. **It is a perfect support for catalysis and especially the Selective Catalytic Reduction (SCR) of NO_x. These TiO_2-based SCR catalysts have been used since the 1980s in power plants to allow them to meet NO_x emissions standards with an estimated removal of 110 million tonnes of NO_x in the last 35 years** (Pasquier, 2016)**.**

3 Supply chain overview

3.1 Titanium dioxide feedstock and production

3.1.1 Titanium dioxide feedstocks

The mineral sands[2] industry is the main supplier of titanium raw materials for the production of TiO_2 feedstocks. TiO_2 is produced from ilmenite, rutile or titanium slag. According to the US Geological Survey (USGS, 2017), the global mine production of ilmenite in 2016 was estimated at being 5.9 million tonnes, while mine production for rutile was estimated at 0.74 million tonnes. Major producers of ilmenite include China, Australia, Vietnam, Mozambique, Kenya and Norway, while for rutile major producers include Australia, Sierra Leone, Ukraine, Kenya and South Africa (USGS, 2017). Overall, the largest producers of titanium dioxide feedstock are China (18%), Australia (17%), South Africa (15%) and Canada (11%) (Iluka, 2015).

There is no mining operation in the EU, but Titania AS (owned by Kronos) operates a mine in Tellnes, Norway. The ilmenite ore deposit was discovered in 1954 and is one of the world's largest[3]. Another facility, also in Norway, operated by TiZir Titanium & Iron produces titanium slag from ilmenite imported from Senegal. Production in Tyssedal, Norway started in 1986[4].

3.1.2 Titanium dioxide production processes

The overall process of manufacture is to take an impure TiO_2 feedstock and to convert this into the pure white TiO_2 pigment. In essence, the process sounds very simple but to achieve this it is necessary to chemically convert the impure TiO_2 into another chemical, separate out the impurities then to convert back to pure TiO_2 — in effect a chemical purification (McNulty, 2012). Pure TiO_2 is produced by two processes, the sulphate process and the chloride process, presented in **Figure 3–1**. The following table highlights some key technical differences between them.

Table 3–1: Comparison of the processes used to produce TiO_2

Sulphate process	Chloride process
Older process – used since 1920s	Newer process – used since 1950s
Lower grade feedstock used	Higher grade feedstock used
Can produce both rutile and anatase	Produces only rutile
Dominates in China, significant capacity in Europe	Dominates in North America and more widespread than sulphate in Rest of World
In Europe, 55% TiO_2 is produced via the sulphate route	In Europe, 45% of TiO_2 is produced via the chloride route

[2] Mineral sands are old beach sands that contain concentrations of the important minerals, rutile, ilmenite, zircon and monazite. These minerals are heavy and are also called 'heavy minerals'. The relative density of common sand minerals such as quartz is around 2.65.

[3] Information available at http://kronostio2.com/en/manufacturing-facilities/hauge-norway (accessed on 25 October 2016).

[4] Information available at http://www.tizir.co.uk/projects-operations/tyssedal-tio2/ (accessed on 2 November 2016).

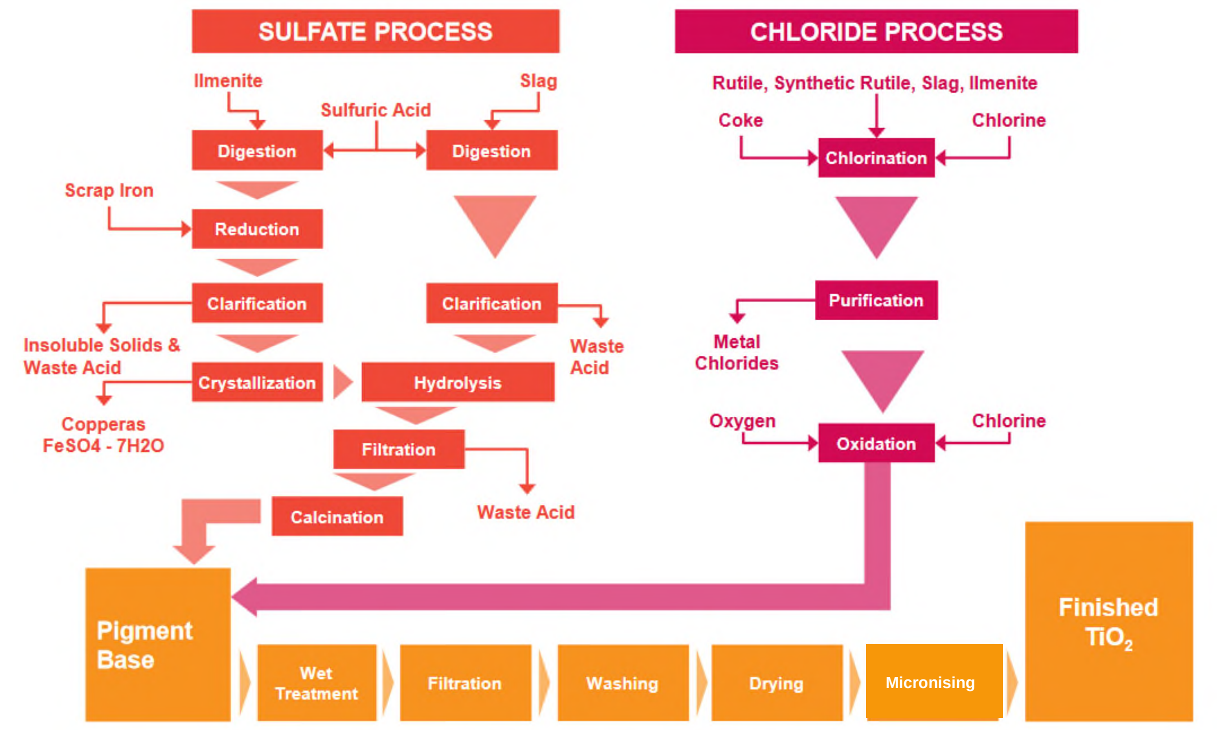


Figure 3–1: Chloride and sulphate TiO_2 production processes
Source: Chemours (2015)

The overall chemistry of the sulphate process can be represented as (McNulty, 2012):

$$FeTiO_3 + 2H_2SO_4 \rightarrow TiOSO_4 + FeSO_4 + H_2O$$

$$TiOSO_4 + H_2O \rightarrow TiO_2n.H_2O + H_2SO_4$$

$$TiO_2n.H_2O \rightarrow TiO_2 + n.H_2O$$

The sulphate process is more complicated in terms of the number of unit operations involved. On the other hand, the overall chemistry of the chloride process can be represented as (McNulty, 2012):

$$TiO_2 + C + 2Cl_2 \rightarrow TiCl_4 + CO + CO_2$$

$$TiCl_4 + O_2 \rightarrow TiO_2 + 2Cl_2$$

In general, higher-grade (% TiO_2) feedstocks are used for the chloride process than for the sulphate process (McNulty, 2012). Australia produces mainly chloride feedstocks; South Africa predominantly produces sulphate ilmenite, which is upgraded to chloride slag with ilmenite also produced in other African countries, including Madagascar and Mozambique. Canada produces sulphate slag and upgraded slag, while China mines mainly sulphate ilmenite from hard rock deposits, which is sold directly or upgraded to sulphate slag (Iluka, 2015).

It is reported that 90% of global TiO_2 feedstocks is used in the manufacture of pigment. The rest is used for the production of welding rods (for example, in steel construction and the ship building industry), or titanium metal (via sponge) for a variety of high-tech aerospace and military applications, medical and sporting equipment (Iluka, 2015).

3.2 Titanium dioxide pigment production

3.2.1 Types and forms of titanium dioxide pigment

Differentiation by crystal form

TiO_2 is a polymorphous and simple inorganic compound, existing in three fundamental crystal forms. All three forms, anatase, rutile and brookite, occur naturally but the latter is rare, and although it has been prepared in the laboratory, it is of no commercial interest (Gázquez, et al., 2014). The chloride production process allows the production of only rutile TiO_2 and is primarily suited for large volume production of standard TiO_2 grades. The sulphate production process is capable of producing both the rutile and anatase grade of TiO_2 (Rockwood, 2012). The key differences between the two commercial crystal forms are shown below.

Table 3–2: Comparison of the two commercial crystal forms of TiO_2

Parameter	Rutile	Anatase
Stability	More stable	Less stable
Lattice structure	Titanium is surrounded octahedrally by six oxygen ions. Each octahedron shares two of its twelve edges	Titanium is surrounded octahedrally by six oxygen ions. Each octahedron shares four of its twelve edges
Density	4.2 g/cm^3	3.9 g/cm^3
Refractive index, opacity	It has the highest refractive index of any white mineral and so it can confer very high opacity	Delivers sufficient opacity, not as high refractive index
Dispersion	Good dispersion	Better dispersion
Production process	Made with both sulphate and chloride processes	Made only by sulphate plants
Global market share	More widely used	Less widely used
Main use sectors: paints, coatings, plastics, paper, inks	Main area of use	May be used
Minor use sectors: fibres, food, cosmetics, pharmaceuticals	Typically, not used in food, pharmaceuticals, fibre applications. Preferred in cosmetics where UV absorbance is important	Used in food, pharmaceuticals, fibres. Not preferred where UV absorbance is important
Source: Kronos (1968); Rockwood (2012)		

Differentiation by particle size

There are two grades of TiO_2 with respect to particle size: pigmentary TiO_2 and nano-scale TiO_2.

Pigment grade TiO_2 has primary particles mainly in the size range of 200–350 nm (TEM[5]) as this is the optimum for scattering visible light; the surface area is typically from 6 to 60 m^2/g (coated and uncoated). Pigmentary TiO_2 is used due to its excellent light-scattering properties, white opacity and brightness and absorbance of UV light. When TiO_2 is incorporated into a polymer, it minimises the degradation of the system (embrittlement, fading and cracking) (TDMA, 2013).

On the other hand, nano-scale (also known as ultrafine) TiO_2 is engineered to have primary particles of a size less than 100 nm with a surface area varying typically from 50 to 200 m^2/g (coated and uncoated).

[5] Transmission Electron Microscopy.

This is a product used when different properties such as transparency, semi-conductive properties and maximum UV light absorption are required.

Applications of nano-scale TiO_2 include (Rockwood, 2012; IHS, 2015; StatNano, 2014; TiPMC, 2015; TDMA, undated; Gázquez, et al., 2014):

- Cosmetic sunscreens (for UV ray absorbance);
- Generation of innovative colour variations for paints and coatings ("frost effect");
- Photocatalysis applications such as surface self-cleaning and wood protection;
- Arsenic removal in wastewater treatment;
- Catalysts supports in the automotive industry to remove harmful exhaust gas emissions, and in power stations to remove nitrous oxides (NO_x);
- Precursors for electronics and energy storage materials; and
- Colour pigment precursors and intermediates for special (electro) ceramics, including dye-sensitised solar cells ("DSSC").

Nano-scale TiO_2 represents only a small proportion of total TiO_2 pigment production. In 2010, it was estimated that the volume of nano-scale TiO_2 would increase at the global scale from ca. 50,000 t/y (representing only 0.7% of the market) to over 200,000 t/y (Research and Markets, 2011). This increase has not yet materialised; instead it has been indeed estimated to be limited to between ca. 1% of the TiO_2 market (TiPMC, 2015) and 2% (TDMA, undated)

3.2.2 Titanium dioxide production capacity and locations

Global producers of titanium dioxide

The first commercial TiO_2 pigment manufacturing plant was set up in 1918 by Titan Co A/S, forerunner of Kronos Titan (Chemours, 2015). According to the US Geological Survey, global TiO_2 production capacity in 2016 was 7.4 million tonnes with largest players being China (ca. 2.9 million tonnes), United States (ca. 1.3 million tonnes), Germany (ca. 0.46 million tonnes), Japan (ca. 0.31 million tonnes) and the United Kingdom (0.3 million tonnes). As of 2015, the most prominent global producers of TiO_2 (i.e. those holding at least 5% of the global market) included, in descending order:

- The Chemours Company;
- Huntsman Pigments;
- Cristal;
- Henan Billions + Lomon;
- Kronos Worldwide; and
- Tronox LLC.

It is important to note two recent developments in the TiO_2 manufacturing industry. Firstly, in late February 2017, it was announced that Cristal had signed a definitive agreement for the acquisition of its TiO_2 business, by Tronox LLC. The transaction would create the largest TiO_2 company in the world, based on titanium chemical sales and nameplate capacity[6]. The transaction was expected to close before the first quarter of 2018. Secondly, in January 2017 Huntsman Corporation announced that it

[6] Information available at http://www.cristal.com/news-room/news/Pages/Cristal%20and%20Tronox%20Sign%20Transaction%20Agreement.aspx (accessed on 21 August 2017).

would spin off its Pigments and Additives business under a new name, Venator Materials Corporation[7].

EEA producers of titanium dioxide

Focusing on the EEA, the main TiO_2 producing countries are shown in **Figure 3–2**. Germany, the United Kingdom, and Finland combined represent over 60% of EEA production capacity. The figure takes into account recent closures of capacity in France (ICIS, 2016; ICIS, 2007b). Overall capacity is at ca. 1,500 ktonnes.

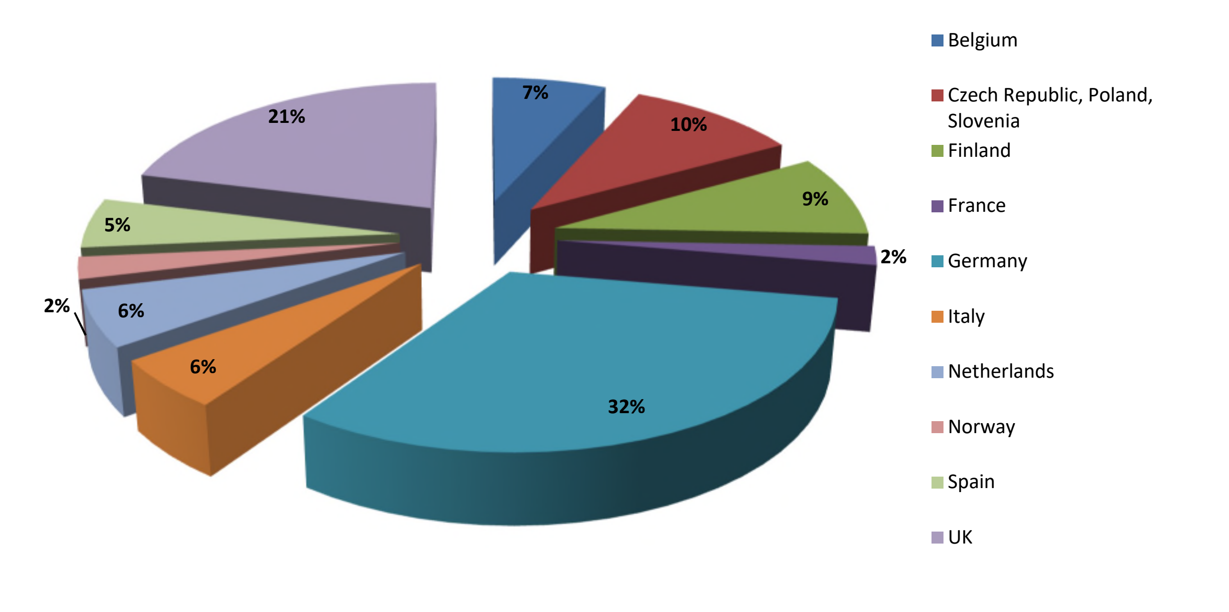
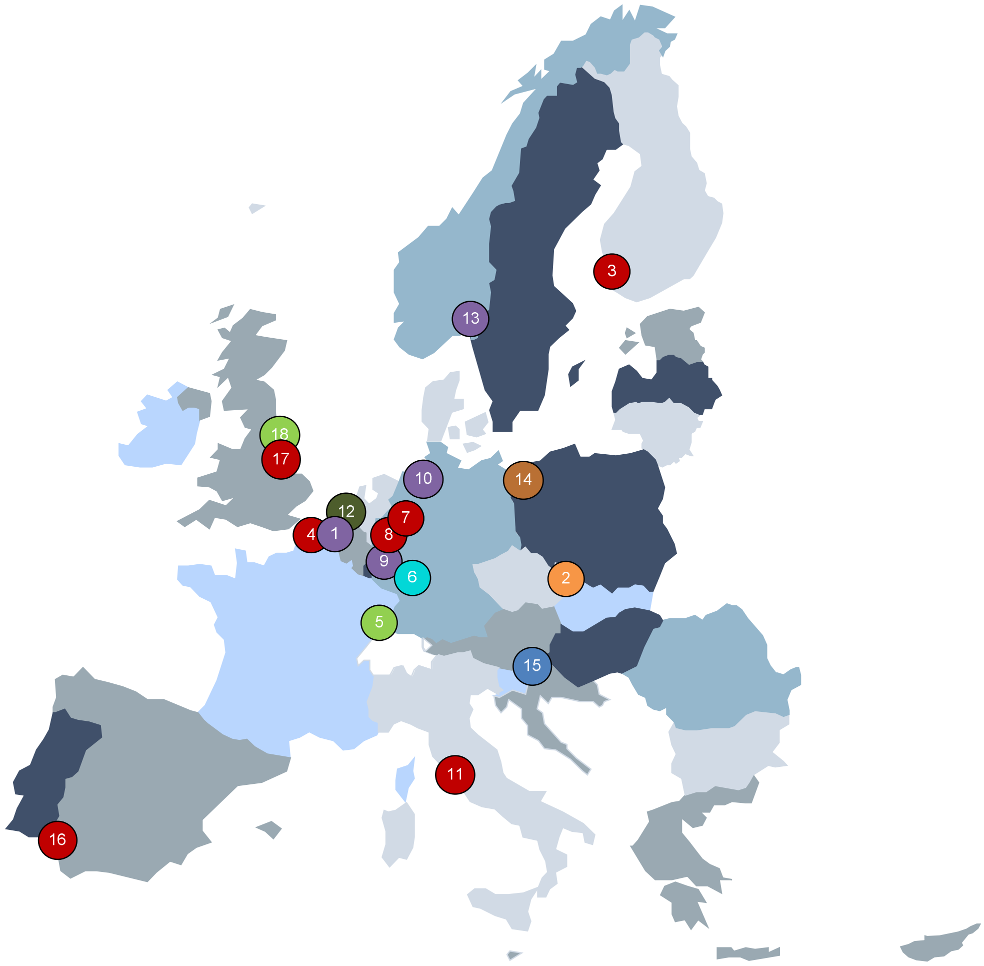


Figure 3–2: Main TiO_2 producing countries in the EEA (shares based on nameplate production capacities)
Source: USGS (http://minerals.usgs.gov/minerals/pubs/commodity/titanium/mcs-2016-titan.pdf) and data from TDMA members

Table 3–3 (overleaf) presents all eighteen EEA TiO_2 production plants. **EEA accounts for almost 20% of the total worldwide production**. It is further known that some TiO_2 production also occurs in Ukraine (by two companies, Krymsky Titan and Sumykhimprom).

[7] Information available at http://www.huntsman.com/corporate/Applications/itemrenderer?p_rendertitle=no&p_renderdate=no&p_renderteaser=no&p_item_id=998540193&p_item_caid=1123 (accessed on 21 August 2017).

Table 3–3: TiO_2 production facilities in the EEA



#	Country	Company	Location	Process
1	Belgium	Kronos	Langerbrugge	Chloride
2	Czech Republic	Precheza	Prerov	Sulphate
3	Finland	Venator Materials	Pori	Sulphate
4	France	Venator Materials	Calais (finishing only)	Sulphate
5	France	Cristal	Thann	Sulphate
6	Germany	Evonik	Hanau	"Chloride"
7	Germany	Venator Materials	Duisburg-Homberg	Sulphate
8	Germany	Venator Materials	Krefeld-Uerdingen	Sulphate
9	Germany	Kronos	Leverkusen (2 plants)	Both
10	Germany	Kronos	Nordenham	Sulphate
11	Italy	Venator Materials	Scarlino	Sulphate
12	Netherlands	Tronox LLC	Rotterdam-Botlek	Chloride
13	Norway	Kronos	Fredrikstad	Sulphate
14	Poland	Grupa Azoty Zakłady Chemiczne "Police" SA	Police	Sulphate
15	Slovenia	Cinkarna	Celje	Sulphate
16	Spain	Venator Materials	Huelva	Sulphate
17	UK	Venator Materials	Greatham Works	Chloride
18	UK	Cristal	Stallingborough	Chloride

Source: based on AEA Energy and Environment (2007) and information from TDMA members

The following EU companies are full members of the Titanium Dioxide Manufacturers Association at Cefic:

- Cinkarna Celje d.d.;
- Cristal;
- Evonik Resource Efficiency GmbH;
- Grupa Azoty Zaklady Chemiczne "Police" S.A.;
- Kronos;
- Precheza AS;
- Tronox LLC; and
- Venator Materials.

Associate members include The Chemours Company, Tayca and Loman Billions.

Finally, with regard to the production of nano-scale TiO_2, the global production capacity is only a fraction of total TiO_2 production and amounts to an estimated 80,000 t/y (TiPMC, 2015).

3.3 Consumption of titanium dioxide pigments

There are several sources of information regarding the consumption of TiO_2 in the EEA and its origin. Having considered electronic sources and information available to TDMA members, the following key figures are established as relevant to this analysis:

- The demand (consumption) of TiO_2 in the EEA was ca. **1,100 ktonnes** in 2015 compared to a global demand of just below 6 million tonnes, thus EEA demand accounts for ca. 20% of global demand for TiO_2;
- EEA demand comprises 67-68% EEA-produced TiO_2 and 32-33% TiO_2 imported from outside the EEA, the majority coming from the USA, Mexico and China[8]; and
- EEA exports of TiO_2 amounted to 360 ktonnes in 2015.

This breakdown is presented in **Figure 3–3**. To put these figures into further perspective, TiO_2 is one of the most consumed pigments globally alongside widely used substances such as calcium carbonate, kaolin and carbon black.

[8] An analysis prepared by the European Commission in 2014 on the basis of 2012 data had found that 31% of EEA consumption was being imported into the EU and of this, the largest share (14%) came from North America, 7% came from the Asia-Pacific Region, 5% was imported from Latin America, 5% was imported from other European countries and 1% was imported from Africa and the Middle East. The EEA exported 399 ktonnes and imported 342 ktonnes TiO_2 in 2012. Except for the NAFTA region, the EEA was a net exporter vis-à-vis every other world region (European Commission, 2014).

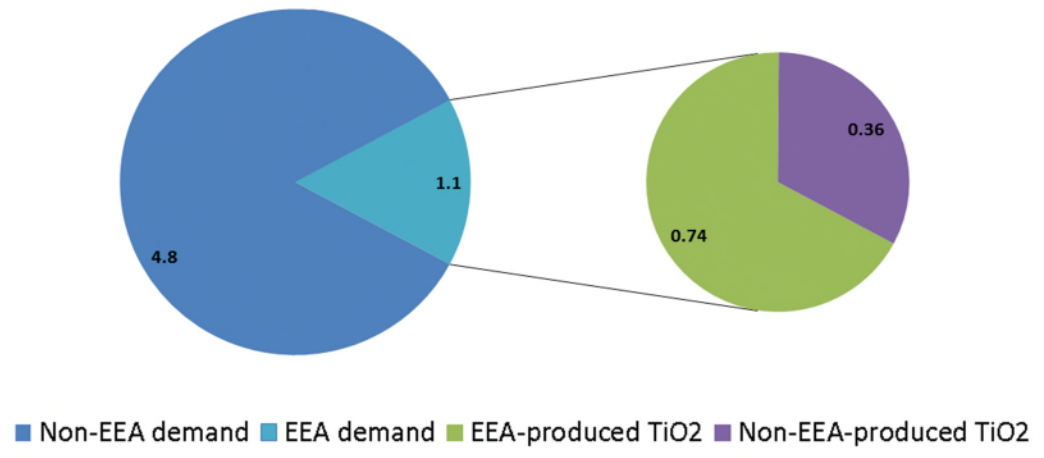


Figure 3–3: Demand and origin of EEA consumption of TiO_2 (2015) – All figures in million tonnes per year
Source: information from TDMA members

There are several drivers behind future demand for TiO_2 pigments, as shown in **Figure 3–4**. Location-wise, the real driver to growth is China, where the coatings and plastics industries continue to expand at high rates (IHS, 2015). Per capita consumption of TiO_2 in China is about 1 kilogram per year, compared with 2.7 kilograms for Western Europe and the USA (IHS, 2015).

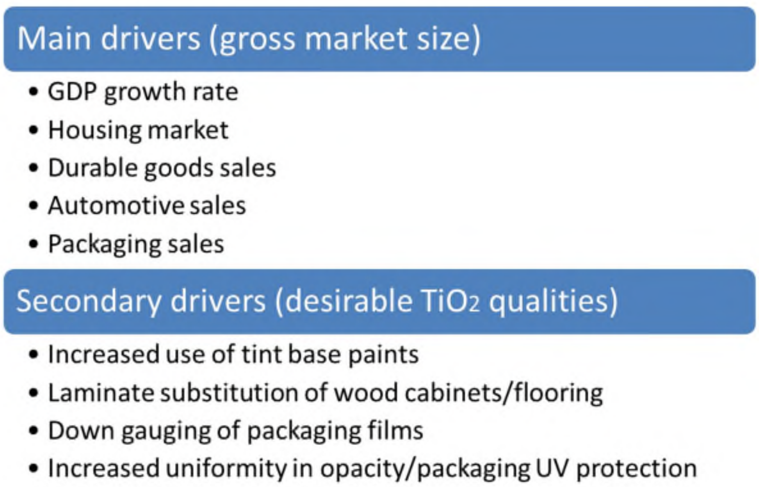


Figure 3–4: Key drivers behind demand for TiO_2 pigments (2014)
Source: Chemours (2015)

3.4 Applications for titanium dioxide

3.4.1 Overview

Table 3–4 summarises publicly available information on the breakdown of the global consumption of TiO_2 pigment for the years 2013[9]. Other sources are available with somewhat variable percentages for specific market segments over the years.

[9] Note that more recent figures may be available; this is currently under investigation.

Table 3–4: Global TiO_2 pigments consumption breakdown by end-use sector	
End-use sector	**Year: 2013**
Paint	53% (assumed architectural 36% and industrial 17%)
Plastic	25%
Paper	Laminates: 10%; Paper: 2%
Inks	4%
Specialty	Food, Pharma, etc.: 1%; Catalysts: 1%; Other (e.g. cosmetics): 4%
Source: Cefic, aggregates of TDMA members' data	

The table identifies four key market segments: paints (incorporating functional coatings and construction products), plastics, paper and inks. These account for over 90% of total TiO_2 pigment consumption in the world. These are described below as "mass applications" of TiO_2 with the remainder grouped under "specialty applications". An overview of the applications that are discussed below is given in **Figure 3–5**.

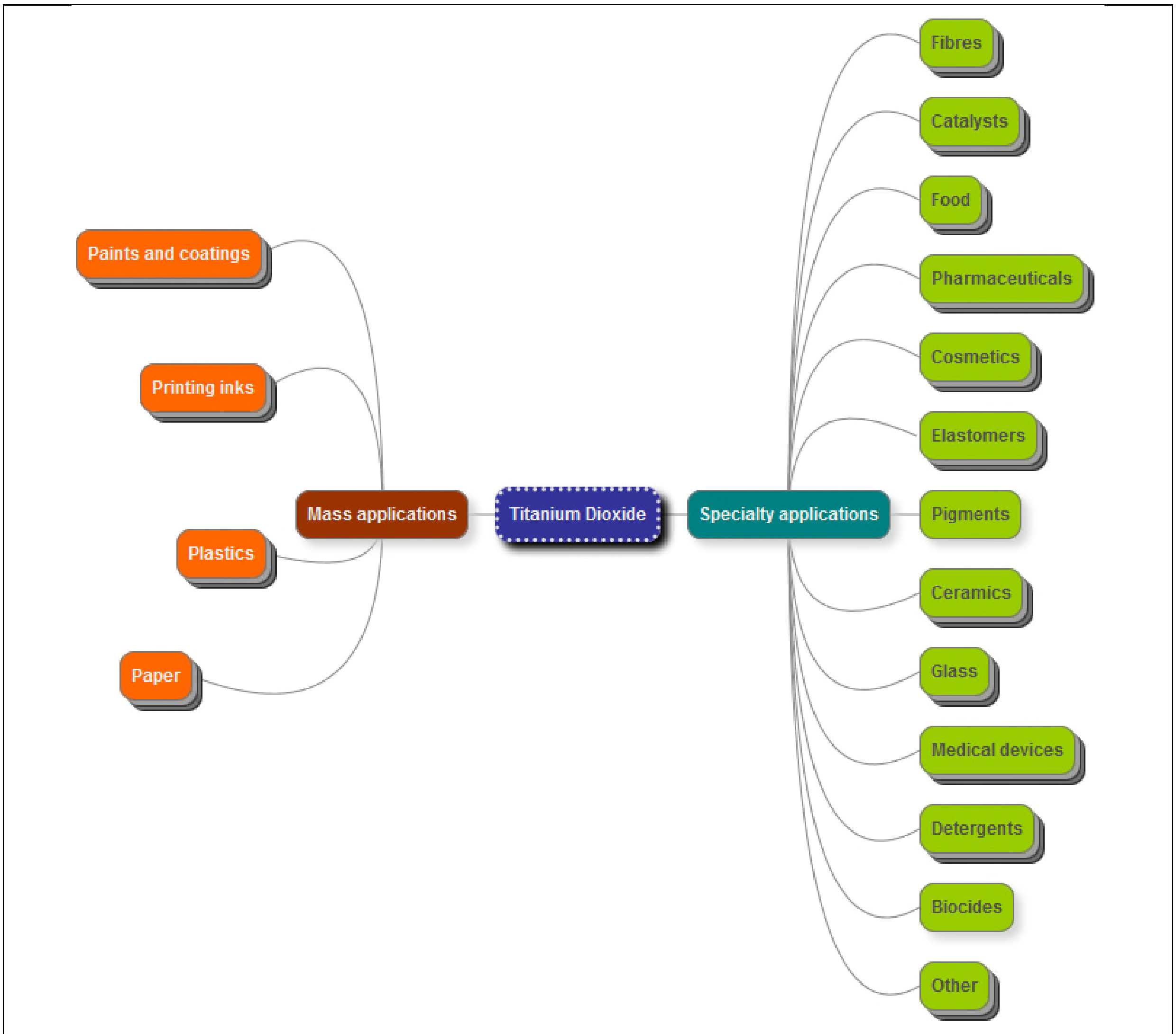


Figure 3–5: Overview of applications of TiO_2 pigments

Table 3–5 overleaf summarises the key technical performance characteristics and advantages of TiO_2 in its different application areas. These are expanded upon later in the document when each application is considered in turn.

Table 3–5: Overview of key technical performance characteristics and advantages of TiO_2 use in its different applications

Properties	Paints and coatings	Plastics	Paper	Inks	Construction products	Fibres	Catalysts	Food	Pharmaceuticals	Cosmetics	Elastomers	Pigments	Ceramics	Glass	Medical devices	Detergents	Biocides
Good hiding power/opacity	✓	✓	✓	✓	✓	✓		✓	✓	✓		✓	✓	✓	✓		
Ability to lighten coloured media	✓	✓		✓	✓			✓				✓					
Base for colour development	✓	✓		✓				✓	✓			✓		✓			
Whiteness and brightness	✓	✓	✓	✓	✓			✓	✓	✓	✓		✓		✓	✓	
Stability to heat, light and weathering	✓	✓	✓	✓	✓	✓		✓			✓	✓					✓
Thermal stability and flame retardancy	✓	✓			✓												
Light reflection	✓	✓								✓							
UV absorbance	✓	✓		✓	✓	✓		✓	✓	✓				✓			
Offers support for catalysts							✓										
Photocatalytic activity	✓													✓			
Approved for use in specific areas		✓						✓	✓	✓							
High efficiency	✓	✓	✓	✓	✓			✓	✓				✓		✓	✓	
Easy dispersion and particle distribution and processability	✓	✓	✓	✓	✓	✓				✓	✓	✓	✓				
Inertness in the presence of other components	✓	✓			✓	✓		✓		✓	✓						
Purity	✓			✓	✓		✓	✓	✓	✓							
Other	✓	✓			✓	✓				✓			✓	✓		✓	✓

3.4.2 Paints and industrial coatings

Range of applications

As a white pigment, TiO_2 is by far the most important raw material for paints and coatings. Paint and coating applications for TiO_2 are numerous and diverse and can generally be distinguished between architectural and industrial.

Architectural paints such as interior coatings ("wall paints"), façade coatings and wood and "trim" coatings, are used extensively in both DIY and professional applications. Examples include emulsions, lacquers, primers, sun protection (black-out) coatings, trim, floor (polyurethane, epoxies), woodcare varnishes and stains, garden paints and roof coatings, to name a few. These coatings are applied on both the interior and exterior of residential and commercial buildings and are applied to a variety of substrates.

Figure 3–6: White paint and industrial coatings, the major use of TiO_2 pigment
Source: Brilliant White (http://brilliantwhite.life/), Cristal

Industrial coatings provide aesthetics and functionality in a wide range of applications in a broad range of environments. Based on consultation with downstream users and literature, the key market segments include (Huntsman, 2016b; Chemours, 2016; VCI, 2016)[10]:

- Automotive and aerospace coatings;
- Marine coatings (yacht, etc.);
- Coil coatings;
- Can coatings;
- Anti-corrosion coatings;
- Powder coatings;
- Natural paints;
- UV-resistant coatings;
- Durable and non-durable powder coatings; and
- Road marking paints.

[10] It should be noted that following the spin-off of Venator Materials from Huntsman, web links to the old Huntsman Pigments and Additives web pages are no longer functional.

Under the industrial coatings heading, a very diverse range of less common coatings may be found. Examples include:

- **Flooring and other functional coatings**: here TiO_2 is used primarily for its white colour but also as a performance additive (conferring, for instance, UV resistance and fire retardancy). Example applications include:

  - Sports flooring coatings;
  - Floor coverings for heavy duty industrial floors;
  - Surface protection systems for concrete components;
  - Functional coatings in cars to e.g. eliminate squeaking as windows move up and down;
  - Functional coatings on wind turbines to aid movement; and
  - Ablatives and fire-resistant coatings and intumescents;

- **Photoactive coatings (construction and air cleaning materials)**: many new applications are based on the photo-activity of TiO_2, including:

  - *Coatings on building materials* (e.g. glass, concrete, stone, plaster, paints, plastics) where outdoor photocatalysis (under UV light) decomposes pollutants such as nitrogen oxides and carbon monoxide and coatings for the protection of facades, roofs, other building components and PV modules against algae and mould can be found;

  - *Self-cleaning materials for outdoor use*, for example in anti-fogging coatings and self-cleaning windows (ICIS, 2007) but also textiles (Montazer & Pakdel, 2011). When used as a photocatalytically active concrete additive to eliminate NO_x, exposure of the concrete surface to light causes the photocatalytic reaction to occur while, at the same time, the reaction of TiO_2 with the light also generates a superhydrophilic surface. Particles of dirt soot and organic substances are undermined by the water and flushed off by the next rainfall. This special cement can be used in concrete block paving, concrete road surfaces, noise barriers, roof tiles and facades, for example, to create durable photocatalytic active surfaces; and

  - *Dispersions for indoor use*; TiO_2 pigments can also be used behind glass, with standard light bulbs and energy-saving lamps, in twilight, in scattered light and in the presence of UV radiation. They can effectively remove undesirable odours, degrade organic stains on surfaces, protect surfaces against germs and mould, and eliminate numerous pollutants, such as nicotine and tar; ammonia and amines; aldehydes and alcohols (e.g. formaldehyde, acetaldehyde, methanol); phenols and other aromatic compounds (e.g. benzene, p-chlorophenol, PCBs) (Kronos Worldwide, 2012; Calderone, 2015):

  Such TiO_2 photocatalysts have been found to be less susceptible to attack by various algae, fungi and bacteria (Kronos Worldwide, 2012) making them suitable for applications such as medical devices, food preparation surfaces, air conditioning filters and sanitary ware surfaces (ICIS, 2007) as well as textiles (Montazer, et al., 2011); and

- **Other functional applications**: these include castings for electrical and decorative applications where TiO_2 is used as a white pigment.

Typical concentrations of titanium dioxide

Typical concentrations of TiO_2 in paints are given in **Table 3–6**.

Table 3–6: Concentration of TiO_2 in paints and industrial coatings	
Application	**Typical TiO_2 concentration (by weight)**
Professional and DIY paints	From 0.1% (varnishes) to 50% (and up to 70% for filling compounds)
General industrial coatings	up to 30%
Anti-corrosion coatings	up to 20%
Automotive refinishing coatings	25%
Eco-friendly natural paints	up to 40%
Wood paints	up to 20%
Road markings	0.2-15%
Source: data from consultation and VCI (2016)	

Technical characteristics and advantages

TiO_2 is the most widely used pigment for white colours and white is the reference colour in domestic appliances and in most products used for buildings. TiO_2 offers an unrivalled array of beneficial effects, as shown in **Table 3–7**.

Table 3–7: Advantages of TiO_2 use in the manufacture of paints		
Properties	**Relevant key advantages**	**Notes, comments and sources**
Good hiding power/opacity	✓	Allows the manufacture of fully opaque coating systems
Ability to lighten coloured media	✓	
Base for colour development	✓	The colour can be engineered to provide users with a broad range of pigments to choose from (Huntsman, 2016). TiO_2 is not only used in white shades, but in other shades as well. It is the only white raw material that makes it possible to produce colours according to relevant standards (RAL, NCS) in a controlled way
Whiteness and brightness	✓	High brightness level, delivering whites which meet the expectations of end users (for example, high brightness makes road markings clearly visible to the road user at all times, including day and night time and inclement weather conditions)
Stability to heat, light and weathering	✓	TiO_2 displays humidity and light resistance and thermal stability
Thermal stability and flame retardancy	✓	It is thermally stable, not combustible and nearly insoluble in water. Thus, it shows retardancy performance; no other additive in combination with intumescent additives gives the same level of fire performance. TiO_2 is stable at the high temperature needed for production and application of adhesives (curing may take place at 400 °C and few pigments will withstand such temperature) where the colour of the glue line is relevant and prevents the yellowing of the pigment
Light reflection	✓	
UV absorbance	✓	TiO_2 protects the polymer matrix from effects of UV radiation by absorbing UV rays that would degrade the organic binder but also offers protection of the substrate on which paint is applied

Table 3–7: Advantages of TiO_2 use in the manufacture of paints		
Properties	**Relevant key advantages**	**Notes, comments and sources**
Photocatalytic activity	✓	Two types of photochemical reaction occur on the surface of TiO_2 when appropriately irradiated: one is the photo-induced redox reaction of adsorbed substances, and the other is the photo-induced hydrophilic conversion of the TiO_2 itself. The combination of these two functions is the basis of numerous novel photocatalytic application
High efficiency	✓	TiO_2, having by far the greatest light scattering power of all white pigments, is the only white pigment showing sufficient hiding properties at relatively low dosage as a result of high tinting strength without a strong, undesirable viscosity increase
Easy dispersion and particle distribution and processability	✓	Due to its good wettability and dispersion, the formation of a large amount of sediment is prevented. TiO_2 is relatively easy to process and does not generally require the use of specialised milling equipment
Inertness in the presence of other components	✓	Thickening which is caused by reactions with the vehicle remains excluded due to the chemical inertness of TiO_2. No impairment in the technical properties of the surface coating occurs, even if the container is repeatedly opened for the withdrawal of small portions (Kronos, 1968). It is compatible with most polymer systems within the paint industry. It also has a low oil absorption value, which allows paints to maintain good flow and levelling properties even when used at high levels as well as the formulation of high gloss finishes which retain their gloss for longer
Purity	✓	
Other	✓	**Advantageous application properties**: flow, levelling, printing and transfer of coatings and desirable film build character (it allows increased film thickness to be applied). **Low coefficient of friction / reduced abrasion**: this is important for numerous functional coatings

3.4.3 Plastics

Range of applications

According to the European Plastics Converters (EuPC), TiO_2 finds wide use in the plastic conversion industry. The plastics converting area covers a variety of sectors where TiO_2 may be used such as packaging, building and construction, automotive, electric and electronic equipment, medical, household, leisure, footwear, clothes, toys and advertising. The main sectors are packaging, building (flooring, wallcovering, furniture, playground and sports surfaces), construction (window profiles, thermal cladding, rainwater and drainage, wood replacement articles, roof, wall, ceiling and flooring coatings, heat reflective panels, water tanks), transport (automotive panels, automotive protective film, caravans, motorhomes, trucks, trains, tarpaulins, road markings), marine (motor boats, yachts, small craft, corrosion resistant coatings, off-shore wind turbines), clothing and sporting goods (EuPC and WSL (2016)).

Figure 3–7: Examples of TiO_2 use in plastic articles
Source: Cristal

In addition to colouring objects white, TiO_2 is also used to brighten colours, increase colour strength or opacify otherwise transparent polymer materials. White is often used to provide contrast to other colours enabling e.g. to display text, symbols or logos. It is therefore used in any application where optics are important (such as packaging, including sleeves on bottles; automotive; and construction, both residential (e.g. white PVC window profiles) and commercial applications). Thermoplastic films are used for road markings and waterproofing membranes for construction and highways. Special effect products can be used to produce unique properties in the end application, for example increasing solar reflectance to maintain cool surfaces in plastic car interiors (Huntsman, 2016c).

In the medical sector, TiO_2 finds use in pharmaceutical containers and coloured plastics used for medical container closures to provide increased opacity and a stable base colour. As the white component in both pigments and masterbatches, it has been used over the past 20 years in polymer materials for medical catheter tubing and injection moulded components.

A significant proportion of the TiO_2 used in this sector is not added directly as a powder but through the inclusion of masterbatches or compounds by the converters. In masterbatch, the TiO_2 is dispersed at high concentrations into a plastic resin, which is then used by plastics converters in film applications as well as in the manufacture of articles by injection moulding and sheets (plastic containers, bottles, packaging and agricultural films (Kronos Worldwide, 2016)). In a coloured masterbatch, TiO_2 may represent more than half of the composition of a colourant; for example, the colourant may contain up to 60% TiO_2 and may be used at a dosage of 2% in the desired plastic parts (SPI, 2016). Notably, the plastic masterbatch sector comprises companies of a variety of sizes, including many SMEs and each company will use TiO_2 pigments in quantities of several hundred tonnes per annum.

Figure 3–8: TiO_2-containing plastic packaging
Source: Cristal

In terms of the types of polymers that may contain TiO_2, these include:

- Polyolefin (Polyethylene and Polypropylene) for blow moulding, blown film, cast film, extrusion coating, high temperature cast film, injection moulding, liquid colourant, often used in packaging;

- PVC, mainly for construction applications (interior rigid, exterior rigid, flexible, plastisol);

- Engineering plastics for automotive and consumer goods (Acrylonitrile butadiene styrene (ABS), Polystyrene (PS) and High Impact Polystyrene (HIPS), Polycarbonate (PC) and PC blends, Polyamide (PA), Polybutylene terephthalate (PBT), Polyethylene terephthalate (PET), Polyphenylene ether (PPE), Polyphenylene sulphide (PPS), Polysulphone (PES), acrylics (PMA and PMMA), etc.); and

- Composites (e.g., EP and UP resin-based materials).

Typical concentrations of titanium dioxide

Consultation has revealed the following typical concentrations of TiO_2 in a range of plastic products:

- Masterbatches: up to 80%;
- Plastics (engineering and decorative): 1-10%;
- uPVC windows: 2-4%;
- PVC plastisol: 5%; and
- Packaging films and containers: 1-20%.

Technical characteristics and advantages

In plastics, TiO_2 is used as a white pigment, UV stabiliser, filler, inorganic flame retardant and mechanical/technical property enhancer. It is present in white masterbatches and is also used in a wide number of colour formulations to obtain the desired colour (NB. white masterbatches are mainly used in films, injection moulding and sheets). In these applications, the known advantages of TiO_2 include those shown in **Table 3–8**.

Table 3–8: Advantages of TiO_2 use in the manufacture of plastics		
Properties	**Relevant key advantages**	**Notes, comments and sources**
Good hiding power/opacity	✓	
Ability to lighten coloured media	✓	
Base for colour development	✓	Desirable colour whiteness and tone (bluish versus yellowish)
Whiteness and brightness	✓	
Stability to heat, light and weathering	✓	Light stabilisation and weatherability, particularly for products such as window profiles
Thermal stability and flame retardancy	✓	
Light reflection	✓	
UV absorbance	✓	Resistance to outdoor conditions and UV light and reflection of incident light. The ability to protect the polymer from the natural elements and degradation via UV attack allows long-term colour stability and, more importantly, the retention of physical performance, preventing the polymer becoming brittle, cracked or easily damaged. TiO_2 is the only white pigment that is stable for outdoor applications. It offers a desirable absorption profile of light wavelengths, preventing certain wavelengths from passing through and affecting materials' properties or the properties of the contents (food, medicines, etc.)
Approved for use in specific areas	✓	See above on food contact materials and pharmaceutical packaging
High efficiency	✓	
Easy dispersion and particle distribution and processability	✓	
Inertness in the presence of other components	✓	Optimal surface chemical treatment that enhances effectiveness and compatibility with a wide range of polymeric carriers to minimise the impact on mechanical/technical properties of the polymeric matrix used. Neutral effect on nucleation of semi-crystalline polymers
Other	✓	Due to their high dielectric constant and their low loss angle, TiO_2 pigments open up the possibility of increasing the dielectric constants of plastics without considerably changing other properties (e.g. specific resistance) (Kronos, 1968)

3.4.4 Paper

Range of applications

TiO_2 is mostly used as an opacifier and less frequently for its whitening, brightness and surface finishing properties in:

- Décor paper for laminate flooring and furniture;
- Packaging, including board;
- Printing and writing;
- Wallpapers; and
- Paper filling.

In paper laminates, several layers of paper are laminated together using melamine resin under high temperature and pressure. The top layer of paper contains TiO_2 and plastic resin and is the layer that is printed with decorative patterns (e.g. wood effects). Paper laminates are used to replace materials such as wood and tile in counter tops, furniture and wallboard (Kronos Worldwide, 2016). Here, a high opacity is required to stop the substrate underneath the printed material showing through following lamination. The TiO_2 is modified to provide excellent colour stability in the laminated article, which enables longer life for the final product.

In packaging, papers that contain TiO_2 are used in food packaging where they are waxed prior to use in packing fatty or greasy foods; to prevent the paper becoming translucent during this process, the paper needs to have a high opacity. TiO_2 is also used in labels, for instance, C1S (e.g. Coated One Side) label papers where one side of the paper is coated for good printability and outlook whereas the reverse side is not (as it is typically attached to a surface (bottle, can, other packaging, etc.) by means of an adhesive). In cartons (board), coatings that contain TiO_2 improve the surface smoothness and gloss which are required to achieve high quality printing.

LWC (Lightweight Coated), Ultra Lightweight Coated (ULWC) and super-calendered low grammage papers are used when printing telephone directories, encyclopaedias, bibles, diaries or patient information sheets for inclusion in pharmaceutical products. TiO_2 can be used to enhance the opacity of such extremely thin, lightweight papers so they can be printed on both sides without the printing showing through (Huntsman, 2016d).

TiO_2 pigments ensure that wallpapers are light (the superior opacity of TiO_2 means that the wallpaper can be thinner and still be opaque) and have a brilliant wet opacity. Ideally, wallpapers can be manually coated or printed using common printing processes. TiO_2 pigments give the paper all these properties and high lightfastness (Huntsman, 2016d). Without the opacity and surface texture/smoothness provided to the wallcovering base material by TiO_2, printing would be practically impossible for most printing methods. For many specialty papers, such as décor papers, TiO_2 is essential as no dull fibre type can be produced without it.

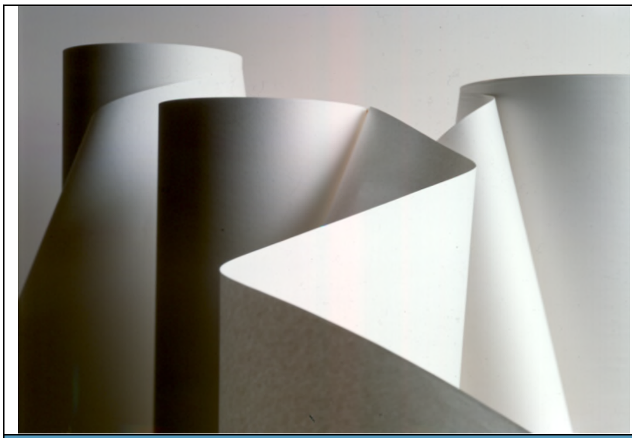


Figure 3–9: TiO_2-containing paper
Source: Cristal

Typical concentrations of titanium dioxide

TiO_2 levels can typically be in the 20-40% range of the décor paper. In wallpapers, TiO_2 may be found in concentrations in the range of 1-10%.

Technical characteristics and advantages

Use of TiO_2 in paper is accompanied by significant technical advantages as shown in **Table 3–9**.

Table 3–9: Advantages of TiO_2 use in the manufacture of paper		
Properties	**Relevant key advantages**	**Notes, comments and sources**
Good hiding power/opacity	✓	It ensures that paper and board maintain high opacity during and after the conversion process (calendering, waxing, impregnation)
Whiteness and brightness	✓	
Stability to heat, light and weathering	✓	It assists in preventing the paper material from fading or changing colour after prolonged exposure to sunlight and other weathering agents (Kronos Worldwide, 2016)
High efficiency	✓	TiO_2 has good S (light scattering coefficient) and K (light absorption coefficient) values – a high light scattering is desirable since the paper then becomes more opaque and whiter. Other pigments, such as calcium carbonate and calcinated clay, may have only one good value, either S or K value. Thus, although TiO_2 is not the cheapest opacifier in terms of cost per kilogram, it is cost-effective and helps maintain important paper/board properties at low dosage. Due to their high tinting strength and hiding power, it is possible to prepare very good white and opaque printing papers even from cheap raw materials by means of a quite thin coating of pigment (Kronos, 1968)
Easy dispersion and particle distribution and processability	✓	TiO_2 adheres well to the paper fibre

3.4.5 Inks

Range of applications

TiO_2 has been used for several decades in toners, inks, backings for inkjet printing substrates, coated layers on specialty foils, and incorporated into PET for some applications (I&P Europe, 2016). Notable applications include (Huntsman, 2016e):

- **Inks for packaging**: in flexible packaging (such as plastic or aluminium films), white is usually printed as a full layer either as first ink layer (surface print) or as last lacer (reverse and lamination). There key function is to produce maximum opacity in order to hide the packed good. The white ink should deliver excellent hiding power to allow high quality colour printing. This is also crucial for the function of most barcode scanners, which need a perfect contrast between the barcode and the background. If the packed material is shining through then the barcodes are difficult to read. For a typical flexible packaging printer, the consumed white inks count for 40-60% of his total ink volume. Moreover, TiO_2 pigments offer a broad performance spectrum: high gloss, low abrasion, performance consistency, sparkling effects where desired, and are suitable for use in solvent, water and oil-based inks as well as in UV curable inks. They perform well in flexo, gravure and screen printing with gravure inks, pad printing, inkjet or sheet fed offset applications and are suitable for flexible, paper and card or metal packaging. Because of the high opacity of TiO_2, the white layer reduces the metallic effect in laminates containing alu-foil or metallised plastic film;

- **Labels**: UV curable printing inks for the narrow to mid–web may contain TiO_2 and are used in self-adhesive labels, wrap around labels, lidding, shrink sleeve, in-mould labelling, etc. TiO_2 is used to produce high opacity white printing inks to allow the conversion of clear/metallic materials;

- **Toner**: TiO_2 pigment offers free flow and charge control;

- **Writing materials and children's modelling materials**: these include coloured pencils, crayons, finger paints, school tempera paints, lacquers and modelling clays (NB. TiO_2 is present in almost all plastic parts of pens and related products); and

- **Inks for textiles and leather**: TiO_2 pigments can support the delivery of a strong opaque colour that helps printed textiles stand out.

Typical concentrations of titanium dioxide

Typical concentrations of TiO_2 in inks and related products are given in **Table 3–10**.

Table 3–10: Concentration of TiO_2 in inks and related products	
Application	**Typical TiO_2 concentration**
White printing inks	Up to 50-60%, even 70% in dispersions
Printing pastes	White concentrate: 80% Ready-to-use compound: 20-30%
Shaded inks	5-10%
Pencils and similar products	3-35%
Correction fluids	Up to 50%
Artists' and recreation colours	0.1-100%
Toner	1-5%
Erasers	ca. 1%
Source: data from consultation	

Technical characteristics and advantages

TiO_2 offers the following technical advantages to inks and ink-related products.

Table 3–11: Advantages of TiO_2 use in the manufacture of inks		
Properties	**Relevant key advantages**	**Notes, comments and sources**
Good hiding power/opacity	✓	In graphic arts (printing), ink is usually applied in a much thinner film than a normal coating (a few microns)*. Ink correction fluid for paper relies on TiO_2 to hide errors. Inks for concealed writing (scratch-off lottery tickets) likewise use TiO_2 because of its superior hiding power (Gázquez, et al., 2014)
Ability to lighten coloured media	✓	
Base for colour development	✓	TiO_2 is used as white pigment, but also for colouration support in allowing (a) the dyes of the formula to be fixed; and (b) the development of a wide range of colours to create pastel shades and increase the colour gamut of the available pigment range
Whiteness and brightness	✓	
Stability to heat, light and weathering	✓	

Table 3–11: Advantages of TiO_2 use in the manufacture of inks		
Properties	**Relevant key advantages**	**Notes, comments and sources**
UV absorbance	✓	TiO_2 protects inorganic pigments from light through UV absorbance
High efficiency	✓	
Easy dispersion and particle distribution and processability	✓	TiO_2 can be readily dispersed, achieve rapid wetting at low viscosities. TiO_2 allows inks to achieve very high print quality (excellent gloss) while not interfering with the technical requirements of printing machinery, including low abrasion, high printing speed and high temperatures (Kronos Worldwide, 2016)
Purity	✓	TiO_2 is accompanied by high purity and high definition of particle size
** By way of example, in UV inkjet technology, the thickness of a full white ink layer (non-opaque, consisting of ca. 20% TiO_2) varies between 20 and 30 µm. If the layer is meant to be opaque (diffusion white layer) then the thickness may be as low as 5 to 10 µm*		

3.4.6 Construction products

Range of applications

"Construction products" is a very diverse term which covers a great variety of articles and mixtures. For example, plastic window frames are a type of construction product as they have one important characteristic that distinguishes them from all other plastic products: they have a long lifecycle of between 30 and (technically) 100 years. There are several other construction products, typically in a coating form, which may contain TiO_2 and can be used alongside architectural paints. These include applications might be considered to be affiliated to either paints or plastics. In these, historically, TiO_2 has replaced other white pigments like "white lead" (lead carbonate) the use of which has been restricted (VCI, 2016). Examples of relevant applications include:

- **Construction products**: a wide variety of construction products may contain TiO_2 as a colouring pigment. These include:
  - Plasters (synthetic plasters, emulsion bound, mineral plasters);
  - Fillers (such as wood and wall fillers);
  - Caulks;
  - Pigmented mortars (e.g. jointing grouts); and
  - Synthetic resin screeds;
- **Adhesives**, for example:
  - Liquid polyaddition, polycondensation and polymerisation adhesives like polyurethanes, epoxides, silane modified polymers, acrylates and anaerobically curing adhesives and adhesive films;
  - EVA- and PE-based thermoplastic hot melts;
  - Outside the construction sector, natural water-based gelatine adhesive for the paper and cardboard industry. These glues are generally yellow, brown or beige. TiO_2 is used to whiten the adhesive without changing other technical properties like other fillers would do. The whitened adhesives are used, for instance, in the back lining of books;

– Water-based PVA dispersion glue. TiO_2 is used to whiten the dispersion so it can be used as a master batch and colour can be added by a downstream user. The customer then uses this adhesive to glue textile fibres to paper to make wallpaper. TiO_2 gives a whitening aspect no other product can provide. All produced products are in liquid form;
– Pigmentation of black-out foils and films; and
– Flock adhesives; and

Figure 3–10: TiO_2 can be found in adhesives
Source: royalty-free photo

- **Sealants**: TiO_2 is used as a white pigment in roles similar to those for adhesives. One such example includes silicone sealants.

As a constituent of adhesive formulations, not only is TiO_2 used in the construction sector but also in the paper and packaging industries, the construction of motorcars, railway vehicles, ships and airplanes, in electrical and electronic applications, the dental sector and other industries. TiO_2 may also be found in coloured adhesives (e.g. light green adhesive to glue artificial lawn or red adhesive to glue tartan tracks) which are first brightened with TiO_2 and then coloured with the desired colour. Often, the use of TiO_2 enables the use of coloured natural resins. Without pigment, application would not be possible with a visible bond seam (VCI, 2016).

Typical concentrations of titanium dioxide

Based on consultation findings and literature (VCI, 2016), typical concentrations of TiO_2 in construction products include:

- Concrete, mortars, grout, plaster: 0.1-10%; and
- Sealants and adhesives: 1-15%.

Technical characteristics and advantages

The technical advantages TiO_2 offers to construction products are largely those described earlier for paints and industrial coatings.

3.4.7 Fibre applications

Range of applications

Textile and leather applications

Anatase grades may be used for delustering man-made fibres. Delustering plays a leading role in the complex production of man-made fibres such as polyester, polyamide, acrylic, viscose, rayon, but also cellulose acetate fibres. A melt-conditioning process helps to provide the fibre producer with greater flexibility in changing between various degrees of delustration (i.e., between lustrous, semi-matte and full-dull grades) (Huntsman, 2016g).

Fibres of variable dullness (depending on the proportion of TiO_2 used[11]) may be used in consumer textiles, including high-class, high-fashion textile products of the most well-known and prestigious fashion brands where dull lustre and handfeel is sought after.

When TiO_2 is used as white pigment, it may act as (VCI, 2016):

- A component of a coating applied on commercial textiles such as those for sun protection (black-out, dim-out) / roller and vertical blinds / decorative textile ceilings;
- A component of printing inks (e.g. inkjet, digital print) and in printing pastes for pigment print;
- A carrier material for biocides; and
- A component for the pigmentation of leather (i.e. pigment dispersions in polymer matrices that are sprayed onto leather to produce pigmented leathers).

Another textiles-related but not fibre-based application for TiO_2 is the pigmentation of thermotransfer coatings used on textiles.

Non-textile applications

TiO_2 may also be used in the delustering (matting) of man-made fibres, e.g. for white pigmentation of glass fibre nonwovens or cigarette filter tow, where cellulose acetate fibre is used.

Typical concentrations of titanium dioxide

TiO_2 is used in delustering within the range of 0.1-1.5% with the level depending on the lustre required by end users (CIRFS, 2016).

Technical characteristics and advantages

The key technical advantages of TiO_2 in its fibre applications are shown in **Table 3–12**.

Table 3–12: Advantages of TiO_2 use in the manufacture of fibres

Properties	Relevant key advantages	Notes, comments and sources
Good hiding power/opacity	✓	Originally, transparent man-made fibres are delustered to differing degrees using TiO_2, thus losing their transparency. The delustering process makes use of anatase pigments' scattering power, which causes the fibre to appear optically whiter, opaquer, more matte and duller
Stability to heat, light and weathering	✓	TiO_2 special surface treated grades ensure good adherence to the substrate and high light-fastness and non-colour fading performance (i.e. UV resilience), which is paramount for man-made fibres designed for outdoor applications. Pigments for textile fabrics are also sweat-fast
UV absorbance	✓	See above
Easy dispersion and particle distribution and processability	✓	Anatase pigments reduce reflection in screen printing processes, permitting much more reliable and faster thread guidance and weaving behaviour, and thus enhancing productivity (Huntsman, 2016f) and have an effect on colour impression

[11] In the field of synthetics fibres, a physical parameter named "ahine" is often used, defined as the amount of reflected light. This is controlled by the amount of TiO_2 added in the manufacturing process or polymerisation; bright contains 0.06% TiO_2; semi-opaque, 0.3% TiO_2; and opaque, 2% TiO_2 (Gázquez, et al., 2014).

Table 3–12: Advantages of TiO_2 use in the manufacture of fibres		
Properties	**Relevant key advantages**	**Notes, comments and sources**
Inertness in the presence of other components	✓	TiO_2 is chemically inert thus it does not react in processing; the TiO_2 grades used are practically free of any coarse fraction and show minimal abrasion, which ensures good filter-pack lives at the spinnerets and decreased amounts of filament breakage during production
Other	✓	Anatase pigments, which have a lower Mohs hardness than their rutile counterparts and are always used for applications in which lower abrasiveness is desired, are selected for this purpose. Their addition impacts on the touch of the articles

3.4.8 Catalysts

TiO_2 is used as a catalyst support (up to 35% of the green body preparation) in Selective Catalytic Reduction (SCR) processes for the reduction of oxides of nitrogen in exhaust gases, not only in mobile applications such as road, rail and marine engines, but also in stationary installations such as power generating and other industrial plants.

Figure 3–11: TiO_2-based catalysts
Source: Cristal

TiO_2 is the catalyst of choice for the desulphurisation of crude oil (the Claus process, where TiO_2 has the technical advantage that it is a sulphur-resistant carrier material), for the oxidative synthesis of organic compounds, and in a large range of other chemical processes (Huntsman, 2016k). TiO_2 is used both as a carrier material and as an acidic catalytically active material for the selective conversion of feedstocks into the desired end products (e.g., phthalic anhydride). Its use as an ingredient of the catalyst in the process reduces raw material cost (e.g., *o*-xylene, naphthalene) for customers, reduces by-product formation (generation of waste), reduces emissions in the process (e.g. lower CO_x), ensures long catalyst lifetimes, and thus means lower costs for customers and reduction of waste from spent catalyst.

3.4.9 Food and feed additives and food contact materials

Range of applications

Titanium dioxide as a food component

In the EU, TiO_2 (E171) is listed in Annex I of Directive 94/36/EEC as a permitted colour in foodstuff and it is presumed as safe. E171 is accompanied by specific purity criteria (Commission Regulation (EU) No 231/2012) and its use is authorised by Regulation (EC) No 1333/2008 on food additives. It can be found at *quantum satis* (i.e. as much as needed) in many foods, for instance:

- Dairy analogues, including beverage whiteners;
- Edible ices – TiO_2 is a key ingredient in a range of pearlescent colourants that are used to colour ice cream coatings and chocolate/confectionary pieces that are used to decorate ice cream products;
- Confectionery including breath refreshening microsweets (where it is often used to provide a barrier between different colours);
- Chewing gum and lollipops;
- Decorations, coatings and fillings, except fruit based fillings;
- Fine bakery wares;
- Casings, coatings and decorations for meat (except edible external coating of pasturmas);
- Soups and broths;
- Cottage and mozzarella cheeses, where it is used to increase opacity (EUFIC, 2016);
- Sauces - including pickles, relishes, chutney, horseradish sauce and piccalilli – excluding tomato-based sauces;
- Salad and savoury based sandwich spreads;
- Flavoured drinks - excluding chocolate milk and malt products, to increase rich texture and turbidity (European Commission, 2014);
- Processed nuts; and
- Desserts.

Figure 3–12: Examples of TiO_2 use in foodstuff
Source: Brilliant White (http://brilliantwhite.life/) and royalty-free photos

TiO_2 is also used as a dyestuff/pigment in dyes for egg shell decoration.

It is also present as an approved colourant feed additive in Annex I of Regulation 1831/2003/EC. In pet foods, it is used to obtain uniformity of colour and appearance (Kronos Worldwide, 2016; Huntsman, 2016i; TDMA, 2013).

Titanium dioxide as a component of food contact materials

Beyond its use as an additive within food, TiO_2 can be found in food contact materials. TiO_2's entries in the Union List of Additives for Food Contact Materials (European Regulation (EU) 10/2011)[12] are shown in **Table 3–13**. It is accompanied by a high SML (specific migration limit) of 60 mg/kg from plastic materials and articles intended to come into contact with food.

[12] It is worth noting that **coated and printed plastic food contact materials** and articles are covered by the scope of European Regulation (EU) 10/2011. Plastics held together by adhesives are also covered by its scope. However, substances used only in printing inks, adhesives and coatings are not included in the Union list because these layers are not subject to the compositional requirements of the Plastics Regulation. The only exceptions are substances used in coatings which form gaskets in closures and in caps. The requirements for printing inks, adhesives and coatings are intended to be set out in separate specific Union measures. Until such measures are adopted, they are covered by national law. If a substance used in a coating, a printing ink or an adhesive is listed in the European Union list, the final material or article has to comply with the migration limit of this substance, even if the substance is used in the coating, printing ink or adhesive only. Even though **colourants** fall under the definition of additives, they are not covered by the Union list of substances. Colourants used in plastics are covered by national measures and are subject to risk assessment in line with Article 19 of the European Union List Regulation.

Table 3–13: Food Contact Material Union list entries for TiO_2			
Entry	**Chemical name**	**Use**	**Restrictions**
610	Titanium dioxide	Additive or polymer production aid	
805	Titanium dioxide, coated with a copolymer of n-octyltrichlorosilane and [aminotris(methylenephosphonic acid), penta sodium salt]	Additive or polymer production aid	The content of the surface treatment copolymer of the coated titanium dioxide is less than 1% w/w
873	Titanium dioxide reacted with octyltriethoxysilane	Additive or polymer production aid	Reaction product of titanium dioxide with up to 2% w/w surface treatment substance octyltriethoxysilane, processed at high temperatures

As discussed elsewhere in this report, the presence of TiO_2 can be established in:

- **Food packaging**: TiO_2 can be found in plastic and paper as a whitening pigment, food-contact coatings, food-packaging adhesives, food-contact polymers, paper/paperboard in contact with aqueous/fatty foods, filler in food-contact rubber articles for repeated use, food-contact textiles/fibres;

- **Food homeware/containers**: TiO_2 may be found in white and pastel ceramic articles and as a pigment in enamels applied on flatware, cookware, hollowware (both decorated and non-decorated) and eventually also other white kitchenware (see discussion in Section 3.4.14); and

- **Printing inks for food packaging**: TiO_2 is used as a pigment for inks applied on food contact materials.

Technical characteristics and advantages

TiO_2 (E171) is the most widely used white food colour because of the key advantages shown in **Table 3–14**.

Table 3–14: Advantages of TiO_2 use in foodstuff		
Properties	**Relevant key advantages**	**Notes, comments and sources**
Good hiding power/opacity	✓	
Ability to lighten coloured media	✓	
Base for colour development	✓	In conjunction with E555 (Potassium aluminium silicate - mica) TiO_2 has a unique use to produce 'glitter' powders which are widely used as decorations for fine bakery wares
Whiteness and brightness	✓	
Stability to heat, light and weathering	✓	
UV absorbance	✓	TiO_2 can prevent premature spoilage in foods that react with UV light

Table 3–14: Advantages of TiO_2 use in foodstuff		
Properties	**Relevant key advantages**	**Notes, comments and sources**
Approved for use in specific areas	✓	As noted above, TiO_2 is considered safe by oral ingestion and is authorised under the EU Additives Regulation (EC) No 1333/2008 at Annex II as a Group II food colour, which may be used in most foods at *quantum satis*. A recent EFSA opinion on the re-evaluation of its safety for use as a food additive published on 14 September 2016 concluded that available data on TiO_2 in food do not indicate health concerns for consumers[13]
High efficiency	✓	
Easy dispersion and particle distribution and processability		
Inertness in the presence of other components	✓	TiO_2 is chemically very stable and inert with very low bioavailability. It does not react with other substances present in foods (for example, food acids) and it will withstand cooking/baking processes unchanged
Purity	✓	

3.4.10 Pharmaceuticals

Range of applications

TiO_2 is presented in Ph Eur monograph 0150[14]. TiO_2's chemical purity meets the requirements of important official pharmaceuticals standards, such as the European pharmacopoeia (Ph. Eur/EP), the Japanese pharmacopoeia (JP) and the US pharmacopoeia (USP) (Huntsman, 2016j). In addition, TiO_2 is the only opacifying agent for materials used for containers that is named in the European Pharmacopoeia's Section 3.1.

Similar to food applications, TiO_2 applications in pharmaceuticals can be both as an additive to medication and as an additive to packaging:

- **Medicine component**:
  - *Excipient (colourant)*: ultra-high purity TiO_2 as per Ph Eur is used in many medicinal products as an excipient, mainly as the colourant E171. Its toxicological safety for dermal or oral applications makes TiO_2 an ideal and safe excipient. It can be found in liquid medicines where it provides uniformity of colour. The use of TiO_2 along with other colourants enables pharmaceuticals manufacturers to produce products with a great variety of colours. Such colour variety is extremely important to avoid medication errors. Without TiO_2, the available colour palette would be much more limited;
  - *Film coating*: TiO_2 is used in the film-coating of tablets and (gelatine) capsules (both pharmaceuticals and nutraceuticals). The pigment is added because this adheres to and covers the tablet core best. Without the use of TiO_2 the colour is not as smooth and the colour, spots or different coloured powder particles would come through and the surface would not be smooth and homogeneous;

[13] Available at http://www.efsa.europa.eu/en/efsajournal/pub/4545 (accessed on 24 October 2016).

[14] See http://www.drugfuture.com/Pharmacopoeia/EP7/DATA/0150E.PDF (accessed on 20 June 2016).

Figure 3–13: Nutraceutical tablets and pharmaceutical capsules that contain TiO_2
Source: royalty-free photos

- **Packaging**: TiO_2 is used in the manufacture of glass containers, opaque child-resistant pharma blister packages and medical container closures as it offers a guarantee of chemical inertness for pharmaceutical applications. TiO_2 achieves the colour and spectral characteristics required by the current regulations and physicochemical characteristics required by current standards for pharmaceutical vessels. It also offers protection from UV radiation in certain bandwidth, which is important when protecting medication in its container from the damaging effects of light, helping extend product shelf life (Kronos Worldwide, 2016; Huntsman, 2016j). According to MedPharmPlast (2016), there are currently at least 275 light-sensitive oral prescription drugs (King, 2009) and over 300 light-sensitive injectable medicinal products (University of Illinois at Chicago College of Pharmacy, 2014). These drugs thus require pharmaceutical packaging that is able to prevent the passage of light, particularly in the spectrum 290 to 450nm to prevent degradation of the pharmaceuticals. This requirement is defined in US Pharmacopeia <671> and is critical for obtaining marketing authorisation for light-sensitive pharmaceuticals. To reduce transmission, colours that filter (e.g. amber) need to be added. In the case of transparent packaging or in other cases an opacifying agent needs to be added to the polymer.

Typical concentrations of titanium dioxide

Typically, TiO_2 is present at concentrations of up to 3%.

Technical characteristics and advantages

Table 3–15 summarises the technical advantages of TiO_2 in pharmaceutical applications.

Table 3–15: Advantages of TiO_2 use in pharmaceuticals

Properties	Relevant key advantages	Notes, comments and sources
Good hiding power/opacity	✓	
Base for colour development	✓	
Whiteness and brightness	✓	
UV absorbance	✓	Offers protection to the active pharmaceutical ingredients (APIs) of medicinal products

Table 3–15: Advantages of TiO_2 use in pharmaceuticals		
Properties	**Relevant key advantages**	**Notes, comments and sources**
Approved for use in specific areas	✓	Established to be safe (being recognised as the E171 food additive)
High efficiency	✓	
Purity	✓	

3.4.11 Cosmetics

Range of applications

TiO_2 is currently listed in Annex IV of the Cosmetics Regulation EC 1223/2009 (list of colorants allowed in cosmetic products); and Annex VI (list of UV filters allowed in cosmetic products), as shown in **Table 3–16**.

Table 3–16: Cosmetics Regulation entries for TiO_2			
Annex		**Entry No.**	**Notes**
IV	List of colorants allowed in cosmetic products	143	The use if TiO_2 (CI 77891) is allowed in all cosmetic products. Purity criteria as set out in Commission Directive 95/45/EC (E 171) and its amendments
VI	List of UV filters allowed in cosmetic products	27	Maximum concentration in ready for use preparation: 25%[15]
VI	List of UV filters allowed in cosmetic products	27a	Titanium Dioxide (nano): Maximum concentration in ready for use preparation: 25%[16]

More specifically, TiO_2's colour, opacity and UV absorbance qualities mean that it can find many applications in cosmetics (at variable concentrations), including:

- **Sunscreens**: TiO_2 (INCI name Titanium Dioxide and Titanium Dioxide (nano)) at the non-nano and nano-scale is an effective inorganic UV-filter and, in the case of the nano-scale TiO_2, colourless. This UV-filter has been recognised as safe by the European scientific body (SCCS) up to a maximum concentration of 25% in cosmetics, when applied on healthy, intact or sunburnt skin. TiO_2 is one of the very few globally approved UV filters/sunscreen actives that are of relevance for global formulations (Cosmetics Europe, 2016). Only two mineral UV-filters are allowed in cosmetics, TiO_2 and ZnO;

- **Colour cosmetics (make-up) and skin care products**: TiO_2 as a colorant can confer satiny effects, lustre effects and interference colours. It can be found in products such as foundation and face powder. Due to its light diffusing qualities, its pearlescent effects find use in lipstick, eye-shadow and blushers. For these applications, no concentration limit has been established;

15 It is understood that in other jurisdictions (e.g. Japan) no upper limit has been established.

16 Not to be used in applications that may lead to exposure of the end-user's lungs by inhalation. Only nanomaterials meeting the characteristics set out in the Regulation are allowed. In case of combined use of Titanium Dioxide and Titanium Dioxide (nano), the sum shall not exceed 25%.

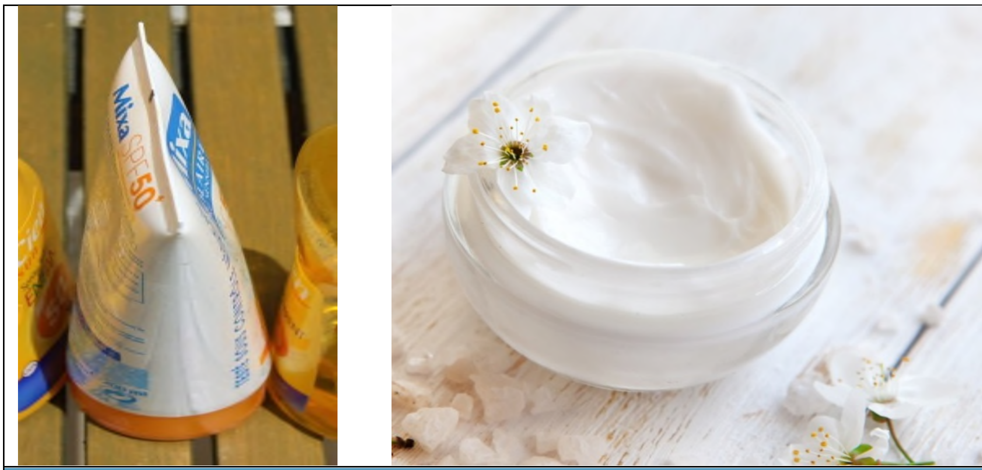


Figure 3–14: Example of a TiO_2 use in cosmetics – Sunscreens and face creams
Source: Brilliant White (http://brilliantwhite.life/) and royalty-free photo

- **Soaps (liquid and solid), shampoos and shower gels and depilatory products and other products**: TiO_2 acts as a pearlescent colourant and has opacifier effects due to its high refractive index;
- **Toothpaste**: TiO_2 can be used both as a white pigment and an abrasive;
- **Hair colour formulations**: TiO_2 is used as an opacifier;
- **Nail polishes**: TiO_2 is used as a colourant and opacifier in UV-curing nail polishes and gels that are sold on the professional and retail cosmetics markets. It may also be present in nail (anaerobic) adhesives; and
- **Other**: TiO_2 can also be used as filler in cosmetic products (Huntsman, 2016h).

Typical concentrations of titanium dioxide

Concentrations of TiO_2 in cosmetic formulations vary considerably across the wide range of cosmetic products that contain the substance. There is insufficient information that would allow us to provide typical concentrations across the cosmetics sector, although some individual consultees have provided example concentration ranges for a small number of products (e.g. toothpaste and nail polish). TiO_2 as colorant is approved for all cosmetic products and has no restriction in the use level. With specific reference to sunscreens, as shown above, the concentration of TiO_2 in formulations is up to 25%.

Technical characteristics and advantages

The wide use of TiO_2 in cosmetics derives from key properties of the pigment, as shown below.

Table 3–17: Advantages of TiO_2 use in the manufacture of cosmetics		
Properties	**Relevant key advantages**	**Notes, comments and sources**
Good hiding power/opacity	✓	When the pigment size becomes bigger, visible light is blocked by TiO_2 and skin appears white. This is particularly useful in decorative cosmetics, such as make-up sticks and powders, where the consumer may want to hide skin problems or simply improve his/her appearance and confidence. In oxidative hair colourants (which represent a fragile, reactive chemical environment), small amounts (0.1%) of TiO_2 boost opacity of the mass, thus increasing mass visibility on hair. This allows stylists or consumers to apply the correct amount of product (i.e. avoids overdosing). In addition to this technical performance and efficacy, TiO_2 does not adversely affect the stability of the colour tint, an undesirable effect which may occur with other (less efficient) opacifiers
Whiteness and brightness	✓	The whitening and opacifying characteristics of TiO_2 can be used to improve the appearance and consumer appeal of cosmetics
Light reflection	✓	TiO_2 provides a very good SPF performance (protection against UVB radiations) and a significant UVA protection. The particles form a protective film on the uppermost skin layer and scatter and absorb the UV rays of the sun. In this manner, the skin is protected against UV radiation and its harmful effects to health (sunburn, DNA damage, skin aging, etc.). Particularly good sunscreen effects can be achieved through the combination with other filter substances. Ultrafine TiO_2 in sunscreen products is invisible to the human eye and leaves no whitish film on the skin, which motivates consumers to use more generous applications that are absolutely essential to achieve sun protection (VCI, 2016)
UV absorbance	✓	
Approved for use in specific areas	✓	Approved as a UV filter in sunscreens. Included in the list of colorants allowed in cosmetic products
Easy dispersion and particle distribution and processability	✓	
Inertness in the presence of other components	✓	TiO_2 shows good compatibilities with several organic filters to allow a broad coverage of the whole UV-range and ensure true broad-spectrum protection from the sun's damaging rays. TiO_2 is one of the very few globally approved UV filters / sunscreen actives relevant for global formulations. TiO_2 is the UV filter of choice for SPF15 or higher products whilst providing a non-greasy feel, a preferable attribute for e.g. secondary sunscreen products (face creams with UV benefit). It can also demonstrate good stability and processability in formulation processes
Purity	✓	
Other	✓	**Skin tolerance**: another outstanding feature of TiO_2 is its optimal skin tolerance; intolerances or allergic reactions to TiO_2 are practically unknown (VCI, 2016)

3.4.12 Elastomers

Range of applications

TiO_2 is used as a filler and pigment in rubber-based applications including:

- **Tyres**: TiO_2 is used as a white pigment in tyres to produce white sidewalls (thanks to its excellent tinting strength which allows the use of very small quantities);

- **General rubber goods**: TiO_2 is used in the manufacture of general rubber goods (GRG), including food contact materials, construction materials, and other industrial products;

- **Rubber-to-substrate parts**: TiO_2 is used in elastomer bonding agents as a pigment, UV protector and filler required at the vulcanisation step to produce a matrix in which the functional crosslinkers are dispensed. TiO_2 is heat resistant, insoluble in water and resistant to aggressive rubber chemicals. End uses include rubber-to-substrate parts such as mounts, stators, bushings, brake pads, etc. Rubber-metal parts with essential functionality in the automotive industry include airbag absorbers, anti-vibration elements, damping sleeves, chassis parts, steering parts, engine bearings and several others;

- **Pastes**: TiO_2 is used for heat stabilisation in (pastes for) silicone rubber; and

- **Fluorinated rubber**: TiO_2 is used in fluorinated rubber and rubber thread.

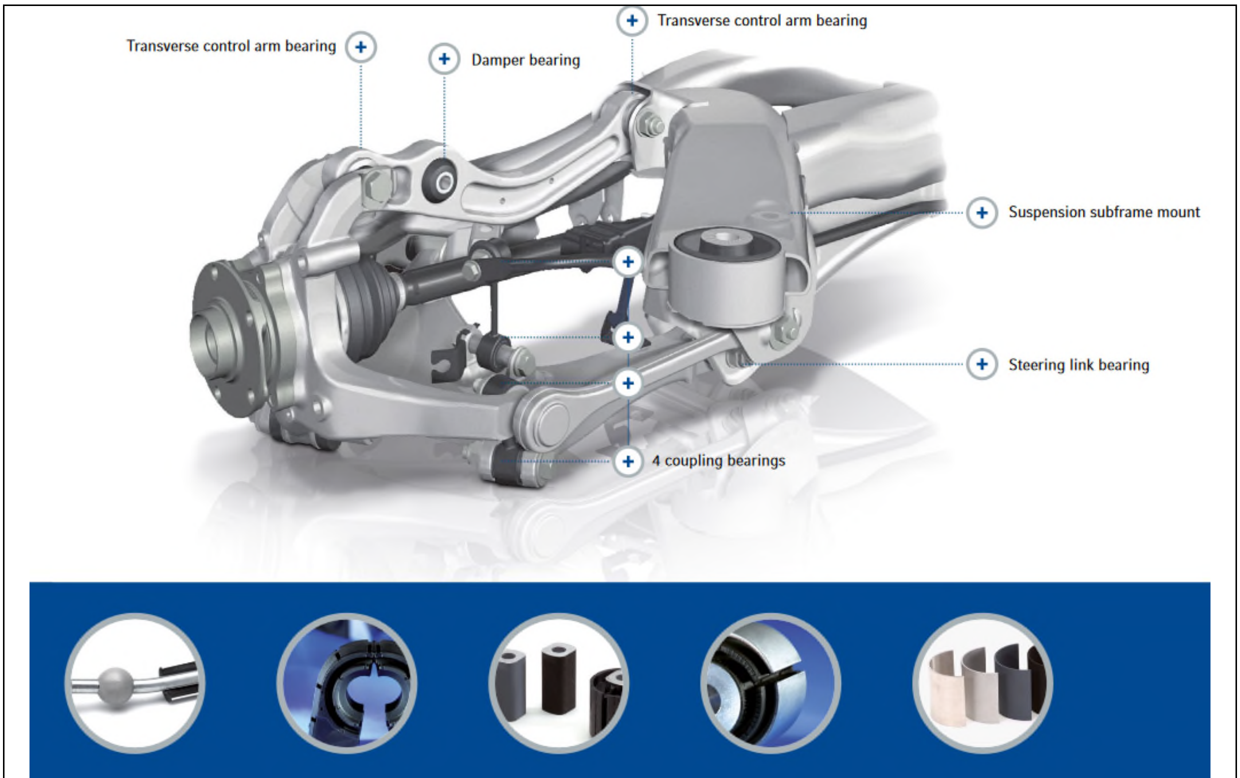


Figure 3–15: Illustration of an automobile front axle. Parts such as damper bearing, steering link bearing or suspension subframe mount those highlighted in the picture are parts made with TiO_2 elastomer bonding agents
Source: GOTEC Gorschlüter Gmbh (available at http://gotec-gmbh.de/user-data/downloads/gotec_IB_ENG.pdf, accessed on 14 December 2016)

Typical concentrations of titanium dioxide

Typical concentrations of TiO_2 in the above products include:

- Colour pastes for silicone rubbers: 30-55%;
- Silicone: 1-5%;
- General rubber goods (GRG): 0.5-20% (depending on the application); and
- Wide sidewall tyres: <1%.

Technical characteristics and advantages

TiO_2 offers the following technical advantages to rubber products.

Table 3–18: Advantages of TiO_2 use in the manufacture of elastomers

Properties	Relevant key advantages	Notes, comments and sources
Whiteness and brightness	✓	
Stability to heat, light and weathering	✓	
Easy dispersion and particle distribution and processability	✓	TiO_2 is not soluble in water and can be dispersed in a solvent system
Inertness in the presence of other components	✓	TiO_2 does not impair the weather resistance and light fastness of the rubber articles. It is resistant to aggressive rubber chemicals. It has no noticeable effect on the mechanical and vulcanisation properties of the rubber

3.4.13 Pigment and pigment preparation manufacture

Range of applications

Overview

TiO_2 is by far the most prominent raw material for the manufacture of pigments and pigment preparations. Pigments and pigment preparations containing TiO_2 are initially used in industrial (e.g. high-quality coatings, paintings, printings inks, plastics, paper, ceramics) and professional (dispersion paints and varnishes) applications and, secondly, in the field of private consumer applications (e.g. cosmetics, pharmaceuticals, ceramics and glass) (Eurocolour, 2016; VdMi, 2016).

It is worth pointing out that TiO_2 is a raw material that is used extensively by SMEs, e.g. manufacturers of complex inorganic pigments, frits and pigment preparations, in quantities up to several hundred thousand tonnes per year each (ANFFECC, 2016; VdMi, 2016b).

Titanium dioxide as a consumed raw material in pigment manufacture

TiO_2 is used as starting material for the synthesis of important inorganic coloured pigments (e.g. with rutile type structure), see **Table 3–19**. Here, TiO_2 is fully converted during the manufacturing process. As a structure-giving component, TiO_2 is the indispensable basis for the manufacture of these colour pigments (ANFFECC, 2016). The key functionality of TiO_2 is the creation of a crystalline structure that is very stable at high temperatures and all kind of atmospheres. This stability prevents defects in the end product.

Table 3–19: Complex Inorganic Pigments based on TiO_2				
EC No.	CAS No.	Name	Formula	Structure
269-052-1	68186-90-3	Chrome antimony titanium buff rutile	$(Ti,Cr,Sb)O_2$	Cassiterite-Rutile
269-054-2	68186-92-5	Chrome tungsten titanium buff rutile	$(Ti,Cr,W)O_2$	Cassiterite-Rutile
232-353-3	8007-18-9	Antimony nickel titanium oxide yellow	$(Ti,Ni,Sb)O_2$	Cassiterite-Rutile
270-185-2	68412-38-4	Manganese antimony titanium buff rutile	$(Ti,Mn,Sb)O_2$	Cassiterite-Rutile
269-047-4	68186-85-6	Cobalt titanite green spinel	$CoTi_2O_4$	Spinel
269-054-2	68187-05-3	Spinels, cobalt tin grey	$CoSn_2O_4$	Spinel
603-450-1	1310-39-0	Pseudobrookite	Fe_2TiO_5	Pseudobrookite

These highly durable exterior and temperature-resistant pigments require not only the purely colouring properties of the pigments, but also additional physical and chemical functions, such as chemical resistance, high resistance to UV light and effective reflection of infrared radiation (Huntsman, 2016m). These certain grades of orange/yellow/brown complex inorganic pigments are used mainly in the ceramic sector and also in other surface applications such as plastics and coatings.

Planar structures based, inter alia, on white and also transparent TiO_2 particles coated with various inorganic coloured pigments form the basis for complex inorganic pigments. These “particle sandwiches” are able to combine the outstanding chemical and physical properties of TiO_2 with virtually boundless colour highlights in the finished coating system (Huntsman, 2016m).

Notably, these pigments have been registered under the REACH Regulation according to the paradigm that these represent toxicologically inert substances because of their crystalline (largely rutile or spinel) structures (IP Consortium, 2016).

Other pigments

TiO_2 is used as the most important white pigment, for example in pigment formulations such as (VCI, 2016; VdMi, 2016; VdMi, 2016b):

- Organic and inorganic pigments (including effect pigments/pearlescent pigments) as a constituent and for finishing and coating;
- Iron oxides and ferrites, as a set-up agent for colorimetric properties;
- Pigment preparations (powder, liquid, paste);
- Masterbatches for subsequent colouring of polymers; and
- Artists’ and recreation (school) colours.

These products are discussed separately later in this section of the document.

Because of its excellent brightening capacity vis-à-vis coloured media, TiO_2 is also used as filler (VCI, 2016; VdMi, 2016; VdMi, 2016b).

Typical concentrations of titanium dioxide

The presence of TiO_2 in pigment preparations ranges between 1% and nearly 100%. Typical concentrations of TiO_2 are given in **Table 3–20**.

Table 3–20: Concentration of TiO_2 in pigments and pigment preparations	
Application	**Typical TiO_2 concentration**
Complex Inorganic (rutile) pigments	Nil
Pearlescent pigments	10 - 100 % (and ultimately 2-25/50% in the final product)
Iron oxides and ferrites	<5%
Ceramic decorating colours	5-60%
Ceramic glass colours	5-25%;
White organic colours	30-60%
Pigments preparations	Up to 100%
Blended pigments	depends on the application
Source: data from consultation (VdMi, 2016b) and VCI (2016)	

Technical characteristics and advantages

The following table summarises the key technical advantages of TiO_2 in this application area.

Table 3–21: Advantages of TiO_2 use in the manufacture of pigments		
Properties	**Relevant key advantages**	**Notes, comments and sources**
Good hiding power/opacity	✓	
Ability to lighten coloured media	✓	(ANFFECC, 2016)
Base for colour development	✓	
Stability to heat, light and weathering	✓	Exceptional light-fastness (ANFFECC, 2016)
Easy dispersion and particle distribution	✓	Optimal particle size distribution in the range of 0.2 - 0.35 µm

3.4.14 Ceramics

Range of applications

Ceramics is a broad term that encompasses a range of applications and is interconnected with applications presented elsewhere, namely pigment manufacture and glass manufacture. In addition to optical performance properties, the main focus of TiO_2 applications is on chemical purity, reactivity and sintering properties. Under ceramics, the use of TiO_2 may include:

- **Pigments**: as shown in Section 3.4.13, TiO_2 is a key raw material in the manufacture of Complex Inorganic Pigments that find applications in ceramics (but also in plastics and coatings). Complex Inorganic Pigments are largely used for yellow and brown colours in the ceramic tile industry. This industry is still of great importance to some Italian and Spanish regions. There are also more innovative applications such as the use of the substance as an additive to the body composition of ceramic tiles to generate yellow pigmentation by means of digital printing. Also, TiO_2 is used as an additive to generate a yellow colour of facing bricks (mainly in Belgium and The Netherlands);

- **Frits, glazes and enamels**: a frit is a ceramic composition that has been fused in a special fusing oven, quenched to form a glass, and granulated. The purpose of this pre-fusion is to render any soluble and/or toxic components insoluble by causing them to combine with silica and other added oxides. Put simply, a frit is the result of the chemical reaction between a mixture of inorganic raw materials (usually metal oxides, e.g. TiO_2). Frits may then be used in the manufacture of glazes and enamels. TiO_2 is mainly used as an opacifier in the production process. TiO_2 is essential in order to obtain very opaque white frits for the production of porcelain enamels (enamels used to coat metallic surfaces) at low temperature (500-800 °C). It is also necessary to obtain no watermark opaque engobes and slips, used in the production of ceramic products. Key products include:

  - White and pastel flatware, cookware, hollowware (both decorated and non-decorated) and eventually also other white kitchenware. At least some of these or similar articles can be found in almost every home, restaurant, hotel, school and hospital kitchen;
  - Sanitaryware enamels;
  - Hot water tanks;
  - Silos;
  - Ovens and cooktops;
  - Architecture; and
  - Rooftiles;

- **Electroceramics**: high-purity pigment grades are used in the production of ceramic materials for electronic components as well as high-quality electroceramics, such as capacitors, PTC resistors, and piezoceramic elements. Examples are barium titanate (BT), lead zirconate titanate (PZT), strontium titanate, magnesium titanate, bismuth titanate and many others. TiO_2 may be used in vitreous enamels for electrodes as well as to act as a stabiliser in the electric arc in the coating of welding electrodes (Huntsman, 2016l);

- **Technical ceramics**: there are many applications of TiO_2 in technical ceramics, e.g. medical components (hip or knee replacement) and protection against abrasion (components for textile industry, automotive applications);

- **Abrasives**: TiO_2 is present as impurity in abrasive grains which are essential raw materials for the production of different types of abrasive products (inorganic bonded abrasives, organic bonded abrasives and coated abrasives)[17]. Abrasive products are essentially required in Europe by various industries such as automotive, aeronautic, turbine industry, mechanics, medical, stone and construction, etc.; and

- **Other**: rutile is added to ceramic materials such as Al_2O_3 and ZrO_2 to improve mechanical and/or thermal properties. In addition, TiO_2 is, at the same time, an important input material in the production of titanium carbides, titanium-tungsten carbides and titanium borides.

Typical concentrations of titanium dioxide

Typical concentration ranges include:

- Frits: 3-20% depending on the application (ANFFECC, 2016);
- Porcelain enamels: 5-25%;
- Ceramic pigments: 5-60% (VCI, 2016; VdMi, 2016; VdMi, 2016b); and
- Complex Inorganic Pigments: no TiO_2 present.

[17] To completely remove TiO_2 totally would be (a) extremely expensive and in addition, (b) the changed product would be likely to have different properties (e.g. reduced robustness) which is crucial for abrasives products.

Technical characteristics and advantages

TiO_2 offers the following technical advantages to ceramic products.

Table 3–22: Advantages of TiO_2 use in the manufacture of ceramics		
Properties	**Relevant key advantages**	**Notes, comments and sources**
Good hiding power/opacity	✓	
Whiteness and brightness	✓	Porcelain and sanitaryware enamels need to be white. TiO_2 crystallises out of the oversaturated enamel frit during the firing of the enamel coating on the metal substrate to give the enamel its brilliant white colour
UV absorbance		TiO_2 increases UV absorption in glass and improves the mechanical, thermal and electrical properties of glass fibres
High efficiency	✓	Due to the thinness of the layer, the bending and impact strength of the enamel is noticeably increased (Kronos, 1968)
Easy dispersion and particle distribution and processability	✓	TiO_2 is well dispersed and also easily soluble in the glaze melt or, if occasion arises, in the frit batch (Kronos, 1968). It can be readily fused in vitreous enamels (and glass)
Other	✓	The susceptibility of glazes to crazing is reduced by an addition of TiO_2 and the gloss of transparent glazes is improved (Kronos, 1968). TiO_2 enhances mechanical and thermal resistance in ceramic glazes. In porcelain enamels, without TiO_2, the chemical resistance against acids is lower. It is important that cookware enamel has very good resistance against citric acid and acetic acid, while for enamels used in industrial applications (for example heat exchangers, architectural panels, chemical vessels) good resistance against sulphuric and hydrochloric acids is required

3.4.15 Glass

Range of applications

TiO_2 applications in glass include:

- Glass with enhanced hardness and higher resistance to abrasion;
- Glass with sun protection properties, good light, anti-reflection and energy performance for window glass in buildings and in cars (TiO_2 is used as a coating, it is not used as a raw material to produce the glass sheet);
- Glass with self-cleaning properties in buildings (TiO_2 is used as a coating, it is not used as a raw material to produce the glass sheet; see photocatalysts, above);
- Radiation protection in the UV range for the pharmaceuticals industry (containers etc.);
- Glass for ophthalmic and optic applications;
- Glass-to-metal-seals for lithium batteries used in medical implantable devices such as pacemakers, heart defibrillators, and neuro-stimulators; and
- Paints and decorating inks used to produce white-colour glass.

These uses are necessary for medical/public health protection, drug safety (inertness of medical drug containers), eye protection and visual correction, and high-end medical applications that save lives.

Typical presence of titanium dioxide in raw materials for glass manufacture

During the chemical reaction to form glass, TiO_2 is transformed into a non-crystalline vitreous new substance (glass). In glass, Ti is incorporated via strong new chemical bonds and becomes an integral part of the glass' three-dimensional structure. The physicochemical properties of the new substance glass (chemical resistance, mechanical resistance, transmittance, colour, etc.) are a function of the composition and the network formed.

The share of TiO_2 in the raw materials used for the manufacture of glass typically is:

- Ceramic glass colours: 4-20%; and
- Special glass: 1-30%.

Technical characteristics and advantages

Technical characteristics and advantages afforded by the use of TiO_2 in the synthesis of glass cannot be achieved by other means. These advantages can be summarised as follows.

Table 3–23: Advantages of TiO_2 use in the manufacture of glass		
Properties	**Relevant key advantages**	**Notes, comments and sources**
Good hiding power/opacity	✓	
Base for colour development	✓	
UV absorbance	✓	Reduces transmission of UV light, viscosity of the glass melt and coefficient of expansion
Photocatalytic activity	✓	Self-cleaning properties when used as coating in window glass
Other	✓	A high refractive index leads to a reduction of the thickness of the glass in optical application. It increases hardness and abrasion resistance as well as resistance to acids. It acts as a crystallisation initiator or crystallisation accelerator

3.4.16 Medical devices

Range of applications

Various medical devices contain TiO_2 as a pigment in bound form, e.g. as dental impression or dental filling or dental temporary or dental lab materials and luting cements. Products include:

- **Dental impression materials**: these are used by dentists to perform impressions on teeth;
- **Dental filling materials**: these are used by dentists to fill cavities (instead of silver-mercury amalgam);
- **Dental luting cements**: these are used by dentists to lute indirect restorations (crowns, bridges, inlays, onlays) to the tooth structure;
- **Dental temporary materials (cements, crown and bridge materials) and crown and bridge materials (non-metallic)**: these are used by dentists to prepare temporary crowns or bridges or to lute such temporary restorations to the tooth; and
- **Dental lab materials**: these are used by dental technicians for a variety of uses.

Figure 3–16: Example of dental impression materials that contain TiO_2
Source: royalty-free photo

Furthermore, TiO_2 is present in various plastic parts in medical equipment/medical devices where it provides two main benefits: firstly, its light resistance provides UV-protection which, in turn, improves the stability of the product; and secondly the white colouration enables dirt and other soiling to be instantly seen, which is beneficial in terms of hygiene (German Medicines Manufacturers Association, 2016). TiO_2 may also be used in surgical medical tapes, wound dressings and bandages. In addition, as noted earlier, TiO_2 is extensively used in the medical plastics industry to protect light sensitive pharmaceutical compounds from photolysis.

TiO_2 has been used for decades in medicinal products and medical devices, as well as in other applications and there are no known examples of adverse reactions caused by the substance (German Medicines Manufacturers Association, 2016).

Typical concentrations of titanium dioxide

The following information is available for TiO_2 in dental formulations:

- Dental impression materials: 0.01 to <1%;
- Dental filling materials: 0.1-4%;
- Dental luting cements: 0.01-0.5%;
- Dental temporary materials: 0.01-0.1%; and
- Dental lab materials: 0.01-0.8%.

Technical characteristics and advantages

These TiO_2-based products have the following advantages:

- Highly improved readability of impressions by dentists. Only materials containing TiO_2 can be well read by optical scanners used in digital dentistry; and

- TiO_2 is the white pigment giving best results in obtaining aesthetic colours for dental materials. With the lowest pigment concentration possible, the most aesthetically pleasing dental products can be achieved.

3.4.17 Detergents

TiO_2 is present in certain detergent products at levels below 1% (with the vast majority being <0.1%). It is used in the following detergent applications:

- **Laundry and cleaning products**: TiO_2 is used as a colourant (whitening) for granular enzymes. It also gives important stability functionalities for the enzymes. Granular enzymes are key cleaning agents in granular detergents and automatic dishwashing products. TiO_2 can also be found in curtain/fabric whiteners; and

- **Toilet solid rim blocks**: TiO_2 is a white colourant and a process aid (for the extrusion of the blocks).

3.4.18 Biocides

Consultation with downstream users of the substance indicates that TiO_2 is used as a carrier and light stabiliser of special biocidal active substances based on silver (AgCl on TiO_2). These are used as in-can preservatives, additives for hygienic paints, additives to extend shelf life (e.g. paints), co-biocides, etc. The substance is currently listed as "under review" in the form of "reaction mass of titanium dioxide and silver chloride" for seven product types. The product types covered are:

1 – Human hygiene;

2 – Disinfectants and algaecides not intended for direct application to humans or animals;

6 – Preservatives for products during storage;

7 – Film preservatives;

9 – Fibre, leather, rubber and polymerised materials preservatives;

10 – Construction material preservatives; and

11 – Preservatives for liquid-cooling and processing systems.

3.4.19 Other minor applications

Several less widespread applications of TiO_2 exist. Some that have been identified in the course of preparing the present report include:

- Liquid chromatography;
- Growth promoter pigment for horticulture (greenhouse applications); and
- Lubricants.

4 Impact analysis

4.1 Introduction

This is the main section of the impact assessment presented in this document. The section starts with a discussion of the key drivers behind the socio-economic impacts that would arise from a Carc Cat 2 harmonised classification for TiO_2 and thereafter discusses the relevant impacts for each downstream use sector taking into account the analysis of the regulatory framework presented in Annex 1 (Section 7) of this document. Having discussed the impacts on the marketing and use of the substance and its mixtures and articles, an analysis of upstream impacts (on TiO_2 manufacturers and their suppliers is provided). Lastly, a discussion on potential impacts outside the TiO_2 supply chains is provided and the Section concludes with an overview on potential impacts on the environment.

4.2 Drivers behind the impacts from the proposed classification of titanium dioxide

4.2.1 Impact driver 1: Existing regulatory requirements

Framework of analysis

There is a wide range of legislative instruments at EU level that link to the CLP Regulation and which therefore would come into play if a harmonised classification of Carc Cat 2 for TiO_2 were to be adopted. Annex 1 (Section 7) includes a series of tables that summarise the relevant legislation (with a focus on EU-wide regulation and initiatives) and provides information on:

- The key provisions of each piece of legislation in relation to both Carc Cat 1B and Carc Cat 2 substances, in order for a quick comparison between the two harmonised classification categories to be made;
- Whether each legislation applies to a single industrial sector/area of application (e.g. cosmetics) or several (e.g. REACH);
- Whether the legislation and its implementation have implications primarily for industrial users (I), professional users (P) or consumers, i.e. the general public (C);
- Importantly, whether the magnitude of the impact that legislative provisions would have on the current applications of TiO_2 would be defined by hazard profile alone (i.e. the new hazard classification) or would take into account the risk of release and exposure (including exposure pathway), and in many situations the availability of alternatives for TiO_2 as well;
- A description of the process that would need to be followed before the new hazard classification translates into some sort of restriction on the use of TiO_2 in specific applications; and
- A final comparison of the severity of regulatory requirements between the two harmonised classification categories.

The tables confirm that a wide variety of legislative instruments would be of relevance. Some of it is cross-sectoral, such as the CLP Regulation itself, which will require changes to labelling of mixtures and their packaging; while other legislation focuses on specific areas of application of TiO_2, for example, pharmaceuticals, cosmetics, food safety and food contact materials. There is also legislation that, whilst having a specific focus, may transcend market sectors and applications; for example, biocides containing TiO_2 may find applications in several end-user sectors (e.g. cosmetics, paints, coatings). The following paragraphs firstly focus on legislation that would have an impact across the manufacture, placing on the market and use of TiO_2 and then discuss impacts specifically relevant to downstream uses of the substance.

Supply chain-wide impacts arising under the CLP Regulation

New labelling requirements

Following the classification of the substance, there would be a need for replacing existing labels on TiO_2 and mixtures that contain the substance in concentrations exceeding 1.0% by weight to reflect its new harmonised classification. This would have direct cost implications:

- Part of the existing stocks of labels and packaging (i.e. those intended for use within the EEA) would need to be disposed of (or recycled, where possible);

- New labels and packaging would need to be designed, produced and supplied to interested parties (NB. Article 35 of the CLP Regulation imposes safety requirements for the packaging of substances and mixtures classified as hazardous – this might affect the packaging specifications of some mixtures of TiO_2); and

- Logistic complexities would arise from the new labels and packaging being selectively used when trading within the EEA.

Estimates for the direct cost of new labelling following the proposed classification of TiO_2 are not available, although some figures can easily be retrieved online from other cases of (re-)classification of substances and products[18]. Realistically, the cost per company may not be prohibitive depending on the type and volume of packaging[19]; however, when aggregated across the numerous uses of the substance, the overall cost would be very substantial. Moreover, given that inhalation is the only exposure route of theoretical concern but the probability for such exposure (and at relevant exposure levels) is extremely low in most cases, the expense for new labels would appear disproportionate and unjustified.

It is useful to juxtapose the labelling requirements for Carc Cat 1B and Carc Cat 2 as prescribed under the CLP Regulation, see **Figure 4–1** (overleaf).

The differences, particularly to someone not conversant with the meaning of key terms (“Danger”, “Warning”, “May cause cancer”, “Suspected of causing cancer”), are arguably subtle. The pictograms are the same and the precautionary statements are the same (NB. the hazard statement would indicate exposure route (i.e. inhalation) only if there is conclusive proof that no other routes

[18] For instance, small changes to the hazard labelling of aerosols would cost £0.14-0.2 million per aerosol manufacturer in the UK, or ca. £150-200 per production line (BIS, 2014). In another case, the cost of changing the labelling/packaging of cement bags was estimated at €0.7-7 per 1,000 kraft paper bags (depending on whether the entire bag or only part of it changes) and a total cost of €1.4-4 million per year for the whole of Europe (Cerame-Unie, 2013).

[19] It must also be remembered that proposed classification would also affect the use of TiO_2 in labels and inks that would need to be used in the new packaging.

of exposure cause the hazard). A tactile warning of danger (raised triangle) would also accompany mixtures containing more than 1.0% TiO_2.

Table 3.6.3

Label elements for carcinogenicity

Classification	Category 1A or Category 1B	Category 2
GHS Pictograms		
Signal Word	Danger	Warning
Hazard Statement	H350: May cause cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)	H351: Suspected of causing cancer (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard)
Precautionary Statement Prevention	P201 P202 P281	P201 P202 P281
Precautionary Statement Response	P308 + P313	P308 + P313
Precautionary Statement Storage	P405	P405
Precautionary Statement Disposal	P501	P501

Figure 4–1: Label elements for carcinogenicity according to the CLP Regulation 1272/2008

Furthermore, a number of precautionary statements would also apply with respect to prevention, response, storage and disposal with a maximum of six to be used. In order of importance, these include:

- **P281: Use personal protective equipment as required** (highly recommended to be used for all market sectors);
- **P501: Dispose of contents/container to …** (mandatory for products sold to the general public);
- **P405: Store locked up** (highly recommended for products sold to the general public, optional for others);
- **P201: Obtain special instructions before use** & **P308/P313: If exposed or concerned: Get medical advice/attention** (recommended); and
- **P202: Do not handle until all safety precautions have been read and understood** (optional).

Labelling creates perception and perception often transcends the scientific basis of the classification and the label itself. Labelling could indeed prove problematic as it would apply to important TiO_2-based mixtures that are placed on the EEA consumer market, such as DIY paints that generally contain TiO_2 concentrations much higher than 1.0%. Importantly, labelling would be required even where exposure by inhalation would be impossible to occur. Thus, consumers would not be able to ascertain the 'real' risk from using a DIY paint or other formulation (e.g. adhesives, sealants, etc.) and could grow reluctant to use products that contain a carcinogen, often at relatively high concentrations. It should be noted that companies are not free to choose what they include in the labels affixed to their products and may only label according to the CLP Regulation with any transgression potentially leading authorities' demands for product withdrawal.

Poison Centre Notifications

According to the newly introduced Annex VIII to the CLP Regulation, before placing mixtures on the market, submitters (i.e. importers and downstream users placing on the market mixtures for consumer/professional/industrial use) shall provide information (product identification, hazard identification, composition information and toxicological information) relating to mixtures classified as hazardous on the basis of their health or physical effects to their national Poison Centres. A universal submission format shall be used across the EU. Importers and downstream users placing on the market mixtures for consumer, professional and industrial use shall comply from 1 January 2020, 1 January 2021 and 1 January 2024 respectively. If relevant information has already been submitted, the obligation for submission of data to Poison Centres is deferred to 1 January 2025. Thus, importers and downstream users of mixtures that are currently not classified as hazardous but contain TiO_2 in concentrations above 1.0% will become obliged to provide information to Poison Centres over the period 2020-2024, depending on whether those mixtures are used by consumers, professional users or industrial users. This new obligation will generate an additional administrative burden and cost.

Supply chain-wide impacts under the Waste Framework Directive

Waste management implications of a Carc Cat 2 harmonised classification

A Carc Cat 2 classification would generate new requirements for the management of TiO_2-containing waste by resulting in the classification of several types of waste as hazardous. According to Annex III (and Table 6 thereof) of Directive 2008/98/EC (the Waste Framework Directive), waste that contains a Carc Cat 2 substance in concentrations above 1.0% would be classified as hazardous with a HP 7 classification. There are clearly many formulations (e.g. paints, inks, adhesives, sealants, etc.) and products (e.g. plastics, elastomers, ceramics, etc.) in which the concentration of TiO_2 significantly exceeds the 1.0% level (by weight) and thus, in principle, associated waste streams might run the risk of being classified as hazardous. The approach to the classification of TiO_2-containing wastes as hazardous is based on the provisions of the Waste Framework Directive and on Decision 2000/532/EC (as revised by EU Decision 2014/955/EU) which established the European List of Wastes (LoW) can be described in **Figure 4–2**.

The LoW is divided into 20 chapters (labelled with 2 digits) based on the key process (source) that generates the waste or specific waste types (e.g. Digit 20 for Municipal Wastes (Household waste and similar commercial, industrial and institutional wastes – Including separately collected fractions)). The waste categories are further divided into sub-chapters labelled with 4-digit codes based on processes and/or input materials used in the process. Finally, each specific waste entry under each sub-chapter is given a specific six-digit code and description (Wahlström, et al., 2016).

The wastes in the LoW are labelled in three different ways depending on their hazard classification (Wahlström, et al., 2016):

- **'Absolute hazardous'** entry: the code is marked with an asterisk (*) and the waste is classified as hazardous waste (no further assessment needed). The producer of the waste does not need to consider what chemicals are in the waste to find out if it is hazardous or not (still the producer needs to establish what hazardous properties the waste displays to ensure appropriate management of it). Even if that waste has no hazardous properties, the absolute hazardous entry still applies;

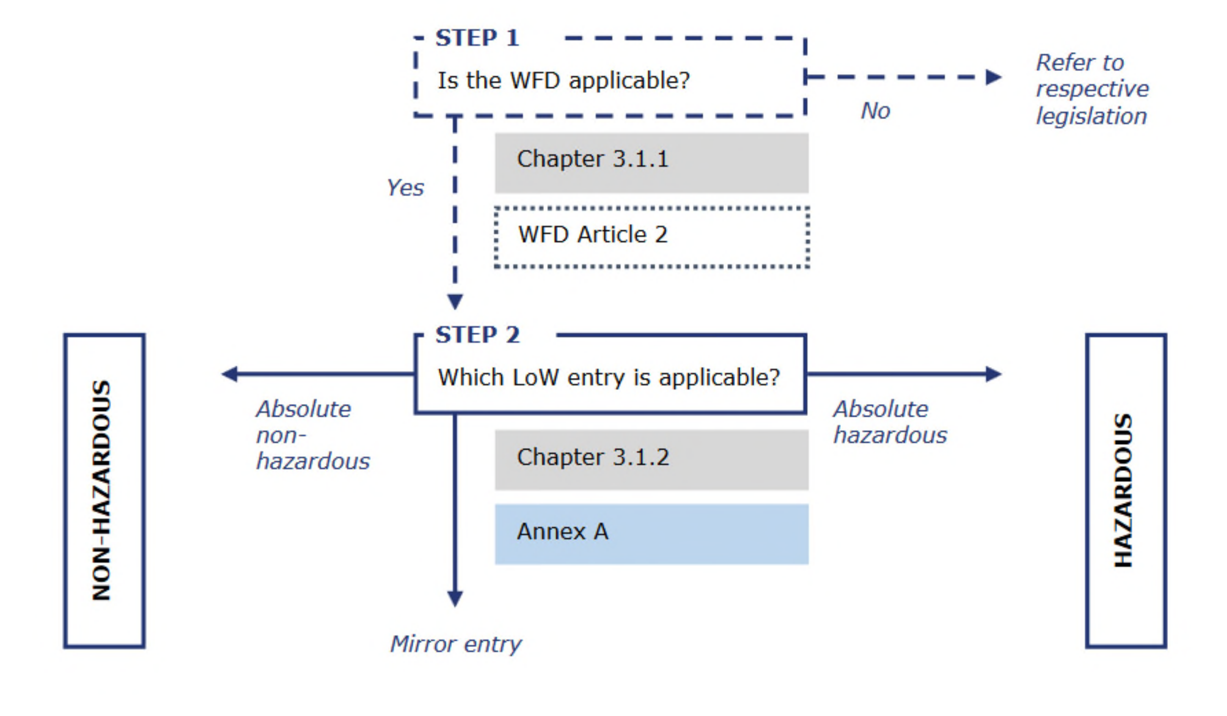


Figure 4–2: Flow chart for determination of applicable LoW entries (BiPRO, 2015)

- **'Mirror'** entry: the mirror entries are typically a pair of two (sometimes more) entries (6-digit codes) one hazardous and the other non-hazardous. The hazardous entry refers to the presence of hazardous substances (general or specific) while the non-hazardous entry applies where the hazardous components are absent and cross-refers to (mirrors) the hazardous entry digit code. However, there are also cases where the mirror entries are unpaired i.e. there is no cross reference from the non-hazardous entry to the hazardous entry. Both for the paired and unpaired mirror entries, the waste producer must show that the waste does not exhibit hazardous properties related to the presence of hazardous substances prior to assigning a non-hazardous waste code. For a mirror pair where the hazardous entry has a specific reference to a hazardous substance (for example, coal tar), the hazardous entry is chosen only if the waste contains the particular hazardous substance (in this case coal tar) at or above levels that make it hazardous. In short, a "mirror" entry waste is a potentially hazardous or non-hazardous waste depending on the presence of specific or generic hazardous substances and thus an assessment must be made whether any given waste is hazardous or not; and

- **'Absolute non-hazardous'** entry: the waste is classified as non-hazardous (no further assessment needed). The producer of the waste does not need to consider what chemicals are in the waste to find out if it is hazardous or not. By way of example, "*02 01 04 waste plastics (except packaging)*" under the general waste category "*WASTES FROM AGRICULTURE, HORTICULTURE, AQUACULTURE, FORESTRY, HUNTING AND FISHING, FOOD PREPARATION AND PROCESSING*" is an "absolute non-hazardous" entry and therefore waste products such as agricultural plastic films would not be classified as hazardous after the adoption of the Carc Cat 2 classification that is being considered by the RAC even if they do contain TiO_2 in concentrations above 1.0% by weight.

A 2015 study reports that of the 842 entries in the LoW, 228 are 'absolute hazardous', 236 are 'absolute non-hazardous', 180 are 'mirror hazardous' and 198 are 'mirror non-hazardous' (BiPRO, 2015).

Following from the above, it may be concluded that:

- A new harmonised classification for TiO_2 would not affect the management of any 'absolute hazardous' waste that contains the substance. These wastes are currently classified as hazardous and will continue to be even after the introduction of the Carc Cat 2 harmonised classification and can therefore be disregarded in this impact assessment;

- A new harmonised classification for TiO_2 would have an impact on the management of waste that currently falls under 'mirror non-hazardous' entries and contains more than 1% TiO_2. Such waste would need to be allocated to the respective 'mirror hazardous' entry that makes a generic reference to "hazardous substances" (for instance, *08 01 16 aqueous sludges containing paint or varnish other than those mentioned in 08 01 15* would be replaced by *08 01 15* - aqueous sludges containing paint or varnish containing organic solvents or other hazardous substances*). It might be perceived that wastes already classified as hazardous under a 'mirror hazardous' entry due to the presence of other hazardous substances would not substantially be affected by the Carc Cat 2 harmonised classification for TiO_2; however, information collected during the preparation of this report indicates that whilst the hazard classification of the waste might not change, the cost of its management might increase, as will be explained later in this document); and

- The management of 'absolute non-hazardous' waste might also be impacted. In principle, if a waste is allocated to an 'absolute non-hazardous' entry, in most cases it is non-hazardous without any further assessment of its composition. However, there are notable exceptions where these 'absolute non-hazardous' entries are linked to other entries in the LoW and the other entries may need to be considered to determine if they are more appropriate to the waste. A good example is empty TiO_2 packaging waste that contains over 1.0% TiO_2 residues. Paper waste of this type (i.e. empty paper bags) is currently classified as *15 01 01 paper and cardboard packaging* but once TiO_2 becomes a Carc Cat 2 substance, the appropriate entry will be *15 01 10* packaging containing residues of or contaminated by hazardous substances* (this is discussed further below).

Where a waste is classified as hazardous, a number of specific obligations apply under the Waste Framework Directive, e.g.

- Labelling and packaging obligations (Article 19);
- The obligation to provide evidence for the tracking of the waste according to the system put by the relevant Member State (Article 17); and
- A mixing ban (Article 18).

Hazardous waste is also required to meet the waste hierarchy prescribed in the Directive and should be minimised, reused or recycled before disposal occurs. Hazardous waste must be classified and is required to be treated before it can be disposed of, in order to prevent or reduce possible harm to human health and the environment. If hazardous waste cannot meet the upper levels of the waste hierarchy then it should either be incinerated or disposed of in a hazardous waste landfill.

According to Cefic, the price for treatment of waste classified as hazardous can be 2 to 3 times the price for the same material classified as non-hazardous[20]. Information from some consultees

[20] Suggestion of Cefic to the European Commission, dated 6 April 2017, available at https://ec.europa.eu/info/law/better-regulation/lighten-load/suggestions/S19535_en (accessed on 1 September 2017).

suggests that an even higher cost increase might be possible. For instance, the EUWID Recycling and Waste Management, a publication-source of information for the international waste management and secondary raw materials sector, has been suggested to indicate price differences for the management of hazardous and non-hazardous waste in the range of 10-30 times[21].

Management of waste packaging with titanium dioxide residues

Handling of waste packaging that contained TiO_2 or TiO_2-containing mixtures would also be affected by the harmonised classification of the substance. This packaging may now become classified as hazardous and would need to be treated accordingly, depending on the level of residue / waste retained in the packaging. Chapter 15 of the LoW contains the following codes for waste packaging classified as non-hazardous under *15 01 Packaging (including separately collected municipal packaging waste)* (NB. all are 'absolute non-hazardous entries'):

- 15 01 01 paper and cardboard packaging;
- 15 01 02 plastic packaging;
- 15 01 03 wooden packaging;
- 15 01 04 metallic packaging;
- 15 01 05 composite packaging;
- 15 01 06 mixed packaging;
- 15 01 07 glass packaging; and
- 15 01 09 textile packaging.

Chapter 15 of the LoW also contains the following codes for waste packaging classified as hazardous:

- 15 01 10* packaging containing residues of or contaminated by hazardous substances; and
- 15 01 11* metallic packaging containing a hazardous solid porous matrix (for example asbestos), including empty pressure containers.

Recent guidance issued in the UK (by industry in association with the Environment Agency) is summarised in **Figure 4–3**.

21 It was suggested in consultation that this significant difference in waste management costs was demonstrated in the recent case of Hexabromocyclododecane (HBCDD)-containing insulation waste in Germany. The German Federal Government revised the German Waste Catalogue Ordinance in March 2016 (the German List of Waste). This ordinance classifies non-hazardous and hazardous wastes. Following the revision, insulation waste, typically expanded polystyrene waste which contains HBCDD above the threshold of 0.1% by weight, had to be classified as hazardous from October 2016. According to waste operators, both utilising energy-from-waste as well as recyclers, this resulted to a state of emergency in Germany. The change in legislation largely brought a hitherto smoothly running and safe disposal route to a standstill. The classification increased the requirements for site logistics and disposal with transport, storage and plant permits becoming necessary. The ban on mixing hazardous waste did not only increase the disposal costs, especially for so-called monocharges, but also led to capacity problems in the waste treatment plants and thus to the unintended waste disposal bottleneck for polystyrene insulation boards in Germany (see details here: http://www.agehda.de/cms/wp-content/uploads/2017/04/Positionspapier_AGEHDA-final.pdf, accessed on 13 November 2017). As a consequence, the German Government issued a memorandum of exemption in December 2016 and in collaboration with industry eventually revised the German Waste Catalogue Ordinance again, which is now effective from August 2017.

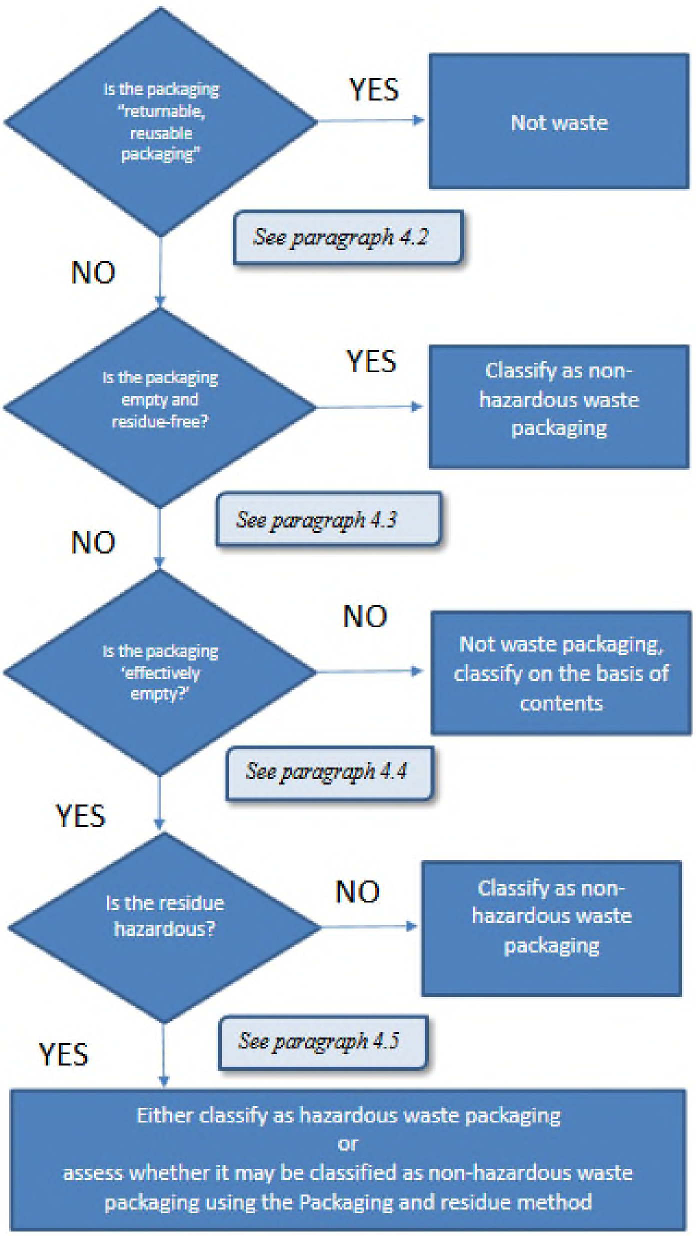


Figure 4–3: Flow chart for assessing whether packaging to be taken offsite is waste or not – UK (IPA, 2017)

The following points are important for the interpretation of the flowchart (IPA, 2017):

- Indicators that packaging may be waste include a package that: (a) is not reusable; (b) requires treatment other than simple rinsing to remove chemical residues; (c) is not 'effectively empty'; or(d) is damaged and requires repair before it can be re-used;

- 'Effectively empty' means that the packaging has been treated in such a way that all reasonable efforts have been made to remove any left-over contents from the packaging, by applying normal industrial standards or processes, or, if the packaging is sealed, has been designed in such a way so that the residue when the packaging has been emptied is minimal. Regarding powders, the use of bag shakers/massagers to remove the powder from FIBCs (flexible intermediate bulk containers) or tipping and shaking of smaller bags would constitute 'all reasonable efforts' and the package would be considered 'effectively empty'. Additionally, for the packaging to be considered 'effectively empty', any contamination on the outside of the packaging must be minimal; and

- If either the residue inside, or any contamination on the outside, of an 'effectively empty' container possesses a hazardous property, then it can be classified as hazardous waste packaging without any further assessment using the LoW code 15 01 10*.

Thus, packaging containing residues of or contaminated by TiO_2 containing more than 1.0% of the substance (by weight), would be classified under 15 01 10* as hazardous waste. Such waste might include 25kg bags, big bags, bulk bags (FIBCs) and potentially containers for slurries (NB. there is still some uncertainty with regard to whether slurries will be classified HP7 hazardous or not or not, as the TiO_2 contained within slurries does not strictly go through a dry powder phase).

A particular separate mention is required for plastic packaging waste. LoW code 15 01 10* for plastic packaging waste may become relevant not only as a result of the presence of TiO_2-containing residues in the packaging waste, but it can be also relevant when the packaging waste contains the substance as an ingredient, i.e. an additive. This interpretation with respect to plastics and possibly other chemical raw materials can be derived from the EU Commission's "Guidance document on the definition and classification of hazardous waste" drafted by JRC in June 2015[22]. According to section *A.5.9 Plastics*, "*A specific plastic waste can be hazardous either because of the additives it contains or because the waste is contaminated with hazardous substances e.g. oils or solvents*".

Role of exposure pathway and bioavailability in hazardous waste classification

The harmonised classification that is being considered by the RAC is expected to specify the inhalation exposure route as the only one of relevance. Generally, inhalation exposure to TiO_2 from end-products and their waste forms is very unlikely, if not impossible, to arise as the pigment is embedded into a matrix (a paint, a coating, a plastic, etc.), and migration is (nearly) zero. Even if some activities would generate some dust (e.g. removal of paints from painted surfaces may generate dust), such activities are generally infrequent and generate dust levels that, with appropriate respiratory protection, are generally low.

On this basis, it would be reasonable to assume that many types of wastes that contain over 1.0% TiO_2 but cannot be inhaled (e.g. there are in the form of a viscous liquid or dust-free solid) would not warrant a hazardous classification. To investigate whether this avoidance of a hazardous classification based on low/no bioavailability (and therefore low/no risk of exposure) would be a possibility, we need to look into waste management practices on the national (and possible also regional) level, since the implementation of the Waste Framework Directive into national waste legislation varies across the EU.

For reasons of time availability, it has not been possible to look into all Member States; instead, a group of six Member States have been selected as case studies: France, Germany, Italy, Poland, Sweden and the United Kingdom. In general, the disposal options available vary depending on the EU State in which it has been produced. Taxes and licencing fees also vary depending on the country and this will have an impact on the cost of disposal. Shipments of hazardous waste are controlled and different EU states have slightly different rules on what wastes can be transported across their borders for disposal. The following paragraphs discuss the regulatory framework in the selected

[22] Available at http://ec.europa.eu/environment/waste/pdf/consult/Draft guidance document 09062015.pdf (accessed on 7 November 2017).

Member States and, information permitting, explain the realism and possibilities for taking the exposure pathway into account when classifying TiO_2-containing waste as hazardous (or not) and national provisions for the treatment if such waste.

Box 4.1: Review of waste management requirements in selected Member States and possibilities for exemptions based on exposure route for a H351 classified substance

France: according to a factsheet for TiO_2 drawn up by the French Institute of Scientific Research (INRS), it is already recommended that waste TiO_2 be considered 'hazardous waste', packaged in closed air-tight containers and labelled before being disposed of[23]. Waste producers locate their own waste disposal service providers (who they can contact for a quote[24]) but are responsible for ensuring that these service providers are compliant with regulation[25]. The quote is based on the type and amount of waste to be disposed of, the form of disposal and transport costs.

The French Environment Code (Article R541-50) stipulates that companies are to file a declaration with the prefect for the area (*département)* where their head office is based or, failing that, where the domicile of the declarant is based, when a quantity greater than 0.1 tonnes of hazardous waste or 0.5 tonnes of non-hazardous waste is collected or transported for disposal.

Producers are responsible for their waste from the moment that it is created until its final stage of disposal has been completed (e.g. treatment or placed in landfill)[26]. For hazardous waste, the waste producer is obliged to issue a hazardous waste tracking slip (*un bordereau de suivi des déchets – BSD*), which is then completed by the carrier and the treatment facility/facilities receiving the waste. Once the waste has been disposed of, the BSD is returned to the producer[27]. Waste producers are also obliged to keep a register monitoring their waste disposal activities[28].

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[23] INRS (2013): Fiche toxicologique – Dioxyde de titane, accessed on 30 August 2017 at: http://www.inrs.fr/dms/ficheTox/FicheFicheTox/FICHETOX_291-2/FicheTox_291.pdf.

[24] Veolia website: Déchets dangereux : des professionnels à votre service 24h/24, 7j/7, available at http://recyclage.veolia.fr/entreprises/solutions-matieres/dechets-dangereux.html (accessed on 30 August 2017).

[25] Legifrance website: Article L541-2 of the French Environment Code, available at https://www.legifrance.gouv.fr/affichCode.do;jsessionid=81A4563FB6861C4317C754D1D72A6334.tpdila09v_1?idSectionTA=LEGISCTA000024357401&cidTexte=LEGITEXT000006074220&dateTexte=20170830 (accessed on 30 August 2017).

[26] Legifrance website: Article L541-2 of the French Environment Code, available at https://www.legifrance.gouv.fr/affichCode.do;jsessionid=81A4563FB6861C4317C754D1D72A6334.tpdila09v_1?idSectionTA=LEGISCTA000024357401&cidTexte=LEGITEXT000006074220&dateTexte=20170830 (accessed on 30 August 2017).

[27] Legifrance website: Article R541-45 of the French Environment Code, available at https://www.legifrance.gouv.fr/affichCode.do;jsessionid=9B5286EBFA0D549DB07EDFA51A65893D.tpdila07v_1?idSectionTA=LEGISCTA000024357355&cidTexte=LEGITEXT000006074220&dateTexte=20170831 (accessed on 30 August 2017).

[28] Legifrance website: Article R541-46 of the French Environment Code, available at https://www.legifrance.gouv.fr/affichCode.do;jsessionid=9B5286EBFA0D549DB07EDFA51A65893D.tpdila07v_1?idSectionTA=LEGISCTA000024357355&cidTexte=LEGITEXT000006074220&dateTexte=20170831 (accessed on 30 August 2017).

Disposal of hazardous waste is organised at a regional level within the regional waste prevention and management plans (*plans régionaux de prévention et de gestion des déchets*)[29].

No information has been identified that would lead us to assume that exposure routes (in essence, levels of risk) are taken into account in classifying a waste as hazardous or not. As such, a waste containing over 1% TiO_2 could be classified as hazardous even if exposure by inhalation could be impossible or very low.

Germany[30]: waste management in Germany is the responsibility of the competent Federal State authorities, who impose delivery and handover obligations for hazardous waste. The waste producer is required to notify the local authority of the type, quantity and composition of the waste, as well as the envisaged disposal facility. The local authority will then assign the waste to a suitable facility. Supervision of hazardous waste disposal is managed through documents such as the Waste Recovery and Disposal Record (Entsorgungsnachweis), Transport Form (Begleitschein) and the Transfer Receipt (Übernahmeschein). Consent by the competent authority can be forgone if the waste is disposed of by a company that is certified in accordance with the Ordinance on Specialised Waste Management Companies. Commercial collection of hazardous wastes from households is prohibited as a permit is required for hazardous waste disposal. There is no separate permit for waste producers, it is contained within the relevant building or Emission Control Act permits. The waste producer must show that they are trying to minimise their waste generation but there is no licencing fee. An entity that is to transfer waste must make a number of notifications, such as those to road traffic authorities, and obtain a Section 45 Close Cycle Management Act licence[31]. Transfer and disposal is carried out by private companies commissioned by the waste producer, rather than the local authority.

The cost of hazardous waste disposal is based on the type and quantity of the waste to be disposed of and the costs associated with transport. There is no landfill tax in Germany as there are restrictions on what can be sent to landfill based on physical and chemical properties. Fees will vary depending on the type of treatment, i.e. incineration or landfill.

As for France, no information has been identified that would lead us to assume that exposure routes (in essence, levels of risk) are taken into account in classifying a waste as hazardous or not. As such, a waste containing over 1% TiO_2 could be classified as hazardous even if exposure by inhalation could be impossible or very low.

Italy: a waste stream containing TiO_2 classified as Carc Cat 2 will be classified as hazardous in the Italy. There does not appear to be any differentiation between exposure pathways and treatment options. It appears that where hazardous waste cannot be reused or recycled, it is mostly sent to a hazardous waste landfill. Waste for incineration tends to be shipped to other countries. Costs of disposal are defined on a case by case basis, depending on the type and amount of hazardous waste to be disposed of. The type and amount of waste informs the form of disposal container that is required (drums, canisters etc.) and their size, which affects the cost.

Waste management plans vary between municipality and the cost of disposal can be influenced by whether or not there is an overarching contractor for waste collection, transport and disposal or whether there are

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29 AdCF website: Les plans régionaux déchets (PRPGD) engagés dans plusieurs régions, available at http://www.environnement-magazine.fr/article/47735-plan-regional-de-prevention-et-de-gestion-des-dechets-ce-qu-il-faut-savoir/ (accessed on 30 August 2017).

30 Umweltbundesamt website: Hazardous waste, available at http://www.umweltbundesamt.de/en/topics/waste-resources/waste-management/waste-types/hazardous-waste (accessed on 30 August 2017).

31 Thomson Reuters Practical law website: Environmental law and practice in Germany: overview, available at https://uk.practicallaw.thomsonreuters.com/4-503-0486?transitionType=Default&contextData=(sc.Default)&firstPage=true&bhcp=1 (accessed on 30 August 2017).

intermediaries. A landfill tax is also incorporated in the cost of disposal. Transporters of hazardous waste are subject to a licence but it is unclear whether premises that produce hazardous waste must be licenced or registered.

Poland: the responsibility for waste management is held by the waste producer, although this may be transferred to the entity that has been authorised for collection or treatment of such waste (this is not the waste carrier). Waste carriers must be authorised by the sub-regional authority (Starosta) and are required to be registered in a nationwide database. The transport permit indicates the codes of waste that the carrier is authorised to transport[32].

In order for hazardous waste to be incinerated there must be a detailed description of the waste (including laboratory analysis), protection and precautionary measures and information on which substances the waste must not be mixed with provided[33]. The cost of hazardous waste disposal is unclear but it appears that it is a similar situation to that of the other EU States, whereby it is based on a quotation from the waste carrier.

As for France and Germany, no information has been identified that would lead us to assume that exposure routes (in essence, levels of risk) are taken into account in classifying a waste as hazardous or not. As such, a waste containing over 1% TiO_2 could be classified as hazardous even if exposure by inhalation could be impossible or very low.

Sweden[34]: a waste stream containing TiO_2 classified as Carc Cat 2 will be classified as hazardous in Sweden. There does not appear to be any differentiation between exposure pathways and treatment options. There is no standard cost for disposal of hazardous waste as it is dependent on the type and amount of waste to be disposed of and the treatment option. A permit is required for incineration operations, which is likely, incorporated into costs for disposal. The tax on incineration depends on the fossil material in the waste and whether the facility produces electricity. The landfill tax in Sweden is €55 per tonne and the average net fee for landfilling is €50-75 per tonne, making the total fee payable approximately €120-170 per tonne, although it is not clear if this is applicable for hazardous waste landfills.

Local authorities are responsible for the collection, transport and treatment of hazardous household waste, with the most common collection system being at manned municipal recycling centres. There is no licence fee for hazardous waste producers but depending on the waste fraction (i.e. WEEE, batteries and medicines), there is producer responsibility, which means that the producers pay a fee to a producer responsibility organisation who arrange the national collection system and treatment. The producer of hazardous waste must ensure that the waste is managed according to the terms of the company's environmental business permit and Sweden's environmental laws.

Hazardous waste producers can choose whether to have their waste collected and treated by either a private company or a municipal waste company as long as the company chosen has the correct environmental business permit. Hazardous household wastes are collected and managed by the Swedish municipalities. The

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32 Improvement of hazardous waste management in the Republic of Serbia website: Waste management of hazardous waste in Poland, available at http://hazardouswaste-serbia.info/fileadmin/inhalte/haz_waste/pdf/Fact_sheets/02_Poland_fact_sheet_presentation.pdf (accessed on 30 August 2017).

33 Improvement of hazardous waste management in the Republic of Serbia website: Waste management of hazardous waste in Poland, available at http://hazardouswaste-serbia.info/fileadmin/inhalte/haz_waste/pdf/Fact_sheets/02_Poland_fact_sheet_presentation.pdf (accessed on 30 August 2017).

34 Avfall Sverige website: Swedish waste management 2016, available at http://www.avfallsverige.se/fileadmin/uploads/Arbete/Remissvar/swm_2016.pdf (accessed on 30 August 2017).

cost of disposal may vary depending on whether the same company is used as that which collects and transports the waste.

United Kingdom[35,36]: a waste stream containing TiO_2 classified as Carc Cat 2 will be classified as hazardous in the UK. There does not appear to be any differentiation between exposure pathways and treatment options. There are two forms of disposal of hazardous waste which cannot be reused or recycled: incineration or hazardous waste landfill. The Environment Agency (EA) has produced decision trees to help waste producers decide which point on the waste hierarchy they should be following to prevent the over use of landfill.

It used to be the case that the producer of hazardous waste would need to register their site at a cost, but this is no longer required. Anyone who transports hazardous waste is required to have a waste carrier licence which costs £234 (+VAT) (ca. €250 + VAT) for a new licence and £154 (+VAT) (ca. €170 + VAT) if the licence is being renewed.

There is no direct fee payable by a waste producer to a disposal facility. The producer tends to enlist the services of a waste disposal company to which they will pay a fee. This fee is dependent on the type and amount of waste being disposed of as different wastes require different carrying methods (2- or 5-litre drums etc.). Not only are different wastes liable to different costs, different types of waste within a waste stream are liable to different costs, for example paints can be charged differently depending on their content. Transport costs and the landfill tax payable by the disposal site operator are also included in the cost (NB. the landfill tax for hazardous waste in the tax year 2017-18 is £86.10 / tonne).

The waste producer is required to classify and test their waste prior to requesting a quotation from the waste disposal company. A material safety data sheet is required so that the technical team at the waste disposal company can determine what risk management they will need to employ when transporting and disposing of the waste.

Certain companies will not take certain wastes, although this tends to be nuclear or explosive wastes and is unlikely to impact wastes containing TiO_2.

The above analysis suggests that the classification is based on hazard alone and the level of risk (i.e. route of exposure) is unlikely to be taken into account when classifying waste as hazardous or not. As such, if the new harmonised classification would be specifically relevant to the inhalation exposure route it would not mitigate the impact of the harmonised classification on the waste management obligations of producers of waste that contains over 1.0% of TiO_2.

Of interest is the analysis presented in a 2015 report commissioned by the European Commission which looked into the scope of exemptions from classification as hazardous for types of plastic and rubber waste. That report by BiPRO investigated how bioavailability of the components that render a plastic or rubber waste hazardous could be taken into account in classifying such wastes as non-hazardous (BiPRO, 2015b). The report notes that Article 12(b) of the CLP Regulations prescribes that "*conclusive scientific experimental data show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable*" should be taken into account when classifying substances or mixtures as hazardous. Although the CLP Regulation defines the term "*biological availability*", a definition or interpretation of the term "*not biologically available*" is not provided in the CLP Regulation or in available guidance; a concept of "*non-biological*

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35 UK Government website: Hazardous waste, available at https://www.gov.uk/dispose-hazardous-waste (accessed on 30 August 2017).

36 Personal communication.

availability" is required in order to enable a sound evaluation of the biological availability. Moreover, there appears to be no direct link between Article 12 of the CLP Regulation and the Waste Framework Directive. Thus, although a low bioavailability of TiO_2 in the vast majority of its wastes (matrices) can be logically assumed, there appears to be no regulatory framework or guidance on reliably demonstrating "*non-biological availability*" and using this as justification for classifying a relevant waste stream as non-hazardous.

Deviations from entries in the LoW and possibilities for exemptions

Variability in approaches to applying the LoW: discussions with experts in the field have revealed that the approach taken to assigning a LoW code to a specific waste and to its classification as hazardous or not may vary. The approach described above assumes that first, a LoW code is assigned based on the nature/origin/generation process of the waste and then the assigned LoW code dictates whether the waste is hazardous, non-hazardous or it requires evaluation or testing as to its hazardous properties. If an 'absolute non-hazardous' entry is found to be the most relevant, there is no need to consider the presence or not of TiO_2, as a suspected carcinogen, in concentrations above 1.0% by weight.

However, another approach is possible and may be taken. The producer of waste might first establish whether the waste is hazardous (for instance, whether it contains more than 1.0% TiO_2) and then seek to identify an appropriate LoW code which best describes the waste and its hazardous (or not) classification. If the waste is found to be hazardous but would normally be assigned to an 'absolute non-hazardous' entry, its producer would need to seek an alternative entry that reflects the established hazardous properties of the specific waste. Decision 2014/955/EU explains that the appropriate entry needs to be sought within Chapters 01 to 12 or 17 to 20. If no appropriate waste code can be found, the Chapters 13, 14 and 15 must be examined to identify the waste. If none of these waste codes apply, the waste must be identified according to Chapter 16 and if the waste is not in Chapter 16 either, the 99 code (wastes not otherwise specified) must be used in the section of the LoW corresponding to the activity identified in step one.

Therefore, for the same waste, depending on circumstances and the approach taken, it may or may not be classified as hazardous.

Selection between 'mirror' entries: it was concluded above that the focus of this impact assessment needs to be on the 'mirror entry' wastes which may be classified as hazardous following the introduction of the Carc Cat 2 harmonised classification for TiO_2. Following discussions with industry experts, it would appear that the producer of the waste may opt for the non-hazardous 'mirror entry' if they hold information to support such classification, including test results. A recent report by BiPRO notes, "*Please note that testing to determine carcinogenicity is neither envisaged for waste nor for mixtures in the CLP Regulation. Mutagenicity tests* (…) *are considered in many cases to be a suitable indicator of potential carcinogenicity*" (BiPRO, 2015). Part B of the Annex to the Test Methods Regulation (COUNCIL REGULATION (EC) No 440/2008) provides the following in-vitro test methods which may be regarded in the assessment of HP 11 'Mutagenic':

- B.10. Mutagenicity –In Vitro Mammalian Chromosome Aberration Test;
- B.13/14. Mutagenicity: Reverse Mutation Test Using Bacteria;
- B.15. Mutagenicity Testing and Screening for Carcinogenicity Gene Mutation – Saccharomyces Cerevisiae; and
- B.17. Mutagenicity –In Vitro Mammalian Cell Gene Mutation Test.

It has not been possible to identify any tests relevant to demonstrating that a constituent of waste can or cannot be inhaled (the critical route of exposure for TiO_2). As such, it has not been possible to conclude what information producers of waste would need to generate to justify a non-hazardous classification for a waste containing over 1.0% TiO_2 (due to the lack of inhalation exposure to the substance).

In other words, although the vast majority of TiO_2-containing 'mirror entry' wastes cannot result in inhalation exposure to the substance and thus should not be classified as hazardous, formally demonstrating this might require tests which would increase companies' costs and administrative burden.

Possibilities for exemptions from the LoW: derogations from 'absolute' entries in the LoW are possible. A waste assigned with an 'absolute non-hazardous' entry is classified as non-hazardous, without any further assessment of its hazardous properties, i.e. even if it contains TiO_2 at a concentration above 1.0% after the substance received a harmonised classification of Carc Cat 2. The only exception to this principle is described in Article 7(2) of the Waste Framework Directive, whereby if the competent authority of the Member State concerned considers that, based on adequate evidence, a given waste to which an 'absolute non-hazardous' code is attributed, is in reality to be classified as hazardous, the waste in question will be classified as hazardous. This should be communicated to the European Commission with a view to possible future amendments of the LoW (BiPRO, 2015). Realistically, given the above discussion on a general lack of risk of exposure by inhalation, the probability of Article 7(2) being acted upon would be low.

On the other hand, under Article 7(3) of the Waste Framework Directive, where a Member State has evidence to show that specific waste that appears on the LoW as hazardous waste does not display any of the properties listed in Annex III of the Directive, it may consider that waste as non-hazardous. The Member State shall notify the European Commission of any such cases without delay and shall provide the Commission with the necessary evidence. In the light of notifications received, the LoW shall be reviewed in order to decide on its adaptation. Therefore, in theory, industry might petition Member States to invoke Article 7(3) of the Waste Framework Directive and thus classify such waste as non-hazardous.

However, in practice, little evidence can be found on whether any Member State has followed the Article 7(3) route. A 2015 report for the European Commission which looked into the implementation of the Waste Framework Directive over the period 2010-2012 reported the contributions of 22 Member States of which none had taken the alternate classification option allowed for by Article 7(3) (Eunomia Research and Consulting et al, 2015). Information on more recent developments is not available so it cannot be precluded that some Member States have notified any derogations to the LoW. A recent submission by Cefic to the European Commission[37] suggests business operators may indeed approach their national authorities to request derogations but often these are not accepted by the receiving authorities. Overall, the probability of derogation under Article 7(3) of the Waste Framework Directive would appear to be low.

Process for periodic review of the LoW: there appears not to be any systematic, established process for amending the LoW to adapt it to 'technical progress'. At present, the approach is dynamic and comes into when the classification of a substance changes under the CLP Regulation and the presence of the substance in a waste automatically affects the classification of that waste (see discussion above). Beyond the action that Member States can take under Article 7(2) and 7(3) (see above), no provision is known to exist that would instigate periodic changes to the LoW.

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[37] Suggestion of Cefic to the European Commission, dated 6 April 2017, available at https://ec.europa.eu/info/law/better-regulation/lighten-load/suggestions/S19535_en (accessed on 1 September 2017).

Transboundary movement of wastes

With a Carc Cat 2 harmonised classification complications over the transboundary movement of wastes containing TiO_2 might be less severe compared to a Carc Cat 1B classification. The Basel Convention includes waste streams potentially relevant to TiO_2:

- Y2-Wastes from the production and preparation of pharmaceutical products;
- Y3-Waste pharmaceuticals, drugs and medicines;
- Y4-Wastes from the production, formulation and use of biocides and phytopharmaceuticals;
- Y12-Wastes from production, formulation and use of inks, dyes, pigments, paints, lacquers, varnish;
- Y13-Wastes from production, formulation and use of resins, latex, plasticisers, glues/adhesives),

However, relevant wastes may not cause exposure as TiO_2 may not be possible to inhale and thus such wastes might not be subject to the provisions of the Convention. In addition, a Carc Cat 2 classification would not lead to the addition of TiO_2 to Annex I of Regulation (EU) No 649/2012 on export and import of hazardous chemicals (such addition would be a possibility with a Carc Cat 1B classification). As such, transboundary movement of the substance and its wastes would be unlikely to be significantly affected.

Supply chain-wide impacts from changes to existing controls on worker exposure to titanium dioxide

In a previous version of this analysis, the focus had been on the Carc Cat 1B harmonised classification that was proposed by the French authorities and it had been explained that such a harmonised classification would trigger compliance requirements under the Carcinogens and Mutagens Directive. This would have meant that employers would first need to investigate the possibility of replacing TiO_2. If substitution was not possible, measures should be taken to minimise worker exposure to the substance.

Consultation that had been undertaken at the time had collected valuable information from a wide range of consultees on the likely cost of implementing different worker exposure control measures; such measures would range from a simple increase in the frequency of monitoring to the implementation of completely closed systems for the handling and use of TiO_2. The cost of such measures had been found to range from ca. €1,000 to up to €20 million per company. For reference, an overview of responses received at the time is provided here as **Figure 4–4.**

It has also been found that for applications where TiO_2 can be used in the form of a slurry to eliminate exposure to powders and thus eliminate the need for additional measures for certain parts of the production lines, a higher raw material price would be payable as the price of slurry is €200-250/tonne higher compared to powder (NB. the previous version of this analysis had provided an order of magnitude of the change in raw material costs, if slurry could replace 10% of the volume of TiO_2 currently used in Europe – the cost increase across markets would be larger than €200 × 1,107,000 × 10% = €22 million per year).

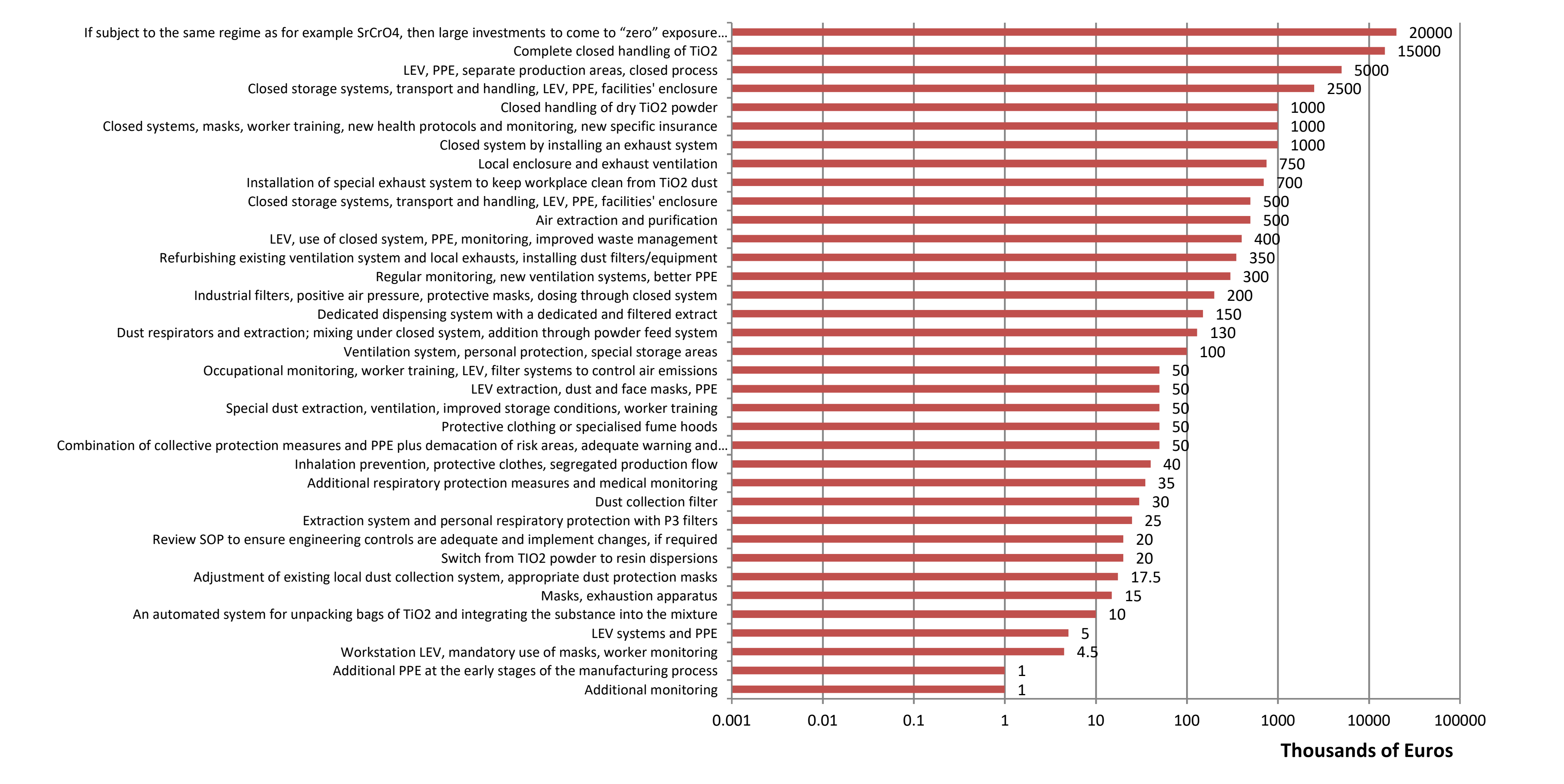

Figure 4–4: TiO_2 users' estimates on the cost of implementing existing worker protection legislation on carcinogens (thousands of Euros)
Source: consultation

However, under a Carc Cat 2 harmonised classification, the substance would fall outside the scope of the Carcinogens and Mutagens Directive. Nevertheless, it is understood that TiO_2 registrants are in the process of updating their REACH registration Chemical Safety Report. If this results in lower Derived No Effect Level (DNEL) values for downstream uses of the substance, the exposure scenarios in the Safety Data Sheet (SDS) will be updated to reflect those and users of the substance would need to comply. This might entail the strengthening of worker exposure controls. As shown in **Figure 4–4**, replacement/installation of an LEV system, worker training and additional monitoring might cost between €1,000 and €100,000 per company in Year 1 plus increased operating costs thereafter. However, such costs would be linked to but could not be attributed to the introduction of a Carc Cat 2 harmonised classification for TiO_2. Irrespective of the developments with the updating of the REACH registration dossier, some employers might voluntarily wish to further minimise exposures to TiO_2 powder after its classification as a suspected carcinogen.

In addition, the new harmonised classification might result in a tightening of existing Occupational Exposure Limits (OELs) in EEA Member States (see some examples in **Table 4–1**). It is understood that the Scientific Committee on Occupational Exposure Limits (SCOEL) has looked into an OEL for TiO_2 and had reached a preliminary opinion that an OEL of 1–2 mg/m^3 would be warranted (based on the minutes of the 86th SCOEL meeting); this is lower than all national OEL examples shown in the table. Again, such action would be linked to the harmonised classification for the substance but could not be assumed to be a direct consequence of it.

Table 4–1: Example national Occupational Exposure Limits for titanium dioxide in Europe

Country	Occupational Exposure Limit in mg/m^3	Notes
Belgium	10	
Denmark	6	Total dust
France	11	Inhalable aerosol
Germany	1.25	Respirable fraction
Ireland	10	Inhalable fraction Limit is 4 mg/m^3 for respirable fraction
Latvia	10	
Poland	10	
Portugal	10	
Spain	10	Inhalable aerosol
Sweden	5	Inhalable aerosol
Switzerland	3	Respirable aerosol
United Kingdom	10	Inhalable fraction Limit is 4 mg/m^3 for respirable fraction

Source: GESTIS (available at http://limitvalue.ifa.dguv.de/, accessed on 18 September 2017) and consultation

Supply chain-wide impacts arising from requirements of the REACH Regulation

A Carc Cat 2 classification would certainly result in a lower regulatory burden under the REACH Regulation compared to a Carc Cat 1B. The substance would not meet the requirements for being nominated as a Substance of Very High Concern (and ultimately being subject to REACH Authorisation, if subsequently prioritised) and the probabilities of a proposal being submitted for a restriction on its marketing and use would be significantly lower. Yet, Article 31 of the REACH Regulation on the provision of Safety Data Sheets (SDS) would equally apply.

Under said article, SDS are to be provided for any substance or mixture that is classified as hazardous under the CLP Regulation and such SDS are to be provided free of charge (upon request), if a mixture contains ≥ 0.1% TiO_2, although provision of an SDS is not required if the economic operator offers or sells dangerous substances or mixtures to the general public and provides sufficient information to enable users to take the necessary measures as regards safety and the protection of human health and the environment. There is the likelihood that, for mixtures which are currently not classified as hazardous, the Carc Cat 2 harmonised classification could create an additional administrative burden and cost in order to prepare the large number of exposure scenarios that would be needed to cover the multiple applications of TiO_2.

A harmonised classification of Carc Cat 2 would mean that TiO_2 would not be transferred into Annex XVII of the REACH Regulation in accordance with Article 68(2) of REACH. TiO_2 could not be listed in Appendix 2 of the Annex and thus entry 28 of Annex XVII which specify the restrictions on use or sale of a carcinogen to the general public either as a substance or in a mixture would not apply. Nevertheless, the harmonised classification might result in restrictions on a national level. By way of example, in France a CMR 2 classified formulation has to be stored under lock (this provision should shortly be amended to storage in a place not accessible to the public), hence such formulation would still be stigmatised as potentially unsafe.

In other cases, industrial users might wish to refrain from using the substance due to their internal policies; several participants to the consultation undertaken in preparation of this report have expressed concerns that many manufacturers and their customers would prefer not to handle formulations and products that are labelled as a suspected carcinogen and thus might refrain from using TiO_2-based formulations and products irrespective of the actual severity of hazard or the actual risk.

Supply chain-wide impacts under other horizontal legislation

Less critical horizontal legislation includes the Industrial Emissions (IPPC) Directive 2010/75/EC, Annex II of which describes in relation to polluting substances "*Substances and mixtures which have been proved to possess carcinogenic or mutagenic properties or properties which may affect reproduction via the air*". Member States shall ensure that permits issued to industrial installations falling within the remit of the Directive will include emission limit values.

Also, as noted earlier, by contrast to a Carc Cat 1B classification, a Carc Cat 2 classification would not trigger requirements imposed by legislation on the control of risks to workers from carcinogenic substances, namely Council Directive 1989/391/EEC and Directive 2004/37/EC, the Carcinogens and Mutagens at Work Directive which requires that employers of users of the substance should consider the use of alternative substances.

Downstream user impacts arising under sector specific legislation

As discussed above, for downstream, users of TiO_2, there would be two key pieces of legislation that would generally affect many downstream users of TiO_2:

- The CLP Regulation 1272/2008/EC (notably, the Regulation does not apply to cosmetics, food and feed additives, medical devices, human and veterinary medicinal products); and

- The Waste Framework Directive 2008/98/EC and associated instruments (LoW under Decision 2000/532/EC as revised by EU Decision 2014/955/EU).

Beyond these two key sources of impacts, and following the formal adoption of the new classification (which typically requires 18 months or longer), downstream impacts under other legislation would follow. Beyond the regulations described above which would, in general, affect much of TiO_2's supply chain, there is also legislation that affects specific downstream uses of the substance and which could lead to restrictions on the use of the substance. Typical examples include the cosmetics, toys, food and its contact materials and pharmaceutical applications where the new classification could lead to a restriction or (at least) a re-valuation of existing authorisations for use (for instance, by the SCCS Committees for cosmetics, and the SCHEER Committee for toys). In some cases, however, rapid, successful action by interested parties could mitigate impacts. For example:

- For cosmetics, a derogation would be a possibility but securing one could be a challenging task and there are only up to 15 months between the CLH being added to Annex VI of the CLP and the Cosmetics Regulation annexes being updated with a review of the existing authorisations for TiO_2 (a preservative, colourant and UV filter) by the SCCS. Therefore, the time for obtaining an SCCS opinion on safe use is short. It is understood that it can take up to 2 years to prepare an SCCS dossier. If cosmetics companies would be interested in safeguarding the use of TiO_2, they would need to prepare a dossier for the SCCS opinion as soon as possible; and

- For pharmaceuticals, a variation to marketing authorisations might be required for the continued use of TiO_2 as an excipient. This would not only take time (for the preparation of the applications) but would be accompanied by considerable cost, given the large number of pharmaceuticals that contain the substance.

By comparison to Carc Cat 1B, a Carc Cat 2 classification under the CLP Regulation would not trigger certain obligations and impacts for the users of TiO_2 which would otherwise be relevant under a Carc Cat 1B classification. Apart from the Carcinogens and Mutagens Directive and the REACH Regulation that were discussed above, legislation on medical devices and biocidal products which has repercussions on the use of Carc Cat 1B substances would not apply to a substance classified as Carc Cat 2. Also, provisions on the marketing of construction products would be less onerous than in the case of a Carc Cat 1B substance.

Conclusion on how the regulatory framework allows a comparison of carcinogenicity in general to carcinogenicity by inhalation

A key finding of this present research is that the European legislation regulating the use of and exposure to carcinogens generally does not distinguish between routes of exposure. Therefore, whilst the French proposal for the classification of TiO_2 specifically indicates that the substance be classified as a carcinogen by inhalation of its powder form and RAC's opinion also recommends a Carc Cat 2 harmonised classification through the inhalation route, the existing regulatory framework does not generally distinguish classification by routes of exposure and as such the uptake of the proposed classification, if implemented, by 'consequent' legislative requirements might not give due regard to the critical route of exposure.

Thus, if the Carc Cat 2 harmonised classification were to be adopted, applications of the substance without any inhalation risk could nevertheless fall within the scope of restrictions that would consequently arise from a multitude of legislative instruments. It should be clear that in the vast majority of cases, TiO_2 is used by the end user within a matrix, typically as a pigment in paints, plastics, inks, paper, rubber, construction products, ceramics, dermally applied cosmetics, etc. from which exposure to TiO_2 via inhalation is either impossible or highly improbable and, where possible, rather infrequent. Exposure to TiO_2 powder by inhalation could only reasonably be envisaged when the substance is handled (in its powder form) by manufacturers or industrial users as a raw material.

Some waste materials that contain TiO_2 might be in a granular or powder form but the substance should not be considered biologically available within such matrices.

It is pertinent to note here the comments made by the International Paint and Printing Ink Council (IPPIC) to the public consultation on the French proposal. IPPIC noted, "*Categorical assertions of a low or no exposure condition and attendant dismissal of cancer hazard listings have been issued in the United States by California Office of Environmental Health Hazard Assessment (OEHHA) under its "Prop 65" regime. OEHHA uses the specific clarifying statement: "*the (hazard) listing does not cover (the material) when it remains bound within a product matrix.*" Similarly, the International Agency for Research on Cancer (IARC), in its Monographs on titanium dioxide, crystalline silica and carbon black, all widely used materials in formulated products, contain specific notes affirming that "exposure to [titanium dioxide, crystalline silica and/or carbon black] does not occur during the use of products in which [titanium dioxide, crystalline silica and/or carbon black] is bound to other materials, such as rubber, printing ink or paint*" (IPPIC, 2016).

4.2.2 Impact driver 2: Availability of alternatives

The second driver behind the impacts that would arise from the proposed classification is the availability of alternatives. There are four key points under this:

1. A Carc Cat 2 harmonised classification would not trigger a legal requirement to substitute TiO_2, where possible, under the Carcinogens and Mutagens Directive (a key difference to a Carc Cat 1B classification). Nevertheless, for reasons of improved worker protection (particularly if pressures arising from worker safety legislation on the national level increase), consumer perception, minimisation of regulatory burden and cost avoidance, users of TiO_2 might be encouraged to give consideration to substituting the substance with another that is not classified for hazards.

2. Although alternative white pigments are available and indeed can be used, due to the physicochemical properties of TiO_2 (see Section 2 above), finding a drop-in replacement that delivers equivalent performance in technical and economic terms is very challenging, if not impossible, in the majority of TiO_2's applications. It is important to note that TiO_2 was initially introduced to replace more hazardous heavy metal (lead) compounds.

3. Potential alternatives for TiO_2 may not be accompanied by the same body of evidence on their hazards and risks across all relevant applications, particularly for applications such as food and pharmaceuticals.

4. TiO_2 is currently being used in very large volumes; demand in Europe is estimated at ca. 1.1 million tonnes per year. The market availability of most of its alternatives is simply nowhere near as large as TiO_2's and most of the potential alternatives cannot demonstrate TiO_2's abundance that would allow for economical production. On the other hand, it can be assumed that without a regulatory impetus driving substitution, substitution may occur for only a modest proportion of TiO_2's demand.

5. The Carc Cat 2 harmonised classification proposed by RAC is based on carcinogenicity arising from marked loading of alveolar macrophage phenomena which are not specific to TiO_2. Any other poorly soluble particle of low toxicity that would be subjected to similar testing in rats would produce a similar carcinogenic effect, irrespective of any robust scientific and epidemiological evidence to the contrary (as is the case for TiO_2). This certainly raises significant concerns:

a. Such poorly soluble powders could potentially be subject to a similar proposal for a harmonised carcinogenicity classification with consequent adverse effects on their supply chains; and

b. Potential albeit significantly less efficient alternatives to TiO_2 are mainly poorly soluble powders; if they were to be used as substitutes for TiO_2 they would not reduce any (theoretical) risk to human health from the use of TiO_2. As such, they would be unsuitable as substitutes for TiO_2 from a risk reduction perspective.

A more extensive analysis of the feasibility and availability of potential alternatives is provided in Annex 2 (Section 8) to this report.

4.2.3 Impact driver 3: Market developments

A third driver behind the impacts arising from the proposed classification is market developments, which generally are difficult to predict. An increase of the regulatory burden associated with the use of TiO_2 and, in the case of some downstream applications, the potential restriction on the use of TiO_2 under sectoral legislation could prompt many companies to review their product portfolios when planning for the future. Relocating manufacturing operations outside the EEA where the carcinogenicity classification for TiO_2 would not apply would not become particularly attractive, especially if TiO_2-products would attract the same labelling requirements when placed on the EEA market irrespective of their country of origin. Whilst a Carc Cat 2 harmonised classification would disadvantage EEA-based operators vis-à-vis their non-EEA competitors, by comparison to a Carc Cat 1B classification, such adverse effects would be of modest magnitude.

4.2.4 Impact driver 4: Industrial/professional user and consumer perceptions

A fourth driver would be professional/industrial user and consumer perceptions of the actual exposure and risk thereof arising from the use of TiO_2. As the existing legislation invariably is hazard-based and does not account for the route of potential exposure or the level of risk, there could be scope for misinterpretation of the new harmonised classification of the substance:

- Firstly, the link between the classification of TiO_2 as a suspected carcinogen and the details of its scientific basis would be lost. Industrial and professional users who have not followed the process of the harmonised classification of the substance and certainly the vast majority of consumers would be unaware of (a) the importance of the exposure route, (b) the fact that the rat lung tumours only developed under inhalation exposure conditions associated with marked particle loading of macrophages and (c) TiO_2 epidemiology studies which consistently show no association between occupational exposure to TiO_2 and lung cancer mortality;

- Secondly, in the mind of consumers (and probably of many industrial and professional users) the classification of TiO_2 as a suspected carcinogen and the new labelling for carcinogenicity on widely available consumer products (e.g. DIY paints) would likely be dissociated from the severity of the hazard classification category (2 vs. 1B) and the importance of the route of exposure attached to the classification itself. As such, the substance and many products that contain it would be tarnished as carcinogenic irrespective of whether inhalation is actually possible across their different applications. Lack of understanding of the refuted scientific basis of the proposed classification combined with lack of appreciation of the differences between hazard and risk (and how the latter is influenced by the route of potential exposure) would make consumers vulnerable to having their buying decisions influenced by poor science which overstates the hazard, ignores the risk and potentially relies on generalisations over the feasibility and suitability of potential alternatives; and

- Thirdly, if the use of TiO_2 continued as a result of derogations and exemptions for applications such as pharmaceuticals, food, cosmetics, etc., consumers would find it perverse that a substance formally classified as a carcinogen could be present in such products. Again, as a result of the likely oversimplification of the substance's hazard profile, consumers might decide to avoid consuming or using products that contain TiO_2 irrespective of the lack of actual exposure to the substance by inhalation. This uncertainty and confusion might damage the confidence that both users and consumers have in health protection measures and government decision-making.

4.2.5 Other impacts

The classification of TiO_2 would pave the way to the potential classification of other poorly soluble particles that could be considered to cause marked loading of alveolar macrophages. Such classification would lead to another set of **indirect impacts** which are discussed in Section 0.

4.3 Specific impacts on downstream users of mass applications of titanium dioxide

4.3.1 Paints and coatings

Key market descriptors

The key economic parameters of the use of TiO_2 are summarised below.

Importance of the application	The majority of paints/shades are of relevance to TiO_2's classification; only dark blue and black would not be impacted. All of the applications for TiO_2 have a socio-economic value, as the paints/coatings/inks industry is essential for the continued activity in virtually every downstream industry, from wall paints in construction and public buildings, through corrosion-preventing coatings for metal (aerospace, cars, bridges, heavy machinery), to high tech coatings for electronics (mobile phones, laptops) and printing inks for food packaging and magazines. Thus, if the harmonised classification were to impact on the use of TiO_2, this would affect everyday life for everyone.
Estimated TiO_2 tonnage used	Based on available information, paints, coatings and inks represent ca. 57% of total demand for TiO_2. Based on past data on market shares, we will assume that the split between architectural paints and coatings, industrial coatings and inks is: 36% : 17% : 4%. This would translate into a total of ca. 630 ktonnes of TiO_2 consumed which an assumed 400 ktonnes used in architectural paints and construction products, ca. 190 ktonnes in industrial and functional coatings and ca. 40 ktonnes in inks.

Estimated tonnage of products that contain TiO_2

Application	EEA production
Architectural coatings	3.3 million tonnes/y
Industrial coatings for automotive, aerospace, marine, etc. uses including coil coatings, can coatings, road marking paints, flooring coatings and functional coatings	2.4 million tonnes/y
Construction materials (plasters, caulks, fillers, mortars)	0.3 million tonnes/y

Estimated value of markets

Application	EEA market value
Architectural coatings	€6.2 billion/y
Industrial coatings	€8.2 billion/y
Construction materials	€0.55 billion/y

The value of painted/coated/printed/bonded end products equal many times the actual value of the paint; for instance, for a new car the paint represents an estimated 2% of the manufacturing costs. The value of the end industries that depend on paints and coatings is a high multiple of the value of the paints/coatings (e.g. the value of the printed material would easily be a 100-fold of the printing ink value). In the UK for instance, the British Coatings Federation has estimated that £180 billion of the UK's GDP (produced by 300,000 employees) is directly dependent on the UK coatings, inks and wallcoverings industry which itself has a turnover of £3 billion. Therefore, with a paints/coatings/inks value of ca. €15 billion, the value of downstream markets could well exceed €750 billion.

Estimates of Gross Value Added

The Gross Value Added for paints, varnishes and printing inks across EU-28 is €5 billion/y.

Number of users of TiO_2

The main EU trade association is CEPE. CEPE represents about 800 paint producers (plus 75 ink producers and 20 artist colour producers across Europe).

Presence of SMEs

Significant. It can be estimated that among CEPE's membership of paint and ink manufacturers more than 85% are SMEs[38].

Number of stakeholders that participated in consultation

Several associations and individual companies had submitted completed questionnaires when the impacts from a Carc cat 1B classification were being assessed (25-50 companies with a combined production of ca. 0.6 million tonnes of paints, coatings, inks, recreation and artists' colours and stationery products (e.g. correction fluids) and a combined associated turnover of over €1.1 billion). Through CEPE's questionnaire response (plus several from national associations-members of CEPE), the vast majority of the EEA paints and coatings market has been captured. 7 responses were received to the questionnaire on Carc Cat 2-related waste issues.

[38] This may vary by sub-sector. For coil coatings, for instance, SMEs may represent 33% of members of the relevant trade association ECCA (European Coil Coating Association).

Locations of stakeholders that participated in consultation	Large paint/ink manufacturers are scattered across the EEA but the following countries are particularly important: Germany, UK, France, Italy, Spain, Poland, Finland, Norway, the Netherlands (NB. the last three countries host specific dominant manufacturers who are key players across the whole of the EEA).
Employment in the sector	110,000 workers are employed by paint, coating and ink manufacturers in the EEA. An estimated 15-20% of these would have regular (daily/weekly) contact with TiO_2 and/or TiO_2-containing products. An estimated 1,000,000 workers are involved in the application of paints/coatings/inks and 30,000 workers[39] are employed in the DIY retail trade.

Relevant legislation

Table 4–2 (overleaf) summarises the relevance of different legislative instruments to the use of TiO_2 in paints and coatings after the adoption of a Carc Cat 2 harmonised classification. Additional detail is available in Annex 1.

Impacts on the marketing and use of titanium dioxide-containing products

Scale of adverse implications of a harmonised carcinogenicity classification

Trade associations and individual companies have estimated that a very large percentage of paints manufactured in the EEA contain TiO_2 in concentrations that typically well exceed 1.0% by weight and thus would be affected by the proposed classification. More specifically, **it is estimated that a harmonised carcinogenicity classification would affect 80-90% of the product range of EEA-based paint and coating manufacturers**.

Reformulation of paint products so that the concentration of TiO_2 could be kept below 1.0% by weight would not be possible. The substance needs to be present in formulations at much higher concentrations to deliver its desired functionality. A well-known paint manufacturer has asserted that when less than about 15-20% TiO_2 is present in the formulation, only translucent paintings/coatings can be formulated.

Replacement of TiO_2 by alternative pigments is not possible in the vast majority of products. Other raw materials (e.g. calcium carbonate, zinc oxide and zinc sulphide, which are widely known white pigments) typically cannot match TiO_2's performance in terms of stability and opacity, brightness, gloss and abrasion resistance. Often, replacement substances raise concerns in ecological and toxicological terms, especially if they contain heavy metals, e.g. lead carbonate. As the carcinogenic effect in animal testing is not substance-specific but characteristic of dusts and as dust exposure can be expected also in the processing of potential replacement substances, a substitution of substances would not change the given situation (VCI, 2016). Annex 2 to this report provides an extensive analysis of available alternative white pigments and the issues surrounding their technical performance compared to TiO_2.

[39] This is an estimate by CEPE but may be an underestimate. For instance, in Greece alone, the Hellenic Coatings Association estimates that ca. 9,000 workers are employed in the paints retail trade.

Table 4–2: Relevance of different regulatory instruments and voluntary initiatives to paints and coatings applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation			
Relevant legislation	**Type**	**Number**	**Relevant to paints and coatings**
CLP	Regulation	1272/2008/EC	Yes
Carcinogens and Mutagens at Work	Directive	1989/391/EEC	No
	Directive	2004/37/EC	
Waste Framework	Directive	2008/98/EC	Potentially
	Regulation	1357/2014	
	Decision	2000/532/EC	
Industrial Emissions	Directive	2010/75/EC	Potentially
REACH	Regulation Annex XVII	1907/2006/EC	No
	Regulation Annex XIV	1907/2006/EC	No
	Regulation Article 31	1907/2006/EC	Yes
Cosmetics	Regulation	1223/2009/EC	No
Toy Safety	Directive	2009/48/EC	Potentially
	European Standard	EN71-3:2013	
Food Contact Materials	Regulation	1935/2004	Yes. For can coatings there is no specific EU wide legislation but reference is made to the Plastics Regulation and CEPE's Code of Practice
	Regulation Plastics in Materials and Articles	EU/10/2011	
	Regulation Recycled Plastic Materials and Articles	282/2008/EC	
	Regulation	(EC) No 450/2009	
Food Additives	Regulation	1333/2008/EC	No
	Directive	94/36/EEC	
	Regulation	231/2102	
	Regulation	1831/2003/EC	

Table 4–2: Relevance of different regulatory instruments and voluntary initiatives to paints and coatings applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation			
Relevant legislation	**Type**	**Number**	**Relevant to paints and coatings**
Medicinal Products	Directive	2001/83/EC	No
	Regulation	1901/2006	
	Directive	2009/35/EC	
	Directive	94/36/EC	
Construction Products	Regulation	305/2011	Potentially. The Construction Products Regulation 305/2011 is already defining some rules about the declaration of performance. The proposed hazard classification for TiO_2 would make it necessary to communicate the relevant information in the declaration of performance. If a Category 2 Carcinogen is present in a mixture at a concentration ≥0.1% then a SDS must be available upon request (as per Note 1 under Table 3.6.2 of the CLP Regulation). The identification of TiO_2 as a carcinogen could make users more reluctant to use constriction products that contain it. Moreover, this regulatory framework is under evolution, towards stronger constraints
Biocides	Regulation	EU/528/2012	No
Medical devices	Directive	93/42/EEC (amendment agreed in June 2016)	No
Restriction of hazardous substances in electrical & electronic equipment (RoHS)	Directive	2011/65/EU	Potentially (but less likely than a Carc Cat 1B classification). It is relevant but impact not automatic. The list of restricted substances would have to be updated following a risk assessment
	Directive	2012/19/EU	
Tobacco additives	Directive	2014/40/EU	No
	Decision	(EU) 2016/787	
Other	- National Health and Safety at Work Legislation - Ecolabelling scheme provisions (see Section 7.2.7). - The CEPE Code of Practice prohibits the use of CMR substances in coatings intended for use in food contact materials unless they have been approved (by EFSA) and any relevant limits on migration are respected (see Section 7.2.3) - The Global Automotive Declarable Substance List (GADSL) would play a role (see Section 7.2.5)		

To further reinforce the unique technical advantages of TiO_2 in the context of paint and coatings manufacture, it is worth considering the pigment's excellent brightening capacity vis-à-vis coloured media. Jotun, a paint manufacturer that contributed to the public consultation on the French CLH proposal, has pointed out that the theoretical elimination of TiO_2 from paint formulations would have a serious impact on the colour variety in particular for high quality decorative products, both interior and exterior. **Figure 4–5** is what is called "gamut mapping"[40] and is produced with colour matching software. One can enter a set of ingredients in the colour matching software and it calculates which colours can be produced, in theory. The complete area in the picture represents the colour range that can be produced from a set of given ingredients, including TiO_2. When TiO_2 is removed from the input ingredients, the theoretically achievable colour range, shown as the darker area, shrinks significantly.

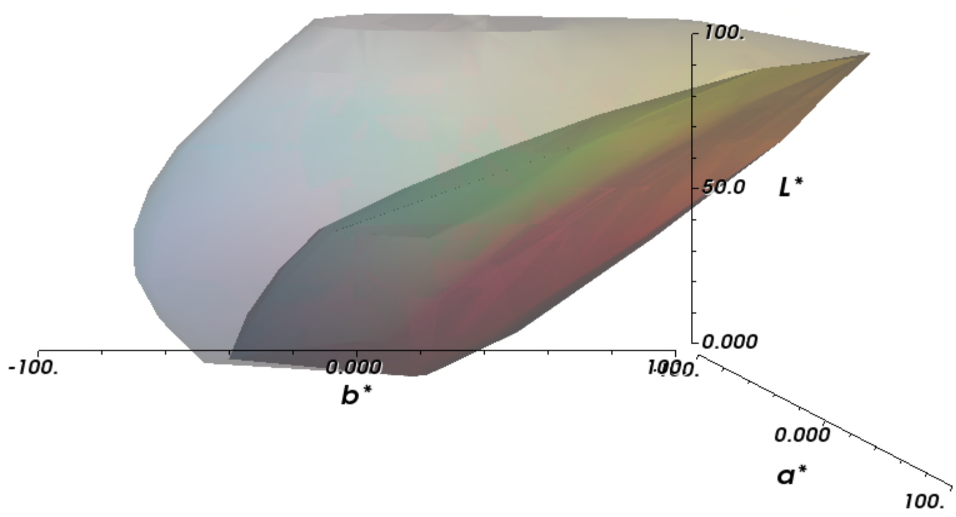

Figure 4–5: Colours that can be achieved with (light + grey area) and without (grey area) TiO_2
Source: Jotun (https://echa.europa.eu/documents/10162/48252319-d727-42aa-8b3e-bb97cb218f0e)

Figure 4–6 represents a second illustration of the impact from the removal of TiO_2 from paint formulations. It is based on the Natural Colour System®© (NCS), a cross-industry colour system used around the world for colour communication between designers and manufacturers, retailers and customers. The NCS system is based on how we perceive colour visually, regardless of surface, pigment, or lighting. The NCS system is a universal way of describing colours as we experience them visually. Each colour has a unique NCS notation to describe how the colour relates to the four basic colours – yellow, red, blue, and green, as well as to black and white – in blackness, whiteness and chromaticness. The NCS code describes the percentage of the colour that consists of these different parts. This makes it possible to describe the colours of all surface materials and ensure that the colours turn out exactly as intended[41]. If one takes the NCS catalogue as an example, out of the 1950 NCS colours, in total only 125 (less than 7%) are currently produced without TiO_2.

[40] The "L*", "a*", "b*" axes are colour coordinates following a certain standard, which is called CIE1976. In simple terms, "L" represents the lightness of a colour, "a" represents colours from green to red and "b" from blue to yellow. By this, all colours can be represented by these three coordinates (*explanation kindly provided by experts at Jotun*).

[41] Information from http://ncscolour.com/about-us/how-the-ncs-system-works/ (accessed on 24 January 2017).

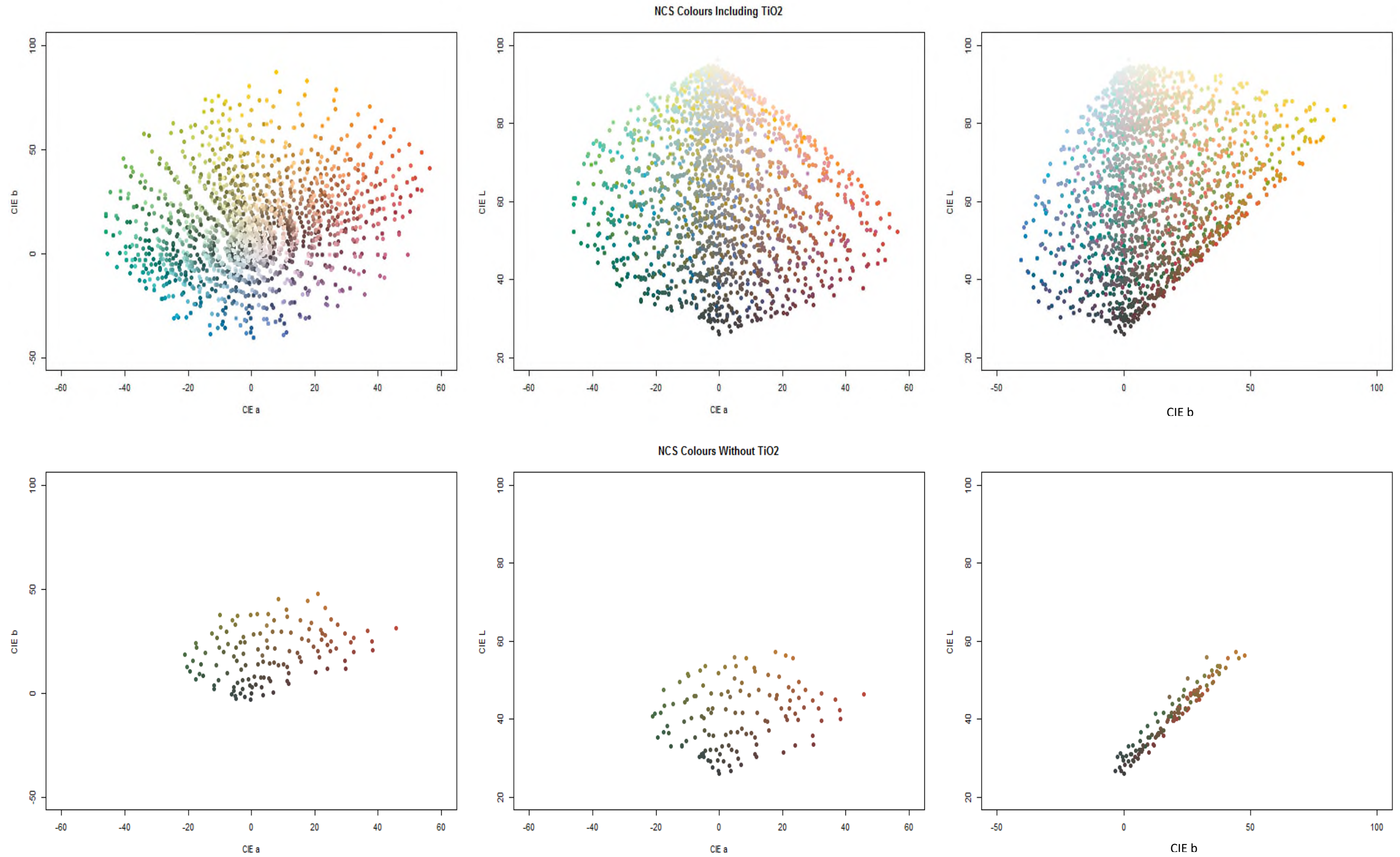

Figure 4–6: NCS colours that can be achieved with (top) and without TiO_2 (bottom)
Source: Jotun (https://echa.europa.eu/documents/10162/48252319-d727-42aa-8b3e-bb97cb218f0e)

Figure 4–6 is created with a data analysis tool. The input data are colour coordinates of existing formulations incorporating TiO_2 (top row) and without TiO_2 (bottom row). That means the data represent the practical colour possibilities with and without TiO_2. As above, each colour dot is represented by three coordinates: L, a and b. So CIE L is the same as L* and so on. All three plots in one row contain the same data points, but represented in different coordinate planes: (a,b) on the left, (a,L) in the middle and (b,L) on the right. In the (a,b) plane one can easily see that all bluish colours disappear without TiO_2, but the lightness (L coordinate) is not represented. Therefore, the other two representations were generated, where one can see that no bright colours can be produced when TiO_2 is missing. More specifically, without TiO_2 the practically achievable colour space would lack:

- All blue and violet colour shades;
- Bright colours; and
- Almost all grey shades.

NCS is based in Sweden where it is the National Standard. It is also the National Standard in Norway and Spain. Another widely used colour matching system used in Europe is RAL which is created and administrated by the German RAL gGmbH. According to the German Paint and Printing Ink Association, out of the 2,328 shades of the RAL system, only 119 (5%) are manufactured without TiO_2. As such, any attempt at reformulation of TiO2-containing colours would impact upon 95% of shades in the RAL colour matching system.

Economic impacts for manufacturers of paints and coatings

<u>Potential loss of markets</u>

A Carc Cat 2 harmonised classification would have the following impacts on the ability of EEA-based paint manufacturers to use TiO_2 and place on the market TiO_2-containing formulations:

- **Hazard labelling and perceptions**: under the CLP Regulation, TiO_2-based paints would be accompanied by appropriate hazard labelling including a pictogram, a signal word, a hazard statement and several precautionary statements. This would alter perceptions of users and would damage the reputation of TiO_2-based paints in terms of their safety, irrespective of the relevance or not of the hazard classification to the inhalation exposure route. As previously explained, the labelling requirements for Carc Cat 2 would be very similar to the non-expert consumer eye to those of Carc Cat 1B. In any case, a GHS 08 pictogram of an 'exploding person', and the terms "Warning" and "Suspected of causing cancer", even if the inhalation exposure route was to be specified, would cause alarm among users, particularly among DIY users who would encounter such labelling on the shelves of their local DIY stores. This would be after several years of becoming used to purchasing paint products with no hazard labelling following the movement away from solvent- to water-based formulations. In certain countries in particular, e.g. France, there is a ban on self-service in DIY stores for potentially carcinogenic formulations, which could physically prevent consumer access to these products. Clearly, such a ban would affect paints placed on the French market irrespective of the location of manufacture.

  Even for professional and industrial users, the presence of such labelling could cause unwillingness to handle and (potentially) be exposed to the pigment and its formulations and could encourage employers to seek alternative pigments or further improve exposure controls. The entire DIY market for TiO_2-containing paints, worth **€3.5 billion per year**, would come under strain while pressure would also develop on the professional and industrial markets, worth an additional **€11.5 billion per year**;

- **Ecolabel schemes**: TiO_2 could no longer be used in paints that hold an ecolabel. Known ecolabelling schemes, such as the EU Ecolabel, the German Blue Angel and the Nordic Swan, list CMR properties under their exclusion criteria. A harmonised classification of Carc Cat 2 would mean that TiO_2-containing paints and varnishes would no longer qualify for any of the relevant ecolabels. By way of an indication of the scale of the impacts, as of September 2016, 4,423 indoor and outdoor paint and varnish products held the EU Ecolabel under 93 licences (European Commission, 2017) while in January 2017, 350 indoor wall paints and 337 emulsion paints held the Blue Angel award (Blue Angel, 2017). Companies that have invested in securing an eco-label of their products would witness a loss of value for those investments;

- **Toys**: Carc Cat 2 substances are not permitted to be used in toys placed on the EEA market, but possibilities for exemptions exist based on (a) concentration, (b) (in)accessibility of the substance. The SCCS would review the use of the substance and would conclude as to whether it might be appropriate to list it in Appendix A of the Toy Safety Directive (List of CMR substances and their permitted uses). Notably, for a Carc Cat 2 substance, it will not be necessary to demonstrate that there are no suitable alternative substances or mixtures available. Therefore, there is a realistic likelihood that use of TiO_2-based paints in toys could be allowed to continue. However, the continued presence of the substance in toys could cause reputational damage to the toy manufacturers and thus they may put pressure on paint manufacturers to attempt to reformulate their products to substitute TiO_2;

- **Food contact materials**: TiO_2 appears in List 1 of approved additives under Council of Europe (CoE) Resolution ResAP(2004)1 on coatings. It is understood however that a Draft CoE/EDQM General Resolution is in preparation which will (once approved) stay above all existing Coe/EDQM resolutions and guides; it is expected that this General Resolution would require that all CMR additives demonstrate zero transfer into foodstuff. It would therefore appear that a harmonised Carc Cat 2 classification might generate the need to demonstrate zero migration from coatings so that the use of TiO_2 in food contact material coatings could be approved under national legislation which implements the CoE Resolution. This could ultimately result in the listing (approval) of TiO_2 being reviewed. TiO_2 is also present in Annex III (Incomplete List of Additives) of the CEPE Code of Practice without any limitation on migration or other use condition; the harmonised classification of TiO_2 would not have any immediate impact under the CEPE Code of Practice, unless EFSA took the decision to review/revoke the authorisation of the substance. Such a development would them be mirrored under the CEPE Code of Practice. It is worth noting that some industry consultees have expressed the view that a Carc Cat 2 classification by inhalation would be unlikely to result in an adverse impact on the continued use of the substance in coatings for food contact materials;

- **Global Automotive Declarable Substance List (GADSL)**: under the GADSL a Carc Car 2 substance would not be "Prohibited" but would be "Declarable" thus making it less appealing for automotive manufacturers and less marketable by paint manufacturers; and

- **Setting precedence and an example for action by other jurisdictions**: similar regulatory action in other global regions could follow. This would further impact upon exports of EEA-made products.

Potential increases in operating costs

There are several implications of a harmonised Carc Cat 2 classification that could increase the manufacturing costs and thus impact the profitability of EEA-based paint manufacturers, including:

- **Cost of paint reformulation to eliminate TiO_2**: as noted above, reformulation of paint products so that the concentration of TiO_2 could be kept below 1.0% by weight would not be possible, thus reformulation could only aim at its complete substitution. However, substitution of TiO_2 is technically infeasible with the exception of very small markets for which TiO_2's brightness and effectiveness are not a priority. Trade associations have advised that, in the past, there have been issues with reduced TiO_2 production capacity resulting in a worldwide shortage of TiO_2 and significant price increase, which caused a notable increase in raw material costs[42]. This incentivised paint manufacturers to seek substitutes, but efforts were met by very limited success. It has thus been confirmed in practice that it is not technically possible to fully match the overall performance of the reformulated products to the originals based on TiO_2. In any case, reformulation of paint products would be a lengthy and costly process. Consultation has revealed the following:

    - ***Consumer formulations***: it could take between 5 and 10 years to successfully reformulate and qualify a suitable alternative to TiO_2 in architectural (decorative) coatings, depending on the application and test protocols required. Given that there are many (thousands) of decorative coatings formulations already on the market, the cost and time required to reproduce colour formulations and technical specifications (i.e. testing to try matching the existing colour range, compatibility and stability) would be vast and, for many SMEs, unachievable, resulting in withdrawal of the smaller players from the marketplace; and

    - ***Industrial formulations***: it could take between 5 and 20 years to successfully reformulate and qualify a suitable alternative to TiO_2 in industrial paints, coatings, printing inks and adhesives, depending on the application and test protocols required. Some products (once they have been successfully reformulated) require at least 5 years of testing and piloting before they can be approved for safe use in e.g. automotive or aerospace applications, or on infrastructure projects. As above for consumer formulations, the sheer number of products that would require reformulation would mean that the time required and the cost involved would be very large and, for many SMEs, unachievable, resulting in withdrawal of companies from the marketplace. It would also result in many downstream users of paints, coatings, inks and adhesives, relocating outside the EEA, as it would still be possible to import finished articles into Europe.

  Among all individual companies that have responded to a questionnaire, only two indicated that some reformulation of some industrial paint formulations could theoretically be possible. One of those indicated that reformulation would take longer than two years, while the other indicated an estimated reformulation cost of €60 million.

[42] AkzoNobel provides an indication of what percentage of variable costs is represented by the cost of TiO_2 for manufacturers of paints and coatings. In 2015, this was estimated at 7% of raw material costs (AkzoNobel, 2016). By comparison, all other pigments combined accounted for only 4% of raw material costs (AkzoNobel, 2013).

Box 4.2: Case study – The challenges of reformulating coil coatings to eliminate TiO_2

The paints used for coil coating are probably among the most sophisticated paints. In the case of coil coating, the liquid paint must have a rather low viscosity to make it possible to coat wet thickness sometimes below 10 µm and at the same time be curable within 8-20 seconds in hot air ovens (250 °C). The liquid paint is then a complex mixture that has specific physical properties (rheology) and chemical properties (to have the correct crosslinking rate in the curing step). Some coil-coating lines use powder coating. In this case, there is also a difficult compromise between the rather short curing time and the kinetics for melting, flowing and crosslinking.

Moreover, the coil-coated products are asked to reach a compromise between hardness and flexibility that is unique in the world of paints. Coil-coated products are bent, stamped, folded, etc. after being painted. The paint needs to avoid any cracking or loss of adhesion in this machining step, so it must be very flexible. However, at the same time the surface must resist scratches in the machining process and its appearance cannot be altered, so it must be very hard. This balance of hardness/flexibility is the result of a very complicated formulation, even more complicated if you consider that the paint thickness usually cannot exceed 25 µm.

Because of the balance between flexibility and hardness on the one hand, and the relatively low thickness on the other, coil coating is such a technically demanding sector that the probability of finding alternative solutions is quite low. When TiO_2 became too expensive and appeared to be unaffordable (after its price moved from US$2500 to over US$4000 per tonne between 2010 and 2012), major paint companies tried to replace it in all types of paints, including paints for coil-coating. In some paint applications it was possible to partly replace TiO_2 with some extenders, where it is mainly asked to cover and where there is no requirement about mechanical properties (for example some latex paints used in DIY as indoor paints). However, in the case of coil-coating, this is simply not possible: after intensive R&D development, in the very best case some companies could find lab alternatives to replace only 2-3% of the TiO_2 loading, which is rather insignificant. The main reason for this is that any substitution of the TiO_2 makes it necessary to either increase the thickness of the paint layer or to increase the concentration of the pigment (because no other compound has the same hiding power and white intensity as TiO_2). In both cases (higher thickness or higher pigment concentration), the balance between flexibility and hardness of the coil-coated product would not be assured anymore and this compromise is a *sine qua non* condition for a product to be painted before being machined. A higher thickness would also have serious consequences on the coil-coating line, because of limitations in the oven's capacity (solvent concentration would increase and there would be a flammability concern) and because of winding problems (tension should be increased to avoid coil-collapsing and this increase would damage the paint layer).

In summary, in the case of coil-coating, the experts have identified TiO_2 as the only option for white pigmentation and as opacifier from all the known available materials both in terms of technical performance and from a health, safety and environmental perspective. Hence, there are no known options for improvement in this respect. If one could imagine that in spite of these technical hurdles some acceptable alternatives are finally discovered one day, the time needed for becoming able to use these alternatives would be very long. There are thousands of different products with a technical compromise as described above that would need to be reformulated and validated through a 2-4 years outdoor exposure. Therefore, the consequences of the proposed classification for TiO_2 for the paint suppliers and for the availability of coil-coated products on the market would be very significant.

Source: information submitted by the European Coil Coatings Association

- **Compliance with waste management regulations**: the discussion presented at the beginning of Section 4 has shown that, irrespective of the relevance of the route of exposure to the harmonised classification, the management obligations for certain types of waste would change following the classification of the substance. The following table shows the types of wastes that might become relevant to hazardous waste management regulations in different Member States based on seven company responses to a questionnaire. The table identifies the following key waste stream generated during the manufacture of paints:

- Empty TiO_2 packaging that contains (>1%) residues of the pigment;
- Off-spec paint that contains TiO_2 as a component;
- Paint residues left in tanks and machinery during paint production;
- Sludges and cleaning waters;
- Solid wastes arising from filtration (e.g. filters, powders) and other cleaning activities;
- Waste from quality control and lab testing.

Some of this waste is already classified as hazardous due to the presence of hazardous components, for example organic solvents used in the manufacture of solvent-based paints. However, this would not necessarily mean that the Carc Cat 2 harmonised classification would not be accompanied by adverse impacts. A French paint manufacturer has noted that manufacturing waste which may be classified as hazardous but at a 'low hazard level' (i.e. water-based paint which is non-toxic, non-corrosive, non-carcinogenic) can be disposed of as hazardous through on-specific routes such as through cement plants or other heavy industries capable of incinerating such waste. However, when the waste becomes 'high level' hazardous (e.g. it is classified as CMR, toxic to the environment, etc.), those heavy industries do not accept it anymore and specialist contractors need to be sought for specialist disposal (incineration that can accept such types of wastes). This increases the costs of waste disposal.

While some other wastes (aqueous sludges) contain less than 1.0% TiO_2 and would therefore remain classified as non-hazardous even after the classification of TiO_2 as a suspected carcinogen, waste streams highlighted in grey colour in **Table 4–3** would become hazardous upon the introduction of the harmonised classification, if they contain more than 1.0% TiO_2. Examples include, (a) TiO_2 packaging, (b) waste paint (off-spec and residues), (c) aqueous sludges with >1.0% TiO_2 and (d) filtering/cleaning residues. TiO_2 is in an inhalable form only within its empty packaging (to be classified as *15 01 10* Packaging containing residues of or contaminated by hazardous substances*) and in filtering/cleaning waste, if in powder form.

Process washings are often recycled and/or fully treated before leaving the site, and sub-standard product is usually reworked into production thus the volumes of hazardous paint waste would likely be small. However, the arising of hazardous waste would require segregation of wastes, collection of hazardous waste by a specialised disposal company and a significant relative increase in the cost of waste treatment.

Few consultees have been able to estimates of the costs involved. One company has suggested that a change in hazard classification for off-spec paint and dust material from filtering operations would increase waste management costs by **30%**. Another company has estimated an overall cost of **€0.1 million** for changing the treatment of waste already classified as hazardous; this is on the basis of cost of €90-150/tonne for incineration of waste by a heavy industry installation vs. a cost of ca. €400/tonne for incineration for CMR-classified wastes by a specialist facility. A third company manufacturing thermoplastic paints has indicated a cost increase for waste sorting and segregation of **€15,000-20,000 per year**;

- **Increased administrative burden**: if a Carc Cat 2 substance is present in a mixture at a concentration ≥0.1% then a SDS must be available upon request (as per Note 1 under Table 3.6.2 of the CLP Regulation). Manufacturers of these products may receive an increased number of requests for SDS. Moreover, the number of products that would need to be reported to national Poison Centres would increase; and

Table 4–3: Relevant waste streams for the use of TiO_2 in paint manufacture

Process generating waste	Type of waste	Waste entry in LoW	Typical TiO_2 content	Example volume generated*	Is TiO_2 inhalable?	Current waste management
Raw material handling	TiO_2 packaging (bulk bags, small bags)	**15 01 06** Mixed packaging *('absolute non-hazardous')*	>1% ≤1%	<0.001 kt/y	Yes	Non-hazardous. **Landfilling or recycling**
Manufacture of paint formulations	Off-spec material	**08 01 11*** Waste paint and varnish containing organic solvents or other hazardous substances ('*mirror hazardous*') **08.01.12** Waste paint and varnish other than those mentioned in 08 01 11 ('*mirror non-hazardous*')	10% >1%	0.1 kt/y 0.3-0.5 kt/y 1-10 kt/y	No	Non-hazardous (e.g. water-based paints) or hazardous (e.g. solvent-based paints) **Incineration or physical & chemical treatment (both haz/non-haz waste)**
	Paint residues in tanks and machinery after production	**08.01.12** Waste paint and varnish other than those mentioned in 08 01 11 ('*mirror non-hazardous*')	1-5%	<0.001 kt/y	Yes	Non-hazardous (thermoplastic plaint) **Collected & recycled or in very small quantities, washed into interceptors**
		08 01 18 Wastes from paint or varnish removal other than those mentioned in 08 01 17 ('*mirror non-hazardous*')	1% >1%	1 kt/y	No	Non-hazardous **Physical & chemical treatment**

Table 4–3: Relevant waste streams for the use of TiO_2 in paint manufacture						
Process generating waste	**Type of waste**	**Waste entry in LoW**	**Typical TiO_2 content**	**Example volume generated***	**Is TiO_2 inhalable?**	**Current waste management**
	Cleaning water with liquid paint waste	**08 01 13*** Sludges from paint or varnish containing organic solvents or other hazardous substances (‘*mirror hazardous*’) **08 01 15*** Aqueous sludges containing paint or varnish containing organic solvents or other hazardous substances (‘*mirror hazardous*’)	1-20% >1%	0.8 kt/y 3-4 kt/y	No	Hazardous **Physical and chemical treatment, incineration or recycling**
	Aspiration filter residues, absorbent materials (powders), floor sweepings	**08 01 21*** Waste paint or varnish remover (‘*absolute hazardous*’) **16 03 03*** Inorganic wastes containing hazardous substances (‘*mirror hazardous*’) **19 01 99** Wastes not otherwise specified (‘*absolute non-hazardous*’)	From >1% to almost 100% TiO_2	0.001-0.005 kt/y 0-0.5 kt/y	Yes (could be damped down with oil from the mix process)	Hazardous or non-hazardous (depending on contents and dust presence) **Incineration, Reuse, Incineration, Physical & chemical treatment**

Table 4–3: Relevant waste streams for the use of TiO_2 in paint manufacture						
Process generating waste	**Type of waste**	**Waste entry in LoW**	**Typical TiO_2 content**	**Example volume generated***	**Is TiO_2 inhalable?**	**Current waste management**
	Industrial sludges	**08 01 13*** Sludges from paint or varnish containing organic solvents or other hazardous substances (‘*mirror hazardous*’) **08 01 19*** Aqueous suspensions containing paint or varnish containing organic solvents or other hazardous substances (‘*mirror hazardous*’) **08 01 20** Aqueous suspensions containing paint or varnish other than those mentioned in 08 01 19 (‘*mirror non-hazardous*’) **06 05 03** Sludges from on-site effluent treatment other than those mentioned in 06 05 02 (‘*mirror non-hazardous*’) **19 08 14** Sludges from other treatment of industrial waste water other than those mentioned in 19 08 13 (‘*mirror non-hazardous*’)	<1% **(NB. with such a concentration, a water--based waste could not be classified as hazardous)**	N/A	No	Non-hazardous (e.g. sludges from water-based paints) or hazardous (e.g. sludges from solvent-based paints) **Physical and chemical treatment (WB); Blending or mixing prior to submission to any of the operations numbered D1 to D12 (SB)**
	Waste thermoplastic from laboratory testing	**07 02 13** Waste plastic (‘*absolute non-hazardous*’)	1-10%	<0.001 kt/y	No	Non-hazardous **Landfilling**
* data based on individual responses to questionnaire						

- **Impacts on economies of scale**: a potential loss of part of the market (mainly due to aversion of consumers towards alarming labels, symbols and hazard statements) would make the production of paints overall more expensive and thus EEA-made paint manufacture less competitive. Companies, particularly smaller ones, might no longer have the production volumes running through their factories to cover their overheads.

Economic impacts on downstream users (industrial and professional)

Users of paints and other coatings and related products would certainly be impacted too:

- **Continued use of TiO_2-based paints**: downstream use of these products, especially transport, handling, application and disposal, would have to be revised to reflect the legislative requirements related to Carc Cat 2-containing mixtures. This would involve additional costs and resources, and may impose limitations on production rates and capabilities. New equipment may be required to be installed, new storage systems and disposal procedures would have to be put in place – waste packaging that contained TiO_2-based mixtures could be classed as hazardous and would need to be disposed of accordingly.

  Companies using TiO_2-based products may be required by their customers to state that they are using a product that contains a Carc Cat 2 substance in the production of an article (e.g. a vehicle). This would potentially not be acceptable to many users further downstream in sectors that produce finished items, articles or components or, for example, food packaging. Brand owners are likely to therefore put pressure on the supply chain to replace TiO_2. This would also attract negative publicity and undue attention from the media, NGOs, professional users (e.g. decorators) and the end consumer, even where the TiO_2 inhalation risk is close to zero (labels, food packaging, adhesives, painted objects, etc.) adding further pressure towards avoiding the use of TiO_2-based products even where the lack of health risk does not warrant such action.

  In addition, importers and downstream users of paints newly classified as hazardous due to the presence of TiO_2 in concentrations above 1.0% by weight would need to submit information to Poison Centres by 2020-2024 depending on the intended use of the mixtures (consumer, professional or industrial). It must be noted, however, that in some EEA Member States information on many or all paint products must be submitted anyway, therefore, the specific impact from a Carc Cat 2 harmonised classification for TiO_2 might actually be small;

- **Impacts from a switch to alternative pigments**: as noted above, alternative pigments with equivalent technical and economic feasibility are not available. Any attempt to use alternatives on a large scale would cause severe technical and performance difficulties and would damage the image of EEA-based paint manufacturers.

  At a more basic level, the availability of many of the potential alternatives is far lower than TiO_2's therefore with the exception of abundant minerals such as calcium carbonate or kaolin, sourcing the required volumes of pigments could prove challenging and would lead to production problems and increased raw material costs. Even where reformulation would be practicable, the results would not be acceptable, for instance:

  - The durability of replacement exterior white coatings and other functional coatings would be worse, so e.g. the finish on aeroplanes and cars would not be acceptable, if no longer based on TiO_2;

– The number of coats required to achieve a result equivalent to that achievable with TiO_2-containing paints would increase and thus the time and effort required for application of paints would increase; and
– Inks are applied at low film weights and TiO_2 substitutes would not be able to achieve the same opacity through the current standard printing procedures.

- **Compliance with waste management regulations**: consultation suggests that labelling waste paint products as hazardous would affect:

  – Wet waste handling at downstream user plants;
  – Waste packaging (if not emptied completely);
  – Waste documentation (waste transfer notes);
  – Waste storage and transport (need to use registered hazardous waste carriers);
  – Waste disposal (need to dispose at sites with the correct permits); and
  – Waste paint recycling (possible impact on End of Waste permitting, etc.).

The following table summarises information collected from consultation. It confirms that waste paint (and cleaning waters) and empty packaging would likely be classified as hazardous following the introduction of the Carc Cat 2 harmonised classification for TiO_2. Conversely, demolition waste would be unlikely to contain more than 1.0% TiO_2 thus would remain classified as non-hazardous (at least as far as the pigment is concerned).

Table 4–4: Relevant waste streams for the use of TiO_2 in downstream use and disposal of paints

Process generating waste	Type of waste	Waste entry in LoW	Typical TiO_2 content	Example volume generated*	Is TiO_2 inhalable?	Current waste management
Paint application	Paint residues in cans and machinery	**08 01 12** Waste paint and varnish other than those mentioned in 08 01 11 (‘*mirror non-hazardous*’)	10%	100 kt/y	No	Non-hazardous **Incineration or landfilling**
	Waste thermoplastic from contracting (waste from cleaning out boilers of residual or surplus materials, etc.)	**07 02 13** Waste plastic (‘*absolute non-hazardous*’)	0-10%	<0.001 kt/y	No	Non-hazardous **Landfilling**
	Empty paint packaging	**15 01 02** Plastic packaging (‘*absolute non-hazardous*’)	Variable residues		No	Non-hazardous **Landfilling / Recycling**

Table 4–4: Relevant waste streams for the use of TiO_2 in downstream use and disposal of paints						
Process generating waste	**Type of waste**	**Waste entry in LoW**	**Typical TiO_2 content**	**Example volume generated***	**Is TiO_2 inhalable?**	**Current waste management**
Paint removal	Old paint from sanding	**08 01 18** Wastes from paint or varnish removal other than those mentioned in 08 01 17 (‘*mirror non-hazardous*’)	1-20%		No (but Yes for paint)	Non-hazardous **Landfilling**
Demolition	Demolition of painted buildings	**08 01 18** Wastes from paint or varnish removal other than those mentioned in 08 01 17 (‘*mirror non-hazardous*’) **17 01 07** Mixtures of concrete, bricks, tiles and ceramics other than those mentioned in 17 01 06 (‘*mirror non-hazardous*’)	<1%		No/Yes	Non-hazardous **Landfilling**
	Empty paint packaging	**17 02 03** Plastic (‘*absolute non-hazardous*’)	Variable residues		No	Non-hazardous **Landfilling / Recycling**
End of life disposal	Cleaning water with paint leftovers (following professional use)	**08 01 11*** Waste paint and varnish containing organic solvents or other hazardous substances (‘*mirror hazardous*’) **08 01 17*** Wastes from paint or varnish removal containing organic solvents or other hazardous substances (‘*mirror hazardous*’)	1-10%	1 kt/y	No	Hazardous **Landfilling**
* data from individual responses to questionnaire						

Plastic packaging, including plastic paint buckets, which contain of 1% or more of TiO_2 would become hazardous waste and would now fall under LoW entries 15 01 10* and (if used on construction sides) under 17 02 04* rather than the entries identified in the table above. As noted in guidance issued by the European Commission, a specific plastic waste can be hazardous either because of the additives it contains or because the waste is contaminated with hazardous substances[43].

Recycling of formulations and articles would also be affected. For instance, it has been suggested that it is very likely that steel and aluminium recyclability would be damaged in the case of a change of classification of TiO_2. Currently, coil-coated products (primary waste, downgraded products, but also products at the end of their useful life) are recycled either internally in the case of integrated plants or via scrap processing companies. The flows could become seriously constrained following the classification of the substance as Carc Cat 2. In another example, consultation suggests that in Germany alone 62 million plastic paint buckets (plus 134 million metal coating cans) are recycled each year. This would no longer be possible in case of a classification since the recycling facilities do not have the necessary permits. The volumes of such waste across the entire EEA would be even higher.

A particular mention must be made of DIY stores across the EEA. As a matter of principle, the retailers such as OBI, B&Q, Castorama, Brico, Leroy-Merlin, etc. do not wish to sell products classified as carcinogenic, and in some cases (e.g. France) are legally obliged to store such products off the shelves to prevent self-service of consumers. A harmonised classification for TiO_2 would encourage DIY retailers towards removing or scaling down their vast range of TiO_2-containing DIY products from shelves. On the other hand, DIY retailers would face significant challenges in identifying and stocking replacement paint DIY products of a product range, quality and technical performance equivalent to TiO_2-containing formulations. These two conflicting drivers could cause significant problems and result in a decline in the footfall in DIY stores and necessitate a switch in business focus towards the professional rather than the DIY user. This, however, would mean a significant loss of market, as will be explained below where impacts on consumers' use of paints, coatings and painted/coated objects are discussed.

Social impacts

Employment impacts

The estimated level of employment associated with the use of TiO_2 in paint and printing inks manufacture is 110,000 workers and many more are employed in downstream user sectors. Paint and printing inks are widely used and there is a very large number of people using/applying paint in Europe. The number of workers involved in the application of paints (at construction sites, industrial production lines, etc.) is estimated to be around 1 million.

Stakeholders have asserted that if a harmonised classification of Carc Cat 1B for TiO_2 was introduced it would lead to the loss of thousands of jobs in paint/coating/ink manufacture[44] and among downstream users. By way of example, a threat on coil-coating would be seen as a wider threat for

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43 Available at http://ec.europa.eu/environment/waste/pdf/consult/Draft guidance document 09062015.pdf (accessed on 7 November 2017).

44 11 individual companies who provided both their current level of employment (with a combined number of jobs of over 13,200) have estimated that the number of jobs lost would exceed 15,000, as non-TiO2 operations would also be impacted by the proposed classification.

the activity in those integrated steel or aluminium making plants, leading to potentially accelerated decline of the European steel and aluminium making industry employing hundreds of thousands of workers. Related industries such as panel manufacturers and profilers, the construction industry, and domestic appliance manufacturers could also potentially be affected. A Carc Cat 2 harmonised classification would not have the direct effect on the removal of DIY paints from the EEA market, however, as discussed above, the cost and administrative burden of compliance and the perception of risk from (theoretical) exposure to TiO_2 when manufacturing, using and disposing of paints and similar products would lead to a decline in sales, costly attempts to reformulate without TiO_2 and an upset to the current market for said products. Such impacts could result in poor market performance particularly of SMEs and possible job losses on a scale perceivably smaller than in the case of a Carc Cat 1B harmonised classification.

Jobs involved in the distribution of paints to the DIY user (estimated at 30,000-35,000 employees) could also be impacted. Job losses in France would be of particular importance since in France the sales of paints in DIY shops would come under severe pressure due to national legislation on the sale of mixtures that contain CMR Cat 2 substances.

Impacts on the welfare of consumers

The proposed classification for TiO_2 would have a profound impact on consumer choice and welfare. The following impacts should be noted:

- **Consumer choice and product availability**: the availability of DIY paints that contain TiO_2 might be reduced as a result of paint manufacturers' reluctance to place on the market formulations labelled as carcinogen and DIY retailers' disinclination to stock such products. If a systematic attempt were to be made to substitute TiO_2, impacts on market availability of DIY products could affect all colours other than black and very dark blue (NB. even those contain other poorly soluble particulate materials such as carbon black), as well as glossy paints and ecolabel awarded products. Therefore, DIY activities as we know them could be curtailed. The hiring of professional decorators, plumbers and builders to undertake work around homes that often is done by homeowners and tenants would become more appealing[45]. In certain countries where the use of pre-painted steel for cladding and roofing is widespread in residential buildings, the urban landscape and residential aspect would be changed;

- **Increased cost implications**: using a professional decorator for paint jobs around the house would increase the cost to consumers, as they would have to pay more for materials and labour. By way of example, a member of the public may currently purchase the DIY paint needed for painting the walls and ceiling of a 120-130 m^2 apartment for, say, €50. A professional painter would charge €500, if not more. The cost of hiring a professional painter is already prohibitive for a large percentage of the population. Following the implementation of the Carc Cat 2 harmonised classification for TiO_2, the fees of professional decorators might even rise if demand for their services was to grow, thus making simple redecoration costlier, even for medium income families. Beyond the DIY uses of paints, reduced durability and increased frequency of paint/coating application would increase costs for the public sector, local authorities, housing associations, etc.;

[45] It is plausible that dust creation from the refurbishment of existing painted objects (walls, ceilings, wood trim in private houses) would also come under the spotlight for risk management – the public might no longer feel comfortable with stripping paint from their houses or use abrading tools, due to concerns over their potential exposure to TiO_2-containing dust.

- **Loss of consumer satisfaction and welfare**: lower quality, lower durability paint may gain part of the paint market; TiO_2-free alternative DIY paints and coatings would have neither the durability nor the 'brilliant white' appearance of existing paints. Higher paint thicknesses would be required to achieve the same opacity / hide the paint that is being overcoated. In addition, paint would probably need be applied in three or four layers, not the current one to two applications. Painted walls would need to be refurbished more regularly due to damage and discolouration. Thus, painting jobs would take longer, would need to be done more often, and homeowners and tenants would be disappointed with the final results compared with what can currently be achieved with TiO_2-based paints. Members of the public might choose to decorate less often, which would have an impact on quality of life / standard of decoration in homes across the EEA (e.g. due to growth of mould in bathrooms). This would mostly affect people on low incomes.

  DIY work is a popular activity for the public in many countries. It offers satisfaction, a sense of ownership and achievement once the job is completed. It is a talking point and something people take pride in. Painting one's home or, say, a community centre can bring groups of people and families together, and strengthens a community and hence society. The message that the classification of TiO_2 would convey is that such activities are potentially harmful and thus should be avoided.

  Consumer satisfaction with articles that require painting, coating, printing and bonding may well be affected if there were subsequent impacts on TiO_2 use in numerous industrial sectors, e.g. for cars, aeroplanes, 'white' goods, furniture etc.

  Disposal of waste paint might be affected (under waste category *20 01 27* Paint, inks, adhesives and resins containing hazardous substances*). Currently, dried-out paint can be disposed of alongside household waste[46]. Following the classification of TiO_2-containing paint, leftover paint might require separate collection and disposal at all times, thus increasing the disposal cost and affecting the convenience of DIY users. In addition, recycling of paint would likely be curtailed or prohibited. Recycling, although still relatively in its infancy, is a major part of Third Sector/charity activities, with paint helping to reintegrate members of the public with difficulties back into the community, and providing a focus for care and rehabilitation;

- **Adverse effects on public health**: as the TiO_2 is not available as powder to the consumers/professionals when within a paint (a TiO_2 suspension), using the paint cannot realistically give rise to inhalation exposure to TiO_2 particles. On this basis, a Carc Cat 2 harmonised classification would not deliver improved consumer health protection. Conversely, the harmonised classification could, in an extreme scenario, result in adverse impacts on public health. TiO_2 is used extensively in the road marking industry to create bright safety coatings, the vast majority of which are used to keep members of the public safe on the road network. If the harmonised classification would impact upon the market availability of TiO_2-based road marking paints (which notably are used by professional users rather than consumers), adverse effects on public health would arise. An increased incidence of traffic accidents due to poorer visual performance of alternative coatings could result in a higher incidence of death and injury[47],

[46] A European Commission brochure recommends, "*Paint and other waste can be taken to a specialised recycling centre. If you do not have access to one then let the paint dry, add sawdust or cat litter, and place it in the dustbin*" (available at http://ec.europa.eu/environment/waste/pdf/WASTE%20BROCHURE.pdf, accessed on 4 October 2017).

[47] Research in the UK estimates that the cost of a fatal road accident in 2012 was £1.6 million while the cost of serious or light injury was £0.19 million and £0.015 million respectively (information from

increased cost to emergency services in responding to an inevitably higher number of accidents, and increased congestion which would have a negative environmental impact as more vehicles would be running for longer therefore creating more potentially harmful emissions into the atmosphere than would otherwise be produced. Nevertheless, realistically, such adverse effects are unlikely to arise.

Competitiveness and competition impacts

Impacts on the competitiveness of EEA-based enterprises

In the context of impacts on the competitiveness of EEA-based enterprises, under the Carc Cat 2 harmonised classification the focus needs to be on changes to production cost rather than on placing of products on the EEA market, as the latter would not be under direct regulatory pressure.

More specifically, the legal obligations arising from a Carc Cat 2 classification could have cost repercussions for the EEA industry both at the paint/coating/ink manufacture level but also downstream. Increased manufacturing costs would harm the competitiveness of EEA companies vis-à-vis their non-EEA competitors (as long as other jurisdictions did not follow the EU example on the hazard classification of TiO_2).

Box 4.3: Case study – Loss of TiO_2 could mean more than the loss of white paints for EEA manufacturers

Although TiO_2 is mainly used as a white pigment, the substance is used in approximately 100% of the order book of the pre-painted metal manufacturers since this pigment is used not only for the whites but also as a base pigment (along with black) to which other pigments are added to gain the final colour and obtain the correct colour saturation. Many of their customers buy a range of colours in pre-painted metal from one supplier. Even if loss of TiO_2 only affected the whiter colours, to remove the most common colour which is white, would affect not only the cost price of the remaining colours but stimulate the end customers to buy/import the total package from alternative sources not regulated by European legislation. Without TiO_2, many European coil-coating lines would probably stop because this pigment would still be used out of the EEA zone and imported as an acceptable final product (a phenomenon already seen with other substances, such as anticorrosive pigments).

Source: information submitted by the European Coil Coatings Association

Loss of competitiveness among paint/coating/ink manufacturers could result in a variety of reactions:

- Those EEA-based companies with affiliates or branches outside the EEA might consider relocating some manufacturing operations where legislation is less stringent and thus compliance and manufacturing costs are lower or alternatively outsource production; or
- Others with global operations might consider the adoption of variable protection standards across operations both logistically unwelcome and reputationally risky and thus adopt measures appropriate to a Carc Cat 2 substance across their global operations.

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http://www.makingthelink.net/tools/costs-child-accidents/costs-road-accidents, accessed on 11 October 2016).

Relocation of the production of DIY and professional architectural paints might not appeal across the board as it is mainly a regional activity and the end product (e.g. a paint) would still be subject to regulatory requirements such as labelling when placed on the EEA market; however, more severe impacts might arise in relation to painted/coated/printed articles and the location of their manufacture. For obvious reasons, the manufacture of finished articles outside the EEA would become less costly and burdensome and thus more appealing. Thus, the local supply of raw materials to manufacture these articles might be preferred on economic and supply security grounds, so relocation of parts of the supply chain might occur. DIY retail chains might also face increased competition from non-EEA e-commerce retailers who could supply consumers with TiO_2-based formulations without the customer being visually alerted to a carcinogenic classification label and thus being less reluctant to purchase DIY paints that contain TiO_2.

Impacts on intra-EEA competition

In terms of intra-EEA competition effects, in principle, these could be modest as the Carc Cat 2 harmonised classification would impact the vast majority (estimated at 80-90%) of paint products placed on the market and effects and thus impacts would arise for the vast majority of paint manufacturers, retailers and users. However, some market distortion might not be avoided for the following reasons:

- Some paint manufacturers may have a strong presence in the market for 'green' or 'eco-friendly' products and thus rely on product differentiation through ecolabelling schemes (for which they invested significantly to attain). The Carc Cat 2 harmonised classification for TiO_2 would take away this market advantage and could instigate a market turn to less 'green' products; and

- Paint manufacturers would consider reformulating their products to avoid the addition of alarming hazard statements, pictograms and warnings on their packaging, particularly for products intended for the consumers. Larger companies might have access to larger resources that would allow then to finance any reformulation work; in comparison, SMEs and specialist manufacturers might face greater hurdles in reformulating whilst maintaining the quality of their final products and their competitive position in the market. SMEs, which represent over 85% of CEPE's membership of paint and ink manufacturers, might therefore be disproportionately impacted by the introduction of the Carc Cat 2 harmonised classification for TiO_2.

4.3.2 Plastics

Key market descriptors

The key economic parameters of the use of TiO_2 are summarised below.

Importance of the application	The plastics converting area covers a variety of sectors where TiO_2 may be used such as packaging, building and construction, automotive, electric & electronic, medical, household, leisure, footwear and clothes. The major sectors are packaging, building and construction and automotive. TiO_2 not only is used in the production of white masterbatches, it is also used in a wide number of colour formulations to obtain the desired colour. 60% to 70% of plastics articles end up with the consumer, while between 30 and 40% of plastics articles end up in sectors such as infrastructure, commercial and industrial, agriculture, etc.

Estimated TiO_2 tonnage used	Based on available information, plastics represent 25% of total demand for TiO_2. In the EEA, this would translate into ca. 275 ktonnes of TiO_2. Of this, 165-190 ktonnes will end up in consumer products with a further 85-110 ktonnes being present in industrial products (using the percentages shown above).

Estimated tonnage of products whose functionality depends on TiO_2[48]

Application	EU production
Plastic packaging (food, pharmaceuticals, other)	15.1 million t/y
Plastics in construction	8.2 million t/y
Plastics in automotive	2.9 million t/y
Plastics in E&E	1.4 million t/y
Plastics in agriculture	0.7 million t/y
Plastics for consumer, household, furniture, clothing, footwear	8.2 million t/y
Total converted plastics	**36.9 million t/y**
Source: EuPC	

Estimated value of markets

The value of the relevant markets in the EU is described below.

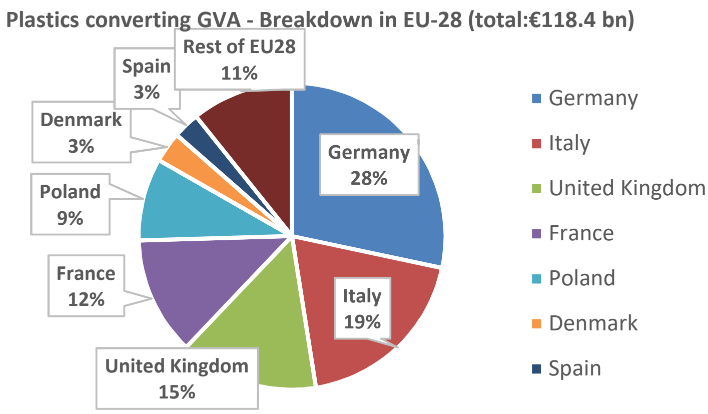
Supply chain	EU market value
Plastics conversion	€170 billion
All plastics value chain (incl. polymer production and machinery)	€270 billion
All plastics value chain including resin manufacture (not only of TiO_2 relevance)	€350 billion

According to PlasticsEurope, the multiplier effect for GDP for the plastics industry is 2.4 (PlasticsEurope, 2015). Therefore, the overall value including downstream markets is estimated at ca. €650 billion.

Estimates of Gross Value Added

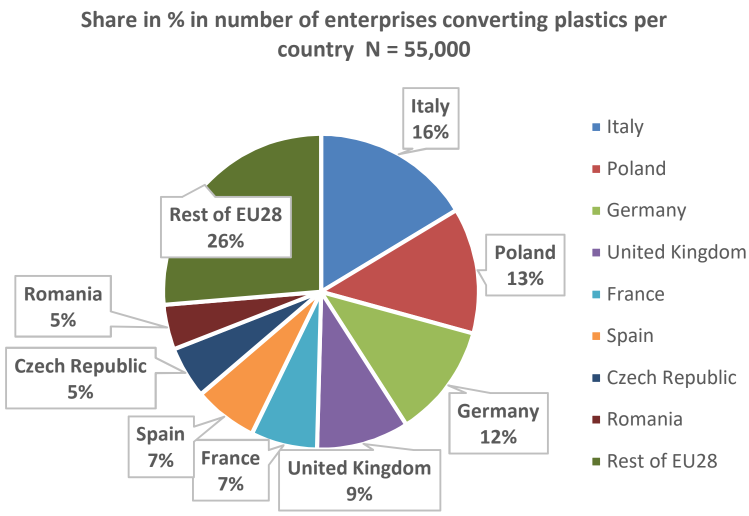
The GVA of plastics converting in 2013 according to Eurostat was €118.4 billion for EU-28. Its breakdown among EU Member States is provided below (with Germany, Italy, the UK and France being the most important partners) (source: EuPC).

[48] When EuPC undertook its market analysis, it considered products as functional units, i.e. products that have a certain function; if the absence of TiO_2 would have prevented those products from performing their function, then those products were assumed to be potentially impacted by a harmonised classification. This applies specifically to plastic packaging for which the high volume shown in the table not only includes products that contain TiO_2 in the plastic but also all those that are labelled with TiO_2-containing labels even if they are transparent and thus the plastic does not contain TiO_2 (e.g. a PET bottle). Without a label there would be no way of differentiating between products or enabling legible information such as a list of ingredients.



Number of users of TiO_2

The main trade association, European Plastics Converters (EuPC) has ca. 55,000 members. The breakdown of these enterprises per Member States is given below (source: EuPC). It is estimated that almost all companies in the converting sector, mainly SMEs, may be potentially impacted by the increased regulatory burden associated with the harmonised classification of TiO_2.



Presence of SMEs

The majority of companies in the sector are SMEs.

Number of stakeholders that participated in consultation

Two European trade associations, EuPC and the European PVC Window Profile and Related Building Products Association (EPPA) and one national association, VdMi representing the German masterbatch producers. EuPC incorporates the European Masterbatchers and Compounders (EuMBC), an association representing a relatively small number (fewer than 20) of large masterbatchers who account for more than 70% of the masterbatches and compounds manufactured in Europe[49].

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[49] The number of EuMBC members represents only a small percentage of the overall number of masterbatchers in the EU. For example, VdMi alone represents 22 German masterbatch manufacturers.

	In addition, an additional 10-25 individual companies active in the plastics field (masterbatch formulation, profiles, consumer products) have submitted completed questionnaires. Individual companies represent almost 1 million tonnes of TiO_2-containing products. In addition, 3 responses were received to the questionnaire on waste issues arising from a Carc Cat 2 harmonised classification.
Locations of stakeholders that participated in consultation	EuPC spans the whole of the EU-28 plastics conversion industry while EPPA has members in Austria, Belgium, Denmark, France, Germany, Poland, Spain and the UK. The individual companies that have participated have operations in many EU Member States (some respondents own several plants).
Employment in the sector	Plastics conversion in Europe encompasses 1.5 million jobs (of which 25,000 work on the manufacture of profiles). According to PlasticsEurope the multiplier effect for jobs for the plastics industry is almost 3 (PlasticsEurope, 2015). Therefore, the overall employment including downstream markets can be estimated at ca. 4.5 million jobs.

Relevant legislation

Table 4–5 summarises the legislation that would be of relevance to the use of TiO_2 in plastics applications in the EEA, after the adoption of a Carc Cat 2 harmonised classification. Additional detail is available in Annex 1.

Table 4–5: Relevance of different regulatory instruments and voluntary initiatives to plastic applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation

Relevant legislation	Relevant to plastics
CLP	Yes, for masterbatch & compounds and their use. Not for plastics articles
Carcinogens and Mutagens at Work	No
Waste Framework	Potentially. It depends if there is a mirror entry in the list of waste. If not, then no impact
Industrial Emissions	Potentially
REACH	**Annex XVII**: No
	Annex XIV: No
	Article 31: No
Cosmetics	Potentially. TiO_2 is on the positive list of the cosmetics regulation, as a colourant as well as a UV-stabiliser used in cosmetics packaging. The regulation would have to be reviewed following a risk assessment
Toy Safety	Potentially Impact not automatic
Food Contact Materials	Potentially but unlikely. TiO_2 is authorised in the positive list. TiO_2 classification does not cause an impact immediately. There could be an impact in case EFSA re-evaluates TiO_2. However, this is unlikely since the proposed classification is carcinogen by inhalation, not relevant for food contact. Reaction by customers may differ however

Table 4–5: Relevance of different regulatory instruments and voluntary initiatives to plastic applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation	
Relevant legislation	**Relevant to plastics**
Food Additives	No
Medicinal Products	No
Construction Products	Potentially
Biocides	No
Medical devices	No
RoHS	Potentially (but less likely than for a Carc Cat 1B classification). It is relevant but impact not automatic. The list of restricted substances would have to be updated following a risk assessment
Tobacco additives	No – but relevant to fibres applications of TiO_2
Other	Global Automotive Declarable Substance List (GADSL)

Impacts on the marketing and use of titanium dioxide-containing products

Economic impacts for manufacturers of plastics

Potential loss of markets

A Carc Cat 2 harmonised classification would have the following impacts on the ability of EEA-based plastics manufacturers to use TiO_2 and place on the market TiO_2-containing articles:

- **Hazard labelling and perceptions**: hazard labelling requirements would arise for masterbatches and compounds rather than plastics articles. Hazard labelling would not be relevant to consumer products or professional users but only to industrial users. Yet, consumer views on the presence of a suspected carcinogen in plastic products might have an adverse effect on the market (NB. consumer-related products account for **60-70% of plastics containing TiO_2**)[50]. The end users' perception of buying products that contain, or are packed or stored in materials that contain a suspected carcinogen would affect their buying behaviour (for instance, when considering cosmetics, personal care products, food, food contact, pharmaceuticals). EuPC can further recount past examples where a change in hazard classification has resulted in reformulation in the short (additives for use in contact with food) to medium term (phthalate plasticisers). In the case of TiO_2, identifying a feasible alternative is currently impossible (see discussion further below).

  For industrial products, the above concerns would also apply to a certain extent. Classification as a Carc Cat 2 substance could potentially trigger substitution especially from public procurement (infrastructure, public building, supplies for public administration) but also from some commercial sectors (outlets, shopping malls, etc.) but any such effect would be less pronounced under a Carc Cat 1B harmonised classification. Pressure from customers might lead

50 It is worth noting the linkages between different applications of TiO_2, here between plastics, paper and printing inks. EuPC assumes that the majority of plastic packaging cannot be sold without a label as this would not be a functional unit. This means also a transparent PET bottle or tray cannot be sold without use of TiO_2 as the packaging will be unable to perform its function. TIO_2 pigment is used as a base colour on the label in order to enable the printed text to be seen. It is the only pigment that allows adequate legibility. For the time being the assumption is that 95% of packaging would be impacted.

to the need to reformulate products which would more specifically impose constraints on production organisation and significant R&D costs as well as the replacement of plastic with alternative materials (metal, wood, cement, for example).

Masterbatchers and compounders (the majority of which are SMEs) could expect some negative effects on their business if the Carc Cat 2 harmonised classification was adopted. Again, this would be driven both by regulatory requirements and customer buying behaviour. TiO_2 would be stigmatised and, thus, even if it legally could be used, there could be a de facto drive towards its substitution in consumer applications/products;

- **Toys**: see discussion on potential impacts on TiO_2-containing paint use in toys. The continued use of the substance might be allowed following a positive opinion by the SCCS, but market (and consumer) perceptions and pressures might lead to efforts to substitute TiO_2 in plastics used in toys;

- **Food contact materials**: TiO_2 is authorised in the positive list for use as a component of plastic food contact materials and a harmonised classification that would apply to exposure by inhalation might not have a direct impact on the use of the pigment. However, if consumers were to be made aware of the presence of the pigment (e.g. via publicity or other campaigns), they might become more reluctant to use such plastic articles;

- **Global Automotive Declarable Substance List (GADSL)**: as in the case of paints, under the GADSL a Carc Car 2 substance would not be "Prohibited" but would be "Declarable" thus making it less appealing for automotive manufacturers and less marketable by plastics manufacturers; and

- **Waste management supply chain**: as will be discussed below, the harmonised classification could have a devastating effect on the recycling of plastic waste (be it building and construction waste, packaging waste, etc.). This would lead to severe market and economic losses for the waste value chain in the EEA.

<u>Potential increases in operating costs</u>

There are several implications of a harmonised Carc Cat 2 classification that could increase the manufacturing costs and thus impact the profitability of EEA-based plastics manufacturers, including:

- **Cost of reformulation to eliminate TiO_2**: the unanimous view of the industry is that TiO_2 cannot be reformulated out of plastics in the vast majority of cases. In some limited cases, substitution of TiO_2 might be a practicable solution but would most likely constitute a case of regrettable substitution. Key implications would be:

  - The need to use pigments in much higher loadings than TiO_2 in order to achieve the required whiteness;

    Additional additives would need to be included in the formulations, for instance additional UV absorbers/blockers would be required to replace TiO_2 functionality in supporting the weatherability of the plastic articles; and

  - Some alternative pigments may carry their own adverse hazard classifications; any and all alternatives would have to be used in greater quantities to obtain a similar level of whiteness. Furthermore, such substitution would also require other non-colourant additives to be added. These non-colourant additives would primarily include UV-blockers.

In order to evaluate possible alternatives already used or evaluated, EuPC prepared a report on alternatives which incorporates the views of members that responded to a EuPC questionnaire. The report is reproduced below and whilst is specific to the plastics sector, it can be read in the wider context of Annex 2 to the present report.

Box 4.4: Comparison of alternatives for TiO_2 in the plastics industry by EuPC

The method used by EuPC was a grid questionnaire to evaluate TiO_2 as well as the possible alternatives. Possible alternatives were suggested based on information obtained in literature (Ruszala, et al., 2015; Zweifel, et al., 2008) and respondents (members) were invited to propose other alternatives.

Respondents were asked to rate these possible alternatives on a Likert scale (1, the worst to 5, the best) for the following properties: whiteness, food preservation, write-ability, opacity, weatherability, and chemical, colour and mechanical stability.

The proposed alternatives included in the question were: calcium carbonate ($CaCO_3$, CAS No. 471-34-1); zinc oxide (ZnO, CAS No. 1314-13-2); different clay minerals: kaolin, talc, perlite, vermiculite, calcined clays and flash calcined clays; cenospheres; and hollow spheres. Furthermore, a space for other comments was added in order to give the possibility to the companies to contribute with qualitative remarks.

Sixteen (16) responses to the questionnaire were collected. All of them evaluated TiO_2, particularly its whiteness and colour stability. The results of TiO_2 are highly positive for all properties, with all scores above 4.3, and a total average of all properties of 4.6, as shown in **Table 4-6**.

The most evaluated alternative is calcium carbonate, followed by zinc oxide, kaolin, and talc. On other alternatives there were insufficient data to make general statements on the appropriateness of the alternative for the plastic converting sector. Conclusions on the most prominent alternatives are as follows:

- **Calcium carbonate**: calcium carbonate has an average score of 3.0 which is comparable to other alternatives, but low compared to TiO_2. The whiteness of calcium carbonate is also an issue. One respondent even suggested not considering calcium carbonate a pigment, but rather a filler additive. Furthermore, as calcium carbonate is able to react with acid ($CaCO_3 + 2\,H^+ \rightarrow Ca^{2+} + H_2O + CO_2$), it might be compromised in outdoor applications, which is reflected in the score of 2.17 for weatherability;

- **Zinc oxide**: apart from being a less efficient whitening agent as determined by various scores, respondents indicated that this substance is also classified as very toxic to aquatic life and very toxic to aquatic life with long lasting effects[51]. Thus, substitution of TiO_2 by zinc oxide might not be a suitable option;

- **Kaolin and talc**: kaolin and talc are clay minerals which are generally considered to be fillers and not pigments. The loading levels required to obtain similar whiteness as a plastic whitened with TiO_2 are much higher for these substances, which can cause problems in terms of the mechanical properties of the plastic; and

[51] It is notable that this hazard classification is of most relevance to the handling of the pigment rather than its release from a plastic matrix. When used in plastics or other matrix materials/special mixtures, the OECD Transformation Dissolution Protocol should be applied (OECD Guidance No. 29). The reduced solubility of the substance is corrected for in its environmental classification.

- **Titanium dioxide**: several companies remarked the fact that TiO_2 is the only pigment that gives such a white colour with stability. Several respondents indicated that to achieve similar properties as plastics coloured with TiO_2, one would need to add other additives with consequent substantial cost increases for the end product. The same situation would be for UV absorbent properties. One of them stated that "*only TiO_2, ZnO and lithopone are white pigments, the other alternatives $CaCO_3$, clay, talc, kaolin are fillers and do not impart really opacity to a film*" and pointed out that TiO_2 has good weatherability. According to another respondent these alternatives are generally fillers developed for incorporation into the polymer matrix alongside TiO_2 in order to reduce cost. Great importance was given to TiO_2 for being a cost effective whitening agent. One respondent described TiO_2 as: "*undoubtedly the most efficient and cost-effective material to provide opacity and whiteness to plastics*." The fact of the need to add higher concentrations to achieve TiO_2-like properties was indicated as well. One respondent explained: "*the best of the alternative materials would require four or five times the concentration to achieve similar levels of opacity and would not approach the whiteness provided by TiO_2*." Some respondents concluded that currently, after having undertaken an extensive evaluation of alternatives, there are no suitable alternatives to this compound available on the market.

Even if the technical shortcomings of the alternatives could be disregarded, the cost of reformulation would be significant. An individual masterbatch manufacturer has noted that they would need to change 10,000 different formulations, the customers would have to review their processes and all new products would have to be tested and re-certified. Other stakeholders have suggested a reformulation cost as high as €4-10 million and a possible timeframe for reformulation of several years.

As noted above, loadings of alternatives would be higher and new additives would be required; organic UV stabilisers are relatively more expensive than TiO_2. Expert judgment within the EuPC indicates that the typical estimated costs for reformulation would be 5% of turnover and dedicated production for niche products would account for a further 5%, as companies would need to plan and organise detailed production campaigns to allow for the production of dedicated TIO_2-free products; and

Table 4–6: Analysis of Alternatives to TiO_2 in plastics (average values for each alternative's properties and the number of responses between brackets)									
Chemical	Whiteness	Food preservation	Write-ability	Opacity	Weather-ability	Stability			Average score
						Chemical	Colour	Mechanical	
TiO_2	4.87 (16)	4.5 (2)	4.33 (3)	4.71 (7)	4.71 (7)	4.83 (12)	4.8 (15)	4.36 (11)	4.6
$CaCO_3$	2.1 (15)	3 (2)	4.67 (3)	3.17 (6)	2.17 (6)	3 (7)	2.6 (10)	3.1 (10)	3.0
ZnO	2.75 (8)	3.5 (3)	3.33 (3)	4 (4)	2.67 (6)	3 (6)	3.14 (7)	3.33 (6)	3.2
Kaolin	2.125 (8)	2.5 (2)	4 (2)	3 (4)	2.5 (4)	4.25 (4)	3 (5)	3.5 (4)	3.1
Talc	1.92 (12)	2.5 (2)	4 (2)	2.8 (5)	2.67 (6)	4.33 (6)	2.86 (7)	3.57 (7)	3.1
Perlite	2 (1)	(0)	(0)	(0)	1 (1)	(0)	1 (1)	(0)	-
Vermiculite	2 (1)	(0)	(0)	(0)	1 (1)	(0)	1 (1)	(0)	-
Calcined clays	1.5 (6)	2 (1)	4 (1)	2.5 (2)	2 (3)	4.33 (3)	3 (3)	3.33 (3)	2.8
Flash calcined clays	1.33 (3)	(0)	(0)	(0)	1 (1)	(0)	1 (1)	(0)	-
Cenospheres	2 (1)	(0)	(0)	(0)	1 (1)	(0)	1 (1)	(0)	-
Hollow spheres	2 (3)	(0)	(0)	3.5 (2)	2.5 (2)	4.5 (2)	2.67 (3)	2 (1)	-
Lithopone (ZnS + $BaSO_4$)	4 (1)	4 (1)	5 (1)	4 (1)	3 (1)	3 (1)	3 (1)	3 (1)	3.6
Barium sulphate	1 (1)	(0)	(0)	(0)	(0)	5 (1)	4 (1)	5 (1)	-
Antimony trioxide (Sb_2O_3)	4	(0)	(0)	4	3	3	3	3	-
Zinc sulphide	2.5 (2)	-	-	3 (1)	3 (1)	4.5 (2)	4 (2)	5 (2)	-

Source: EuPC

- **Compliance with waste management regulations**: the following table brings together the limited amount of information submitted by a small number of plastics manufacturers. With the exception of TiO_2 packaging waste which might be classified as hazardous depending on the content of residues in it (i.e. it would be allocated to the 15 01 10* absolute hazardous entry), the key waste stream that contains TiO_2 is off-spec materials which are recycled into the process where possible (NB. this is not always possible, for instance, a masterbatch manufacturer noted that they produce more than 2,000 active products with different compositions and pigments and cannot feasibly separate the off-spec waste into different streams according to their specific chemical composition). These off-spec materials are assumed to be classified as 'absolute non-hazardous' waste and therefore, the Carc Cat 2 harmonised classification would be unlikely to have an impact on their management. As the number of responses is small, it is possible that the table below may not capture all relevant streams (for example, the LoW includes a potentially relevant 'mirror' entry *07 02 11* Sludges from on-site effluent treatment containing hazardous substances*). Information on the potential cost increases from changes to waste management practices has not become available; and

Table 4–7: Relevant waste streams for the use of TiO_2 in plastics manufacture

Process generating waste	Type of waste	Waste entry in LoW	Typical TiO_2 content	Example volume generated*	Is TiO_2 inhalable?	Current waste management
Raw material handling	TiO_2 packaging	**15 01 06** Mixed packaging *('absolute non-hazardous')*	N/A	N/A	Yes	Non-hazardous. **Landfilling or recycling**
Manufacture of masterbatch	Filter waste from premixing of pigment formulations	Not provided; assumed **16 03 03*** Inorganic wastes containing hazardous substances ('*mirror hazardous*')	>1%	1-10 t/y	Yes	Hazardous **Landfilling**
	Off-spec material	Not provided; assumed **07 02 13** Waste plastics ('*absolute non-hazardous*')	>1%	100-500 t/y	No	Non-hazardous **Incinerated**
Manufacture of polymers (e.g. polyolefin pellets or PVC films)	Off-spec material and trimmings	No LoW entry – Waste returns to the process **07 02 13** Waste plastics ('*absolute non-hazardous*')	>1%	20 - 30 kt/y 5-10/kt/y	No	Non-hazardous **Recycling into the process (if the off-spec material is hazardous due to other components, it is incinerated by authorised contractors)**

Table 4–7: Relevant waste streams for the use of TiO_2 in plastics manufacture						
Process generating waste	**Type of waste**	**Waste entry in LoW**	**Typical TiO_2 content**	**Example volume generated***	**Is TiO_2 inhalable?**	**Current waste management**
	Dust generation (from change of recipe, cleaning of production facilities or attrition of pellets)	**07 02 13** Waste plastics (‘*absolute non-hazardous*’)	Variable	N/A	No	Non-hazardous. **Landfilling**
* data based on individual responses to questionnaire						

Economic impacts on downstream users (industrial and professional)

The above discussion on impacts covers adequately the entirety of the supply chain for plastics with the exception of consumers (discussed further below) but also the management of plastic waste at the end of their life. The Carc Cat 2 harmonised classification could have an impact on the management of some types of plastic waste, for example,

- Plastic packaging:
  - 15 01 10* packaging containing residues of or contaminated by hazardous substances;
- Plastic waste from construction and demolition:
  - 17 02 04* Glass, plastic and wood containing or contaminated with hazardous substances from demolition activities;
- Entries which (can) contain plastic but do not explicitly refer to plastic, such as:
  - 17 04 10* cables containing oil, coal tar and other hazardous substances;
  - 17 06 03* other insulation materials consisting of or containing hazardous substances;
  - 17 09 03* other construction and demolition wastes (including mixed wastes) containing hazardous substances;
- Plastic waste from waste management operations:
  - 19 10 03* fluff-light fraction and dust containing hazardous substances;
  - 19 12 11* other wastes (including mixtures of materials) from mechanical treatment of waste containing hazardous substances;
- Non-specified wastes which may contain plastic, such as:
  - 16 02 15* hazardous components removed from discarded equipment.

On the other hand, several relevant waste categories are classified as ‘absolutely non-hazardous’, including:

- 02 01 04 Waste plastics (except packaging) from agricultural activities;
- 12 01 05 Plastics shavings and turnings from mechanical treatment of metals and plastics;
- 15 01 02 Plastic packaging;
- 16 01 19 Plastic from End-of-Life Vehicles;
- 17 02 03 Plastic from demolition; and
- 19 12 04 Plastic and rubber from mechanical sorting of waste.

Yet, these entries may well be replaced by hazardous ones. As discussed in Section 4.2.1, based on draft guidance by the European Commission (dated 2015) the presence of a hazardous additive (in this case TiO_2 at concentrations above 1.0% by weight) could render specific plastic wastes as hazardous. Such a change in hazard classification could have serious impacts on the recycling of plastic waste. According to estimates available to EuPC[52], between 600 and 700 ktonnes of plastics from long life applications (construction, automotive, electric and electronic, excluding packaging) are recycled. Over time, recycling may increase to, at least, 1,000 ktonnes/y. All of those streams could be potentially affected since it is not feasible to segregate materials containing TiO_2 (the large majority) from others. For TiO_2 used in packaging, due to their short lifecycle, the TiO_2 will remain in the packaging recycling stream for a short time once replaced by an alternative (except for longer life packaging such as crates and pallets (which represent ca. 250 ktonnes/year). Knowing that the margins of recyclers are typically low, any cost increase in the waste value chain, be it administration/certification/validation or additional treatment operation etc., will place the recyclers under pressure. As a consequence, any TiO_2-containing plastic waste management operation would come under risk.

Impacts on recycling could extend beyond recycling of post-consumer waste and also affect plastic manufacturers as some of them may source 3rd party plastic scrap which they feed into their manufacturing process as recyclate.

Social impacts

Employment impacts

Estimating employment impact without clarity on what economic and market impacts would arise is difficult. Pressure from the supply chain to reformulate and increased regulatory burden at the manufacturing step would put pressure on employment levels. Given the very large number of workers in the sector, even a small percentage effect would result in a large number of job losses (loss of 1% of EEA-based jobs would mean redundancy for 15,000 workers).

Impacts on the welfare of consumers

The proposed classification for TiO_2 could have significant impacts on consumer choice and welfare. The following impacts should be noted:

- **Loss of certain types of consumer products from the market**: a major impact on brands and their ability to commercialise their products could be expected as a result of the business cost and negative perceptions associated with a carcinogenicity hazard classification for a key additive of many plastic articles;

- **Loss of performance**: if TiO_2 were to be substituted, the durability of all materials exposed to light in long life applications (windows, gutters, furniture, automotive interiors) would be

[52] Based on a 2012 report by Consultic.

significantly reduced. Alternative materials (such as wooden windows) would require periodic re-painting; however, durable exterior architectural paints typically contain TiO_2. Such maintenance would therefore not be possible to be undertaken by members of the public. In addition, if certain plastic packaging solutions for food or agricultural feedstock lost their capability of protecting the goods from decomposition by radiation, spoilage might occur faster and the quality of packed goods might be affected. Worsening of the physicochemical characteristics of the polymeric matrices used, could in some cases result in a push towards the use of more expensive polymers for the same application;

- **Loss of consumer satisfaction**: loss or marginalisation of TiO_2 over negative perception and consumer pressure would mean loss of design capability (dull, unstable colours); and

- **Adverse impacts on public health**: loss of TiO_2 would make it very difficult to display information important to the consumer (e.g. food ingredients, safety). TiO_2 is the only opacifying agent for plastic containers recognised by the European Pharmacopoeia's Section 3.1. Its presence is necessary for the absorption of UV radiation and thus the protection of the shelf-life of a large number of light-sensitive pharmaceuticals. Similarly, TiO_2 supports longer shelf-lives for foodstuffs and cosmetics when used in packaging materials.

On the other hand, plastic waste streams within municipal waste (*20 01 39 Plastics*) are an 'absolute non-hazardous' category and its management would not be directly impacted, although the presence of a suspected carcinogen could have an impact on the recycling of such waste

Competitiveness and competition impacts

The increase in manufacturing costs and the supply chain pressure towards avoidance of TiO_2 could cause loss of turnover and worsening of the quality/performance of EEA-made plastic products. Therefore, EEA-based plastics converters would be disadvantaged vis-à-vis their non-EEA competitors who could import cheaper to make, better quality TiO_2-containing articles into the EEA which would bear no label indicating the presence of a suspected carcinogen.

The TiO_2 business is a very global one; raw materials are easily sourced on the global market because of the quantities involved (the savings on cheaper raw materials exceed the transportation costs). Similarly, for the rest of the value chain, from powder to intermediate articles, it is reasonable to expect that non-EEA players could obtain a competitive advantage to offer items such as films, sheets, extruded parts, etc. to finished article producers. Over time, under the constant pressure of market needs, a shift of the value chain to outside of EEA might be expected, for reasons of proximity and integration with suppliers of masterbatches and other preparations based on TiO_2.

Within the EEA, the plastics industry might lose some of the performance advantage it has versus the manufacturers of alternative products (e.g. wooden window frames). An increased regulatory burden could also drive consolidation in the industry, leading to less competition and SMEs would be most vulnerable in the face of such a trend.

4.3.3 Paper

Key market descriptors

The key economic parameters of the use of TiO_2 are summarised below.

Importance of the application	There are three key areas for TiO_2 applications in the paper sector: • Décor paper for laminate flooring and furniture and laminates for packaging; • Wallpapers; and • Unlaminated paper for packaging and printing/writing. The importance of TiO_2 would appear to be higher for the first two areas, although specific areas of packaging and printing also show a dependence on the unique physicochemical properties of TiO_2.
Estimated TiO_2 tonnage used	It is estimated that the paper sector accounts for 12% of TiO_2 consumption. This would be equivalent to ca. 130 ktonnes/y. Based on data available to Cefic (for the year 2013), laminates are the most prominent area of use and accounts for ca. 80% of total paper consumption, i.e. ca. 105 ktonnes/y.

Estimated tonnage of products that contain TiO_2

Application	EEA production
Paper laminates (data for respondents only)	250-500 ktonnes/y
Wallcoverings	244 ktonnes/y
Packaging and printing/writing paper (data for respondents only)	40-50 ktonnes/y
NB. data are incomplete. CEPI statistics indicate the production of 35 million tonnes of graphic papers, 44.5 million tonnes of packaging papers and 3.9 million tonnes of other papers in Europe (CEPI, 2016)	

Estimated value of markets

Application	EEA market value
Paper laminates (data for respondents only)	€500-750 million/y
Wallcoverings (IGI membership)	€1.2 billion/y
Packaging and printing/writing paper (data for respondents only)	€25-50 million/y
NB. data are incomplete. A calculation can be made on the value of laminated board: - Average value of décor paper in laminate: €0.30/m² coated board - Value of laminate: €5-15/m² of coated board - Volume of laminated board consumed in Eurozone: 3 billion m² - As both sides of board are coated $1.5{\times}10^9$ m² × €10/m² = €15 billion	

Estimates of Gross Value Added

Information on the specific applications of concern is not available. The entire paper industry in Europe has a turnover of €75 billion with a value added of €15 billion, according to CEPI[53]. If the same % of value added (20% = 15 ÷ 75) were to be used, the value added of the

[53] Data available at: http://www.cepi.org/system/files/public/static-pages/CEPI_in_brief_infographic.jpg (accessed on 13 October 2016).

	wallcoverings industry would be €0.24 billion and for the laminated paper products €0.1-0.15 billion. A 2011 report estimated that for every €1 of turnover made by pulp, paper and board mills, €1.05 was being made upstream and €2.88 was being made downstream (Poyry, 2011). It is uncertain whether the same ratios would apply for the products of interest here.
Number of users of TiO_2	The number of users is uncertain. 54 EU-based wallcovering manufacturers are members of the IGI trade association. CEPI, the Confederation of European Paper Industries indicates that there are 515 pulp, paper and board producing companies in the EU[54].
Presence of SMEs	In the wider paper sector there is a large number of SMEs, however, several are part of or owned by large enterprises. Within the wallcoverings sector, the majority of companies are SMEs, but for laminates, SMEs might be in the minority.
Number of stakeholders that participated in consultation	10-25 companies and <5 trade associations have submitted completed questionnaires. In addition, only 1 response was received to the questionnaire on waste issues arising from a Carc Cat 2 harmonised classification.
Locations of stakeholders that participated in consultation	Germany, Sweden and the UK are the countries where most stakeholders who made a contribution are located in. With regard to laminate production, France, Germany, and Spain appear to be important contributors to EEA production. Among wallcovering producers Germany, the UK, the Netherlands and Italy host the largest number of companies.
Employment in the sector	According to a 2011 report (using data for the year 2008), the level of employment in the pulp, paper and board industry in Europe was ca. 208,000 (Poyry, 2011). In the same year, the number of employees upstream was estimated at 337,300 and downstream at 1,051,700.

Relevant legislation

Table 4–8 summarises the legislation that would be of relevance to the use of TiO_2 in plastics applications in the EEA, after the adoption of a Carc Cat 2 harmonised classification. Additional detail is available in Annex 1.

Table 4–8: Relevance of different regulatory instruments and voluntary initiatives to paper applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation

Relevant legislation	Relevant to paper
CLP	Yes
Carcinogens and Mutagens at Work	No
Waste Framework	Potentially

54 Data available at: http://www.cepi.org/node/20504 (accessed on 13 October 2016).

Table 4–8: Relevance of different regulatory instruments and voluntary initiatives to paper applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation	
Relevant legislation	**Relevant to paper**
Industrial Emissions	Potentially
REACH	**Annex XVII**: No
	Annex XIV: No
	Article 31: No
Cosmetics	No
Toy Safety	Potentially
Food Contact Materials	Yes
Food Additives	No
Medicinal Products	No
Construction Products	Potentially
Biocides	No
Medical devices	No
RoHS	Potentially (but unlikely) Self-adhesive labels may be used in packaging of electronic devices and they may also be attached directly to the devices. Customers require that the paper has to meet the demands of RoHS concerning restricted substances
Tobacco additives	Yes – TiO_2 may be used in cigarette paper

Impacts on the marketing and use of titanium dioxide-containing products

Economic impacts for manufacturers of paints and coatings

<u>Potential loss of markets</u>

A Carc Cat 2 harmonised classification would have the following impacts on the ability of EEA-based paper manufacturers to use TiO_2 and place on the market TiO_2-containing articles:

- **Hazard labelling and perceptions**: the hazard labelling requirements of the CLP Regulation would not apply to the final paper articles. Still, customers and consumers may be confused about the implications of the carcinogenicity classification of TiO_2 and develop a negative perception on the products that contain it, even if the TiO_2 in the final product is within a matrix and it is not volatile or directly accessible. Customers (paper users) may not wish to handle products that contain a carcinogen. In addition, decorative (also known as décor) paper is used to manufacture articles that are present in consumers' daily lives such as flooring, furniture, doors, walls, facades and the widespread presence of a hazardous substance in bedrooms, living rooms, kitchens, workplaces could have an adverse impact on the décor paper industry as well as the ready-to-assemble furniture and flooring sector. Similar effects could be envisaged with other consumer-facing applications such as paper for food packaging paper;

- **Toys**: see discussion above on paints and plastics. Market perceptions and pressures might have a bearing on whether paper manufacturers consider substitution of TiO_2;

- **Food contact materials**: the relevant CoE Resolutions on paper/board and inks list TiO_2 as an approved additive (NB. paper that is used in food contact articles but that is separated from the food by a functional barrier is outside the scope of the paper/board Resolution). A Carc Cat 2 harmonised classification for the substance could lead to the review of its listing and its potential removal; and

- **Setting precedence and an example for action by other jurisdictions**: similar regulatory action in other global regions could follow. This would further impact upon exports of EEA-made products.

Potential increases in operating costs

There are several implications of a harmonised Carc Cat 2 classification which could increase the manufacturing costs and thus impact the profitability of EEA-based paper manufacturers, including:

- **Cost of reformulation to eliminate TiO_2**: given the typical concentrations of TiO_2 in paper formulations, a concentration of TiO_2 as low as 1.0% by weight would not confer the desired properties to the end products. For products where aesthetics, durability, wet opacity control and light-weightness are important, namely laminates and wallcoverings, there are no feasible alternatives that could be used to replace TiO_2. TiO_2's high refractive index cannot be matched by other pigments. Zinc sulphide might come close but it has to be added at higher loadings, around 20-50% higher. There may be limited opportunities for partly replacing TiO_2 with some spherical plastic pigments which could contribute to a certain extent to shade and opacity, but this would only be limited to some final applications, due to conversion conditions and final product requirements[55]. As a result, estimates for the cost of reformulation cannot be provided with confidence, although a figure of **€0.4 million per company** has been suggested in the field of wallcoverings. In any case, lengthy trials would be required for any alternative to be tested. Estimates for the length of such efforts range **between 2 and 5 years** without a guarantee of success.

  On the other hand, some current users of TiO_2 have noted that in some limited cases, where performance requirements are low, TiO_2's use may not be critical and could be replaced either in part (for instance, by a composite pigment of calcium carbonate and TiO_2 (but this too contains TiO_2)) or potentially in full (by aluminosilicate and magnesium aluminosilicate or higher loadings of calcined clay and precipitated calcium carbonate). Talc and chalk might also be considered in printing paper where opacity requirements are low, but these cannot really be considered feasible alternatives for TiO_2, as the latter is a relatively costly additive that is generally reserved for paper grades that have a high opacity requirement. Again, reformulation would be accompanied by considerable cost; and

- **Compliance with waste management regulations**: wastes relevant to paper manufacture are listed on LoW under Chapter 3 (*Wastes from wood processing and the production of panels and furniture, pulp, paper and cardboard*) and specifically under sub-chapter *03 03 Wastes from pulp, paper and cardboard production and processing*. All types of waste listed there are 'absolute non-hazardous' entries. A single questionnaire response received identifies two waste streams of relevance with a TiO_2 content potentially above 1.0%:

  – Sludges with calcium carbonate (*03 03 09 lime mud waste*); and
  – Fibre waste (*03 03 10 fibre rejects, fibre-, filler- and coating-sludges from mechanical separation*).

[55] Conversion of laminate paper and covering of wooden panels requires several process steps such as printing, impregnating and pressing.

These are currently classified as non-hazardous and would probably remain classified as non-hazardous even after the introduction of the Carc Cat 2 harmonised classification for TiO_2. In both waste streams, TiO_2 is not present in an inhalable form.

However, it is possible that the presence of a suspected carcinogen in concentrations above 1.0% might affect the management of these waste streams. TiO_2-containing waste paper (broke or paper "crumble") may currently be directed to land spreading or energy recovery in an incinerator. If the disposal of this TiO_2-containing waste along these routes becomes less attractive:

- Its handling and disposal would become costlier (NB. sludge and waste paper are generated in volumes of thousands of tonnes each year); and
- Waste paper feedstock for incinerators would need to be replaced by fossil fuel thus increasing the operating costs of the recipient incinerators.

Some paper manufacturers might wish to separate TiO_2-containing sludge from water purification from other waste streams. This is usually not possible due to mixing with other production sludge (without TiO_2) in a long water treatment plant circuit. If this were to become possible with the intention of ceasing the recycling of TiO_2-containing sludge, the cost increase associated with the disposal of the waste (e.g. by incineration) would be very significant (one paper manufacturer estimates the increase at the level of **€200/tonne of sludge** this increasing waste management costs by **€2-3 million/year**).

Economic impacts on downstream users (industrial and professional)

The above discussion on impacts covers adequately the entirety of the supply chain for paper with the exception of consumers (discussed further below) but also the management of end of life paper waste. The Carc Cat 2 harmonised classification could have an impact on the management of some paper waste, for example, *15 01 10* packaging containing residues of or contaminated by hazardous substances*.

19 12 01 Paper and cardboard from mechanical sorting of waste is classified as 'absolutely non-hazardous' and would in theory remain unaffected; however, in practice since the paper/board may contain TiO_2, its recycling may become less attractive as there could be a risk of dust release during the recycling process. Consequently, paper/board that contains TiO_2 could become an unwanted grade in the recycling system.

Social impacts

Employment impacts

Employment impacts may vary depending on whether TiO_2-based products are critical to any one company or not. The Global Wallcoverings Association (IGI) has suggested that all 26,000 jobs in the sector would be at risk following the adoption of a Carc Cat 1B classification. Among the individual companies that have made an input to the analysis of impacts from a Carc Cat 1B hazard classification, the vast majority noted that jobs would be lost but that the scale of losses would vary[56]. It would be likely that a Carc Cat 2 harmonised classification would have a less pronounced impact.

[56] The total employment of the respondents is ca. 3,600 workers of which at least 1,270 would likely lose their jobs.

Impacts downstream should also be taken into account, even though they cannot be quantified. A Carc Cat 2 harmonised classification for TiO_2 could affect the whole supply chain in the laminate industry, including the décor paper producer, the laminate décor printer, the laminating companies, as well as the wood based industry (furniture and flooring as well as wood board and panel producers, since the demand for their products would decline).

Impacts on the welfare of consumers

A harmonised classification for TiO_2, either Carc cat 1B or Carc Cat 2, could have notable impacts on consumer choice and welfare. The following impacts should be noted:

- **Loss of certain types of consumer products from the market**: some consumer products would become costlier to manufacture in the EEA with an impact on their competitiveness and therefore their production may be affected, scaled back, relocated outside the EEA or discontinued. Relevant products include wallcoverings with adequate opacity and lightfastness, a variety of paper-based packaging and laminated products (flooring, furniture, etc.). Wallcoverings are primarily sold on design and colour to make the products aesthetically pleasing to the eye. White inks and coatings are used and manufacturers also blend white with other colours to change the opacity levels to create pastel shades and increase the colour gamut. Any effort to substitute TiO_2 would reduce the product options available to the consumer and would make products duller and unexciting;

- **Increased cost and loss of performance**: the use of alternatives in the place of TiO_2 would certainly increase production costs and impact upon the performance of paper products. Surface treatment using décor paper, especially wood-based board product, delivers a high performance, low cost, resistant and easily maintained surface at a very competitive cost. Alternative surfaces are generally either less resistant or significantly more expensive (paint/lacquers or veneer). Solid wood furniture requires the use of comparatively much more wood and also more expensive wood to manufacture one unit of furniture or flooring. The combination of low cost and high performance provides the consumers with an affordable, high quality product.

  Wallcoverings that do not contain TiO_2 would be less durable to weathering, available in a narrower variety of colours and would need to be replaced more frequently; and

- **Loss of consumer satisfaction**: TiO_2-based products would suffer a loss of consumer confidence with TiO_2-free products, such as wallcoverings, offering poorer visual effects leading to a poorer home and office environment. Paper-based articles such as diaries, bibles, etc. would become bulkier with more 'show through' from page to page.

Notably, paper and cardboard waste (*20 01 01 Paper and cardboard*) generated as part of municipal solid waste is an 'absolute non-hazardous' entry and should not be impacted by the Carc Cat 2 harmonised classification. However, the presence of a suspected carcinogen in consumer products could have an indirect adverse effect on the levels of recycling of such waste.

Competitiveness impacts

Non-EEA products would not face the administrative and cost burden of the regulatory obligations triggered by a Carc Cat 2 harmonised classification for TiO_2 and thus non-EEA paper products that contain TiO_2 could become more competitive and would also be of better quality, if EEA-based manufacturers attempted to substitute the pigment. In addition, paper and board produced within the EEA are sold globally, both intermediate paper/board as well as converted products. An increase in operating costs would make the products exported from the EEA less competitive. For bulk producers (e.g. DIY wallcoverings or laminates) price sensitivity is key and the proposed classification could severely harm competitiveness.

Relocation (outsourcing) of activities outside the EEA could be a possibility, at least for certain production steps (e.g. manufacturing of paper) and where companies already have facilities established. However, such a step is not to be taken lightly and it is very doubtful that a harmonised classification for TiO_2 could instigate such a move. If relocation were to be considered, ancillary industries would also be affected, for example, the wooden substrates industry (furniture and flooring) would be affected as access to covering material would become more difficult.

4.3.4 Inks, toners, recreation colours and stationery products

Key market descriptors

The key economic parameters of the use of TiO_2 are summarised below.

Importance of the application

See discussion above on paints and coatings which are products closely related to printing inks. About 50% of screen and pad inks are white, of which about 95% is manufactured using TiO_2. Toner and materials relevant to digital printing are similarly important to everyday life, primarily in a business/office environment, but also for consumers at home.

Estimated TiO_2 tonnage used

As noted above, we assume that printing inks (but not digital printing inks, i.e. toner) account for ca. 4% of total TiO_2 consumption, i.e. ca. 40 ktonnes/y. The consumption of TiO_2 in toner is considerably lower at a range of 30-150 t/y or more (toner contains 1-5% TiO_2).

Estimated tonnage of products that contain TiO_2

Application	EEA production
Printing inks	0.6 million tonnes/y
Toner	Unknown The total quantity placed on the EEA market is >3,000 tonnes/y
Artists, recreation and school colours	Unknown >1,000 tonnes/y based on consultation results
Stationery and correction fluids	Unknown >20,000 t/y based on consultation results
Members of the I&P Europe Association also place on the market: - A small tonnage of industrial coatings (imported from outside the EEA); - Paper for printing and writing; - Special camera film (containing TiO_2 as a whitener); and - Plastic foils, special films and security cards	

Estimated value of markets

Application	EEA market value
Printing inks	€2.1 billion/y
Toner	>€1 billion/y
Artists, recreation and school colours	Unknown >€0.1 billion/y based on consultation results
Stationery and correction fluids	Unknown >0.1 billion t/y based on consultation results

	As regards printing inks, the value of the printed material would easily be 100-fold of the printing ink value, i.e. over €200 billion/y. The market for toner-related products is also much larger and needs to include electronic equipment that relies on the toner, i.e. printers and copiers. Its value is estimated at over €10 billion/y.
Estimates of Gross Value Added	The GVA of the EU paints, coatings and printing inks has been provided above (€5 billion/y).
Number of users of TiO_2	There are ca. 75 ink producers (members of the European Printing Inks Association) and 20 artist colour producers across Europe. In addition, there are at least 58 members of the European Writing Instrument Manufacturers Association who use TiO_2. Europe Imaging & Printing Association (I&P Europe) has 32 member companies.
Presence of SMEs	As noted earlier, among CEPE's membership of paint and ink manufacturers more than 85% are SMEs. EWIMA also confirmed this percentage noting that in the writing instruments industry most companies are family-owned SMEs.
Number of stakeholders that participated in consultation	10-25 organisations, including trade associations. In addition, 5 responses were received to the questionnaire on waste issues arising from a Carc Cat 2 harmonised classification.
Locations of stakeholders that participated in consultation	The key trade associations have members across the EEA. Individual respondents are based in Austria, Denmark, France, Germany, Italy, the Netherlands, Spain, Sweden and the UK.
Employment in the sector	As noted above, 110,000 workers are employed by paint, coating and ink manufacturers in the EEA. Printing inks that contain TiO_2 are in use in the segment of printed packaging and are applied in small and large print-shops. The employment in this segment of the graphic industry in EEA is estimated at 50,000.

Relevant legislation

Table 4–9 (summarises the relevance of different legislative instruments to the use of TiO_2 in printing inks, toner and associated products after the adoption of a Carc Cat 2 harmonised classification. Additional detail is available in Annex 1.

Table 4–9: Relevance of different regulatory instruments and voluntary initiatives to printing inks and toner applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation

Relevant legislation	Relevant to inks
CLP	Yes
Carcinogens and Mutagens at Work	No
Waste Framework	Potentially
Industrial Emissions	Potentially

Table 4–9: Relevance of different regulatory instruments and voluntary initiatives to printing inks and toner applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation	
Relevant legislation	**Relevant to inks**
REACH	**Annex XVII**: No
	Annex XIV: No
	Article 31: Yes
Cosmetics	Yes. For instance, relevant to cosmetic pencils, "tattoo stickers" or nappies
Toy Safety	Potentially. Might no longer be allowed to be printed with white or high-covering inks (exemptions are a possibility)
Food Contact Materials	Potentially, and depending on national rules on the use of CMR substances in printing inks (CoE Resolution)
Food Additives	No
Medicinal Products	No
Construction Products	No
Biocides	No
Medical devices	No
RoHS	Potentially (but less likely than for Carc Cat 1B). It is relevant but impact not automatic. The list of restricted substances would have to be updated following a risk assessment
Tobacco additives	Yes – TiO_2 may be used in tipping inks (filter paper)
Other	Ecolabelling scheme provisions (see Section 7.2.7). NB. The EuPIA (European Printing Ink Association) Exclusion Policy would not apply (see Section 7.2.4)

Impacts on the marketing and use of titanium dioxide-containing products

Economic impacts for manufacturers of paints and coatings

<u>Potential loss of markets</u>

A Carc Cat 2 harmonised classification would have the following impacts on the ability of EEA-based inks, toner and recreation colours manufacturers to use TiO_2 and place on the market TiO_2-containing formulations and articles:

- **Hazard labelling and perceptions**: the analysis presented above on the impact of the new hazard labelling on consumer and industrial/professional user perceptions would apply here too and perhaps impacts might be even more pronounced because (a) several of the products referred to in this section are used by children and (b) some products may be in the form of powders or generate dust which could heighten the concerns of users, thus leading to aversion to using TiO_2-containing products. For instance, in the case of toners, any dust seen on or around the printer (from whatever source) would be seen as potentially containing TiO_2 and so be perceived as carcinogenic;

- **Toys**: see earlier discussion on paints. It is worth noting that TiO_2 is present in significant concentrations in many products such as painting materials which are sold to children, even very young infants, and in some cases inhalation exposure to these products cannot be excluded. As such, irrespective of whether the SCCS might issue an opinion allowing the listing of the substance on Appendix A to Annex II (permitted uses of CMR substances), there will be significant market and consumer pressure towards the substitution of a suspected carcinogen in such toy products;

- **Cosmetics**: some pencil manufacturers may also produce cosmetic pencils (e.g. lipliners and eyeliners) and printing inks may be used in applications such as "tattoo stickers". The cosmetic industry asks the packaging manufacturer to comply with the Cosmetic Products Regulation, and the packaging manufacturer/printer, to cover himself, asks the ink manufacturer to comply with the Cosmetic Products Regulation, so to not use prohibited substances listed in Annex II of the Regulation. The Carc Cat 2 harmonised classification for TiO_2 would have impacts similar to those for toys, i.e. a SCCS would be required (without a requirement to demonstrate the unavailability of feasible alternatives) which may result in the substance being approved (or not) for use in cosmetics. Still, market and consumer perceptions and pressures might lead to attempts at substitution even if SCCS delivers a favourable opinion;

- **Printing inks and food contact materials**: whilst Carc Cat 2 substances fall outside the scope of the EuPIA Exclusion Policy on printing inks (see Section 7.2.4), a specific CoE Resolution (Resolution ResAP (2005)2 on "Packaging Inks Applied to the Non-Food Contact Surface of Food Packaging" makes specific referenced to CMR 1A/1B/2 classifications falling within the exclusion criteria listed in the accompanying Technical Document 1. As such, implementation of the Resolution would mean that inks classified as Carc Cat 2 could no longer be used for non-food contact on food packaging. CoE Resolutions are not legally binding, but are considered as statements of policy for national policy makers of the Partial Agreement member states[57]. In any case, the potential reputational damage from allowing the presence of a suspected carcinogen in products available on the consumer market would encourage ink manufacturers to aim to substitute the substance anyway; and

- **Setting precedence and an example for action by other jurisdictions**: similar regulatory action in other global regions could follow. This would further impact upon exports of EEA-made products.

<u>Potential increases in operating costs</u>

There are several implications of a harmonised Carc Cat 2 classification which could increase the manufacturing costs and thus impact the profitability of EEA-based ink/toner/colour manufacturers, including:

- **Cost of reformulation to eliminate TiO_2**: information available from consultation shows a mixed picture over the perceived ability of TiO_2 users to reformulate their products in order to remove TiO_2:

  - ***Consumer ink formulations***: reformulation of consumer inks and associated products is generally infeasible and this is particularly the case for the white inks used in flexible packaging where alternative pigments with acceptable performance are not available. One company who made an input to consultation particular has recounted past research on alternatives (such as barium sulphate, lithopone, chalk) which has confirmed that only TiO_2 can deliver the quality required. Yet, if lower quality products were to be acceptable, reformulation might be considered but would be distinctly disadvantageous on economic grounds. The estimated costs of reformulation range

[57] Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

between €50,000 and over €5 million (notably, the highest estimates are from companies that have indicated that reformulation would be a theoretical possibility). The time theoretically required for reformulation would be between **2 and 5 years**;

- ***Consumer/industrial toner mixtures***: identifying a feasible alternative for TiO_2 in toner is very challenging. TiO_2 has been used as a charge control agent in toners for many years. It stabilises the electrostatic charge and improves the flowability of toner powders in ambient conditions. It leads to high-definition print and promotes the stable operation of the printers and copiers. In addition, it is not possible to use a coloured particle for colour toner. No other materials meet such requirements at an acceptable performance level. Any alternative would have to pass many tests concerning the print quality and stable operation of the printers or copiers at the various printing environments (temperature, humidity, paper type, preservation conditions, etc.) before it could substitute TiO_2. It is of note that toners are customised for every model of the printer or the copier, and there are many types of both. Hence, there would be a need to test each combination of toner-printer/copier. An estimate of the potential cost of a theoretical reformulation would be in the **tens of millions of euros** (including the cost of scrapping existing inventories) and the time required could range from **2 to over 10 years**. Each time a reformulated product has to be introduced to a customer, this new product offer is also open to competition, meaning that a market loss is always a possibility;

- **Industrial ink formulations**: reformulation is not possible for performance reasons in terms of opacity and ink film thickness and it is important to consider that printing inks are used for plastic/glass/metal articles in the shape of packaging, toys, medical devices, automotive products and many others. Estimates with regard to the cost and duration of a reformulation programme suggest a cost of **€5 million** over a period of **5 years**;

Overall, if products are reformulated, alternative pigments would be costlier as they would need to be used at higher loadings than TiO_2 (could be 5-10 times higher). Small companies, in particular, could not easily absorb the costs of reformulation due to regulatory changes so would need to pass these on to customers, making products more expensive and their market position less competitive;

- **Compliance with waste management regulations**: some information is available from a smaller number of relevant downstream users of TiO_2 and is summarised in **Table 4–10**. The information is incomplete but it indicates that several of the relevant waste streams are already classified as hazardous. On the other hand, products such as those intended for use by children are expected to be classified non-hazardous at present and thus following the introduction of the Carc Cat 2 harmonised classification they could be re-classified as hazardous (see greyed entries). The same would apply to TiO_2 packaging with residue levels above 1.0%. However, some consultees have expressed doubts that waste which could lead to no exposure by inhalation would actually be classified as hazardous due to the presence of TiO_2. Limited information has become available on the possible costs of re-classification; one company has asserted that disposing the packaging as hazardous waste could lead to a six-fold increase in waste disposal costs for empty TiO_2 packaging; another company involved in the manufacture of recreation/school products estimated an additional cost of **€0.1 million per year** for the treatment of waste; and

Table 4–10: Relevant waste streams for the use of TiO_2 in toner, ink and school colour and stationery manufacture (NB. grey entries subject to change classification)						
Process generating waste	**Type of waste**	**Waste entry in LoW**	**Typical TiO_2 content**	**Example volume generated***	**Is TiO_2 inhalable?**	**Current waste management**
Toners						
Toner manufacture	Toner filer dust from dust collectors in aspiration system	**08 03 17*** Waste printing toner containing hazardous substances (‘*mirror hazardous*’)	0.1%	30 t/y	Yes (toner)	Hazardous **Incineration**
	Scrap from toner manufacturing	**08 03 17*** Waste printing toner containing hazardous substances (‘*mirror hazardous*’)	0.1%	15 t/y	Yes (toner)	Hazardous **Incineration**
Toner filling	Toner powder waste	**08 03 18** Waste printing toner other than those mentioned in 08 03 17 (‘*mirror non-hazardous*’)	Most of toner: <1%. Smaller amount: 1-10%	10 t/y	Yes (toner)	Hazardous **Incineration**
Returns	Toner bottles returned by clients (out of spec)	**08 03 17*** Waste printing toner containing hazardous substances (‘*mirror hazardous*’)	0.6%	12 t/y	Yes (toner)	Hazardous **Incineration**
Printing inks						
Raw materials	TiO_2 packaging (paper bags)	**15 01 01** Paper and cardboard packaging *(‘absolute non-hazardous’)*	ca. 1%	200 kt/y **across ink industry in EEA**	Yes	Non-hazardous **Incineration or recycling**
Ink manufacture	Ink waste	**08 03 12*** Waste ink containing hazardous substances (‘*mirror hazardous*’)	20-40%	14 t/y 50 t/y	No	Hazardous **Incineration**

Table 4–10: Relevant waste streams for the use of TiO_2 in toner, ink and school colour and stationery manufacture (NB. grey entries subject to change classification)						
Process generating waste	**Type of waste**	**Waste entry in LoW**	**Typical TiO_2 content**	**Example volume generated***	**Is TiO_2 inhalable?**	**Current waste management**
	Ink sludge	**08 01 13*** Sludges from paint or varnish containing organic solvents or other hazardous substances (‘*mirror hazardous*’)	N/A	17 t/y		Hazardous (flammable)
Pencils/pens						
Raw materials	TiO_2 packaging (paper bags)	**15 01 01** Paper and cardboard packaging *(‘absolute non-hazardous’)*	Varies	<1 t/y	Yes	Non-hazardous **Landfilling**
Pencil/pen manufacture	Waste lead of pencils	**08 01 12** Waste paint and varnish other than those mentioned in 08 01 11 (‘*mirror non-hazardous*’)	>1%	>100 t/y	No	Non-hazardous **Recycling**
	Contaminated rags from cleaning of masterbatch tank	Not provided. Assumed to be **15 02 02*** Absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by hazardous substances) (‘*mirror hazardous*’)	<1%	<1 t/y	No	Hazardous
School paints and stationery						
Manufacture of paints	Liquid or dried paints (water-based)	**08 01 12** Waste paint and varnish other than those mentioned in 08 01 11 (‘*mirror non-hazardous*’)	>1%	N/A	No	Non-hazardous **Recycling**

Table 4–10: Relevant waste streams for the use of TiO_2 in toner, ink and school colour and stationery manufacture (NB. grey entries subject to change classification)						
Process generating waste	**Type of waste**	**Waste entry in LoW**	**Typical TiO_2 content**	**Example volume generated***	**Is TiO_2 inhalable?**	**Current waste management**
	Liquid or dried paints (solvent-based)	**08 01 11*** Waste paint and varnish containing organic solvents or other hazardous substances (‘*mirror hazardous*’)	>1%	N/A	No	Hazardous **Recycling**
Manufacture of crayons	Waste crayon material	**08.01.12** Waste paint and varnish other than those mentioned in 08 01 11 (‘*mirror non-hazardous*’)	>1%	N/A	No	Non-hazardous **Recycling**
Manufacture of erasers	Waste eraser material	**07 02 13** Waste plastic (‘*absolute non-hazardous*’)	>1%	N/A	No	Non-hazardous **Recycling**
* data based on individual responses to questionnaire						

- **Increased administrative burden**: if a Carc Cat 2 substance is present in a mixture at a concentration ≥0.1% then a SDS must be available upon request (as per Note 1 under Table 3.6.2 of the CLP Regulation). Manufacturers of these products may need to supply or receive an increased number of requests for SDS.

Economic impacts on downstream users (industrial and professional)

Any impacts on the use of TiO_2 in the manufacture inks/toner/colours upstream could have repercussions on the industrial and professional use of these products downstream. Without TiO_2 in ink formulations, the protective and decorative effect obtained with white inks would no longer be obtainable. Packaging manufacturers would be forced to redesign packaging structures which are to date functional, safe and validated by tests accepted by the authorities, and trusted by the consumer. This would require significant effort in terms of new packaging development, validation, promotion to the market, leading to an increased use of different material combinations (e.g. paper labels on plastic films) which could impair established recycling processes, with foreseeable and unavoidable environmental impacts.

On the other hand, it is of note that toner preparations do not contain free TiO_2 particles. If the absence of exposure to TiO_2 particles was not taken into account and TiO_2 use was discontinued, there would be a significant negative impact on the laser printing business.

Similar to paints, importers and downstream users placing on the market mixtures that would be newly classified as hazardous due to the presence of TiO_2 in concentrations exceeding 1.0% by weight would be required to submit information to Poison Centres by 2020-2024, depending on the intended uses of their mixtures.

Finally, in relation to waste, implications on the handling of waste ink and printing toner would arise.

Social impacts

Employment impacts

Note that the discussion above on employment impacts on the paints sector incorporates ink manufacturers. In comparison to a Carc Cat 1B classification, certain direct restrictions on key products would still arise (toys, cosmetics, food contact materials in countries implementing the relevant CoE Resolution), although the use of the substance in printing inks would fall outside the scope of and the sectorally important EuPIA Exclusion Policy. In any case, given the customer-facing nature of many applications and the strong likelihood of negative perceptions developing among users and consumers, negative business impacts on the EEA ink/toner/colour industry would be unavoidable and would lead to adverse employment impacts.

Such impacts cannot be quantified; by way of comparison, among those companies and associations that have responded to a questionnaire on the impacts from a Carc Cat 1B harmonised classification and which are relevant to inks, toners and ancillary products, an estimated ca. 1,500 jobs are expected to be lost (8 questionnaire responses).

Impacts on the welfare of consumers

A Carc Cat 2 harmonised for TiO_2 could have notable impacts on consumer choice and welfare. The following impacts should be noted:

- **Loss of certain types of consumer products from the market**: as noted earlier, formulations currently sold to the consumer would either be sold with a potentially alarming hazard label attached or, at least some of them, might be removed from the market either as a result of regulatory pressure (i.e. unfavourable SCCS opinions for the use of the substance in toys and cosmetics), voluntary action or market and consumer pressure. Efforts towards the substitution of TiO_2 could result in loss of products from the market, for instance, several shades of recreational paints, writing inks, crayons, etc. Elimination of TiO_2 from toners would render laser printers and copiers unusable. Certain packaging articles such as paper bakery bags would be hard to manufacture without TiO_2. All flexible food packaging made of plastics in which product information (e.g. batch number and consumption date) is printed with inks over a white area would have to be redesigned or would need to be combined with an adhesive paper label, which would impair the recycling of packaging waste;

- **Increased cost and loss of performance**: as TiO_2 displays unsurpassed performance in the applications of concern (alternative white pigments do not match TiO_2 with regard to opacity, whiteness and fastness properties), any reformulation of products would lead to the loss of performance. If consumers did not have access to high quality art and school products, they would need to use low quality products or use expensive electronic equipment such as computers and tablets.

  Food packaging articles in which white colour has a protective function against sunlight could be replaced by more expensive and less recyclable alternatives involving multilayer materials (e.g. increase use of aluminium foil on flexible packaging).

  Printers and copiers using toner would not work without a toner, and people would have to purchase new printers and copiers of the inkjet type[58]. Under certain circumstances (but not always), the cost of running an inkjet printer might prove to be higher than the cost of a laser printer[59];

- **Waste management and recycling impacts**: disposal of waste inks might be affected (under waste category *20 01 27* Paint, inks, adhesives and resins containing hazardous substances*) similar to waste DIY paint which might require separate collection and disposal. Whilst colours are not typically recycled, ink and toner cartridges are but their recycling might be impacted by negative perceptions among consumers;
- **Loss of consumer satisfaction**: removal of TiO_2-containing recreation/school products from the market would deal a blow to the creativity of children. For instance, a box of watercolours for children would contain only 4 (black, orange, blue and sienna (brown)) instead of 12 colours because the rest contain TiO_2. A switch to electronic products could be envisaged. In addition, as noted above, alternative pigments would generate poorer white colours.

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58 TiO_2 may also be used in inkjet inks as a white colourant. However, white ink is limited to a special purpose and is not used in all products. As a result, the impact of the proposed classification would be limited.

59 The cost will depend, among other factors, on how heavily the printer is used. An example comparison can be found here: http://www.itpro.co.uk/office-printers/innovation-at-work/25093/inkjet-vs-laser-printers (accessed on 7 November 2017).

Inkjet printers are not suitable for large volume printing, and takes more time for a print than toner type printers; and

- **Adverse effects on public health**: elimination of TiO_2 from the packaging construction would lead to reduced opacity and thus reduced protection from light. This might lead to reduced shelf-life of the packed goods.

Competitiveness impacts

As noted above, increased manufacturing costs (due to the cost of reformulation) would make EEA-made formulations and articles less competitive when exported from the EEA. In any case, reformulation, if at all possible, would result in loss in quality. As white is an essential part of the colour shade range, customers located outside the EEA would prefer colours sourced from non-EEA suppliers where the white colour of the range has a better quality, compared to a white colour generated without TiO_2.

In addition, users of TiO_2-based formulations, e.g. packaging manufacturers, would be disadvantaged as they would have to either adapt processes to allow their workers to use carcinogenic formulations (at a cost) or switch to poor quality TiO_2-free formulations. The use of TiO_2-based formulations outside the EEA would become cheaper and easier thus it would be more convenient to move the use outside the EEA, generate articles and then import these into the EEA.

In the longer term, other global jurisdictions may also adopt the new hazard classification resulting in a global impact which would create a level playing field but would still have a profound effect on the users of TiO_2-based inks, colours and toners.

4.3.5 Construction products and coatings

Key market descriptors

These products are generally considered to be part of the paints and coatings market but it should be noted that applications are very diverse and may rely on different properties of TiO_2. Within this group, one may identify mass and specialty applications such as:

- Adhesives and sealants requiring whiteness, opacity, good dispersion properties and weatherability for construction applications. In addition to white colour, TiO_2 can be found in virtually all sealant colours apart from black;

- Adhesives for non-construction applications, for instance, water-based gelatine adhesives for the paper and cardboard industry which are used in the back lining of books[60] or dispersion glues such as those used to glue textile fibres on paper to generate wallcoverings[61];
- Ablatives and fire protection coatings in which TiO_2 offers fire resistance performance alongside fire resistant/ intumescent components;

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[60] These glues are generally yellow, brown or beige. TiO_2 is used to whiten the adhesive without changing other technical properties like other fillers would do.

[61] TiO_2 is used to whiten the dispersion so it can be used as a masterbatch and the desired colour can be added by the customer (i.e. the wallcovering manufacturer).

- Fillers, grouts, mortars with "fresh colours" and good durability; and

- Photocatalytic active materials (cement) used in construction to reduce the concentration of pollutants in the air. Photocatalytic cement can be used in concrete block paving, concrete road surfaces, noise barriers, roof tiles and facades, to create durable photocatalytic active surfaces

The number of responses collected was not sufficiently high to allow for a detailed analysis to be provided here, however the following can be noted:

- According to CEPE, construction materials such as plasters, caulks, fillers and mortars that contain TiO_2 are produced at a volume of 0.3 million tonnes per year and have a market value of €0.55 billion;

- Across the 10-25 relevant organisations that returned a completed questionnaire on potential impacts from a Carc Cat 1B harmonised classification, the volume of relevant TiO_2-related products produced in the EEA is ca. 50,000 tonnes with a market value of ca. €115 million/y. Adhesives and sealants are the most prominent product groups in both volume and value terms. The responding companies have operations in Belgium, the Czech Republic, France, Germany, Greece, Hungary, Italy, Lithuania, the Netherlands, Poland, Portugal, Slovenia and the UK.

  According to the Association for the European Adhesive and Sealant Industry (FEICA), the European market for adhesives and sealants exceeded €13 billion in 2014. It is estimated that close to 15,000 standard adhesive and sealant formulations are in use in Europe, based on five formulation technology platforms: (a) reactive systems; (b) water-borne; (c) solvent-born; (d) hot melts; and (e) based on natural raw materials. There are about 450 adhesive and sealant companies in Europe manufacturing at some 700 sites. Several hundred of them are SMEs (SMEs hold only 18% of the market and the top 60 companies account for about 80% of adhesive and sealant sales in Europe). The European adhesive and sealant industry employs more than 41,000 workers, of which 6,000 are employed by SMEs (FEICA, 2015);

- The construction sector accounts for more than 5% of the total EU-28 (gross) value added[62]. According to consultation, the sealant sector accounts for approximately 0.1% of the total construction sector, therefore 0.005% of the total EU-28 value added; and

- As regards photocatalytic cement, fewer than five companies are believed to manufacture such a product. Most of them are not SMEs.

[62] Information available at http://ec.europa.eu/eurostat/statistics-explained/index.php/Construction_production_(volume)_index_overview (accessed on 23 October 2016).

Relevant legislation

Table 4–11 summarises the relevance of different legislative instruments to the use of TiO_2 in construction products after the adoption of a Carc Cat 2 harmonised classification. Additional detail is available in Annex 1.

Table 4–11: Relevance of different regulatory instruments and voluntary initiatives to construction products applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation	
Relevant legislation	**Relevant to construction products**
CLP	Yes
Carcinogens and Mutagens at Work	No
Waste Framework	Potentially
Industrial Emissions	Potentially
REACH	**Annex XVII**: No
	Annex XIV: No
	Article 31: Yes
Cosmetics	No
Toy Safety	Potentially
Food Contact Materials	Yes (adhesives)
Food Additives	No
Medicinal Products	No
Construction Products	Yes
Biocides	No
Medical devices	No
RoHS	Potentially (but less likely than for Carc Cat 1B). It is relevant but impact not automatic. The list of restricted substances would have to be updated following a risk assessment
Tobacco additives	No
Other	Global Automotive Declarable Substance List (GADSL)

Impacts on the marketing and use of titanium dioxide-containing products

Economic impacts for manufacturers of paints and coatings

Potential loss of markets

A Carc Cat 2 harmonised classification would have impacts similar to (but also perhaps not as wide as) those for paint manufacturers and thus the above analysis is not repeated here. In short:

- Hazard labelling would have an impact on user and consumer perceptions and would affect the marketability of formulations containing TiO_2, especially for DIY uses. There is no complete overview of the affected markets. The information submitted to the online questionnaire would suggest that the split between consumer and industrial applications (generally in the form of mixtures) is 15 : 85 respectively;

- Under the GADSL a Carc Car 2 substance would not be "Prohibited" but would be "Declarable" thus making it less appealing for automotive manufacturers and less marketable by adhesive/sealant manufacturers; and

- Similar regulatory action in other global regions could follow. This would further impact upon exports of EEA-made products.

Potential increases in operating costs

There are several implications of a harmonised Carc Cat 2 classification which could increase the manufacturing costs and thus impact the profitability of EEA-based manufacturers of construction products, including:

- **Cost of reformulation to eliminate TiO_2**: when asked whether reformulation of their products is possible, the majority of companies indicated that it is not and as such estimates of the cost of reformulation were not offered. In a few cases, some users of TiO_2 noted that reformulation to products of impaired performance might be possible. The cost of reformulation has been estimated **from €0.2 million to over €5 million**. The time that would be required for reformulation would be **1-5 years**. Following reformulation, the new products would need to be qualified by downstream users and some examples have been provided: re-qualification by automotive OEMs may take **up to 5 years** and by the aerospace industry may take **up to 10 years**. Replacement of TiO_2 would result in poorer quality products which would affect the faith of customers in the industry as products would no longer be their usual brilliant white;

- **Compliance with waste management regulations**: limited information has been made available through consultation. A sealant manufacturer has suggested that several types of waste re currently mixed and the mixture ends up containing less than 1% TiO_2. Following the introduction of the Carc Cat 2 harmonised classification, wastes should be segregated and disposed of separately. Segregation and storage costs might amount to **€5,000** with an additional cost of disposal of **€10,000** (for an amount of waste in the range of 10-100 t/y, see **Table 4–12**). For adhesives, some waste types currently classified as non-hazardous, might be re-classified as hazardous, although some 'absolute non-hazardous' entries in the LoW may continue to remain relevant to the users of TiO_2. Empty TiO_2 packaging might be classified as hazardous, depending on pigment residues;

- **Increased administrative burden**: if a Carc Cat 2 substance is present in a mixture at a concentration ≥0.1% then a SDS must be available upon request (as per Note 1 under Table 3.6.2 of the CLP Regulation). Manufacturers of these products may need to supply or receive an increased number of requests for SDS; and

- **Impacts on economies of scale**: a potential loss of part of the market (mainly due to aversion of consumers towards alarming labels, symbols and hazard statements) would make the production of construction products overall more expensive and thus EEA-based manufacture less competitive.

Table 4–12: Relevant waste streams for the use of TiO_2 in construction products manufacture						
Process generating waste	**Type of waste**	**Waste entry in LoW**	**Typical TiO_2 content**	**Example volume generated***	**Is TiO_2 inhalable?**	**Current waste management**
Sealants						
Manufacture of coloured sealants	Hardened pasty sealants	**07 02 15*** Wastes from additives other than those mentioned in 07 02 14 (‘*mirror non-hazardous*’)	Coloured products contain 1-2% TiO_2. Paint component (pigment) contain over 90% TiO_2). Transparent products contain no TiO_2. These wastes are currently not separated and overall waste contains ≤1% TiO_2	40 t/y	No	Non-hazardous **Incineration**
Manufacture of coloured pastes on silicon oil basis	Hardened pasty paints			0.25 t/y	No	
Adhesives						
Bagging of TiO_2 into mixes	Empty TiO_2 packaging (paper bags)	**15 01 01** Paper and cardboard packaging (‘*absolute non-hazardous*’)	<1%	<2 t/y	Yes	Non-hazardous **Landfilling**
Manufacture of TiO_2-containing dispersion	Residue in mixing vessels	**06 11 99** Wastes not otherwise specified (‘*absolute non-hazardous*’)	>1%	<1 kt/y	No	Non-hazardous **Treatment by waste contractor**
Manufacture of TiO_2-containing latex compounds	Residue in mixing vessels	**07 02 13** Waste plastic (‘*absolute non-hazardous*’)	>1%		No	
Manufacture of TiO_2-containing adhesives	Residue in mixing vessels	**08 04 10** Waste adhesives and sealants other than those mentioned in 08 04 09 (‘*mirror hazardous*’)	>1%		No	Non-hazardous **Treatment by waste contractor**
* data based on individual responses to questionnaire						

Economic impacts on downstream users (industrial and professional)

Users of adhesives, sealants and other construction products would be impacted in ways similar to the users of TiO_2-containing paints. By way of summary:

- **Continued use of TiO_2-based construction products**: downstream use of these products, especially transport, handling, application and disposal, would have to be revised to reflect the legislative requirements related to Carc Cat 2-containing mixtures. This would involve additional costs and resources, and may impose limitations on production rates and capabilities. New equipment may be required to be installed, new storage systems and disposal procedures would have to be put in place – waste packaging that contained TiO_2-based mixtures could be classed as hazardous and would need to be disposed of accordingly (see below);

- **Information submission to Poison Centres**: similar to paints and inks, importers and downstream users placing on the market mixtures that would be newly classified as hazardous due to the presence of TiO_2 in concentrations exceeding 1.0% by weight would be required to submit information to Poison Centres by 2020-2024, depending on the intended uses of their mixtures;

- **Impacts from a switch to alternative pigments**: the quality of alternative pigments would not match that of TiO_2 and any attempt to use alternatives on a large scale would cause severe technical and performance difficulties and would damage the image of EEA-based construction product manufacturers;

- **Compliance with waste management regulations**: labelling construction products as hazardous might affect that handling of waste that consists or contains such products. Implications for the handling of demolition waste might also arise, as discussed for paints; and

- **Impacts on DIY retailers**: the discussion on impacts on DIY retailers who stock professional and DIY paints (and alongside them a wide variety of TiO_2-containing construction products) would apply here with a potential reduction in their customer base a distinct outcome of the Carc Cat 2 harmonised classification.

Social impacts

Employment impacts

Through loss of market share (as a result of a restriction on consumer uses), loss of product quality (following a reformulation) and loss of competitiveness against non-EEA manufacturers, it is possible that job losses within the EEA would arise. There is insufficient information to allow the quantification of such impacts.

Impacts on the welfare of consumers

The proposed classification for TiO_2 could have notable impacts on consumer choice and welfare. The following impacts should be noted:

- **Loss of consumer products from the market**: as noted above, consumer products that contain more than 1.0% by weight TiO_2 could be removed from the market, irrespective of the actual risk of exposure by inhalation, as a result of market and consumer perception and pressure and/or voluntary action. This would mean that the current range of DIY products (adhesives, sealants, building materials, etc.) could become narrower;

- **Increased cost and/or loss of technical performance**: formulations without TiO_2 would have worse weatherability and would become discoloured more quickly, leading to more frequent (and thus costlier) replacement;

- **Loss of consumer satisfaction**: alternative formulations, particularly for consumer use would generally be less white and would have worse weatherability. For example, white silicone sealants are used in the majority of kitchens and bathrooms and their TiO_2-free replacements would not produce the same aesthetically pleasing effect;

- **Waste management implications**: disposal of waste construction products might be affected (under waste category *20 01 27* Paint, inks, adhesives and resins containing hazardous substances*). Following the classification of TiO_2-containing paint, leftover products might require separate collection and disposal, thus increasing the cost and affecting the convenience of DIY users; and

- **Potential adverse impacts on public health**: TiO_2 is an irreplaceable component in intumescent products and coatings. The function of TiO_2 is as a nucleating agent and a main component of the developed char. It is absolutely critical to product performance and there are no known successful alternatives. These intumescent products are key and critical to the preservation of buildings in the event of a fire ensuring there is time for people to escape safely. Therefore, the very nature of these products is to preserve human life.

Competitiveness and competition impacts

Competitiveness impacts

As discussed for other applications earlier (e.g. paints and coatings), production of these products outside EEA would become less costly. This would affect the competitive position of EEA-based manufacturers and would make the import of TiO_2-based formulations more attractive. On the contrary, EEA-made TiO_2-based formulations intended for export would become more expensive and thus less competitive. It is possible that the larger manufacturers might consider relocating their production facilities outside Europe and import the finished formulation back into Europe instead. SMEs might not be able to do this and would either be forced to close or would have to rely on third party toll producers outside of Europe to produce the finished formulation for them. This would be a substantial loss of a significant business, particularly for construction applications, where a large number of SME sealant formulators are producing sealant cartridges containing TiO_2.

On the other hand, consumer products reformulated to eliminate the use of TiO_2 would be of worse quality than before and their exports to non-EEA markets would suffer. DIY retail chains might also face increased competition from non-EEA e-commerce retailers who could supply consumers with TiO_2-based formulations without the customer being visually alerted to a carcinogenic classification label and thus being less reluctant to purchase DIY products that contain TiO_2.

Intra-EEA competition effects

Manufacturers who supply both consumers and industry/professionals would have a disadvantage compared to manufacturers who supply only industry/professionals as they would potentially need to supply two separate types of formulations with and without TiO_2. This would increase the logistical complexities and ultimately the cost of manufacture. In addition, customers may also be given the incentive to turn to alternative products (e.g. boards rather than intumescent coatings).

4.4 Specific impacts on downstream users of specialty applications of titanium dioxide

4.4.1 Fibre applications

Key market descriptors

The key economic parameters of the use of TiO_2 are summarised below.

Importance of the application

Man-made fibres that rely on TiO_2 for delustering and whiteness/opacity are widely used as articles for the production of carpets, wallcovering in houses, hotels, offices, cars, airbags, swimwear, garments (for example, viscose filament yarn which is used in high-class, high-fashion textile products of the most well-known and prestigious fashion brands), hosiery, laces, outwear, sportswear, shoes, bags, tent, flags, backpacks, luggage, hygiene non-wovens (diapers for babies and incontinence articles for adults, viscose dull fibre uses in wipes, tampons and sanitary textiles), etc. which are daily in contact with the consumers. The order of importance would appear to be:

- Clothing textiles;
- Non-wovens and hygiene;
- Carpets and other household products;
- Automotive; and
- Others (geotextiles, fishing nets, etc.).

Delustered fibres are also used in cigarette tow (filters)..

Estimated TiO_2 tonnage used

Uncertain – some literature sources suggest that fibres may account for 1-2% of TiO_2 consumption; the 2013 Cefic data groups fibres into the "Other" category which collectively accounts for 4% of total consumption.

Estimated tonnage of products that contain TiO_2

Application	EEA production
Man-made fibres for textiles, carpets, non-wovens, etc.	2-3 million tonnes/y*
Cigarette tow	Unknown
* RPA estimate	

Estimated value of markets

Supply chain	EEA market value
Man-made fibres for textiles, carpets, non-wovens, etc.	€7.5-10 billion/y*
Cigarette tow	Unknown
* RPA estimate (Eurostat data for 2011-2015 show a turnover of €7.7-9 billion/y)	

The combined value of the products sold by companies that responded to the questionnaire on impacts from a Carc Cat 1B classification is over €250 million/y.

Estimates of Gross Value Added	According to Eurostat, the value added of the manufacture of man-made fibres in the EU was ca. €2.1 billion in 2014.
Number of users of TiO_2	The European Man-Made Fibres Association (CIRFS) has 31 full members, 9 associate members. The Global Acetate Manufacturers Association (GAMA) has two member companies in the EEA.
Presence of SMEs	The majority of fibre producers are large companies according the EU definition of an SME. There are no SMEs among the acetate tow manufacturers.
Number of stakeholders that participated in consultation	Fewer than 10 organisations including the European Man-Made Fibres Association (CIRFS) and the Global Acetate Manufacturers Association (GAMA). A total of 7 questionnaire responses were received on the last questionnaire on waste management impacts.
Locations of stakeholders that participated in consultation	CIRFS has member companies in Austria, Belarus, Czech Republic, France, Germany, Ireland, Italy, Lithuania, Netherlands, Portugal, Romania, Slovakia, Spain, Switzerland, Turkey and the United Kingdom. Its members account for ca. 85% of European production of the main fibres within the scope of CIRFS (polyester, polyamide, acrylic, viscose, acetate, elastane and aramid)[64]. Most important locations include Germany, Portugal, Italy, Slovenia, Croatia, and the UK.
Employment in the sector	The total number of jobs in the man-made fibre industry is estimated at around 20,000.

Relevant legislation

Table 4–13 summarises the legislation that would be of relevance to the use of TiO_2 in fibre applications in the EEA, after the adoption of a Carc Cat 2 harmonised classification. Additional detail is available in Annex 1.

Table 4–13: Relevance of different regulatory instruments and voluntary initiatives to fibre applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation

Relevant legislation	Relevant to fibres
CLP	Yes - Only in receiving and handling raw materials
Carcinogens and Mutagens at Work	No
Waste Framework	Potentially
Industrial Emissions	Potentially
REACH	No
Cosmetics	No
Toy Safety	Potentially. Impact not automatic
Food Contact Materials	Yes
Food Additives	No
Medicinal Products	No

64 Information available at http://www.cirfs.org/Portals/0/Docs/2013%20CIRFS%20FACTSHEET.pdf (accessed on 24 October 2016).

Table 4–13: Relevance of different regulatory instruments and voluntary initiatives to fibre applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation	
Relevant legislation	**Relevant to fibres**
Construction Products	No
Biocides	No
Medical devices	No
RoHS	Potentially
Tobacco additives	Yes
Other: - OEKO-TEX® certification (see Section 7.2.8) - Ecolabelling schemes (see Section 7.2.7)	Yes

Impacts on the marketing and use of titanium dioxide-containing products

Economic impacts for manufacturers of fibres

Potential loss of markets

A Carc Cat 2 harmonised classification would have the following impacts on the ability of EEA-based fibre manufacturers to use TiO_2 and place on the market TiO_2-containing articles:

- **Hazard labelling and perceptions**: hazard labelling requirements would arise for masterbatches and compounds rather than plastics articles. Hazard labelling would not be relevant to consumer products or professional users but only to industrial users. Yet, consumer views on the presence of a suspected carcinogen in consumer products might have an adverse effect on the market. Due to the requirements of the production processes and the quality requirements of the end products, TiO_2 is present in fibres in the range of 0.1-1.5%. Most man-made fibres come into contact with consumers in everyday life (this includes clothing, underwear, sports clothing, etc.). TiO_2 presence would affect consumers' perceptions, even if the risk for consumer exposure by inhalation is non-existent. Also, industrial users of the fibres might become reluctant to use them in case their processes give rise to exposure to dusts;

- **Restrictions under specific regulation**: under regulatory regimes such as the Toy Safety Directive and the regulations on food contact materials, the continued use of TiO_2-containing fibres would be dependent on securing an exemption or authorisation. For this, testing would need to be undertaken to demonstrate that, for instance, the TiO_2 in the polyamide and polyester yarn is completely bound and strongly encapsulated in the polymer, making its inhalation impossible. It can be estimated that commissioning such testing to specialist laboratories would come at a cost of €1-1.5 million.

  Directive 2014/40/EU on the manufacture, presentation and sale of tobacco and related products impacts upon the use of additives classified as CMR substances and Decision (EU) 2016/787 sets out the priority list of additives in tobacco products and includes TiO_2 into the list and requires that manufacturers and importers submit enhanced reports on the safety of the substance. As the Directive does not distinguish between Carc Cat 1B and Carc Cat 2 substances, the harmonised classification would need to be taken into account in the generation of the enhanced report for the TiO_2 and might have an indirect role in making the substance more susceptible to future regulatory action (a ban), even though the TiO_2 is bound in the filter within tow fibres;

- **Food contact materials**: polymer fibres find applications in food contact materials. A Carc Cat 2 harmonised classification on the use of the substance in food contact materials might arise could and these are discussed in Section 4.4.3 below (that section explains that for applications covered by existing harmonised classification and where TiO_2 has already been assessed and authorised into a positive list, i.e. plastics, the likelihood of the substance being removed from the Union List (Regulation No 10/2011) is low, taking into account that probability of exposure by inhalation in this context is small);

- **OEKO-TEX® certification and ecolabelling schemes**: classification of TiO_2 as Carc Cat 2 would mean that textiles that contain the substance in their fibres could no longer attain these, thus becoming less attractive to consumers who value these schemes and consider participation in such schemes important in making purchasing decisions; and

- **Quality of TiO_2-free products**: in the context of attempting to substitute TiO_2 with a non-hazardous alternative, it is not known if the manufacturing processes would deliver an acceptable quality without TiO_2, so replacement of TiO_2 would lead to loss of sales and market share.

<u>Potential increases in operating costs</u>

There are several implications of a harmonised Carc Cat 2 classification which could increase the manufacturing costs and thus impact the profitability of EEA-based fibre manufacturers, including:

- **Cost of reformulation to eliminate TiO_2**: elimination or reduction of TiO_2 in fibres would mean that the level of fibre lustre and whiteness required by consumers could not be achieved and the number of affected products would be particularly large; this is already known through industrial-scale tests. For specific uses of TiO_2 reformulation could potentially be a technically feasible option, however the requalification of these particular products in the value chain would be a very complex, time consuming and costly process. It is not possible to be 100% sure of the outcome as to whether or not these reformulated products would be accepted in the marketplace or by appropriate regulatory or certifying bodies.

  Some estimates on the time that would be required indicate that **at least 2 years** would be needed and the associated cost could range between **€0.5 and €2 million per** company (NB. The range is an estimate generated by the authors on the basis of company-specific inputs to consultation). On top of that, additional costs would arise for the costlier raw materials used, including an increase in the amount of fibre used,) for masterbatch formulation; this was estimated by a fibre manufacturer at **€0.3 million/y**. Notably, for an alternative to give the same results on fibres it would need to demonstrate properties similar to TiO_2 (i.e. be an insoluble chemically inert metallic oxide with a particles size below 1 µm).

  On the other hand, for the use of TiO_2 in cigarette tow, a TiO_2-free product might be possible to manufacture and this is currently being studied. Substitution, however, would likely be accompanied by considerable cost; and

- **Compliance with waste management regulations**: the harmonised classification could increase the cost of waste management for fibre manufacturers as some types of waste generated during the manufacturing phase might be classified as hazardous. **Table 4–14** summarises information received from a total of seven questionnaire responses on the types of TiO_2-containing waste that arise during the manufacture, processing and disposal of fibres (all collected with the kind support of the CIRFS trade association). The table identifies, where possible, the relevant LoW entries and the waste management processes currently used. The following key points can be made:

- Relevant waste types that might be affected by the Carc Cat 2 harmonised classification include (a) TiO_2 packaging contaminated with the substance – currently handled as non-hazardous, depending on the levels of TiO_2 residue it might be classified as hazardous (under *15 01 10* Packaging containing residues of or contaminated by hazardous substances*), (b) off-spec additive slurry batches – these may currently be already managed as hazardous due to the presence of hazardous solvents, but this is not always the case, (c) off-spec material that contains >1% TiO_2 – again, some off-spec TiO_2-containing polymer may already be managed as hazardous due to the presence of hazardous solvents but this is not always the case, and (d) solid residues from filtration (greyed entries in the table). Potential for inhalation exposure to TiO_2 might only arise in relation to the disposal of packaging waste that contains TiO_2 power residues;

- The cost arising from the above waste types being classified as hazardous as a result of a Carc Cat 2 harmonised classification for TiO_2 have been estimated to range **from ca. €4,000 per year** for incinerating TiO_2 packaging (instead of landfilling it) to **€50,000 per year** for incinerating filter cake that contains TiO_2 (although some companies may already incinerate this waste stream).

Irrespective to the above increases in waste management costs, the most important waste-related impact on fibre manufacturers arising from the Carc Cat 2 harmonised classification would be that on recycling of off-spec and offcut material. Recycling issues would affect not only those companies that use TiO_2 as a raw material (alone or in a mixture) but also those companies processing polymer that contains TiO_2.

In the spinning process of **polyamide** yarns, there is always some amount of TiO_2-containing waste generated (spinning processes generate on average an equivalent of 10% waste for each kg of yarn production). This type of waste is largely used in EU (and globally) as an input material for engineering plastics and finally applied in the automotive industry, machinery, household appliances, etc. At present, even if in the EU these pre-consumers scraps are classified as waste, they can be considered as a very homogeneous waste (chemically it is a polyamide polymer in a physical status of fibre instead of granule), containing a minor amount of additives, such as stabilisers and pigments, including TiO_2 at a level that exceeds 1.0%. For this reason, the producer of the waste is paid for supplying the waste material, instead of paying for its disposal. The classification of TiO_2 as Carc Cat 2 would change the classification of this waste to hazardous (HP7) and make its direct use 'as is' as raw material for engineering plastics manufacture impossible. Moreover, the final product/article will also acquire the same hazard classification. Options available to the waste producer would be:

- Pay to have the waste disposed of as hazardous (by incineration with disposal of final ashes containing TiO_2); or
- Install systems that would allow the "separation" of the polyamide from TiO_2 and then recycle the polyamide resin. This is not a simple or common industrial process[65].

[65] According to EU regulations, it is forbidden to go below the established limits by diluting hazardous waste with other not hazardous or pure product, thus it would be legally almost impossible to recycle the waste generated by fibre spinning operations.

More generally, for fibres that contain TiO_2, the hazardous waste classification of any post-consumer (or pre-consumer) waste would seriously hinder recycling activities and therefore circular economy policy implementation due to:

- The additional significant administrative and financial burdens of hazardous waste managing and transporting through EEA Member States; and

- Limited national/regional authorisations of hazardous waste recycling activities, which possibly could not be additionally extended, due to national/local legislation. This means, that the EEA portfolio of available end-of-life/recycling solutions for waste containing TiO_2, would diminish.

Consequently, this might bring about a situation where (a) the producer of waste would no longer have available the best available end-of-life/recycling solutions, (b) instead of making a profit from sale of the waste they would need to pay for its disposal, and (c) waste might be sold to non-EEA customers at a lower value.

A quick estimate of the increase in waste treatment costs from the proposed classification of TiO_2 on fibre manufacturers can be provided. For **polyamide fibres**, considering an average waste equivalent of 10% for each kg of yarn production, the economic loss can be evaluated as follows:

- Loss of income from the sale of waste: 10% × €1 = €0.1/kg yarn produced (where €1 is the unit minimum price for the sale of 1 Kg of PA6 waste);
- Cost of disposal of the – now – hazardous waste: 0.1 × €0.15 = €0.015/kg of yarn produced (where €0.15 is the average cost of the "waste to energy" (incineration) disposal of 1 Kg of PA6 waste); and
- Total minimum loss estimate would therefore be **€0.115/kg yarn produced**; in view of the often very limited contribution margin generated by nylon yarn, this loss might offset most, if not all, of the profit.

A similar calculation for polyester fibres could also be provided, however, their TiO_2 content is typically lower than in polyamide and might not exceed 1.0% by weight, thus polyester fibre waste would not be classified as hazardous.

Overall, the Carc Cat 2 harmonised classification would not equally affect all companies involved in fibre manufacture; however, where TiO_2 is used as a powdered raw material and during polyamide manufacture the impacts of the substance's hazard classification could have significant adverse effects and costs for the recycling of TiO_2-containing polymer waste.

Table 4–14: Relevant waste streams for the use of TiO_2 in fibre manufacture and downstream use						
Process generating waste	**Type of waste**	**Waste entry in LoW**	**Typical TiO_2 content**	**Example volume generated***	**Is TiO_2 inhalable?**	**Current waste management**
Manufacture of TiO_2-containing polymer additive slurries	Off-spec additive slurry batches	**16 03 05*** Organic wastes containing hazardous substances (*'mirror hazardous'*) **07 02 01*** Aqueous washing liquids and mother liquors (*'absolute hazardous'*)	>1%	0.01-0.1 kt/y	No	Hazardous due to contamination by a hazardous solvent. **Incineration**
	TiO_2 packaging	**15 01 06** Mixed packaging *('absolute non-hazardous')*	>1%	0.001-0.01 kt/y <<0.001 kt/y	Yes	Non-hazardous (based on MSDS contents). **Landfilling or sent for (ultimate) recycling**
Manufacture of TiO_2-containing polymer	Granulate, 'melt cake' from PET polycondensation unit	**04 02 21** Wastes from unprocessed textile fibres (*'absolute non-hazardous'*)	>1% (deep dull; low quantity) <1% (dull; major quantity) <<1% (bright; minor PET polymer quantity)	Low (as a percentage of production) 100-1,000 kt/y	No	Normally non-hazardous; **Thermal and mechanic recycling** (if clean and usable PET polymer/fibre waste); 'dirty' waste products are **landfilled or incinerated**
	Off-spec TiO_2-containing polymer	**16 03 05*** Organic wastes containing hazardous substances (*'mirror hazardous'*)	>1%	0.001 –0.01 kt/y	No	Hazardous due to contamination by a hazardous solvent. **Incineration**
Manufacture of polymer fibres (staple fibres; tows, filaments)	PET 'melt-cake'; fibre products in different make-ups (bulk fibre products, tows, on bobbins, etc.)	**04 02 21** Wastes from unprocessed textile fibres (*'absolute non-hazardous'*) **04 02 99** Wastes not otherwise specified (*'absolute non-hazardous'*)	>1% (deep dull; low quantity) <1% (dull; major quantity) <<1% (bright; minor PET polymer quantity)	Medium (< 3% of total production) included above (100-1,000 kt/y)	No	Normally non-hazardous; **Thermal and mechanic recycling** (if clean and usable PET polymer/fibre waste); 'dirty' waste products are **landfilled or incinerated**

Table 4–14: Relevant waste streams for the use of TiO_2 in fibre manufacture and downstream use						
Process generating waste	**Type of waste**	**Waste entry in LoW**	**Typical TiO_2 content**	**Example volume generated***	**Is TiO_2 inhalable?**	**Current waste management**
	Off-spec TiO_2-containing man-made fibre	**16 03 06** Organic wastes other than those mentioned in 16 03 05 (*'mirror non-hazardous'*)	>1% <1%	0.001 –0.01 kt/y <0.1 kt/y	No	Non-hazardous. **Landfilling (Company C) Incineration (Company D)**
	Solid residues from filtration	N/A Mirror entry (NB. unspecified, possibly **07 02 15** Wastes from additives other than those mentioned in 07 02 14)	1%	0.3 kt/y	No	Non-hazardous. **Incineration**
	Liquid slurries from filtration	N/A Absolute hazardous entry (NB. unspecified, possibly **07 02 01*** Aqueous washing liquids and mother liquors)	>1%	0.1 kt/y	No	Hazardous. **Incineration**
Processing of polymer fibres (drawing, twisting, texturising, warp drawing, warping)	Waste out of subsequent processing steps for PET fibre	**04 02 22** Wastes from processed textile fibres (*'absolute non-hazardous'*)	>1% (deep dull; low quantity) <1% (dull; major quantity) <<1% (bright; minor PET polymer quantity)	Major (< 10% of total production)	No	Normally non-hazardous; however, in combination with additional added hazardous chemical substances a classification as 'hazardous waste' is potentially possible. **Incineration**
* based on individual responses to questionnaire						

Economic impacts on downstream users (industrial and professional)

The above discussion on impacts covers adequately the entirety of the supply chain for fibres with the exception of consumers (discussed further below) but also the management of end of life textile waste. The Carc Cat 2 harmonised classification would not be envisaged to have an impact on the management of waste as this is typically classified as 'absolute non-hazardous' (see **Table 4–15**). However, the presence of a carcinogen might prove a disincentive towards the recycling of end-of-life waste.

Table 4–15: Relevant waste streams for the use of TiO_2 in fibre waste at the end of its useful life

Process generating waste	Type of waste	Waste entry in LoW	Typical TiO_2 content	Example volume generated*	Is TiO_2 inhalable?	Current waste management
End of life textiles containing TiO_2	Discarded textiles	**20 01 11** Textiles ('*absolute non-hazardous*') **20 03 01** Mixed municipal waste ('*absolute non-hazardous*')	<1%	100 –1000 kt/y	No	Non-hazardous. **Landfilling or recycling** (where schemes available)
Demolition activities	Paint of demolition building waste	**17 01 01** Concrete ('*absolute non-hazardous*') **17 01 02** Bricks ('*absolute non-hazardous*') **17 01 07** Mixtures of concrete, bricks, tiles and ceramics other than those mentioned in 17 01 06 ('*mirror non-hazardous*')	<1%	0.05 kt/y	No	Non-hazardous. **Landfilling**
* based on individual responses to questionnaire						

Social impacts

Employment impacts

A significant proportion of the 20,000 jobs in the man-made fibres industry in Europe could be at risk based on the profitability of the manufacturing process. The companies that have provided a response to the questionnaire on the impacts from a Carc Cat 1B harmonised classification have a combined workforce of several thousand workers and estimates on potential jobs lost indicate that thousands of jobs could be impacted. Some companies expect that their entire workforce would be at risk. Whilst impacts from a Carc Cat 2 harmonised classification would be less pronounced, they would still be significant as a result of the envisaged increase in manufacturing costs.

Impacts on the welfare of consumers

The Carc Cat 2 harmonised classification for TiO_2 could have notable impacts on consumer choice and welfare. The following impacts should be noted:

- **Loss of certain types of consumer products from the market**: if TiO_2 were to be substituted, the quality of end products would be impaired and unavoidably it would not be possible to successfully place some of the products on the market. There is a very large number of different polyamide products manufactured in the carpet and textile sectors and these are very often "tailor made" for each customer. For textiles, there could be a shift to natural fibres (cotton, wool) but as there is not a sufficient quantity of natural fibres to cover even half of the needs of a growing global population, a limitation of synthetic fibre production would result in severe market disruption;

- **Higher cost and loss of technical performance**: substitution of TiO_2 would bring into question the technical performance/suitability of fibres for several key applications such as non-woven wallpaper, filtration, hygiene and medical single use products. The cost of substitution would, at least in part, be passed to the consumer;

- **Loss of consumer satisfaction**: several examples can be provided:

    - In the field of wallpapers, if synthetic fibres of suitable quality were no longer available, consumers would have use non-dimensionally stable wallpaper products that are much more difficult and much more time consuming to use, while the aesthetic result would also be negatively affected;
    - In automotive filtration, if synthetic fibres currently used in state-of-the-art production technologies for the manufacture of durable filtration media were no longer technically suitable, there would be higher maintenance costs due to more frequent oil changes;
    - Fibre used as filling material in high quality quilts/pillows would lose consumer acceptance when made from recycled feedstock, as the fibre appears more yellowish without TiO_2 pigment;
    - In the carpet sector, a switch to hard flooring (wood, ceramic, marble, etc.) would reduce the level of comfort (e.g. in hotels, airports, etc.); and

- **Adverse impacts on public health**: a drive by the synthetic fibre industry towards finding a substitute for a reliable ingredient such as TiO_2 might create situations where a substitute's effects are unknown, and the effects on human health might in time turn out to be adverse, while TiO_2 poses no real risk. TiO_2 also has a UV-protection function, thus with its potential replacement, protection against skin cancer might be reduced.

Competitiveness impacts

EEA-based companies would have to deal with the complexities, administrative burden and cost associated with using TiO_2 as a powder and handling wastes that would be classified as hazardous, while non-EEA competitors would carry on in their operations without this burden. Key competitors are mainly located in Asia where advantages already exist in relation to production costs. With the additional regulatory burden, the cost per kg of manufactured product would increase by several euro cents. Thus, export competitiveness (for example, polyamide carpet yarn specialties are of importance in this field) would be affected. The industry is already under economic pressure.

It is very important to consider that over 80% of textiles purchased by EEA consumers are imported from China or other Asian countries. In addition, over 80% of these textiles are made with fibres and yarn manufactured in China, or other Asian countries. Whilst fibre material contains TiO_2 at a concentration above 0.1% and often above 1.0% by weight, many products that are one stage lower in the value chain (textile/nonwovens) contain less than 0.1% TiO_2 due to dilution effects from blending with other generic fibre components. Thus, non-EEA manufacturers of textiles/nonwovens would remain free to use unrestricted fibres from non-EEA sources without the burden of the TiO_2 harmonised classification and would still be able to export their articles to the EEA from a position of competitive advantage. In other words, article manufacture would become less costly outside the EEA.

In theory, a future harmonised classification of TiO_2 should oblige all countries to handle the substance in a similar way, to protect workers' health. Nevertheless, the EEA waste regulations are not the same as those in Asian or American countries.

As far as the tobacco industry is concerned, the industry today uses one common formulation of cellulose acetate with TiO_2. Following the implementation of a harmonised classification, manufacturers might consider establishing a second line of products for export out of the EEA. This would result in considerable additional costs that might not be fully recovered by price increases.

4.4.2 Catalysts

Limited information is available on the use of TiO_2 in catalysts, although the importance of the relevant catalysts is significant. Catalysts uses may account for 1% of total TiO_2 consumption in the EEA or ca. 10 kt/y.

A Carc Cat 2 harmonised classification might lead catalysts manufacturers to consider introducing new measures such as the use of closed production systems, improvement of air exhaust systems, improvement of PPE, etc. As already discussed such measures could attract considerable costs. Whether customers (users of the catalysts) would accept to use a catalyst that contains a suspected carcinogen would be seen on a case by case basis.

Given that this application area is strictly limited to industrial use, it is far less likely that substitution of TiO_2 would be given much consideration. In any case, eliminating TiO_2 from its catalysts uses would not be feasible. Inability of catalysts manufacturers to use TiO_2 could have significant repercussions on the production of chemical substances that rely on the relevant catalysts and also on the users of those chemicals. One catalyst manufacturer has suggested that sales of a specific type of TiO_2 catalyst are associated with revenues of several millions of Euros. Loss of these catalysts would also wipe out a market for the produced chemical worth several hundreds of millions of Euros. Consequently, users of said chemical would need to source alternative products which are known to have a higher market price, reduced performance and lifetime/durability. Competitors of EEA companies along this supply chain would gain a market advantage if the use of TiO_2 would no longer be possible in the EEA and production of the chemical in question would move outside the EEA with associated loss of added value creation from the industry and loss of jobs.

In relation to waste management, spent catalysts that contain more than 1.0% TiO_2 might be classified as hazardous waste under LoW entry *16 08 02* Spent catalysts containing hazardous transition metals or hazardous transition metal compounds* as would be TiO_2 packaging containing residues of the substance (*15 01 10* Packaging containing residues of or contaminated by hazardous substances*). Thus, the cost of disposing these materials could substantially increase (unless these materials are already classified as hazardous due to the presence of other hazardous components – there is currently no information on this aspect).

Overall, it can be assumed that in the field of catalysis, the impacts of a Carc Cat 2 harmonised classification for TiO_2 would probably be limited to the increased cost of worker protection measures to be taken by companies handling TiO_2 as a raw material and the management of spent catalysts as wastes.

4.4.3 Food and feed additives and food contact materials

Key market descriptors

Limited information has been collected from consultation which does not allow the presentation of sufficiently representative industry-wide figures. Given the numerous food categories in which TiO_2 can be used, it is appropriate to assume that it is quite widely used as a food colour in the EEA. The flexible packaging market in the EEA has a value of several billion euros and the value of the market for food packaging inks is the range of hundreds of millions or euros (actual figures are confidential and are not reproduced here).

Relevant legislation

Table 4–16 summarises the legislation that would be of relevance to the use of TiO_2 in food and feed additives applications in the EEA, after the adoption of a Carc Cat 2 harmonised classification. Additional detail is available in Annex 1.

Table 4–16: Relevance of different regulatory instruments and voluntary initiatives to food, feed additives and food packaging applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation

Relevant legislation	Relevant to food
CLP	Only in receiving and handling raw materials
Carcinogens and Mutagens at Work	No
Waste Framework	Potentially
Industrial Emissions	Potentially
REACH	No
Cosmetics	No
Toy Safety	No
Food Contact Materials	Yes
Food Additives	Yes
Medicinal Products	No
Construction Products	No
Biocides	No
Medical devices	No
RoHS	No
Tobacco additives	No
Other	CoE Resolutions and the CEPE Code of Practice impact upon the use of CMRs in food contact materials and articles

Impacts on the marketing and use of titanium dioxide-containing products

Economic impacts for food, feed and food packaging manufacturers

<u>All relevant uses or titanium dioxide</u>

Compliance with national legislation on worker protection could become costlier for all users of TiO_2 as a raw material through the introduction of stricter controls on the exposure to TiO_2 powder.

Titanium dioxide as a food additive

Possibilities for reformulation: there is no other white colourant approved under Regulation 1333/2008 that meets the performance of TiO_2 and thus reformulation is not feasible. The only other white additive is E170, calcium carbonate, which does not have the opacity of TiO_2 and has severe technical limitations as described in Section 8.4 of Annex 2:

- It is a much less effective white colour than TiO_2. There are applications where the layer thickness of a print on a foodstuff (for instance, prints on dark and milk chocolate) is too thin to enable any other product to be opaque enough (and white/neutral in colour) in order to have a clear visual effect;

- It will readily react with any acids present in foods to generate carbon dioxide and a (possibly soluble) calcium salt with no white colouring properties;

- It could not be used as a colour in any foods with low pH as it would neutralise the acid present, adversely affecting the product flavour, quality and possibly shelf life;

- It also could not be used as a white colour in cake batters, scone doughs, etc. since it would interfere with the raising agent system;

- It could not be used as a replacement to produce white glitter powders since E555 (Potassium aluminium silicate - mica) is only authorised for use as a carrier for titanium dioxide (and E172 iron oxides which produce red/brown colour glitter powders); and

- It is normally used in foods to function as an acidity regulator, anticaking agent, stabiliser or nutrient source (of dietary calcium) rather than as a colour. It is also used as a firming agent in many canned or bottled vegetable products.

Overall, calcium carbonate could not in practice be used as a viable replacement for TiO_2 in most of its current applications as a food colour.

Scope for a restriction on use and envisaged market losses: according to Article 6 of Regulation 1333/2008, a food additive may be included in the Community lists in Annexes II and III only if it meets the following conditions and, where relevant, other legitimate factors, including environmental factors:

1. It does not, on the basis of the scientific evidence available, pose a safety concern to the health of the consumer at the level of use proposed.
2. There is a reasonable technological need that cannot be achieved by other economically and technologically practicable means.
3. Its use does not mislead the consumer.

Recently, TiO_2 was re-evaluated by EFSA (European Food Safety Authority, 2016) and it was concluded that dietary exposure does not pose health concerns. Whilst a carcinogenicity harmonised classification (either Cat 1B or Cat 2) might lead to the review of the evaluation result, given the extremely low probability of exposure to TiO_2 by inhalation through food and the lack of feasible substitutes of equivalent performance, it may be presumed that an approval for the continued use of TiO_2 could be secured. The mechanism for securing an approval would have to be led by the Member States' Food Safety Authorities.

However, classification of a food ingredient as Carc Cat 2 is likely to cause significant concern among consumers and consequently a drop in sales of those products identified as containing the white colourant.

Compliance with waste management regulations: wastes associated with the food industry are described by LoW entries under the following sub-chapters:

- 02 02 Wastes from the preparation and processing of meat, fish and other foods of animal origin;
- 02 03 Wastes from fruit, vegetables, cereals, edible oils, cocoa, coffee, tea and tobacco preparation and processing; conserve production; yeast and yeast extract production, molasses preparation and fermentation;
- 02 05 Wastes from the dairy products industry; and
- 02 06 Wastes from the baking and confectionery industry.

All entries thereunder are 'absolute non-hazardous' thus the Carc Cat 2 harmonised classification for TiO_2 might not have a very pronounced impact[66]. On the other hand, TiO_2 packaging would become hazardous waste, depending on the level of residue in it, under entry *15 01 10* Packaging containing residues of or contaminated by hazardous substances*.

<u>Titanium dioxide as an animal feed additive</u>

TiO_2 is present in Annex I of Regulation 1831/2003 under Category 2 (colourants). As no other white pigment appears to be listed and following the discussion on food additives above, it would be unlikely that its entry would be removed from the Annex. Nevertheless, its new classification might make manufacturers of feed additives (as well as users, if they became aware of TiO_2's presence) less inclined to use the substance or any animal feed that contains it.

<u>Titanium dioxide as an additive in food contact materials</u>

Possibilities and cost of reformulation: no other pigment can deliver the required performance in terms of opacity and ink film thickness. TiO_2 is used at large concentrations (e.g. 15-60%); alternatives such as ZnS would require even higher concentrations and would still not be able to provide the opacity and performance currently required by the packaging market.

The protective and decorative effect currently obtained with white inks (and in some other cases with TiO_2-coloured substrates like plastic film or paper) would no longer be achievable, forcing food packaging manufacturers customers to develop new packaging designs and possibly the use of different materials to compensate for the lack of hiding effect provided by white inks. This would require significant effort in terms of new packaging development, validation, marketing, possibly leading to an increased use of different material combinations (e.g. paper labels on plastic films) in place of packaging that is to date consolidated, validated by tests, accepted by the authorities, and trusted by the consumer.

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[66] It is worth noting that when consulting on the originally proposed Carc Cat 1B harmonised classification, a company involved in the production of food for human consumption estimated that segregation of solid and water waste plus installation of a water purification station would cost an estimated **€0.3 million**.

Scope for a restriction on use and envisaged market losses: in respect of food contact materials, the implications of the proposed classification on the use of the substance in the manufacture of food contact materials is difficult to predict with certainty for a number of reasons:

- The existing legislation is not fully harmonised for the vast majority of food contact materials; and
- If the Carc Cat 2 harmonised classification would specifically apply for exposure via the inhalation route, this would clearly be of little relevance to the use of food contact materials. Still, it cannot be certain how this will be viewed by the relevant authorities and approaches may differ on the Member State level. Relevant industry organisations have noted a trend towards stricter regulation on CMR substances in food contact materials both at transnational and national level.

The discussion below explains the possible consequences of a Carc Cat 2 harmonised classification and demonstrates that impacts in the field of food contact materials could potentially be severe, but the lack of exposure by inhalation might prevent extensive market impacts and losses. The following impacts may be envisaged:

- **Impacts for food contact materials for which specific harmonised EU legislation applies**: there are two areas where specific legislation for food contact materials applies: plastics and active and intelligent packaging. Under the relevant legislation, the following impacts might be envisaged:
    - Plastic food contact materials – the Union List: Recital 27 of the Plastics Regulation (EU) No 10/2011 indicates that CMR substances should not be used in plastic food contact materials or articles without previous authorisation. Authorised substances are included in the Union list and TiO_2 is currently an authorised substance, under entries 610, 805 and 873 in Table 1 of Annex I (see also **Table 3–13**), for use as an additive or polymer production aid because safe use has been proven and accepted by EFSA based on its current classification. Under Article 15(3), declarations of conformity with the Regulation "*shall be renewed when substantial changes in the composition or production occur that bring about changes in the migration from the materials or articles or when new scientific data becomes available*". In theory, the authorisation of the substance might be reassessed by EFSA and this might result in lower limits for the migration of TiO_2 from food contact articles into food, or even a restriction forbidding its use;
    - *Recycled plastic materials and articles*: Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods prescribes that only authorised monomers and additives should be added to the recycled plastics and their migration limits should also be respected by recycled plastic food contact materials. Use of TiO_2 in recycled plastic would be unlikely to be authorised, if it can no longer be found on the Union List;
    - *Active and intelligent packaging materials*: Regulation (EC) No 450/2009 requires that CMR substances cannot be used in such materials and packaging even if not in direct contact with food or the environment surrounding the food and even if they are separated from the food by a functional barrier. Only substances which are included in the 'Community list' of authorised substances may be used in components of active and intelligent materials and articles. The Regulation does not describe an exemptions procedure and as the Community list has apparently not been published yet, it is

possible that the Carc Cat 2 harmonised classification, if introduced before the List is published, may hinder the placing of TiO_2 on the list;

- **Impacts for food contact materials for which no specific harmonised EU legislation currently exists**: as described in Section 7.2.2 of Annex 1 to this document, where no harmonised rules exist, the use of chemical substances in food contact materials needs to comply with the generic provisions of the Framework Regulation (EC) No. 1935/2004[67] as well as with any applicable national rules, Council of Europe (CoE)/ European Directorate for the Quality of Medicines (EDQM) Resolutions, and other industry-led voluntary codes of practice. We may look at these in turn:

  - *Framework Regulation (EC) No. 1935/2004*: Article 11(5) of the Regulation prescribes that, "*The applicant or any business operator using the authorised substance or materials or articles containing the authorised substance shall immediately inform the Commission of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health. If necessary, the Authority shall then review the assessment*". Article 12(1) also prescribes that, "*On its own initiative or following a request from a Member State or the Commission, the Authority shall evaluate whether the opinion or the authorisation is still in accordance with this Regulation, in accordance with the procedure laid down in Article 10, where applicable. The Authority may, where necessary, consult the applicant*". The classification for TiO_2 as a Carc Cat 2 substance may therefore trigger a re-evaluation of its authorisation for food contact use;
  - *National rules*: Article 6 of Framework Regulation (EC) No. 1935/2004 notes, "*In the absence of specific measures referred to in Article 5, this Regulation shall not prevent Member States from maintaining or adopting national provisions provided they comply with the rules of the Treaty*". There are several CoE/EDQM Resolutions which exclude the use of CMR substances from coatings, paper/board and printing inks in food contact materials. TiO_2 may currently be present in approved additive lists, however, the classification of the substance under the CLP Regulation may trigger a re-evaluation of such approvals or enforcement practice under national legislation that implements said CoE/EDQM Resolutions. To what extent such re-evaluations may take place is uncertain; one would have to study the national legislation of the 31 EEA member states for each of the non-harmonised categories of food contact materials and articles in their respective national languages to establish what the actual impact might be[68]; and
  - *Industry initiatives*: Sections 7.2.3-7.2.4 of Annex 1 explain the provisions of the CEPE Code of Practice which prohibits the intentional use of CMR substances (monomers, starting substances and additives) in coatings intended for use in food contact material unless they have been authorised by EFSA and any set migration limits are respected. On the other hand, whilst the EuPIA Exclusion Policy does not allow the presence of Carc Cat 1B printing in ink components inside food packaging, not even behind a

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[67] Article 3 of the Framework Regulation applies under which food contact materials should not transfer their constituents to food in quantities which could: (a) endanger human health; or (b) bring about an unacceptable change in the composition of the food; or (c) bring about a deterioration in the organoleptic characteristics thereof.

[68] For instance, the new Belgian Royal Decree concerning Varnishes and Coatings intended to come into contact with food stuffs (which is a national provision based on a CoE/EDQM Resolution) prescribes in its Article 4 that substances classified as CMRs cannot be used.

functional barrier, the Policy is not applicable on Carc Cat 2 substances. Overall, the Carc Cat 2 harmonised classification would not have an impact on the use of TiO_2 in food contact material coatings under the CEPE Code of Practice, unless EFSA decided to revoke the authorisation of the substance; similarly, the Carc Cat 2 harmonised classification would not have repercussions on the use of the substance in printing inks under the EuPIA Exclusion Policy. In any case, food contact materials manufacturers might wish to avoid using coatings or inks that contain a suspected carcinogen and thus voluntarily take steps to eliminate the use of the substance.

Overall, the landscape is somewhat uncertain in relation to food contact material-related applications of the pigment:

- For applications covered by existing harmonised classification and where TiO_2 has already been assessed and authorised into a positive list, i.e. plastics, the likelihood of the substance being removed from the Union List is low, taking into account that probability of exposure by inhalation in this context is small. Accordingly, if EFSA did not elect to (or concluded not to) revoke TiO_2's existing authorisation listings, the substance could continue being used as an additive in the relevant food contact materials;

- On the other hand, it is important to consider the wider regulatory landscape. Existing EU food contact legislation, existing food contact material resolutions of the CoE/EDQM (see Section 7.2.2 of Annex 1) and national food contact material legislation in EU Member States would appear to refer to CMRs in general, without making any distinction between exposure pathways and might not even distinguish between carcinogens of category 1A, 1B or 2. EFSA recently proposed to the European Commission an updated, more severe risk assessment methodology for chemicals in food and food contact materials[69] thus there is a general trend towards stricter regulation in food and food contact material safety[70]. It has further been suggested that national authorities do not always follow EFSA advice and practice and therefore national legislation may indeed focus on hazard rather than exposure and risk. Overall, since most recent risk management measures (taken by the European Commission, the Coe/EDQM or the national authorities) restrict the use of CMRs in general unless proven safe and included in a positive list (at EU level if harmonised or at national level if not harmonised) without distinction between exposure pathways, there is a possibility that national authorities may disregard the importance of exposure pathway in their risk management approaches and restrict the use of TiO_2 following its classification as a Carc Cat 2 substance.

In any case, the presence of a suspected carcinogen in food contact materials and articles (in plastics, labels, inks, containers, etc.) could bring about a major market change, a shift in public opinion and unpredictable reactions from consumers. It is worth remembering that safety criteria used for food contact materials are typically far stricter than for the evaluations of the safe use of chemicals in general with limits of 10, 0.1 or even 0.01 ppb in food contact and drinking water materials as opposed to 1.0-0.01% by weight for CMR chemicals in general, industrial and professional use.

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69 See Opinion No. 4357 of the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids, "*Recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials*", available at https://www.efsa.europa.eu/en/efsajournal/pub/4357, accessed on 17 January 2017.

70 Manufacturers of food contact materials and articles may also wish to place on the market products that contain no hazardous substances.

On the basis of the above analysis and having received contributions from key industry organisations, it may be concluded that the time required and the cost of reformulating all food contact mixtures and articles, and of testing the reformulated products for compliance with food contact and other legislation, and for testing consumer acceptance will be very high especially when considering the food contact supply chain (in and outside the EU) as a whole.

Compliance with waste management regulations: issues of waste are addressed elsewhere in this document, for instance, under paints (coatings), plastics, inks, etc.

Economic impacts on downstream users (industrial and professional)

Downstream industry impacts are mostly relevant to the food contact materials industry. As explained above, any attempt to substitute TiO_2 in formulations such as coatings or inks, could have significant repercussions for food packaging manufacturers and potentially result in changes to packaging materials used. Alternatively, pressures may develop from downstream actors (e.g. food producers and/or retailers) who might face negative perceptions by consumers and thus request that food contact materials used with the products they sell are free of TiO_2. The scope for variation in impacts between EEA Member States will be particularly wide given the significant role of national regulatory frameworks in this industry sector.

Social impacts

Employment impacts

Insufficient information is available to estimate the total employment associated with the use of TiO_2. An industry association representing companies in the food industry has indicated that the use of TiO_2 is small in relation to other food ingredients handled (automatically or manually) and that it is therefore unlikely that social impacts can be attributed to any ban imposed. The association has stated that it would not anticipate any direct job losses in respect of the current usage of TiO_2.

Impacts on the welfare of consumers

The Carc Cat 2 harmonised classification for TiO_2 could have impacts on consumer choice and welfare, depending on actions taken by enterprises currently involved in its use. The following potential impacts should be noted:

- **Loss of certain types of consumer products from the market**: given the absence of other approved white colourants of similar opacity and the low probability of consumer exposure to TiO_2 by inhalation, it can be assumed that market availability of foodstuff that contains the substance would not be impacted. It is also worth noting that several TiO_2-containing products (e.g. confectionery) are deemed 'discretionary products', rather than staple goods, and so consumers might be able to switch to other products in the range as food products could be produced with different decorations. On the other hand, a greater impact on the market presence of food packaging products could be expected. For example, white shopping and paper bakery bags would be hard to manufacture without TiO_2. If TiO_2 were to be eliminated, all flexible food packaging made of plastics which has product information (e.g. batch number, consumption date) printed with ink over a white area could disappear, or be combined with an adhesive paper label, which would hinder the recycling of the packaging waste;

- **Increased cost and loss of performance**: assuming a continued use of TiO_2, impacts on food products would be limited. If TiO_2 were to be replaced by calcium carbonate (E170), additional loadings would be required and the opacity of the feedstuff would be worse thus impairing the aesthetic properties of the product. On the other hand, in relation to food packaging, white articles with a protective function against sunlight could be replaced by more expensive and less recyclable alternatives involving multi-materials (e.g. increased use of aluminium foil or paper on plastic flexible packaging). Alternative white pigments do not match TiO_2 in terms of opacity, whiteness and fastness properties and/or contain substances such as barium;

- **Loss of consumer satisfaction**: it is almost impossible to match the effects of TiO_2 or TiO_2-containing pearlescent pigments with other ingredients. The absence of white from the portfolio of colours available for the graphic communication of brand and product information in packaging and food packaging would result in the disengagement of customers from their preferred brands and a general perception of decreased quality in consumer goods or foods applying this kind of "whiteless" packaging; and

- **Adverse impacts on public health**: any effort to substitute TiO_2 would make it very difficult to display information that is important to the consumer (e.g. food ingredients, safety). Since packaged food would no longer be protected from light degradation due to the lack of opaque films, there would be a significant increase in the likelihood of food poisoning resulting from food going off in the packet before its sell-by date. This would probably result in reduced sell-by dates, and increased volumes of food being discarded beyond this date. This would affect the whole food supply chain (supermarkets etc.).

Competitiveness and competition impacts

Impacts on the competitiveness of EEA-based enterprises

When food or food contact materials are exported to extra-EEA markets (such as Turkey, North and South America and Africa), increased manufacturing costs would hinder companies' ability to compete with local producers or extra-EEA producers who would not be affected by the new harmonised classification. With few, if any, possible technical options the Carc Cat 2 harmonised classification would provide additional stimulus for some companies to move production of food contact materials to non-EEA countries with a lower regulatory burden (as well as lower labour costs).

Impacts on intra-EEA competition

The most prominent impact that would be likely to arise is that food contact materials, and more specifically packaging, which contains TiO_2 in a variety of forms (in coatings, inks, labels) might become less attractive to downstream actors (food retailers and producers) and thus a shift to alternative packaging might ensure. This could also have the unintended consequence of food packaging becoming less suitable for recycling, depending on the substitute packaging material selected.

4.4.4 Pharmaceuticals

Key market descriptors

Consultation has generated little information that would help us provide an overview of the markets for TiO_2-containing pharmaceuticals. By way of background, the European pharmaceuticals industry involves 1,900 companies (members of the European Federation of Pharmaceuticals Industries and Associations – EFPIA) has a market value (ex-factory) of ca. €192 billion, a positive trade balance of ca. €86.5 billion and employs ca. 725,000 workers (EFPIA, 2016).

The German Medicines Manufacturers' Association (BAH), which has actively participated in the consultation exercise, has noted that its more than 320 members may use between 100 kg and several tonnes of TiO_2 per year.

Relevant legislation

Table 4–17 summarises the legislation that would be of relevance to the use of TiO_2 in pharmaceuticals applications in the EEA, after the adoption of a Carc Cat 2 harmonised classification. Additional detail is available in Annex 1.

Table 4–17: Relevance of different regulatory instruments and voluntary initiatives to pharmaceuticals applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation	
Relevant legislation	**Relevant to pharmaceuticals**
CLP	Applies to raw materials, but not to medicines (for either human or animal use)
Carcinogens and Mutagens at Work	No
Waste Framework	Potentially
Industrial Emissions	Potentially
REACH	No
Cosmetics	No
Toy Safety	No
Food Contact Materials	No
Food Additives	Yes TiO_2 used in pharmaceuticals as colourant has to meet the criteria purity of E171 also used in food
Medicinal Products (colouring matters)	Yes
Construction Products	No
Biocides	No
Medical devices	No
RoHS	No
Tobacco additives	No

Impacts on the marketing and use of titanium dioxide-containing products

Economic impacts for manufacturers of pharmaceuticals

Potential loss of markets

A Carc Cat 2 harmonised classification would have the following impacts on the ability of EEA-based pharmaceuticals manufacturers to use TiO_2:

- **Scope for a restriction on the use of TiO_2 and possibilities for exemptions**: according to a 2007 opinion by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency, "*in the event that CMR toxicity has been identified for an excipient, the rule is to avoid and replace this excipient. In the rare cases where this would not be possible, the use of such CMR excipients in a medicinal product would only be considered after careful evaluation of the benefits of the medicinal product in the target patient population versus the potential risks (…) any risk identified for an excipient and in particular a CMR substance, would be acceptable only on condition that this excipient cannot be substituted with a safer available alternative, or that the toxicological effects in animal models are considered not relevant for humans (e.g. species specific, very large safety ratio), or where the overall benefit/risk balance for the product outweighs the safety concern with the product. Overall, the use of any excipient with a known potential toxicity, and which could not be avoided or replaced, would only be authorised if the* *safety profile was considered to be clinically acceptable in the conditions of use, taking into account the duration of treatment, the sensitivity of the target population and the benefit-risk ratio for the particular therapeutic indication*" (European Medicines Agency, 2007). As a result, and given the discussion presented earlier on food additives and how the use of TiO_2 in food might conceivably continue after the introduction of the proposed classification, it is possible that TiO_2 use in pharmaceuticals might continue given that inhalation exposure is generally of no relevance to medicine consumption. The cost of this review and approval process cannot be estimated; however, the large number of impacted products could make this a costly exercise.

If the use of TiO_2 in the EEA were to be prohibited, it could be expected that countries outside the EEA would follow suit. Then the manufacturers would have to carry out the same activities as mentioned above, for example re-registration. This could take additional years and lead to additional high costs. These thousands of regulatory induced variations would not confer any additional benefit to the patients;

- **Adverse impacts from negative patient perceptions**: it would clearly be confusing for patients to be informed that an ingredient used in so many different medicinal products is actually a suspected carcinogen. While there is essentially no safety risk associated with consuming pharmaceuticals, dietary supplements and foods containing TiO_2[71], it is unlikely that patients and the public at large would be sufficiently informed to know that the critical route of exposure is inhalation and may become reluctant to orally consume medication they perceive as potentially detrimental to their health. Such perceptions could have an adverse impact on the sales of pharmaceuticals and nutraceuticals and would inevitably cause some companies to try to unnecessarily reformulate their products due to concern over consumer perceptions; and

- **Potential loss of global markets**: if the use of TiO_2 in the EEA were to be prohibited, it could be expected that countries outside the EEA would follow suit. Then the manufacturers would have to carry out the same activities as mentioned above, for example re-registration. This could take additional years and lead to additional high costs. Importantly, these thousands of regulatory induced variations would not confer any additional benefit to the patients.

<u>Potential increases in operating costs</u>

A harmonised Carc Cat 2 classification for TiO_2 could increase the manufacturing costs and thus impact the profitability of EEA-based pharmaceuticals manufacturers, in the following ways:

- **Cost of reformulation to eliminate TiO_2**: TiO_2 is added to film coatings because this adheres to and covers the tablet core best. Without the use of TiO_2, the colour is not as smooth and homogeneous, and the colour, spots, and different coloured powder particles show through. Better coverage means better stability of the ingredients and better appearance.

  As noted by BAH, there are no alternatives available offering the same/required characteristics of TiO_2 (excellent white pigment, chemical inertness, high stability against UV light) and some may be accompanied by their own hazards in pigmentary form (e.g. ZnO). Much higher volumes of alternative pigments and longer application times would be required to obtain a similar whiteness.

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[71] The US Food and Drug Administration (FDA) has reported in their Inactive Ingredient Database that up to 49.27 mg of TiO_2 per dosage form may be safely used. The Japanese Pharmaceutical Excipients Directory indicates that up 384 mg of TiO_2 per day may be safely consumed (Colorcon, 2016).

Since TiO_2 is used in the great majority of coloured pharmaceutical and dietary supplement tablets and capsules, either as a sole colourant or in combination with other pigments to produce a range of colours, it is estimated that TiO_2 is used in thousands of medicinal and dietary supplement products globally. This is especially significant since medicinal product manufacturers and global regulatory authorities have carefully reviewed drug and dietary supplement products for potential hazards within the context of clinical trials and other safety studies involving animals and humans (Colorcon, 2016).

Therefore, there would be a need for complete reformulation of many products with a high effort not only in terms of R&D. A change in the formulation of a medicinal product requires comprehensive studies of efficacy, safety and stability of the new formulations. New stability studies would last for several years (the shelf-life of most medicines is three or more years). A technical dossier showing compatibility, stability and drug efficacy would need to be developed, which is expected to cost several million Euros per medicinal product. Since TiO_2 is used in hundreds of pharmaceutical products in Europe, the total industry costs for a change could easily be in the range of billions of Euros. Only after all of these activities have been carried out, which may take years, could reformulated products be brought on the market to replace the existing portfolio in the EEA.

Finally, it is worth noting that testing the stability of the newly changed formulations would necessitate an unprecedented volume of tests. Their organisational and financial challenges would exceed anything previously seen in this field (VCI, 2016); and

- **Compliance with waste management regulations**: the harmonised classification could increase the cost of waste management for pharmaceuticals manufacturers as some types of waste generated during the manufacturing phase might be classified as hazardous. Relevant waste categories (mirror entries) from the LoW in the context of pharmaceuticals manufacture include:

  - 07 05 11* Sludges from on-site effluent treatment containing hazardous substances;
  - 07 02 13* Solid wastes containing hazardous substances; and
  - 15 01 10* packaging containing residues of or contaminated by hazardous substances (for empty TiO_2 packaging).

  No questionnaire response was received from this industry sector; information on the scale of the impact is not available.

Economic impacts on downstream users (industrial and professional)

The above discussion on impacts covers adequately the entirety of the supply chain for pharmaceuticals, with the exception of consumers (discussed further below). It must be noted that the pharmaceuticals sector has linkages to the use of TiO_2 in other sectors, such as plastics, in relation to the packaging used for pharmaceutical products.

Social impacts

Employment impacts

Employment impacts cannot be estimated as they would largely depend on whether TiO_2 would remain an approved excipient. If reformulation became necessary, the large cost of reformulation and variations to marketing authorisations could have an impact on the levels of employment in the pharmaceuticals sector, particularly among smaller companies.

Impacts on the welfare of consumers

The Carc Cat 2 harmonised classification for TiO_2 could potentially have notable impacts on consumer choice and welfare, depending on the action taken by the manufacturers of pharmaceuticals and nutraceuticals. The following potential impacts should be noted:

- **Loss of consumer products from the market**: if a reformulation was required, it can be considered certain that reformulation of some products would prove too costly with their consequent removal from the market;

- **Increased cost and loss of technical performance**: the cost of reformulation would most likely be passed on to consumers (patients);

- **Loss of consumer satisfaction**: clearly, if TiO_2 was classified as a suspected carcinogen, its continued use in medicinal products would cause significant confusion and alarm among patients. If TiO_2 was substituted, the unsightly appearance of medicinal products without any real health benefit would cause dissatisfaction and reduce patients' confidence in the quality of the products. Moreover, TiO_2 has a very high level of stability under UV light enabling further protection of the APIs of medicinal products, as is the case with the capsule shells of opaque capsules, for example. Its substitution (as well as its removal from the packaging) could lead to shorter shelf lives and expiry dates for medicinal products;

- **Adverse impacts on public health**: whether TiO_2 would be reformulated out of products or would continue to be used with higher manufacturing costs, ultimately the increased cost of medication would be passed on to the national health services of EEA Member States. If reformulation took place, pharmaceutical manufacturers might choose to use a potential TiO_2 replacement with a less well understood safety profile and/or shorter history of use, thereby increasing the risk of harm to consumers. In addition, the use of TiO_2 alongside other colourants enables pharmaceuticals manufacturers to produce medicinal products with a great variety of colours. Coloured pharmaceutical products are highly desirable, since they support brand identification and reduce the potential for medication errors. Without TiO_2, the available colour palette would be much more limited and as the number of possible colour options for pharmaceutical products decreases, the probability of medication errors increases.

Competitiveness and competition impacts

Impacts on the competitiveness of EEA-based enterprises

EEA pharmaceutical companies also sell their medicinal products outside the EEA. An increase in their cost of manufacture and their market prices would lead to lower sales figures outside the EEA.

Impacts on intra-EEA competition

Particularly for SMEs it would be difficult to invest in higher safety requirements for manufacturing, or in reformulating products. It could be that some smaller companies would prove unable to hold on to their full portfolio or face the risk of business closure. A concentration of the business activity to some larger companies would be a possibility. The scale of such effects would crucially depend on whether TiO_2 would remain an approved excipient.

4.4.5 Cosmetics

Key market descriptors

The key economic parameters of the use of TiO_2 are summarised below.

Importance of the application	TiO_2 is widely used as a colourant as the only white base providing proper coverage available for all type of formulations, as an opacifier or as UV filter and is chosen due to its safety, efficacy and performance. TiO_2 is one of the few globally approved UV filters/sunscreen actives which are of relevance for global formulations. TiO_2 is regulated under the European Cosmetic Products Regulation as a cosmetic colourant (CI 77891, Annex IV) approved for all cosmetic products without any restrictions and as a UV filter (Annex VI) with a maximum concentration of up to 25%.
Estimated TiO_2 tonnage used	Relatively low (compared to uses such as paints, plastics, etc.) – less than 1% of total EEA consumption of TiO_2 (but note below the important impacts on a multitude of cosmetic products).
Estimated tonnage of products that contain TiO_2	According to Cosmetics Europe, a search in the Mintel Global New Products Database (GNPD) indicated that over 20,000 cosmetics products launched in the last 5 years contained TiO_2. This is over 10% of all European cosmetic product launches included in this database. More detailed survey data from Cosmetics Europe membership has not been made available.
Estimated value of markets	Information specific to TiO_2-based cosmetic products is not available. More widely, the European cosmetics and personal care market was valued at €77 billion at retail sales price in 2015 and is the largest in the world. Skin care products are the largest segment with a total value of €19.9 billion while the value of decorative cosmetics stands at €10.7 billion per year (Cosmetics Europe, 2016b).
Estimates of Gross Value Added	According to Cosmetics Europe, the cosmetics industry brings at least €29 billion in added value to the European economy every year, of which approximately €8 billion is contributed directly by the manufacture of cosmetic products (the remaining €21 billion is generated indirectly through the supply chain).
Number of users of TiO_2	There are more than 5,000 enterprises manufacturing cosmetics in Europe (source: Cosmetics Europe).
Presence of SMEs	The vast majority of cosmetics companies are SMEs. In 2015, there were 4,605 SMEs manufacturing cosmetics in Europe (source: Cosmetics Europe).
Number of stakeholders that participated in consultation	Three key trade associations have participated, Cosmetics Europe, European Federation for Cosmetic Ingredients (EFfCI) and ASPA-INGRECOS (the French member of EFfCI) plus a small number (<5) of individual companies.

Locations of stakeholders that participated in consultation	Cosmetics Europe represents companies across the EU. Its membership consists of 27 national associations of the EU Member States and beyond, 17 major international companies, four supporting association members, four supporting corporate members and three correspondent members. Cosmetics Europe represents more than 4,000 companies throughout the EU via the active representation of its member national associations. EFfCI represents more than 100 cosmetic ingredients companies in Europe. Further downstream, there are 20,100 enterprises involved in the wholesale of cosmetics (with significant numbers in Italy, Spain and France) and 45,700 specialist stores and 55,000 outlets retailing cosmetics. About half a million hairdressing and beauty salons (the majority of which are also SMEs or micro-enterprises) also rely on the use of cosmetics; the number of European spas is also growing and may be a source of inward investment to Europe in the form of "wellness tourism" (source: Cosmetics Europe).
Employment in the sector	The cosmetics industry supports at least 2 million jobs, including direct, indirect and induced economic activity. Of these, 152,000 workers are employed directly in the manufacture of cosmetic products, and around 1.6 million workers are employed indirectly in the cosmetics value chain (source: Cosmetics Europe).

Relevant legislation

Table 4–18 summarises the legislation that would be of relevance to the use of TiO_2 in cosmetics applications in the EEA, after the adoption of a Carc Cat 2 harmonised classification. Additional detail is available in Annex 1.

Table 4–18: Relevance of different regulatory instruments and voluntary initiatives to cosmetics applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation

Relevant legislation	Relevant to cosmetics
CLP	Only in receiving and handling raw materials
Carcinogens and Mutagens at Work	No
Waste Framework	Potentially
Industrial Emissions	Potentially
REACH	No
Cosmetics	Yes
Toy Safety	Potentially. Impact not automatic
Food Contact Materials	No
Food Additives	Yes TiO_2 used in cosmetics as colorant has to meet the criteria purity of E171 also used in food
Medicinal Products	No
Construction Products	No
Biocides	No (but Ag/Ti preservatives listed in Cosmetic Products Regulation)
Medical devices	No
RoHS	No
Tobacco additives	No

Impacts on the marketing and use of titanium dioxide-containing products

Economic impacts for manufacturers of cosmetics

Potential loss of markets

A Carc Cat 2 harmonised classification would have the following impacts on the ability of EEA-based cosmetic manufacturers to use TiO_2 and place on the market TiO_2-containing formulations:

- **Restriction under the Cosmetic Products Regulation and cost of securing an exemption**: first and foremost, the use of TiO_2 is subject to the provisions of the Cosmetic Products Regulation. Article 15(1) of the Regulation prescribes that "*The use in cosmetic products of substances classified as CMR substances, of category 2, under Part 3 of Annex VI to Regulation (EC) No 1272/2008 shall be prohibited. However, a substance classified in category 2 may be used in cosmetic products where the substance has been evaluated by the SCCS and found safe for use in cosmetic products. To these ends the Commission shall adopt the necessary measures in accordance with the regulatory procedure with scrutiny referred to in Article 32(3) of this Regulation*". Therefore, the immediate effect of the Carc Cat 2 harmonised classification would be an initiation of a risk management procedure that can result in a ban on the use of the substance (NB. classification under the CLP Regulation does not mean an automatic ban on the use of a CMR substance in cosmetic formulations).

  This risk management procedure may result in an exemption from the generic ban prescribed by the Regulation. To secure such an exemption, the substance must be evaluated by the Scientific Committee on Consumer Safety (SCCS) and found safe for use in cosmetic products. In comparison to a Carc Cat 1B harmonised classification, this burden is lower (for a Carc Cat 1B classification an exemption requires that a series of stringent conditions be fulfilled, i.e. that (a) the substance complies with the food safety requirements as defined in Regulation (EC) No 178/2002; (b) there are no suitable alternative substances available; and (c) an application is made for a particular use of the product category with a known exposure). In addition, the evaluation by the SCCS of a Carc Cat 1B ingredient would need to take into overall exposure from other sources and vulnerable population groups.

  The use of TiO_2 in cosmetic products is longstanding and an extensive toxicological data set is available. The safety of TiO_2 has been acknowledged by a wide range of scientific and regulatory bodies throughout the world (e.g. EU EFSA, US FDA), resulting in its safe use in various products, including food products. For cosmetic products, the SCCS has reviewed and concluded on the safety of TiO_2 on various occasions. The nano-form of TiO_2 has been reviewed by the SCCS in 2013[72] and has been authorised for use as a UV filter in cosmetic products in August 2016. The exemption procedure would require the industry to invest time and resources to screen potential alternatives and to prepare a new safety dossier on the nano-scale and the non-nano form of TiO_2 for submission to the SCCS.

  It is to be noted that such exemptions are not granted in a procedural or (semi-)automatic manner, i.e. each application would be very carefully reviewed on whether an exemption is actually warranted. There is precedence where applications for exceptions were not granted although (in industry´s view) all conditions had been fulfilled.

[72] Available at http://ec.europa.eu/health/scientific_committees/consumer_safety/docs/sccs_o_136.pdf (accessed on 21 October 2016).

In case an exemption would not be granted for use of TiO_2 in cosmetic products, a very large number of cosmetic products would be impacted and a very useful, safe ingredient would be lost. Only two minerals UV-filters are on the positive list for use in cosmetics, TiO_2 and ZnO;

- **Consumer perceptions**: if TiO_2 was to be removed from cosmetic formulations, the performance of products might not meet consumers' needs and expectations and may thus lead to loss of business for the affected product categories. If an exemption was granted for the continued use of TiO_2, the communication of such classification to the public (and the presence of TiO_2 in the list of ingredients) would pose the risk of causing unnecessary alarm among consumers who may wish to avoid the use of cosmetic products that contain a carcinogenic substance.

- **Toys**: Carc Cat 2 substances are not permitted to be used in toy cosmetics placed on the EEA market, but possibilities for exemptions exist on the basis of (a) concentration, (b) (in)accessibility of the substance. The SCCS would review the use of the substance and would conclude as to whether it might be appropriate to list it in Appendix A of the Toy Safety Directive (List of CMR substances and their permitted uses). Even if the substance were to be listed, the continued presence of the substance in toys could cause reputational damage to the toy manufacturers and thus they may put pressure on paint manufacturers to reformulate their products to substitute TiO_2; and

- **Setting precedence and an example for action by other jurisdictions**: similar regulatory action in other global regions could follow. This would further impact upon exports of EEA-made cosmetics.

<u>Potential increases in operating costs</u>

There are several implications of a harmonised Carc Cat 2 classification which could increase the manufacturing costs and thus impact the profitability of EEA-based cosmetic manufacturers, including:

- **Cost of reformulation to eliminate TiO_2**: there is currently no guarantee that suitable alternatives for TiO_2 which are technically and economically feasible with the same efficiency can be found. TiO_2 has an excellent safety profile, as recently confirmed by the SCCS for its current cosmetic uses. Other colourants, opacifiers and UV filters may be subject to scrutiny themselves or less preferred by consumer (groups). In addition, these other materials may not be a suitable technical alternative for TiO_2 based on their function and task in the finished product, performance of the finished product and conditions of use. There is currently no guarantee that suitable alternatives which are technically and economically feasible with the same efficiency as TiO_2 can be found.

  Reformulation of cosmetic products to substitute critical ingredients such as TiO_2 cannot simply be a one-to-one replacement and would require full R&D involvement including formulation, packaging and stability assessment and conducting a regulatory and safety assessment. This could be expected to lead to costs in the range of **tens of millions of Euros** spread over the typical lead time for such reformulation programmes (**3-8 years**); and

- **Compliance with waste management regulations**: the following list shows the types of wastes that might become relevant to hazardous waste management regulations in different Member States. The scale of these impacts cannot be quantified due to lack of information

- 07 06 11* Sludges from on-site effluent treatment containing hazardous substances; and
- 15 01 10* Packaging containing residues of or contaminated by hazardous substances (for empty TiO_2 pigment packaging).

Economic impacts on downstream users (industrial and professional)

Impacts on professional users of cosmetic products would depend on whether SCCS (re-)approves the use of TiO_2 in cosmetic formulations. In addition, waste management of waste packaging that contains TiO_2 residues may be classified as hazardous and its handling might need to change.

Social impacts

Employment impacts

A discussion on the overall effects on employment across the EEA cannot be provided due to the lack of specific information. The scale of any impacts would depend on whether the SCCS (re-)approves the continued use of TiO_2 in cosmetic formulations.

Impacts on the welfare of consumers

The Carc Cat 2 harmonised classification for TiO_2 could have notable impacts on consumer choice and welfare if it affected industry's ability (or willingness) to use the product. The following potential impacts should be noted:

- **Loss of certain types of consumer products from the market**: a restriction on the use of TiO_2 would have an impact on the market availability of product variants used by consumers on a daily basis, e.g. skin care products, toothpaste, make-up products (foundation, eye shadow, depilatory products, etc.);

- **Increased cost and loss of technical performance**: replacements for TiO_2, if available, could make products costlier, e.g. due to increased manufacturing costs, increased ingredient costs and higher dosage levels. For example, in sunscreens, TiO_2 can be replaced by ZnO but the two substances are different in terms of efficiency (and ZnO is a substance with an unfavourable ecotoxicity hazard profile). Sunscreens would require increased UV filter dosages thus their formulations would cost more, and would be undesirably whiter on the skin (in comparison to nano-scale TiO_2). Furthermore, alternative pearlescent pigments may not be available;

- **Loss of consumer satisfaction**: without TiO_2 as a whitening pigment, make-up products and other cosmetics would be less efficient and/or appealing for consumers; and

- **Adverse impacts on public health**: an important application of TiO_2 is its use as a UV filter to protect the public from skin cancer following exposure to the sun. Two mineral UV filters are authorised under the Cosmetic Products Regulation: TiO_2 and ZnO. ZnO contributes mainly to UVA protection and has a relatively low performance against UVB radiation whilst TiO_2 provides UVB protection which is a major contributor to high Sun Protection Factor (SPF) products[73].

[73] Commission Recommendation 2006/647/EC notes that UVB radiation is the main contributor to increased cancer risk, although, the risk generated through UVA radiation cannot be neglected. Furthermore, UVA radiation is cause of premature ageing of the skin. Sunscreen products should contain both UVB and UVA

Competitiveness and competition impacts

Impacts on the competitiveness of EEA-based companies

Whilst any restriction on the use of TiO_2 in cosmetic products would apply equally to EEA-made and non-EEA-made cosmetics placed on the EEA market, the EEA cosmetics industry is a major exporting force and the proposed classification would cause increased manufacturing costs and thus loss of competitiveness on the global level.

In case of classification of TiO_2, there would be detrimental competitive effects in all cases. Even if an exemption was granted and the use of TiO_2 was allowed to continue EEA-based cosmetics manufacturers would be disadvantaged because importers who manufacture outside of the EEA area could manufacture their products at a lower cost.

In the longer-term, since many jurisdictions globally follow directly or indirectly the EEA Cosmetic Products Regulation for products placed on their markets, any restriction in the EEA might eventually result in similar action (and thereby loss of business, but also a more level playing field) elsewhere.

Impacts on intra-EEA competition

SMEs might be placed at a greater disadvantage by a TiO_2 classification. Larger EEA-based manufacturers of cosmetic products with a greater capacity to cover the costs of reformulation or capability of moving certain production processes outside of the EEA would be able to reformulate or relocate as they see fit and maintain a better competitive position in comparison to SMEs or companies without an international footprint.

4.4.6 Elastomers

Limited information is available on the use of TiO_2 in rubber products. In general terms, the classification might increase some production costs (worker protection) but the incentive to substitute TiO_2 would be weak, particularly as the rubber industry does not supply formulations to the general public. Where TiO_2 is used as a pigment in non-black/coloured rubber components (General rubber goods (GRG)), it would be difficult to identify a technically equivalent pigment. On the other hand, tyres with white sidewalls containing TiO_2 pigment could be replaced by tyres with black sidewalls without any loss of performance. For other rubber applications where TiO_2 is used as a filler (e.g. in food-contact rubber articles for repeated use) the socio-economic importance of the substance is unclear and thus impacts from its substitution cannot be described.

In terms of waste management, the relevant sub-chapters of the LoW would appear to be *07 02 Wastes from the MFSU of plastics, synthetic rubber and man-made fibres* and *07 07 Wastes from the MFSU of fine chemicals and chemical products not otherwise specified*. Relevant 'mirror entries' could include those relevant to sludges containing hazardous substances (07 02 11*and 07 07 11*), *07 02 14* Wastes from additives containing hazardous substances* and *07 02 16* Wastes containing hazardous silicones*. TiO_2 packaging would also become hazardous waste, depending on the level of residue in it, under entry *15 01 10* Packaging containing residues of or contaminated by hazardous substances*. On the other hand, rubber waste arising from the mechanical treatment of waste (for

protection. An increased sun protection factor (i.e. mainly UVB protection) should include an increase in the UVA protection as well. Therefore, the protection against UVA and UVB radiation should be related.

example sorting, crushing, compacting, pelletising) not otherwise specified (19 12 04) is classified as 'absolute non-hazardous'. No information has been obtained through consultation.

The socio-economic parameters of rubber applications for TiO_2 are not known, although it is understood that the majority of GRG manufacturers are SMEs (>95%).

4.4.7 Pigment and pigment preparation manufacture

Key market descriptors

The key economic parameters of the use of TiO_2 are summarised below.

Importance of the application	TiO_2 finds wide application in the pigments and pigments preparation sector, e.g. for both organic and inorganic pigments (including effect pigments/pearlescent pigments) as constituent and for finishing and coating (VdMi, 2016). Pigments and pigment formulations are the basis of colouring a wide range of products: paints, coatings, plastics, ceramics, rubber, etc. TiO_2 is also used as a raw material for the synthesis of Complex Inorganic Coloured Pigments (CICPs), which are used widely in the ceramic sector and the plastics sector. For CICPs in particular specific market descriptors are available and are presented below. It should be noted that some pigment-related discussion may appear elsewhere in this section (e.g. artists' colours are discussed under inks).
Estimated TiO_2 tonnage used	Data encompassing all pigments are not available. Pigments and preparations are ultimately used in the other applications discussed here and thus are considered under their respective applications.
Estimated tonnage of products that contain TiO_2	As above, all-encompassing data are not available although for CICPs a specific estimate of 11 ktonnes/y is available. The volume of pigments/formulations produced by manufacturers who have provided information to the questionnaire on the potential impacts from the originally proposed Carc Cat 1B harmonised classification is in the range of tens of thousands of tonnes.
Estimated value of markets	The market value of pigments/preparations produced by manufacturers who have provided information to the questionnaire investigating potential impacts from the originally proposed Carc Cat 1B classification is in the range of €50-75 million/y with an additional €35 million/y specifically relating to CICPs. The total annual turnover of this sector is about €8.1 billion (Eurocolour, 2016; VdMi, 2016).
Estimates of Gross Value Added	No data available.
Number of users of TiO_2	Eurocolour is the umbrella association for manufacturers of pigments, dyes and fillers in Europe and, all together, it represents about 100 companies within Europe (Eurocolour, 2016). For CICPs in particular, an estimated 40 TiO_2 users exist in the EEA with a further 30 manufacturers of ceramic decorating/glass colours.

Presence of SMEs	75 % of Eurocolour's members are SMEs (Eurocolour, 2016). Among CICP manufacturers, 50-60% are SMEs, while the share of SMEs among ceramic decorating/glass colours exceeds 80%.
Number of stakeholders that participated in consultation	<10, including the industry associations Eurocolour, VdMi (Germany), and a REACH Consortium but several pigment manufacturers may be included under other applications below.
Locations of stakeholders that participated in consultation	Not provided here due to small number of participants. As regards CICP manufacturers, these are located in Germany, Italy, the Netherlands, Spain and the UK with the most important manufacturers being located in Spain and Italy. Manufacturers of other ceramic pigments can be found in (at least) Belgium, Germany, Italy, the Netherlands, Poland, Portugal and Spain.
Employment in the sector	Eurocolour members have a total of 23,000 employees in Europe. CICP manufacturers have a workforce of 2,000 employees.

Relevant legislation

Table 4–19 summarises the legislation that would be of relevance to the use of TiO_2 in pigments applications in the EEA, after the adoption of a Carc Cat 2 harmonised classification. Additional detail is available in Annex 1. The table distinguishes between the manufacture of pigments and their downstream consumption.

Table 4–19: Relevance of different regulatory instruments and voluntary initiatives to pigments applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation

Relevant legislation	Relevant to pigment manufacture	Relevant to pigment use
CLP	Yes	Yes
Carcinogens and Mutagens at Work	No	No
Waste Framework	Potentially	Potentially
Industrial Emissions	Potentially	Potentially
REACH	No	Article 31 only
Cosmetics	No	Yes
Toy Safety	No	Yes
Food Contact Materials	No	Yes
Food Additives	No	Yes
Medicinal Products	No	Potentially
Construction Products	No	Potentially
Biocides	No	No
Medical devices	No	No
RoHS	No	Potentially
Tobacco additives	No	Potentially

Impacts on the marketing and use of titanium dioxide-containing products

The focus here is on pigment manufacturers. Impacts on downstream users of pigments (e.g. paint manufacturers, plastic masterbatch manufactures, etc.) are examined elsewhere in this document.

Potential loss of markets

A Carc Cat 2 harmonised classification would have the following impacts on the ability of EEA-based pigment manufacturers to use TiO_2:

- **Company policies and process and product requirements**: for some companies the classification of a raw material as a suspected carcinogen could give an incentive to discontinue its use. Also, there are products that have been marketed as alternatives to pigments bearing hazardous properties (e.g. chrome-based pigments) and as such the use of a raw material classified as a suspected carcinogen could make such products unmarketable; and

- **Customer perceptions**: the Carc Cat 2 harmonised classification would result in pigment formulations being similarly classified and being stigmatised irrespective of the risk of exposure. This would disincentivise downstream users from using them as they would also need to take measures for the control of the exposure of their workers to TiO_2. Beyond emotional responses to the presence of a Carc Cat 2 substance, customers may also need to adhere to Restricted Substance Lists, particularly in the case of manufacturing consumer products, and thus would avoid using TiO_2-based pigments to prevent any negative impact on their reputation.

Potential increases in operating costs

There are several implications of a harmonised Carc Cat 2 classification which could increase the manufacturing costs and thus impact the profitability of EEA-based pigment manufacturers, including:

- **Cost of reformulation to substitute TiO_2**: pigment and pigment preparation manufacturers may be able to reformulate their products; however, this would be at the expense of performance, the loss of variety of colour and functionality and at a considerable cost. Some past attempts to implement alternatives have been unsuccessful; for example, alternatives have shown poor brilliance of fluorescent colours. Some manufacturers, however, may be forced to reformulate as their internal policies may prevent them from using a suspected carcinogen, even if its performance cannot be matched by the available alternatives. No alternative for TiO_2 is available for the pearlescent pigments (specific properties mandatory for the expected properties and performance profile). Neither is any alternative available for TiO_2 as a raw material for the synthesis of CICP (VdMi, 2016b).

  Some estimates on the costs of reformulation have been provided and these would clearly depend on the number and variability of the affected products. For instance, for one pigment manufacturer, the cost would be ca. €200 per formulation and considering the number of formulations affected (more than 20,000 formulations for synthetic resins and plastics), the total cost could exceed **€4 million**. Another manufacturer expects a reformulation cost in the range of **€50,000-100,000**. These costs would consume funds intended for other planned R&D and for supporting regulatory-driven initiatives aimed at reducing or eliminating other molecules with well-characterised and more widespread risks.

  As detailed in Annex 2, known alternatives are much less efficient and thus would require higher loadings to achieve the necessary opacity with negative impacts on cost, technical quality and effectiveness, and ultimately the competitiveness, of the product;

- **Compliance with waste management regulations**: as previously discussed, TiO_2 packaging that contains residues at a level above 1.0% would be classified as hazardous. Some information on wastes generated during the manufacture of pigments is shown in the table below based on a small number of questionnaire responses. It would appear that significant volumes of waste pigment could be classified as hazardous following the classification of TiO_2 as Carc Cat 2 (grey entry in the table). Filter waste has also been identified as a relevant waste type although the waste code obtained from consultation is doubtful (it is assumed that the correct one most likely is *15 02 03 absorbents, filter materials, wiping cloths and protective clothing other than those mentioned in 15 02 02* which would change to its 'mirror' entry *15 02 02* absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by hazardous substances* following the introduction of the Carc Cat 2 harmonised classification for TiO_2. Specific information on the associated costs is not available but it is certain that costs of administration, handling, labelling and disposal would increase; and

Table 4–20: Relevant waste streams for the use of TiO_2 in pigments manufacture

Process generating waste	Type of waste	Waste entry in LoW	Typical TiO_2 content	Example volume generated*	Is TiO_2 inhalable?	Current waste management
Manufacture of pigment preparations	Pigment waste	**16 03 04** Inorganic wastes other than those mentioned in 16 03 03 ('*mirror non-hazardous*')	From <1% to >>1%	400 t/y	Yes	Non-hazardous **Landfilling**
	Air extraction filter waste	**08 02 01** Waste coating powders ('*absolute non-hazardous*')	>1%	20 t/y	Yes	Non-hazardous

* data based on individual responses to questionnaire

- **Increased administrative burden**: if a Carc Cat 2 substance is present in a mixture at a concentration ≥0.1% then a SDS must be available upon request (as per Note 1 under Table 3.6.2 of the CLP Regulation). Manufacturers of these products may need to supply or receive an increased number of requests for SDS.

Social impacts

Employment impacts

Quantified estimates across the pigment manufacturing industry cannot be provided due to the relatively small number of companies that have contributed information by means of a completed questionnaire. However, among those companies that have responded and on the assumption that a Carc Cat 1B harmonised classification might be introduced, estimates of potential job losses ranged between zero and 25% of their workforce. Any job losses under a less severe Carc Cat 2 harmonised classification would arguably be more modest.

Impacts on the welfare of consumers

Pigments and pigment preparations are generally not sold to consumers (with some exceptions, such as artists' colours and the like which are considered in Section 4.3.4). Impacts may arise in relation to the use of consumer products that contain TiO_2-based pigments but these are discussed under the other sector-specific applications presented elsewhere in this report.

Competitiveness and competition impacts

Impacts on the competitiveness of EEA-based companies

EEA-based pigment manufacturers (and their customers) would see their products (a) perform worse, and (b) cost more to manufacture, if reformulated to eliminate TiO_2. The majority of products are tailor-made, are developed for specific applications and are approved by customers. New formulations would not hold approvals and would need to be tested and qualified by customers. This would require time and be costly. Exports of EEA-made pigments would become less competitive as non-EEA manufacturers supplying non-EEA markets would not need to declare or be restricted by their continued use of TiO_2.

If processed TiO_2 (e.g. masterbatches in which TiO_2 is inaccessible inside the plastic matrix) were freely imported, the European downstream users (e.g. producer of masterbatches, pigment preparations) would be confronted with a competitive disadvantage in the home market as well.

Under these circumstances the production of intermediates with TiO_2 contents above 1.0% by weight as well as the manufacture of finished products outside the EEA might become more appealing.

Impacts on intra-EEA competition

Within the EEA, SMEs would likely be disadvantaged vis-à-vis their larger counterparts because of limited capabilities (R&D, marketing, equipment) in order to protect their workers and formulate feasible alternatives. Large companies with wide ranges of products would be better placed to cope with a loss of TiO_2-containing products compared to smaller businesses which concentrate on a smaller product portfolio.

4.4.8 Ceramics

Key market descriptors

The key economic parameters of the use of TiO_2 are summarised below.

Importance of the application	TiO_2 finds wide application in the ceramics sector at different levels of the supply chain: 1. As a raw material used upstream from the manufacturer of the ceramic product, such as: – Raw material in the manufacture of CICPs which find ceramic applications (e.g. tiles); – Pigment in formulations for ceramic products (tiles, bricks), including specialist pigment (TiO_2 used as an additive for the development of yellow colour in digital tile printing); and

– Opacifier in frits[74], glazes (that contain frits) and enamels – enamels can find industrial uses but also consumer uses (e.g. tableware);

2. As a raw material for the manufacturer of glazes that are used as photocatalytic coatings on construction products (e.g. certain ceramic wall tiles or roof tiles, some sanitaryware, and R&D in tableware); and

3. As an impurity in essential raw materials used by ceramics manufacturers. Examples include:
   – TiO_2 is present in natural clays used in nearly every "classic" ceramic product (or body preparation), such as ceramic tiles, sanitaryware and tableware;
   – Roof tiles and bricks;
   – Refractory products; and
   – Abrasive products (NB. these also include non-ceramic products).

Estimated TiO_2 tonnage used

Low – less than 1% of total consumption. In the enamel industry, ca. 1,000 t/y are used (Cerame-Unie, 2016).

Estimated tonnage of products that contain TiO_2

Application	EEA production
Frits and related TiO_2 mixtures	230 ktonnes/y
General ceramics products (tiles, bricks, sanitaryware, tableware)	Unknown

Estimated value of markets

Application	EEA market value
Frits and related TiO_2 mixtures	€130 million/y
European ceramic tiles and porcelain enamel manufacturing sector (based on Cerame-Unie data)	€9 billion/y

Estimates of Gross Value Added

GVA data are unavailable.

The European ceramic tiles and porcelain enamel manufacturing sector in Europe has a turnover of around €9 billion and ca. $^{1}/_{3}$ of it is associated with the Spanish ceramic tiles manufacturing sector.

74 Frits are ceramic compositions that have been fused in a special fusing oven, quenched to form a glass, and granulated. Frits form an important part of the batches used in compounding enamels and ceramic glazes. TiO2 is added to frits for opacity and to achieve the intended mechanical resistance of the glazed article.

Number of users of TiO_2	<table><tr><th>Application</th><th>Number of TiO_2 users</th></tr><tr><td>Frits</td><td>34 companies plus affiliates</td></tr><tr><td>Enamel products (companies using enamel coatings on cookware, hot water tanks, silos, ovens, cooktops, architecture, etc.)</td><td>100-150 companies</td></tr><tr><td>Tiles and brick manufacturers (Cerame-Unie members)</td><td>>700</td></tr></table> The ceramics industry as a whole encompasses about 2,000 companies.
Presence of SMEs	<table><tr><th>Application</th><th>SME presence</th></tr><tr><td>Frits</td><td>Large majority</td></tr><tr><td>Enamel products</td><td>80%</td></tr><tr><td>White flatware, hollowware and cookware</td><td>Large majority</td></tr><tr><td>Ceramics industry in general</td><td>80%</td></tr><tr><td colspan="2">NB. Spain's ceramic tile manufacturers: 75%</td></tr></table>
Number of stakeholders that participated in consultation	10-25, including two industry associations and a REACH Consortium.
Locations of stakeholders that participated in consultation	<table><tr><th>Application</th><th>Locations</th></tr><tr><td>Frits</td><td>Belgium, Czech Republic, France Germany, Italy, the Netherlands, Spain, the UK. Most important manufacturers are located in Spain, Italy and Germany. More than 80% of frits and related mixtures are produced in Spain</td></tr><tr><td>Tableware</td><td>Very many small manufacturers can be found on Mediterranean islands (Malta, Majorca)</td></tr></table>
Employment in the sector	<table><tr><th>Application</th><th>Number of workers</th></tr><tr><td>Frits</td><td>3,200</td></tr><tr><td>European sector of ceramic tiles and porcelain enamel</td><td>45,000</td></tr><tr><td>European ceramics industry in general (Cerame-Unie members)</td><td>200,000</td></tr><tr><td colspan="2">Note: the Spanish sector of frits, inorganic pigments and preparations employs more than 3,500 workers, with the majority involved in frits manufacture. The number of workers in tile manufacture in Spain is 15,000</td></tr></table>

Relevant legislation

Table 4–21 summarises the legislation that would be of relevance to the use of TiO_2 in ceramics applications in the EEA, after the adoption of a Carc Cat 2 harmonised classification. Additional detail is available in Annex 1.

Table 4–21: Relevance of different regulatory instruments and voluntary initiatives to ceramics (frits, enamels, tiles, consumer ceramics) applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation	
Relevant legislation	**Relevant to ceramics**
CLP	Yes
Carcinogens and Mutagens at Work	No
Waste Framework	Potentially
Industrial Emissions	Potentially
REACH	No
Cosmetics	No
Toy Safety	No
Food Contact Materials	Yes
Food Additives	No
Medicinal Products	No
Construction Products	Potentially
Biocides	No
Medical devices	No
RoHS	Potentially
Tobacco additives	No

Impacts on the marketing and use of titanium dioxide-containing products

Economic impacts for manufacturers of ceramics

Potential loss of markets

Impacts on the ability of the ceramics industry to use TiO_2 and TiO_2-containing materials from a Carc Cat 2 harmonised classification can be summarised as follows:

- **TiO_2 impurities in raw materials**: a Carc Cat 2 harmonised classification would not cause particular concerns over TiO_2 impurities in key raw materials, as its presence is generally at levels below 1.0%. This would not be the case with a Carc Cat 1B classification because minerals such as kaolin, ball clays, vermiculite, refractory materials and zircon which contain TiO_2 impurities above 0.1% wt. are raw materials relevant to the ceramics industry[75];

- **Market and consumer perceptions**: due to the presence of TiO_2 as an impurity in key raw materials, nearly every "classic" ceramic product (or body preparation) such as tableware, sanitaryware, tiles, bricks, roof tiles, clay pipes, etc. contains a certain (low) amount of TiO_2. Theoretically, some market losses could be expected on account of the customers' and end consumers' reaction to the presence of a suspected carcinogen in ceramic products; this could

[75] The main European trade association, Cerame-Unie, had undertaken an in-depth analysis of the issue of TiO_2 impurities. If one considers the classic composition used for the production of porcelain stoneware, comprising up to 18% of china clay (kaolin) and 32% of plastic clay with a relative content of TiO_2 impurities of 0.3% and 0.5%[75] which leads to a total amount of TiO_2 in the final product of 0.21%. Considering all the other raw materials used such as feldspar, quartz and talc, it can be estimated that the total TiO_2 content ranges between 0.163% - 0.375%, i.e. above 0.1% (Cerame-Unie, 2017).

make them reluctant to use mixtures and articles that contain TiO_2, even if firmly contained within a ceramic matrix. In applications where ceramic and enamelled articles frequently come into contact with the consumer, the presence of a suspected carcinogen could become difficult to defend; and

- **Regulatory requirements**: as far as food contact materials and articles are concerned, Section 4.4.3 has discussed the implications of the existing harmonised and non-harmonised EEA and national legislation on the use/presence of carcinogenic substances in food contact materials. The proposed classification for TiO_2 could have adverse effects on the marketing of ceramic and enamelled articles that are used for food contact.

<u>Potential increases in operating costs</u>

There are several implications of a harmonised Carc Cat 2 classification which could increase the manufacturing costs and thus impact the profitability of EEA-based fibre manufacturers, including:

- **Cost of reformulation to eliminate TiO_2**: possibilities for reformulation are non-existent for good reasons:
  - TiO_2 is an impurity in the main raw materials used by ceramics manufacturers; and
  - Where used intentionally, TiO_2 is an indispensable component of frits and thereafter the glazes and enamels manufactured. It is important to note the close links of these applications to the manufacture of inorganic pigments which are used in the pigmentation of ceramic structures; and

- **Compliance with waste management regulations**: no information has been collected from consultation. In general, the harmonised classification could increase the cost of waste management for ceramics manufacturers as some types of waste generated during the manufacturing phase might be classified as hazardous. Some potentially relevant waste types include:
  - 10 12 11* Wastes from glazing containing heavy metals; and
  - 15 01 10* packaging containing residues of or contaminated by hazardous substances (for empty TiO_2 packaging).

  However, given that raw materials typical contain TiO_2 impurities in concentrations below 1.0% by weight, waste management implications would likely be limited.

Economic impacts for downstream users of ceramics

The above discussion on impacts covers adequately the entirety of the supply chain for ceramics with the exception of consumers (discussed further below).

Social impacts

Employment impacts

It is not possible to provide a specific estimate on job losses. The number of jobs could be at risk as a result of lost competitiveness would be notably lower than for a Carc Cat 1B classification.

Impacts on the welfare of consumers

Although in principle use of TiO_2 would be allowed to continue in the EEA, the proposed classification would make the use of the substance costlier in the EEA. From a more theoretical perspective, complete loss of TiO_2-containing ceramic products from the consumer market could have adverse consequences:

- The available range of colours would diminish. TiO_2 allows tile manufacturers to transform the clay body into a white colour. This either allows the product to be white or means that it can be other light colours (white, yellow, metallic, grey, etc.). Alternative pigments cannot achieve the same colouring; ceramic tiles coloured with orange pigments and with a characteristic brown tonality would disappear; and

- The range of available tile products would be affected. Certain roof tiles/bricks could no longer be produced. It would no longer be possible to manufacture enamelled hot water tanks/boilers (N.B. ca. 90% of all hot water tanks used in Europe are enamelled hot water tanks). Without TiO_2-containing enamels, it would no longer be possible to manufacture enamelled cookware or enamelled steel/cast iron sanitary ware. Replacement of enamelled hot water tanks with stainless steel ones would not be affordable.

Competitiveness impacts

Based on available information, impacts on the competitiveness of EEA-based operators would likely be limited as the increases to manufacturing costs are expected to be modest. In addition, in comparison to a Carc Cat 1B classification the incentives for relocation of production would be far less strong.

4.4.9 Glass

Key market descriptors

The key economic parameters for the use of TiO_2 are summarised below.

Estimated TiO_2 tonnage used	Low - less than 1% of total.
Estimated tonnage of products that contain TiO_2	No data specific to TiO_2. More generally, in 2016, the EU-28 glass production reached a volume of 34.5 million tonnes of which 956,000 tonnes were special glass[76].
Estimated value of markets	No data.
Estimates of Gross Value Added	No data.
Number of users of TiO_2	70 (special glass); 1,200 glass manufacturers across the EU[77].

[76] Information available at: http://www.glassallianceeurope.eu/images/cont/panorama-2016-eu28_file.pdf (accessed on 29 August 2017).

[77] Information available at: http://www.glassallianceeurope.eu/images/cont/gae-leaflet-may-2012_1_file.pdf (accessed on 20 October 2016).

Presence of SMEs	10% (special glass).
Number of stakeholders that participated in consultation	<5.
Locations of stakeholders that participated in consultation	Brussels (but with members from Austria, Bulgaria, France, Germany and the UK using TiO_2 or TiO_2-based products).
Employment in the sector	No data specific to TiO_2 use. More generally, the EU-28 glass industry employs about 185,000 people (incl. processors)[78].

Relevant legislation

Table 4–22 summarises the legislation that would be of relevance to the use of TiO_2 in glass applications in the EEA, after the adoption of a Carc Cat 2 harmonised classification. Additional detail is available in Annex 1.

Table 4–22: Relevance of different regulatory instruments and voluntary initiatives to glass applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation

Relevant legislation	Relevant to glass
CLP	Yes
Carcinogens and Mutagens at Work	No
Waste Framework	Potentially
Industrial Emissions	Potentially
REACH	No
Cosmetics	No
Toy Safety	No
Food Contact Materials	Yes
Food Additives	No
Medicinal Products	No
Construction Products	No
Biocides	No
Medical devices	No
RoHS	Potentially
Tobacco additives	No

Impacts on the marketing and use of titanium dioxide-containing products

Due to the absence of regulation that directly affects the use of Carc Cat 2 substances in the manufacture of glass products, adverse impacts from the harmonised classification of TiO_2 would be low and probably limited to a potential tightening of occupational exposure measures. Glass articles do not contain TiO_2 per se; as such no adverse reaction of consumers might be expected. Such impacts are not possible to define with any degree of accuracy.

Similarly, due to the absence of TiO_2 in glass articles, the Carc Cat 2 harmonised classification would not have implications for the management of waste glass, but might affect waste generated during glass manufacture, for example wastes falling under the following LoW entries:

[78] Information available at: http://www.glassallianceeurope.eu/en/industries (accessed on 20 October 2016).

- 10 11 09* Waste preparation mixture before thermal processing, containing hazardous substances;
- 10 11 15* Solid wastes from flue-gas treatment containing hazardous substances;
- 10 11 17* Sludges and filter cakes from flue-gas treatment containing hazardous substances;
- 10 11 19* Solid wastes from on-site effluent treatment containing hazardous substances; and
- 15 01 10* Packaging containing residues of or contaminated by hazardous substances.

Reformulation to eliminate or reduce TiO_2 presence would not be possible in glass products if the same properties are required. TiO_2 is not substitutable as a raw material, be it for glass manufacture or decoration, because its use is essential to achieve a certain optical quality/property of the glass which cannot be achieved otherwise. If a suitable substitute could be found (this is very unlikely), the reformulation would be associated with costs far higher than the compliance costs. Furthermore, even if an alternative to TiO_2 use could be found, the formulation change may for instance result in damage to the mould or require larger tubes. In other words, substitution would not only be a matter of a new composition.

Social impacts

Employment impacts

No estimates can be provided.

Impacts on the welfare of consumers

TiO_2-based glass offers significant health benefits – medical/public health protection, drug safety (inertness of medical drug containers), eye protection and visual correction, high end medical applications that save lives. However, if manufacture of these products in the EEA would be affected as a result of the repercussions of the Carc Cat 2 harmonised classification for TiO_2, they would be imported as finished articles from outside the EEA and consequently consumers would still have access to them.

If consumers still wished to buy EEA-made products which did not contain TiO_2, they would be forced to buy:

- Less effective optical products (thicker, less clear);
- Products which are less resistant to abrasion and hardness on the surface; and
- Products with spectral characteristics that would not meet the requirements of current regulations, in particular in the pharmaceutical sector, where protection of medicinal products from UV radiation would be worse.

Competitiveness and competition impacts

Manufacturing costs for EEA-based glass manufacturers could somewhat increase as a result of the Carc Cat 2 harmonised classification for TiO_2 but loss of competitiveness vis-à-vis their non-EEA counterparts would likely be limited.

4.4.10 Medical devices

Key market descriptors

Information available is limited to dental restoration products. The Federation of the European Dental Industry (FIDE) represents nearly 600 companies located in Austria, Belgium, Denmark, France, Italy, Luxembourg, the Netherlands, Spain and the UK. Among them, Germany, Italy, the UK, France and Spain are the most important locations for manufacturers of dental restoration products that contain TiO_2. Many companies (85 %) of the dental industry in Europe are SMEs.

The volumes of TiO_2-based products manufactured range from a few hundred kilograms to 100 tonnes per company per year.

In addition, most devices contain small amounts of TiO_2 as pigment in plastic parts, as discussed above.

Relevant legislation

Table 4–23 summarises the legislation that would be of relevance to the use of TiO_2 in medical device applications in the EEA, after the adoption of a Carc Cat 2 harmonised classification. Additional detail is available in Annex 1.

Table 4–23: Relevance of different regulatory instruments and voluntary initiatives to medical devices (dental restoration materials) applications of TiO_2 following a harmonised classification of Carc Cat 2 by inhalation

Relevant legislation	Relevant to medical devices
CLP	Only in receiving and handling raw materials
Carcinogens and Mutagens at Work	No
Waste Framework	Potentially
Industrial Emissions	Potentially
REACH	Potentially
Cosmetics	No
Toy Safety	No
Food Contact Materials	No
Food Additives	No
Medicinal Products	No
Construction Products	No
Biocides	No
Medical devices	No
RoHS	Potentially
Tobacco additives	No

Impacts on the marketing and use of titanium dioxide-containing products

Economic impacts for manufacturers of medical devices

Potential loss of markets

A Carc Cat 2 harmonised classification would have the following impacts on the ability of EEA-based medical devices manufacturers to use TiO_2 and place on the market TiO_2-containing devices:

- **Restrictions under the new Medical Devices Regulation**: as opposed to CMR Cat 1A and 1B substances, the new Medical Devices Regulation (EU) 2017/745 does not include any concentration limit or labelling requirement for devices containing a Carc Cat 2 substance. As such, the Regulation would not restrict the use of TiO_2;

- **Patient perceptions and market pressures**: without labelling, the average patient would not become immediately aware of the presence of TiO_2 in the medical devices needed for his or her treatment. As such, it would be unlikely that negative perceptions might develop. However, consumers might become aware of the new hazard classification of the substance and potentially through information campaigns by NGOs, the presence of TiO_2 in medical devices might become more widely known. This could lead to negative perceptions among members of the public.

In addition, medical devices are not excluded from the requirements of the REACH Regulation. Substances and mixtures which are used in medical devices are comprehensively under an obligation to be registered and approved as appropriate. Medical devices are only exempted from REACH Title IV (Information in the Supply Chain) if they are used invasively or used in direct physical contact with the human body. This means that medical devices, such as dental fillings, that are introduced directly into the tooth by the dentist are exempted from REACH Title IV; however, Title IV would apply if the medical device is processed by a dental technician before application on the patient. This implies a lot of work without additional benefit for the patients (German Medicines Manufacturers Association, 2016) and could potentially lead to reluctance to use TiO_2-containing materials.

<u>Potential increases in operating costs</u>

Cost of substitution of TiO_2: although the Medical Devices Regulation would not require or instigate the substitution of TiO_2 from medical devices, the Carc Cat 2 harmonised classification would encourage manufacturers of devices to seek alternatives. Whilst information for a variety of devices containing TiO_2 is not available, by way of example, substitution of TiO_2 in dental restoration products is discussed here.

In the field of dental restoration products, the replacement of TiO_2 by another white pigment is not feasible, because alternatives either do not achieve the same shading effect or must be used in much higher concentrations, which could affect the performance of the product or result in undesired toxicological effects compromising the biocompatibility of the products (German Medicines Manufacturers Association, 2016). Some alternative white pigments are hazardous (e.g. ZnO in respect of the aquatic environment) or show similar inhalation hazards as TiO_2, based on their particle size.

Due to their poor refractive indices, the loading of the alternatives would probably increase by a factor of 10-100 in comparison to TiO_2. This would consequently mean the use of a lower polymer loading. This change to the formulation would lead to significant changes to the physical properties of the materials to the extent that they would no longer meet the existing requirements.

In practice, without TiO_2, the aesthetic restorative treatment would no longer be feasible in Europe because TiO_2 is an essential basic element for the colour scheme and the adjustment of translucency and opacity of the materials. The result would be that essential materials could no longer be produced. This would result in the complete re-development of many products involving significant effort:

- Performance and aesthetics of products would need to be maintained and verified. TiO_2 safeguards the stability and hygienic properties of the products and for dental impression materials helps make the impressions scannable (e.g. allows the easy scanning of impressions in the digital workflow for producing indirect restorations);
- Handling properties (usability of products) would have to be demonstrated;
- The shelf-life of products would need to be verified (this step alone can take several years);

- Possibly, biological re-evaluations would be needed including animal testing according to ISO 10993-series[79] and ISO 7405[80]; and

- Possibly clinical evaluations (including clinical studies) would be needed. These re-evaluations would be needed to verify the fulfilment of essential requirements of the Medical Devices Directive to prepare a new declaration of conformity (EC marking).

Only after all these activities could reformulated products be brought onto the market to replace the existing product portfolio in the EEA. As there are many products that would be affected, the aforementioned activities would take years and be accompanied by significant costs for each product. Finally, the replacement of TiO_2 would require re-registrations in some non-EEA countries which could take additional years and lead to additional high costs.

Overall, substitution of TiO_2 in dental impression materials, particularly in the absence of direct regulatory pressure towards it, would not be a feasible proposition.

Compliance with waste management regulations: waste management legislation would appear to have limited impact. The only 'mirror' entries that are of relevance to the provision of healthcare to humans are *18 01 06** and *18 02 05* Chemicals consisting of or containing hazardous substances*, in addition to TiO_2 packaging that might be classified as hazardous waste. For dental care, waste such as amalgam is already classified as 'absolute hazardous'.

Social impacts

Employment impacts

Given the limited envisaged effects, no discernible effect on employment in the EEA can be envisaged following the introduction of the Carc Cat 2 harmonised classification for TiO_2.

Impacts on the welfare of consumers (patients)

Following from the above, the Carc Cat 2 harmonised classification would neither confer any improvement to the protection of consumer (patient) health nor provide sufficient incentive for substitution of TiO_2 in medical devices. Its continued use, however, could cause confusion and uncertainty among patients and might lead to a refusal of products containing TiO_2.

Competitiveness and competition impacts

Due to the absence of discernible adverse impacts on the current users of TiO_2, issues of competitiveness and competition would be of limited relevance. However, any attempt to substitute TiO_2 by EEA-based companies could generate significant administrative burden and costs and would impact upon their competitiveness.

4.4.11 Detergents

As noted in Section 3.4.17, TiO_2 is present in certain detergent products at levels below 1% (with the vast majority being <0.1%). As such a Carc Cat 2 harmonised classification would have a limited

79 Standard on the biological evaluation of medical devices.

80 Standard on the evaluation of biocompatibility of medical devices used in dentistry.

impact on the manufacture and marketing of detergent products. However, it cannot be precluded that some adverse publicity over the presence of a suspected carcinogen in consumer products might ensue. This might provide an incentive towards substituting the substance on some detergent formulations. It should be noted however that finding alternative pigments might not be technically feasible.

Similarly, waste management implications are unlikely to arise. In a single questionnaire response received, the presence of TiO_2 in waste from the manufacture of solid rim blocks is discussed. Due to its presence in concentrations below 1.0%, the Carc Cat 2 harmonised classification would not impact upon the disposal of associated waste.

Consequently, impacts on consumers (e.g. product availability and performance) or on the competitiveness of the EEA industry would likely be limited.

4.4.12 Biocides

JMAC Composite is the reaction mass of TiO_2 and silver chloride and is a preservative active with antimicrobial properties that reduces the spread of bacteria over the long term. It is claimed to have low toxicity, non-sensitising performance and very low environmental impact. JMAC meets EU Ecolabel standards for use in paints and coatings (Clariant, 2016).

Manufacturers of paints and coatings benefit from easy and economical formulation. The JMAC biocides are effective at very small ppm addition levels and offer low viscosity liquid dispersion. Safe handling is assured through the non-flammable and non-corrosive nature of JMAC (Clariant, 2016).

For in-can preservation, the excellent thermal and pH stability of JMAC biocides means they can be used in a wide range of industrial applications, such as polymer emulsions, paints, sealants and adhesives (Clariant, 2016). The product supports sustainable consumption of consumer products.

The Biocidal Products Regulation does not restrict the use of Carc Cat 2 substance. Therefore, overall impacts on this sector from the harmonised classification would be very limited with the exception of:

- Market losses arising in relation to ecolabelling schemes (TiO_2-containing paints could not qualify for any known ecolabel); and

- Cost increases associated with waste management requirements ('mirror' entries in the LoW relating to chemical manufacture and waste packaging for TiO_2) and, potentially, though the introduction of stricter controls on occupational exposure to TiO_2.

4.5 Summary of impacts on downstream uses of titanium dioxide

4.5.1 Key market metrics for downstream industry sectors and estimate of overall downstream sector impacts

Table 4–24 summarises the key market metrics presented above for the different applications of TiO_2. As shown in the table, whilst for the major applications of TiO_2 detailed information is available, for the majority of minor applications, information is incomplete or non-existent.

Table 4–24: Summary of key metrics of markets for the different applications of TiO_2

Application area	Potentially affected turnover	GVA	Number of companies	Share of SMEs	Number of workers	Downstream markets
Paints & coatings	Arch: €6.2 billion/y Ind: €8.2 billion/y Constr: €0.55 billion/y	€5 billion	800	85%	110,000	Value: €750 billion Workers: 1,000,000 (incl. 30,000 in DIY retail)
Plastics	€270 billion	€118.4 billion	55,000	>>50%	1,500,000	Value: €650 billion Workers: 4,500,000
Paper and wallcoverings	>€1.7 billion Total sector: €75 billion	>€0.34 billion	Wallcoverings: 54 CEPI members: 515	>>50% (not for laminates)	Total sector: 208,000	Value: €4.9 billion Workers: 1,051,700
Inks	>€3.3 billion	Included in paints & coatings	>150	>85%	Included in paints above	Value: €200 billion Workers: >50,000
Construction products	Included in paints & coatings	No data	Adhesives & sealants: 450	>>50%	Adhesives & sealants: 41,000	No data
Fibres	€7.5-10 billion	No data	42	>50%	20,000	Could be included in plastics above
Catalysts	No data					
Food, feed and packaging	No data	No data	No data	No data	No data	No data
Pharmaceuticals	Total sector: €192 billion	No data	Total sector: 1,900	No data	Total sector: 725,000	No data
Cosmetics	Total sector: €77 billion	Total sector: €8 billion	Ingredients: 100 Cosmetic products: 5,000 Distribution: 120,800	92%	Total sector: 152,000	GVA: €21 billion Workers: 1,600,000
Elastomers	No data					
Pigments	TiO_2-specific: Unknown Total sector: €8.1 billion	No data	100	75%	23,000	
Ceramics	€174 million Total ceramics and enamel: €3 billion	No data	>200 Total sector: 2,000	>80%	>50,000	No data
Glass	No data	No data	70 Total sector: 1,200	10%	Total sector: 185,000 (incl. processors)	No data
Medical devices	No data					
Detergents						
Biocides						

More widely, the extent to which the additional regulatory burden, supply chain and consumer perceptions and wider market dynamics would affect the use of TiO_2 and the marketing of products that rely on/contain TiO_2 cannot be defined with accuracy.

There are also several cost elements that would arise on which limited reliable information is currently available across the range of TiO_2's applications, for instance:

- **Role of user and consumer perceptions**: the classification of a key raw material like TiO_2 as a suspected carcinogen will unavoidably change perceptions of safety among the users of the substance. Most crucially, many formulations and articles that contain significant concentrations of TiO_2 are placed on the consumer market and in the case of formulations will be accompanied by labels that include alarming pictograms and hazard statements. Moreover, products that contain the substance may be ingested (food, pharmaceuticals, nutraceuticals), may come in contact with food (food contact materials) or come in contact with (textiles) or be applied to the skin (cosmetics). Irrespective of the harmonised classification being specific to the inhalation route and the lack of/very low inhalation exposure probabilities, consumers would certainly develop very negative perceptions over the safety of all these products. However, it is difficult to estimate with certainty how this would translate into market losses, product withdrawals, reformulation attempts and costs;

- **Probabilities of securing exemptions**: exemptions from restrictions could be obtained for the uses of TiO_2 in toys and cosmetics. In addition, the review of existing approvals in the field of food additives and pharmaceuticals might confirm the substance as being safe. This, whilst some impacts might initially appear severe, mitigating action might be taken to moderate them;

- **Changes to the cost of disposal of TiO_2-containing waste**: this report explains the types of TiO_2-containing wastes that are generated during the downstream uses of the substance and which might be classified as hazardous. Yet, the information available is limited, mostly qualitative and cannot be extrapolated to cover entire industry sectors. It is worth noting however an important statistic from Cefic which suggests that classification of a waste as hazardous increases the cost of its management by a factor of 2-3; and

- **The cost of reformulation of products that contain TiO_2**: in some cases, some estimates have been provided for different applications, but the cost in each sector and across sectors cannot be estimated as the need for reformulation may vary across sectors and would depend on whether certain exemptions can be secured or not (in toys, cosmetics, foods, pharmaceuticals). In addition, in some cases, for example pharmaceuticals, reformulation would also result in applications for variations to existing marketing authorisations. These could be accompanied by a substantial cost which cannot be estimated at present;

Overall, there is significant uncertainty over the monetised scale of the impacts arising among downstream users of TiO_2 from a Carc Cat 2 harmonised classification. However, this cannot prevent us from reaching some clear, general conclusions:

- The value of markets that could be affected would be very large. The combined estimated value of paints, coatings, construction products, inks, plastics, fibres and wallcoverings that contain TiO_2 exceeds €300 billion. The value of downstream markets is a multiple of this. For paints and coatings for instance, it can be estimated that downstream markets could be 50 times larger in value;

- The number of companies affected could be very large and most of them would be SMEs. For instance, this report documents the existence of 800 paint and ink manufacturers, 55,000 plastic converters, 55 wallcovering manufacturers, 5,000 cosmetics manufacturers. Further downstream, distributors, formulators and users amount to hundreds of thousands of companies;

- The number of workers whose employment might be affected is also large. Information available for paints, coatings, construction products, plastics, wallcoverings, pigments, fibres and cosmetics suggest an overall employment of over 2 million workers involved in the manufacturing of formulations and articles that contain TiO_2. Further downstream, the number of workers handling and using these formulations and articles becomes considerably larger: an estimated 1 million workers might use TiO_2-containing paints and coatings and 4.5 million workers are using plastics containing TiO_2;

- Consumer uses would be particularly affected with potential impacts arising for toys, cosmetics, food, food contact materials, pharmaceuticals as well as ecolabelled products (mostly paints and inks). If consumers opted to avoid using DIY products, the cost of renovation and maintenance of properties would significantly increase. The presence of a suspected carcinogen in a multitude of products found in homes, offices, shops, vehicles, food and its packaging, pharmaceuticals, cosmetics, medical devices, toys, magazines, detergents etc. could cause significant market upset, changes in aesthetics, increased costs and ultimately a great source of confusion and concern over exposure to TiO_2 (which in most cases is minimal or non-existent); and

- Industrial processes that involve TiO_2 would become costlier in the EEA because of an increase in waste management costs (and possible loss of recycling opportunities). Unilaterally classifying a substance as ubiquitous as TiO_2 as a suspected carcinogen would undermine the competitiveness of the EEA industry.

4.5.2 Estimation of the impacts on EEA-based demand for titanium dioxide

It was shown above that quantification of impacts on users of TiO_2 is not possible with a minimum degree of accuracy based on available information. However, a qualitative assessment of such downstream impacts could assist us in estimating the likely loss of demand for TiO_2 in the EEA. The discussion that follows summarises the driving forces behind impacts on the downstream uses of the substance and how these translate into decreases in demand for TiO_2.

Impacts on consumer markets from the proposed hazard classification

Impacts on the consumer markets are shown in **Table 4–25** and would be defined by:

- **Restrictions under EU-wide sectoral legislation and potential for securing exemptions and derogations**: the proposed classification could cause the removal from the market of several products intended for use by consumers as a result of specific (sectoral) legislation on cosmetics and toys, or through the re-evaluation of authorised uses in fields such as food, food contact materials and pharmaceuticals. In some cases, industry might be in a position to secure a derogation or exemption. It may be assumed that in some cases (food and pharmaceuticals) the absence of approved alternatives and of any/significant inhalation exposure might favour continued use. In other cases (cosmetics), securing an exemption might be more challenging (but less burdensome than under a Carc Cat 1B hazard classification);

Table 4–25: Projected TiO_2 supply market losses following the implementation of a Carc Cat 2 harmonised classification for TiO_2													
				Market loss			Cost increases					Key impact drivers		
Application area	% of total EEA TiO_2 demand*	Share of consumer use in each application area	Formulations (F) or articles (A)	Regulation-driven restrictions	User and consumer perceptions	Loss of competitiveness	Product labelling	Hazardous waste management	Reformulation costs	Economies of scale	Administrative burden	Market losses	Cost increases	Overall impact
Paints & coatings	53% in total 36%: architectural 17%: industrial	56% of architectural**, i.e. 20% of total demand	F	✓	✓	✓	✓	✓	✓	✓	✓	Alarming labelling of consumer products Loss of ecolabels No use in toys 80-90% of DIY paints potentially affected*** Potential FCM impacts	Costly and technically infeasible reformulation Waste management Loss of economies of scale	**Significant impact** <u>Market loss assumptions</u>: Consumer losses: 25% Ind/prof losses: 10%
Plastics	25%	60-70%, i.e. 15-18% of total demand	A		✓	✓		✓	✓	✓		Consumer and user perceptions (but no labelling) over the safety of packaging of cosmetics, personal care products, food, pharmaceuticals Possible impacts on recycling of post-consumer waste	Costly and technically infeasible reformulation Waste management (recycling issues)	**Moderate impact** <u>Market loss assumptions</u>: Consumer losses: 10% Ind/prof losses: 5%
Paper and wallcoverings	12%	Ultimately, 100% Wallcoverings: 80%	A	✓	✓	✓		✓	✓			Consumer and user perceptions (but no labelling) re: wallpaper, flooring, furniture, doors, walls, printed paper No use in toys Potential FCM impacts	Costly and technically infeasible reformulation Waste management	**Low impact** <u>Market loss assumptions</u>: Consumer losses: 5% Ind/prof losses: N/A

Table 4–25: Projected TiO_2 supply market losses following the implementation of a Carc Cat 2 harmonised classification for TiO_2															
				Market loss			Cost increases					Key impact drivers		
Application area	% of total EEA TiO_2 demand*	Share of consumer use in each application area	Formulations (F) or articles (A)	Regulation-driven restrictions	User and consumer perceptions	Loss of competitiveness	Product labelling	Hazardous waste management	Reformulation costs	Economies of scale	Administrative burden	Market losses	Cost increases	Overall impact
Inks	4%	Probably <50% in the form of consumer inks, toner, recreation and school colours, correction fluids	F/A	✓	✓	✓	✓	✓	✓	✓	✓	Alarming labelling of consumer products No use in toys No use in cosmetics (unless SCCS approval) Potential FCM impacts	Costly and technically infeasible reformulation Waste management Loss of economies of scales	**Significant impact** <u>Market loss assumptions</u>: Consumer losses: 25% Ind/prof losses: 10%
Construction products	Included above	Included above	F/A	✓	✓	✓	✓	✓	✓	✓	✓	See paints & coatings above	See paints & coatings above	**Significant impact** Included above
Fibres	0-1%	Unknown; significant use in textiles	A	✓	✓	✓		✓	✓	✓		Consumer perceptions - most man-made fibres come into contact with consumers in everyday life (this includes clothing, underwear, sports clothing, etc.) Restrictions under Toy Safety Directive. Criteria of OEKO-TEX® scheme no longer met	Costly and technically infeasible reformulation Waste management and loss of recycling/reuse opportunities	**Moderate impact** <u>Market loss assumptions</u>: Consumer losses: 5% Ind/prof losses: 5%
Catalysts	1%	No	-					✓				Limited	Low – waste management (?)	**Low impact** <u>Market loss assumptions</u>: Consumer losses: N/A Ind/prof losses: 2.5%

Table 4–25: Projected TiO_2 supply market losses following the implementation of a Carc Cat 2 harmonised classification for TiO_2														
				Market loss			Cost increases					Key impact drivers		
Application area	% of total EEA TiO_2 demand*	Share of consumer use in each application area	Formulations (F) or articles (A)	Regulation-driven restrictions	User and consumer perceptions	Loss of competitiveness	Product labelling	Hazardous waste management	Reformulation costs	Economies of scale	Administrative burden	Market losses	Cost increases	Overall impact
Food, feed and food contact materials	0-1% (food) (food contact materials also included elsewhere, e.g. coatings, plastics, paper, inks, ceramics)	100%	Food	✓	✓							Very negative consumer perceptions over digesting a suspected carcinogen Use of TiO_2 would be challenged but an exemption for food could probably be secured	Low	**Significant impact** <u>Market loss assumptions</u>: Consumer losses: 25% Ind/prof losses: N/A
			FCM	✓	✓	✓		✓	✓			Potential impacts under national legislation implementing CoE/EDQM Resolutions. Any EFSA review could have repercussions. CEPE Code of Practice (if Negative consumer perceptions	Costly and technically infeasible reformulation	

Table 4–25: Projected TiO_2 supply market losses following the implementation of a Carc Cat 2 harmonised classification for TiO_2														
				Market loss			Cost increases					Key impact drivers		
Application area	% of total EEA TiO_2 demand*	Share of consumer use in each application area	Formulations (F) or articles (A)	Regulation-driven restrictions	User and consumer perceptions	Loss of competitiveness	Product labelling	Hazardous waste management	Reformulation costs	Economies of scale	Administrative burden	Market losses	Cost increases	Overall impact
Pharmaceu-ticals	0-1%	100%	Medi-cines	✓	✓	✓		✓	✓			Very negative consumer perceptions over digesting a suspected carcinogen Use of TiO_2 would be challenged but an exemption for food could probably be secured	Significant cost of reformulation	**Significant impact** Market loss assumptions: Consumer losses: 25% Ind/prof losses: N/A
Cosmetics	0-1%	Significant, but professional uses also occur	F	✓	✓	✓		✓	✓	✓		Cosmetics Regulation → TiO_2 use banned unless exemption granted (less burdensome compared to Carc Cat 1B) Negative consumer perceptions	Costly and technically infeasible reformulation Waste management Loss of economies of scales	**Significant impact** Market loss assumptions: Consumer losses: 25% Ind/prof losses: 10%
Elastomers	0-1%	Unknown but exists (general rubber goods, e.g. erasers)	A		✓			✓				Assumed to be limited (but uncertain due to lack of information)	Low	**Low impact** Market loss assumptions: Consumer losses: 5% Ind/prof losses: 2.5%

Table 4–25: Projected TiO_2 supply market losses following the implementation of a Carc Cat 2 harmonised classification for TiO_2														
				Market loss			Cost increases					Key impact drivers		
Application area	% of total EEA TiO_2 demand*	Share of consumer use in each application area	Formulations (F) or articles (A)	Regulation-driven restrictions	User and consumer perceptions	Loss of competitiveness	Product labelling	Hazardous waste management	Reformulation costs	Economies of scale	Administrative burden	Market losses	Cost increases	Overall impact
Pigments/ pigment preparations	0-1%	Yes, but in minor quantities	F/A		✓	✓	✓	✓	✓		✓	Alarming labelling of consumer products (e.g. school colours) Losses associated with downstream uses (paints and impacts on ecolabels, toys, FCMs, cosmetics)	Costly and technically infeasible reformulation Waste management	**Significant impact** <u>Market loss assumptions</u>: Consumer losses: 25% Ind/prof losses: 10%
Ceramics	0-1%	Industrial use of TiO_2. Ultimately some ceramic products are sold to consumers	A	✓	✓			✓				National legislation on FCM Some negative consumer perceptions	Low	**Low impact** <u>Market loss assumptions</u>: Consumer losses: 5% Ind/prof losses: 2.5%
Glass	0-1%	Nil. Glass articles do not contain TiO_2	A					✓				Assumed to be low	Waste management(?)	**Low impact** <u>Market loss assumptions</u>: Consumer losses: Nil Ind/prof losses: 2.5%
Medical devices	0-1%	Rare use by consumers, but used on patients	F/A		✓			✓				Some negative consumer perceptions Carc Cat 2 outside the scope of new Medical Devices Regulation	Waste management	**Low impact** <u>Market loss assumptions</u>: Consumer losses: 5% Ind/prof losses: Nil

Table 4–25: Projected TiO_2 supply market losses following the implementation of a Carc Cat 2 harmonised classification for TiO_2

				Market loss			Cost increases					Key impact drivers		
Application area	% of total EEA TiO_2 demand*	Share of consumer use in each application area	Formulations (F) or articles (A)	Regulation-driven restrictions	User and consumer perceptions	Loss of competitiveness	Product labelling	Hazardous waste management	Reformulation costs	Economies of scale	Administrative burden	Market losses	Cost increases	Overall impact
Detergents	0-1%	Up to 100%	F		✓							Low – TiO_2 concentration too low to require hazard labelling but negative consumer perceptions might develop	Low	**Significant impact** <u>Market loss assumptions</u>: Consumer losses: 5% Ind/prof losses: N/A
Biocides	0-1%	Unknown; mostly used industrially	F	✓				✓				Loss due to loss of markets for some paint products. Carc Cat 2 substances outside the scope of Biocidal Products Regulation	Waste management	**Low impact** <u>Market loss assumptions</u>: Consumer losses: N/A Ind/prof losses: 2.5%

* in literature sources, some of the minor applications have been identified as accounting for 1% or more of total demand. These include catalysts, textiles, enamel and rubber. There is no concrete information that would allow such a distinction to be made so all minor applications are assumed to account for up to 1% of total EEA demand.
** this is based on the estimate that DIY uses account for €3.5 billion/y out of €6.2 billion of the total architectural coatings market (based on CEPE data)

- **Provisions of ecolabelling/certification schemes**: consumer products that currently meet the criteria of ecolabelling schemes (EU Ecolabel, Blue Angel, Nordic Swan) or certification (OEKO-TEX®) would no longer do so and might need to be reformulated or removed from the market. In the absence of technically and economically feasible alternatives, products might altogether be removed from the market;

- **Restrictions under national Consumer Safety Legislation**: assessing impacts under national legislation is beyond the scope of the present project. As such, it cannot be certain what the impacts on a national level might be, although some impacts are to be expected. By way of example, in France a CMR 2 classified formulation has to be stored under lock (this provision should shortly be amended to storage in a place not accessible to the public), hence such formulations would still be stigmatised as potentially unsafe. More drastically, national legislation implementing CoE Resolutions on additives for food contact materials could mean that the use of TiO_2 in coatings, paper/board or printing inks could come under regulatory pressure; and

- **Consumer perceptions of hazard/risk**: given the ubiquity of TiO_2 in all aspects of consumer, public and personal life (food and its contact materials and packaging, medicines, medical devices, furniture and flooring, printed material and wallpaper, ceramics and tableware, to name only a few), and the new carcinogenicity labelling requirements that would arise, the proposed classification would have a severe impact on consumer perception on the safety of both formulations <u>and</u> articles that contain TiO_2 and would significantly impact upon their sales in the EEA. As previously noted, companies are not free to choose what they include in the labels affixed to their products and may only label according to the CLP Regulation with any transgression potentially leading authorities' demands for product withdrawal.

On the other hand, and in contrast to a Carc Cat 1B hazard classification, there would be no scope for TiO_2 to be added to an Appendix of Annex XVII to the REACH Regulation which would ban the placing on the market of mixtures for consumer use if they contained TiO_2 in concentrations above 0.1% by weight.

Impacts on professional and industrial markets from the proposed hazard classification

Quantifying the impacts arising for professional and industrial downstream users is not as straightforward because for most applications there are no specific regulatory requirements that would restrict the use of the substance. Sections 4.3 and 4.4 of this SEA explain that impacts may arise in a number of ways:

- Partial loss of consumer markets (for mixtures, in particular) would more generally affect economies of scale (particularly for paints, coatings, inks and construction products manufacture);

- Industry initiatives, though voluntary in nature, play a key role in the market acceptance of CMR substances in certain sectors. As noted above, the CEPE voluntary Code of Practice for coatings used in food contact materials could result in the substance being removed from coating formulations if its authorisation was revoked by the European Food Safety Agency (EFSA);

- Some companies using TiO_2 may have their own internal policies that prevent them from using CMR substances, although it is less likely that this would be the case for a CRM Cat 2 substance in comparison to CMR 1A/1B substances; and

- Similar to consumers, the supply chain may be reluctant to use a Carc Cat 2 substance even where legislation itself does not prohibit its use.

An important difference between the Carc Cat 2 and Carc Cat 1B hazard classification is that the former does not trigger obligations for employers under the Carcinogens and Mutagens Directive 2004/37/EC (including the requirement to consider alternatives to TiO_2), although legislation on the national level and a revision of SDS (following an update to TiO_2's registration dossier) may require employers to review their compliance with worker health protection rules.

Approach to estimating the decrease in demand for titanium dioxide in the EEA

The approach taken to estimating the decrease in TiO_2 demand is informed by the analysis presented over several pages in Section 4 but out of necessity requires assumptions and a degree of informed but subjective judgement. The steps followed are:

1. Distinguish TiO_2 consumption in each application area between consumer and industrial/professional in order to quantify the respective percentages of total EEA demand for TiO_2.

2. For the vast majority of the specialty applications of TiO_2, demand for TiO_2 is uncertain and is assumed to be <1%. In such cases, the following assumptions are made:

    a. Where only consumer or only industrial/professional use of the substance takes place, this is assumed to account for 0.5% of total EEA demand for TiO_2.

    b. Where both consumer and industrial/professional use of the substance take place, each is assumed to account for 0.25% of total EEA demand for TiO_2.

3. Impacts per application area described in **Table 4–25** are classified as "Significant", "Moderate" or "Low". In terms of projected loss of demand this translates into the following:

    a. "Significant" loss: 25% of consumer-related consumption of TiO_2 is assumed lost and/or 10% of industry-related consumption of TiO_2 is assumed lost;

    b. "Moderate" loss: 10% of consumer-related consumption of TiO_2 is assumed lost and/or 5% of industry-related consumption of TiO_2 is assumed lost;

    c. "Low" loss: 5% or less of consumer-related consumption of TiO_2 is assumed lost and/or 2.5% or less of industry-related consumption of TiO_2 is assumed lost.

4. **Table 4–26** can be generated on the basis of the above assumptions. The table suggests that **over 12%** of the total TiO_2 demand in the EEA would be lost following the introduction of the Carc Cat 2 harmonised classification. The large majority of this would be due to a reduction in demand in paint manufacture

Therefore, a reasonable assumption would be that **10-15% of current total TiO_2 demand in the EEA might be lost as a result of a Carc Cat 2 hazard classification of the substance**. At the same time, given the non-existent/minimal potential for inhalation exposure by consumers, no real benefit to consumer health would accrue. It is acknowledged that.

By way of comparison, a previous version of this report which focused on the impacts from the originally proposed Carc Cat 1B harmonised classification had estimated that the overall loss of demand for TiO_2 would be in the range of 25-50%. It is important to note again that quantification of the impacts from a classification of Carc Cat 2 is fraught by uncertainty even larger than for a Carc Cat 1B classification and the above estimate is based on a series of informed assumptions. The scale of impacts on the mass applications of TiO_2 (paints, coatings, inks, plastics, paper) is not possible to accurately scope, as they are invariably more likely to result from NGO, media and stakeholder pressure than from regulatory requirements. The real impact may prove to be far more severe than what is described here, particularly if user and consumer perceptions of the risks from exposure to TiO_2 dramatically deteriorate.

Table 4–26: Estimation of loss in demand for TiO_2 in the EEA following the introduction of a Carc Cat 2 harmonised classification

Application area	Share of TiO_2 demand		Simplified share of TiO_2 demand		Demand loss ratio post-Carc Cat 2		Loss of total TiO_2 demand in EEA post-Carc Cat 2	
	C*	I/P*	C	I/P	C	I/P	C	I/P
Paints and coatings	20%	33%	20%	33%	25%	10%	5.00%	3.30%
Plastics	16.5%	8.5%	16.5%	8.5%	10%	5%	1.65%	0.43%
Paper	12%	0%	12%	0%	5%	0%	0.60%	0.00%
Inks	<2%	>2%	1%	3%	25%	10%	0.25%	0.30%
Construc-tion	Incl. above	Incl. above	Incl. above	Incl. above	-	-	-	-
Fibres	<1%	<1%	0.50%	0.50%	10%	5%	0.05%	0.03%
Catalysts	0%	1%	-	1.00%	-	2.5%	0.00%	0.03%
Food	<1%	0%	0.50%	-	25%	-	0.13%	0.00%
Pharma-ceuticals	<1%	0%	0.50%	-	25%	-	0.13%	0.00%
Cosmetics	<1%	<1%	0.25%	0.25%	25%	10%	0.06%	0.03%
Elastomers	<1%	<1%	0.25%	0.25%	5%	2.5%	0.01%	0.01%
Pigments	<1%	<1%	0.25%	0.25%	25%	5%	0.06%	0.01%
Ceramics	<1%	<1%	0.25%	0.25%	5%	2.5%	0.01%	0.01%
Glass	<1%	<1%	0.25%	0.25%	0%	2.5%	0.00%	0.01%
Medical	<1%	<1%	0.25%	0.25%	5%	0%	0.01%	0.00%
Detergents	<1%	0%	0.50%	-	5%	-	0.03%	0.00%
Biocides	0%	<1%	-	0.50%	-	2.5%	0.00%	0.01%
		Total	**101%**			**Total**	**8.0%**	**4.1%**
						Grand total	**ca. 12%**	
*** C: consumer, I/P: industrial/professional**								

4.6 Impacts on producers of titanium dioxide

4.6.1 Key market parameters for titanium dioxide

As shown in **Table 3–3**, there are 17 TiO_2 production facilities in the EU plus one in Norway (Fredrikstad). The majority of production is based on the sulphate process (see Section 3.1.2) and the split between sulphate and chloride process is assumed to be 55:45. In terms of production capacity, Germany leads with an assumed 32% of the total EEA capacity of over 1.4 million tonnes of TiO_2 (see **Figure 3–2**), followed by the UK (21%) and Finland (9%).

Based on the information presented in Section 3.3, in the year 2015 (which has been used as the basis of the analysis below) the figures shown in **Table 4–27** applied.

Table 4–27: Key metrics of TiO_2 market in the EEA (2015)		
Parameter	**Volume (ktonnes/y)**	**Value* (€million/y, approx.)**
EEA demand for TiO_2	1,100	2,660
EEA-made TiO_2 consumed in the EEA	*740*	*1,800*
Non-EEA-made TiO_2 consumed in the EEA	*360*	*860*
EEA exports of TiO_2	360	860
* assumes a price of €2,400/t although the current price (Q3 of 2017) is higher, see below		

4.6.2 Value of titanium dioxide market and profitability of EEA-based operations

Value of the market

The market price for TiO_2 has varied significantly over the years. The relevant IPPC BREF Document documents a significant decline in prices from ca. US$7,000 per tonne in 1954 to just over US$2,000 in 2002 (European Commission, 2007). In the 2000s, the price of TiO_2 increased so that, in 2012, TiO_2 was sold on average at around €3,000 per tonne (or ca. US$4,000/t)[81]. That increase did lead some users to explore alternatives without success (as explained later in this document). The price of TiO_2 pigments has significantly declined since 2012. Recent price data for the Chinese market (TIZE, 2016) suggest that, at the end of 2014, the price per tonne was ca. US$2,100 or ca. €1,700 per tonne[82]. In addition, in July 2016, the average price of TiO_2 in the North American market was ca. US$1.215 per lb or US$2,675 per tonne or ca. €2,400 per tonne[83] with a range of US$1.18-1.25/lb (free delivered) for smaller-volume buyers (ICIS, 2016). The latest information on the price of TiO_2 suggests that prices have increased to €2,600-2,850 per tonne (ICIS, 2017). If €2,700 is assumed to be the average price in the EEA at present[84], the value of the total market in the EEA can be estimated at 1,107,000 tonnes × €2,700 per tonne = €3 billion per year[85].

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[81] The average exchange rate for the year 2012 was US$1 = €0.778 (based on http://www.ukforex.co.uk/forex-tools/historical-rate-tools/historical-exchange-rates, accessed on 20 January 2017).

[82] The average exchange rate for the month of December 2014 was US$1 = €0.812 (based on http://www.ukforex.co.uk/forex-tools/historical-rate-tools/historical-exchange-rates, accessed on 20 January 2017).

[83] The average exchange rate for the month of July 2016 was US$1 = €0.904 (based on http://www.ukforex.co.uk/forex-tools/historical-rate-tools/historical-exchange-rates, accessed on 20 January 2017).

[84] It has been suggested that a high price correlation can be observed between world regions. There are only minimal price differences which reflect costs of freight and duties between regions. Price differences between the EEA and North America are influenced by the Euro-Dollar exchange rate fluctuations (European Commission, 2014).

[85] It is worth noting that past market research had assumed a gradual increase to the value of the market until 2020 (Market Report Company, 2015; Zion Research, 2016).

Profitability of titanium dioxide manufacturers

With regard to the profitability of the TiO_2 manufacturing industry, some key points can be made:

- The TiO_2 industry suffered a major downturn during the financial crisis in 2008-2009. It recovered sharply in 2012 but then declined until late 2016/early 2017 when TiO_2 prices started rising;

- Data on Pre-tax Operating Income for all EEA plants for the year 2013 (generated by a third party) have been supplied by consultees. These show relatively low levels of pre-tax income at the time. Out of 18 plants, a minority had a negative pre-tax operating income margin and half of all plants had a single-digit pre-tax operating income margin; and

- Since 2013, the decline has continued for several of the companies concerned (although on a per plant basis, some may have shown some improvement). EBITDA data for the four largest suppliers to the EEA market have been consulted (but cannot be reproduced here) and show that, for some companies, EBITDA margin figures remain at single-digit figures[86]. Accordingly, pre-tax operating income levels are even lower or negative. However, recent market price increases for the pigment have markedly improved economics over the first half of 2017.

A previous version of this impact assessment which focused on impacts from the originally proposed Carc Cat 1B harmonised classification for TiO_2 had assumed that pre-tax operating income across the industry is nil. This is unlikely to be correct at the end of 2017 given that the price of the pigment has substantially improved during 2017.

Gross Value Added of titanium dioxide manufacture

There are several ways of calculating Gross Value Added (GVA); the "income" approach to estimating GVA as this is the most straightforward. Under this approach, the definition is:

GVA = compensation of employment + gross operating surplus

The compensation of employment translates basically into the sum of salaries, national insurance contributions, and possibly redundancy wages plus profits. On the other hand, in the previous version of this report where the focus was on the proposed Carc Cat 1B classification, it had been assumed that profits were nil, thus only compensation of employment was considered. This is no longer accurate, given the recent market price increases for TiO_2. It has not been possible to obtain highly sensitive profit data from TiO_2 manufacturers and thus we conservatively assume that the gross operating surplus is equivalent to 3% of turnover in the EEA[87]. This is equivalent to €90 million, based on a turnover of €3 billion.

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[86] Publicly available information corroborates this (Huntsman, 2016n; ICIS, 2016).

[87] By way of example, in 2014 the gross operating surplus of the European chemicals industry exceeded 9% of turnover (see http://ec.europa.eu/eurostat/statistics-explained/images/9/96/Sectoral_tab2_analysis_of_key_indicators%2C_Manufacturing_%28NACE_Section_C%29%2C_EU-28%2C_2014.png, accessed on 7 October 2017).

As far as wages are concerned, information for members of TDMA is similarly limited. However, there is information on employment levels which has been used as follows:

- Some companies have provided employment data per plant and these have been used;
- For some companies, data have been obtained from the open electronic literature;
- For others, where only total employment is known and data on capacity per plant are available, workforce is allocated on the basis of production capacity share;
- Total employment in EEA has been estimated at ca. 8,150;
- Total labour costs for the manufacturing sector in each of the countries of interest are obtained from Eurostat[88] and are reproduced in **Table 4–28**; and
- An 8-hour day, 240 working days per year assumption is made for all workers in all countries.

The full calculations cannot be provided as they might potentially disclose sensitive information. The overall labour cost is estimated at ca. €470 million/y.

Table 4–28: Total labour cost per hour in the manufacturing sector, 2015

Country	Total labour cost per hour (€/h)
Belgium	43.3
Czech Republic	9.8
Germany	38.0
Spain	22.6
France	36.9
Italy	27.4
Netherlands	34.7*
Poland	7.6
Slovenia	15.4
Finland	36.8
United Kingdom	28.3
Norway	48.2

Source: Eurostat
* Value is for 2014; a value for 2015 was not available at the time of accessing the Eurostat database

Therefore, the GVA for the manufacture of TiO_2 can be calculated at €470 million + €90 million = €560 million; this is likely to be an underestimate as the assumptions made on the gross operating surplus are conservative. The estimate presented for the compensation of employment, €470 million, should be consider a floor for the sector (and would reflect periods of poor profitability).

4.6.3 Analysis of economic impacts on titanium dioxide manufacturers

Titanium dioxide market outcomes from a Carc Cat 2 harmonised classification

Based on the analysis above, the proposed classification would result in the loss of up to 15% of the EEA market for TiO_2. Such a loss (but even a more modest one of 10% of total demand) would cause a significant adverse impact:

- **Capacity underutilisation would jeopardise the economic viability of EEA plants**: in recent years, there has been overproduction of TiO_2 pigment, with an average capacity utilisation

[88] Labour cost levels by NACE Rev. 2 activity, available at http://ec.europa.eu/eurostat/web/labour-market/labour-costs/database (accessed on 31 October 2016).

within the industry of just under 80% (Roskill, 2016). Capacity utilisation rates for TiO_2 plants were predicted to rise in 2016, normalise in 2017 and exceed 90% by 2018 and 2019 (ICIS, 2016b). If 15% (or even 10%) of the EEA market were lost, capacity utilisation of the EEA-based TiO_2 manufacturing plants would decline. TiO_2 plants running at a capacity utilisation below 80% or less cannot be sustained economically for any prolonged period of time. These plants have very high fixed costs which must be absorbed over very high/nearly full capacity utilisation rates. TiO_2 production for some plants might become economically unsustainable and could lead to consolidation (i.e. some plants might need to shut down to ensure profitability of the remaining ones);

- **Opportunities for increased TiO_2 exports are small**: unless the introduction of the new hazard classification for TiO_2 in the EEA is emulated by other jurisdictions, the use of TiO_2 outside the EEA would continue as normal and indeed non-EEA manufacturing could become more competitive and thus more attractive. Thus, theoretically, EEA manufacturers of TiO_2 might be able to export increased volumes of TiO_2 to non-EEA downstream users. Still, access to overseas markets would be easier for the larger multinational producers, as opposed to the smaller ones who may have a more regional focus and less capability of becoming competitive exporters. In any case, all EEA-based TiO_2 producers would be disadvantaged by additional freight and duty costs, plus a costlier manufacturing base in the EEA. It is unrealistic to expect any significant increase to the currently estimated 360 ktonnes/y TiO_2 exports from the EEA;

- **Spare capacity outside the EEA is significant**: as shown in Section 3.3, EEA demand for TiO_2 amounts to ca. 1.1 million tonnes per year, while global demand is at 5.9 million tonnes per year and global capacity is 7.2 million tonnes. Hence, a surplus capacity of around 1.3 million tonnes exists, which is similar to the current Western European capacity and exceeds current EEA demand for the pigment. As a result, non-EEA TiO_2 manufacturers (including multinationals currently operating in the EEA) would be in a good position to take over the EEA market for the pigment.

Overall, loss of 10-15% of the EEA market for TiO_2 (in addition to the cost of regulation that TiO_2 manufacturers would face, for example, on waste management (see discussion below)) would probably lead to TiO_2 plant closures in the EEA. This could have a significant knock-on effect on EEA-based supply chains but also on non-EEA users of the pigment: EEA-made TiO_2 is currently being exported plus some TiO_2 grades may only be made in European plants so these grades may no longer be available to customers outside Europe.

Impacts on ancillary operations

Titanium chemicals

Many TiO_2 manufacturing plants also produce high value titanium chemicals including titanium tetrachloride, titanium oxychloride, titanium oxysulphate, and sodium titanate. These chemicals are used in a wide range of process industries with applications including manufacture of titanium metal and pearlescent pigments, surface treatment of metals and catalyst manufacture.

Co-products of titanium dioxide manufacture

<u>Overview</u>

Both the sulphate and chloride manufacturing processes generate important co-products which are placed on the market and form an essential part of the overall manufacturing scheme. Co-products from TiO_2 manufacture include:

- From the sulphate process:
  - Iron salts, including copperas (ferrous / iron (II) sulphate heptahydrate, $FeSO_4.7H_2O$) and ferric/iron (III) chlorosulphate, $FeClSO_4$);
  - Gypsum (calcium sulphate, $CaSO_4.2H_2O$);
  - Sulphuric acid;
- From the chloride process:
  - Iron salt, ferrous/iron (II) chloride ($FeCl_2$);
  - Hydrochloric acid; and
- Water treatment and agricultural products from further treatment of the above co-products.

<u>Iron salt co-products</u>

Manufacture of iron salts through the sulphate process: in the sulphate process, manufacturing processes for the different hydration states of ferrous sulphate and ferric sulphate are interlinked, with copperas (iron (II) sulphate heptahydrate) being the common starting point and quite probably the highest volume iron compound manufactured (as shown in **Figure 4–7**). The following manufacturing steps are involved:

- Preparation of ferrous sulphate heptahydrate (copperas) as a by-product of the sulphate process for the production of TiO_2;
- Preparation of ferrous sulphate monohydrate directly from the sulphate process for manufacturing TiO_2;
- Preparation of dry ferrous sulphate monohydrate and ferrous sulphate heptahydrate (copperas);
- Preparation of ferric sulphate from ferrous sulphate heptahydrate (copperas); and
- Preparation of ferric chlorosulphate from ferrous sulphate heptahydrate (copperas).

Uses of iron salt co-products: the most important applications for iron sulphates from the TiO_2 sulphate manufacturing process are in potable and wastewater purification where they act as coagulants or flocculants. Copperas is the main iron source for the production of iron based chemical coagulants. They can also be used to eliminate H_2S (odour) or to remove phosphate in water. They are precursors to other iron-based substances such as oxides and hydroxides used as pigments and they are used in horticulture and agriculture. Ferrous sulphate is a reducing agent and as such is used to reduce harmful Cr(VI) to Cr(III) in cement; this is where filter salts are used due their lower purity unlike copperas which can be used in water treatment and feed applications.

Ferrous chloride from the TiO_2 chloride manufacturing process finds use in water treatment it acts as a coagulant or flocculant. It can also be used to eliminate H_2S (odour) or to immobilise elements such as arsenic. It is also a precursor to other iron-based substances such as oxides and hydroxides used as pigments.

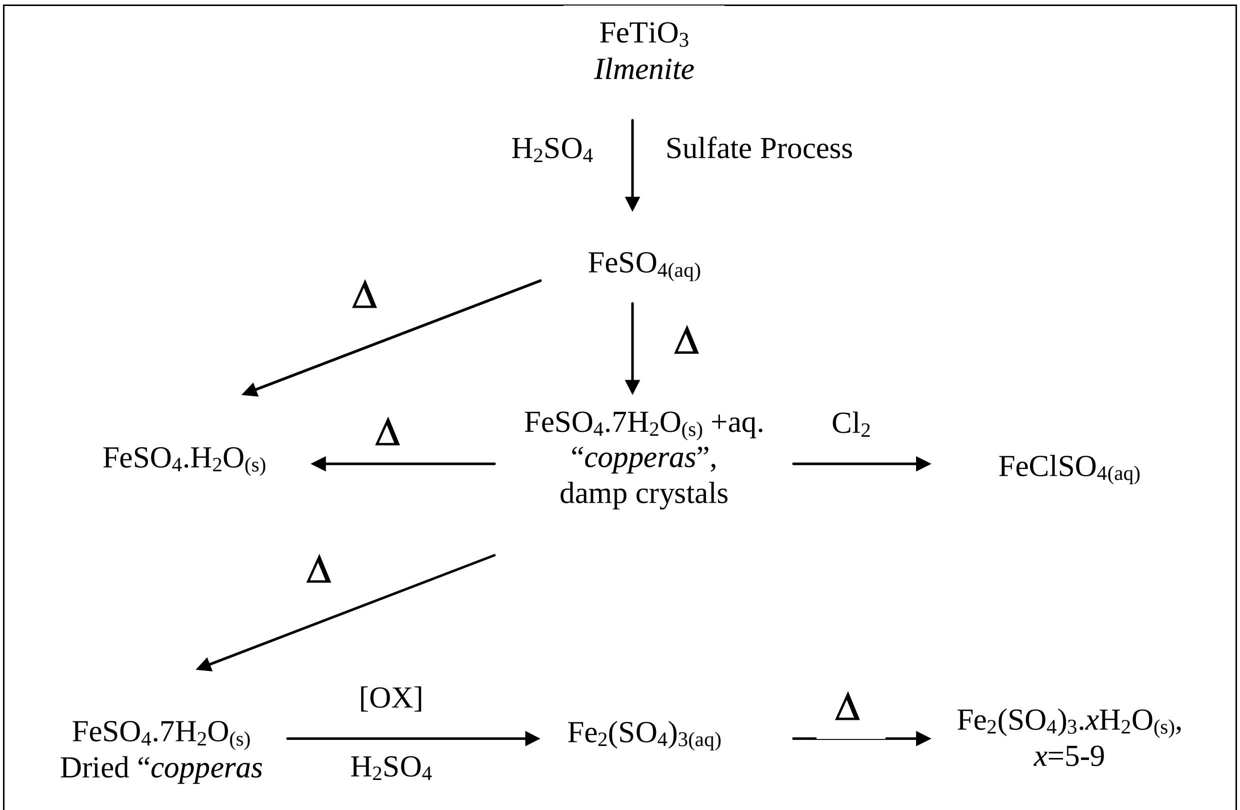

Figure 4–7: Simplified process flow diagram for production of iron sulphates
Source: TDMA

Other uses of iron salts include:

- Biogas production;
- Use of iron chlorides and iron sulphates as reactive products/precursors, e.g. in the manufacture of pigments and other iron compounds, also including use as a catalyst;
- Use of aqueous ferric chloride as a metal etchant;
- Land remediation applications;
- Laboratory chemicals;
- Agrochemicals; and
- Adhesives and sealants.

<u>Gypsum co-product</u>

Another co-product, gypsum, is formed from the solution resulting from the final stages of TiO_2 washings. This solution is processed by sending it to a neutralisation plant. The neutralisation step consists of adding lime ($Ca(OH)_2$) or limestone ($CaCO_3$) to the weak acid stream, generating a co-product called red gypsum, formed mainly of gypsum and iron hydroxides (Gázquez, et al., 2014).

Red gypsum is essentially a waste for which extensive efforts have been made in recent times to identify suitable uses. According to literature, red gypsum has agricultural use but can also be used as a solidifying agent for loose clay soils to make them stable (for highways, etc.). Red gypsum, blended with organic fertiliser, is also used for capping and landscaping activities of quarries, landfills and contaminated sites. Finally, it can also be used in the cement industry (European Commission, 2007).

Production volumes of titanium chemicals and co-products

The production volumes of titanium substances are substantial, particularly for titanium tetrachloride. The REACH registrations for these substances identify volumes in the following ranges:

- Titanium tetrachloride: 100,000 – 1,000,000 tonnes per year;
- Titanium oxychloride: 10,000 – 100,000 tonnes per year;
- Titanium oxysulphate: 1,000 – 10,000 tonnes per year; and
- Disodium titanate: 1 - 10 tonnes per year.

It is estimated that the total production volume for the above substances is in the order of a million tonnes per year.

Iron sulphates represent the highest volume of the TiO_2 industry by-products. The sulphate process for the manufacture of TiO_2 is the only production process for iron sulphates of any importance. It produces up to 2.5 tonnes of copperas per tonne of TiO_2 (European Commission, 2007; Environment Agency, 2004). Exact annual production volumes are not available but a conservative estimate for Europe would be over 2,000,000 tonnes of copperas and a smaller quantity (perhaps 20% of the copperas volume) of the other iron salts (so called 'filter salts'). These substantial volumes make these iron compounds of high market importance and significant contributors to the overall profitability of TiO_2 manufacturing operations.

High volumes of gypsum are also produced, in the order of several hundreds of thousands of tonnes per year.

Impacts from the Carc Cat 2 harmonised classification for titanium dioxide

<u>Reduction of production and sales volumes</u>

As described above, following the introduction of the harmonised classification, manufacture of TiO_2 in the EEA would likely continue under conditions of capacity underutilisation thus leading to potential plant closures. Irrespective of plant closures, a decline in demand for TiO_2 would lead to a decrease in TiO_2 production volumes and a concomitant decrease in the production and sales of titanium chemicals and co-products. For titanium tetrachloride and the other titanium chemicals the affected TiO_2 manufacturing plants collectively account for the majority of the volume placed on the EEA market. Thus, downstream users of these products would likely be affected by any shortages in supply. Similarly, a reduction in TiO_2 manufactured volumes would result in a reduction of the volumes of iron salts and red gypsum.

Importantly, any impact on the production and sales of titanium chemicals and the co-products would further exacerbate the impacts on the profitability of TiO_2 manufacture. For instance, the sale and/or use of copperas is a necessity for ensuring the viability of the economics of the sulphate route production process. As such, a decline in the sales of TiO_2 arising from its harmonised classification would instigate a self-feeding decline in the profitability of TiO_2 plants as a whole.

Impacts on sales from the presence of titanium dioxide impurities

Whilst all co-products contain TiO_2 impurities above 0.1%, only some contain impurities that exceed the 1% threshold that is relevant to the Carc Cat 2 harmonised classification. More specifically:

- Copperas contains less than 1% TiO_2 impurities;
- Filter salts are less pure than copperas and contain more than 1% TiO_2; and
- Red gypsum may contain more than 1% TiO_2 as an impurity - this may vary by plant. Gypsum is the major volume co-product that may contain more than 1% TiO_2.

The downstream use of filter salts and red gypsum would be impacted, as these co-products would be classified as Carc Cat 2 as result of the presence of TiO_2 impurities. By way of example, ferrous sulphate is used to reduce Cr(VI), a CMR, to Cr(III) in cement; being sold with impurities of a suspected carcinogen above the 1% level could make users reluctant to use. In addition, for red gypsum, the presence of a suspected carcinogen as an impurity would impede the valorisation of this waste product and would make the development of new applications less attractive.

The sales of copperas might be impacted too. The salt is used as the main iron source for the production of iron based chemical coagulants and in potable water purification. The presence of a suspected carcinogen as an impurity even at a level below 1% might result in adverse user perceptions of the safety of the product.

Waste management impacts

The classification of TiO_2 as a Carc Cat 2 substance would have implications on the management of waste that is generated during the manufacture of TiO_2, titanium substances and co-products. **Table 4–29** summarises information obtained from several TiO_2 manufacturers. Some key parameters are:

- All waste types identified as relevant contain TiO_2 at concentrations that exceed 1% and in some cases, are significantly high;

- In general, the key waste streams are currently classified as non-hazardous and mostly fall under 'absolute non-hazardous' entries in the LoW;

- The most voluminous waste streams (digestion residues, neutralised solids, red gypsum), containing TiO_2-containing materials that could become available an inhalable form; however, these wastes are typically handled as wet cakes thus reducing the likelihood of exposure; and

- The sulphate route to TiO_2 would appear to be accompanied with higher volumes of TiO_2-containing waste.

Calculations made by industry experts would suggest that across the EEA the following (approximate) volumes of key wastes arise (NB. the figures assumed a 90% capacity utilisation rate):

- Filter cake: 550 kt/y;
- Red gypsum: 2,700 kt/y;
- Sluice acid: 50 kt/y; and
- Digester (reactor) residues: 10 kt/y.

Overall, the total volumes of waste could be very significant, in the range of 3,000-4,000 kt/y.

Table 4–29: Relevant waste streams for the manufacture of TiO_2						
Process generating waste	**Type of waste**	**Waste entry in LoW**	**Typical TiO_2 content**	**Example volume generated per plant***	**Is TiO_2 inhalable?**	**Current waste management**
TiO_2 manufacture via either route	Off-spec pigment	**06 11 99** Wastes not otherwise specified ('*absolute non-hazardous*')	>>1%	<1 kt/y	No	Non-hazardous **Landfilling**
	Sand/pigment (mixture of SiO_2 with TiO_2)	**17 05 04** Soil and stones other than those mentioned in 17 05 03 ('*mirror non-hazardous*')	>>1%	1-10 kt/y	Yes	Non-hazardous **Landfilling**
	Mixed waste from TiO_2 technology (scales from production vessels, scrap parts and big bags contaminated with TiO_2, contaminated sweepings from the production areas, etc.)	**06 11 99** Wastes not otherwise specified ('*absolute non-hazardous*')	>1%	1 kt/y	Yes	Non-hazardous **Landfilling**
TiO_2 manufacture via the chloride route	Neutralised solids derived from ore impurities	**06 11 01** Calcium-based reaction wastes from titanium dioxide production ('*absolute non-hazardous*')	>>1%	10-100 kt/y	Produced as damp cake so not inhalable as produced but could be if allowed to dry	Non-hazardous **Landfilling**
	Sluice acid	**06 01 06*** Other acids ('*absolute hazardous*')	>1%	1-10 kt/y	No	Hazardous **Re-use**

Table 4–29: Relevant waste streams for the manufacture of TiO_2						
Process generating waste	**Type of waste**	**Waste entry in LoW**	**Typical TiO_2 content**	**Example volume generated per plant***	**Is TiO_2 inhalable?**	**Current waste management**
TiO_2 manufacture via the sulphate route	Digestion (reactor) residue	**06 11 99** Wastes not otherwise specified (‘*absolute non-hazardous*’)	>>1%	100-1,000 kt/y	No, but could become inhalable if dried	Depends if neutralised, majority is. **Landfilling**
	Red gypsum from acid neutralisation	**06 11 01** Calcium-based reaction wastes from titanium dioxide production (‘*absolute non-hazardous*’)	>1%	100-500 kt/y	No, but could become inhalable if dried	Non-hazardous **Landfilling**
Titanium tetrachloride manufacture	Filter cake	**06 11 01** Calcium-based reaction wastes from titanium dioxide production (‘*absolute non-hazardous*’)	>1%	10-100 kt/y	No, but could become inhalable if dried; also, radioactive components will become a hazard	Non-hazardous **Landfilling and reuse**

* data based on individual responses to questionnaire (figures have been rounded)

Note: the table does not include other types of TiO_2-containing waste that may arise during the operation of the TiO_2 manufacturing plants but which have already been discussed elsewhere in this document (i.e. empty packaging contaminated with TiO_2, waste paint, etc.)

All manufacturers who have made a contribution to this analysis (and who operate facilities in several EEA Member States) anticipate that the classification of TiO_2 as a Carc Cat 2 would render these wastes hazardous. More specifically:

- In sulphate plants, digester (reactor) residue would be classified as a carcinogen. Some residue may already be disposed of as hazardous waste but for those currently treated and disposed of as non-hazardous waste the result of the Carc Cat 2 harmonised classification would be either increased costs or viability problems, if a suitable disposal outlet could not be found. More importantly, in terms of waste volumes, where outlets for co-products (red gypsum and potentially filter salts) could not be found due to a change in hazard classification, the resulting high volumes of hazardous waste could force plant closures due to cost or lack of suitable disposal options; and

- In chloride plants, the main wastes would also be classified as hazardous. This would mean significant disposal cost increases or viability problems if no hazardous waste outlets could be identified.

It is recognised that the key entries in the table are 'absolute non-hazardous' and thus a change to the hazard classification of one constituent of these wastes should not normally lead to the classification of waste as hazardous if there are no corresponding 'absolute hazardous' entries in the LoW (see the case of packaging which may switch from an 'absolute non-hazardous' entry to an 'absolute hazardous' one if a hazardous contaminant is present at relevant concentrations). However, classification of these waste streams as hazardous could be a real possibility due to:

- **The discretion of Member State authorities to deviate from the LoW**: the Waste Framework Directive in its Article 7(2) permits Member States to classify waste as hazardous even if it does not appear as such on the LoW. Member States have to report this to the European Commission and the Commission will consider a change of LoW. In this particular case, given the volumes, high concentrations of the suspected carcinogen and the possibility of exposure by inhalation, it is entirely possible that Member States would take action.

  It is also worth remembering that there may be differences in the implementation of the Waste Framework Directive on the Member State level. In 2010, the TiO_2 industry in the UK was successful in demonstrating through detailed modelling to the UK government that that landfill sites used for the solid mineral waste can be recovered for agricultural use following a post-use aftercare period of just 5 years compared to normally many decades. As such, the UK government was convinced that a hazardous waste landfill tax rate for filter waste was disproportionate. Following the introduction of the Carc Cat 2 harmonised classification, it might be possible that the UK government might take a pragmatic approach and accept that this waste remains non-hazardous. On the other hand, a further example has been given of the Czech Republic. The Czech No. 185/2001 Law on wastes in its Article 6 stipulates: "*Waste generator is obliged to classify waste as hazardous if a) the waste has at least one of hazardous properties stated in Commission Regulation (EU) no. 1357/2014 replacing Annex III to Directive 2008/98/EC on properties of waste which render it hazardous, b) the waste is stated in the List of Wastes as the hazardous waste, or c) the waste is mixed or contaminated by some of the wastes stated in the List of Wastes as hazardous*". In other words, if TiO_2 is present at concentrations above 1%, the waste is classified as hazardous irrespective of its LoW entry;

- **The approach (i.e. sequence of actions) taken to using the LoW**: the producer of waste or a national authority might first establish that the waste hazardous and then seek to identify an appropriate LoW code which best describes the waste and its hazardous classification. Thus, the 'standard' 'absolute non-hazardous' entry might be considered irrelevant; and

- **The perceived hazard characteristics of the waste**: the above hazard classification activities are likely to be influenced by two key factors: (a) the presence of significant concentrations of TiO_2 in the waste, and (b) the potentially inhalable form of TiO_2 in the waste. Key waste streams are generated as solids with high moisture content where inhalation exposure to TiO_2 is not possible; yet, such material could become dry and dusty prior to its disposal (e.g. the capping of the landfill cell) thus would lend itself to exposure by inhalation. This could lead Member State authorities to insist that such waste be treated as hazardous.

Some estimates of the cost increases arising from the classification of waste as hazardous has been provided. Organisation measures aimed at introducing separation of waste so that TiO_2-containing waste is not mixed with a different category of waste would cost an estimated €0.1-0.5 million per plant. On the other hand, the storage, transportation and disposal of the hazardous waste would increase waste management costs by €10-20 million/per year per company. Additional costs of increased taxation might also arise; for example, in the UK the landfill tax rate would increase by a factor of over 30 (from £2.70 per tonne to £86.10 per tonne) meaning an increased annual landfill tax cost in the range of €5-10 million for UK manufacturers of TiO_2.

Due to the absence of a complete set of data for all TiO_2 manufacturers, the overall costs cannot be estimated with accuracy. In addition, some of the estimates that have been provided has been claimed to be confidential. However, taking into account the number of manufacturers (18), the volumes of wastes involved and the company-specific cost estimates available, it could be realistic to expect a cost increase in the range of **several hundreds of millions per year**, excluding loss of sales for products that could no longer be achieved (e.g. gypsum) as a result of downstream users' reluctance to use the classified material.

Conclusion on the economic impacts on titanium dioxide manufacturers from a Carc Cat 2 harmonised classification

The above analysis shows that the Carc Cat 2 harmonised classification for TiO_2 would have significant direct impacts on the demand for the substance, currently estimated at 10-15% of current demand in the EEA. This will result in underutilisation of the capacities of TiO_2 manufacturing plants and will threaten their viability. Crucially, these direct impacts will be exacerbated by loss of production and sales of ancillary products (due to the presence of impurities of a suspected carcinogen) and the potential classification of important waste streams as hazardous thus requiring costlier disposal and losing any potential of their reuse (this refers to red gypsum for which efforts have been made to develop new applications). If indeed waste stream such as neutralised solids, digestion residues, red gypsum and filter cakes require disposal as hazardous waste, due to the very large quantities involved, the cost of waste management would become too high and thus render the manufacture of TiO_2 and of ancillary products uneconomical; as shown above, the cost of changes to waste management as a percentage of the collective GVA of the manufacturers could become unsustainably high. The TiO_2 industry economics are well known to be very cyclical, and such a severely increased waste management burden could well make the difference between the continued viability of the operation during depressed periods of the cycle. In conclusion, the harmonised classification could potentially result in the collapse of Europe's TiO_2 manufacturing base, depending on the severity of impacts on waste management, which would likely vary across the EEA Member States.

4.6.4 Employment impacts

The total employment in the 18 TiO_2 manufacturing plants in the EEA is estimated at ca. 8,150 workers. Specific figures per plant, company or country cannot be provided for confidentiality reasons. A rough split among EEA Member States is provided in **Table 4–30**. The table also provides the domestic employment multipliers for each country for the 'chemicals' sector, as presented in a 2012 study for the European Commission (which analysed 2005 data) (Stehrer & Ward, 2012).

Table 4–30: National shares of total employment in TiO_2 manufacturing plants

Country	Share of total number of workers in the EEA	Domestic employment multiplier (chemicals sector)
Belgium	5-10%	2.2
Czech Republic	5-10%	2.3
Germany	30-40%	2.8
Spain	1-5%	2.7
France	5-10%	4.9
Italy	1-5%	3.3
Netherlands	1-5%	3.0
Poland	1-5%	2.7
Slovenia	10-20%	2.0
Finland	5-10%	2.6
United Kingdom	10-20%	3.3
Norway	1-5%	2.3*
Total	**8,150 workers**	

Source: TDMA member information, employment data retrieved from the Internet
* in the absence of data, the EU-27 average is used

Using these multipliers for each Member State, it can be estimated that direct employment at TiO_2 manufacturing plants creates ca. 22,800 jobs in the domestic economies (overall multiplier: 2.8).

If some TiO_2 manufacturing plants were to stop production following the introduction of a Carc Cat 2 classification for TiO_2 and a decline in demand for the substance, hundreds of jobs could be lost (by way of illustration, 15% of 8,150 equals ca. 1,200 jobs) and, with them, a proportion of the relevant indirect employment described above.

Taking into account the full range of impacts (decline in TiO_2 demand, partial loss of production of titanium chemicals and co-products, loss of market for co-products due to concerns over carcinogenicity and drastic increases in waste management costs), the profitability of all TiO_2 manufacturing plants would suffer and the number of plant closures and associated job losses would be substantially larger, potentially affecting the entire workforce of the 18 manufacturing sites.

4.7 Impacts on upstream suppliers

4.7.1 Ore mining and slag production in the EEA

There is only one commercial mining operation in the EEA, the ilmenite ore deposit at Hauge i Dalane on the southwest coast of Norway operated by Titania AS (owned by Kronos)[89]. The facility

[89] Note that feedstock production does take place in the periphery of the EEA, in Ukraine.

was founded in 1902 and has continuously produced ilmenite ($FeTiO_3$), the most abundant titanium mineral, since 1916. Currently, production stands at 850,000 tonnes of ilmenite concentrate[90]. Global production of ilmenite in 2016 was estimated at ca. 5.86 million tonnes (USGS, 2017), meaning that the Titania AS operations account for ca. 15% of global production (global production of rutile is estimated at ca. 6.6 million tonnes per year (USGS, 2017)). Titania AS employs more than 280 personnel[91], including apprentices, many of whom live in the nearby municipality of Sokndal. The company has a long history of providing employment for local people and has education programs with Universities and also has several apprentices and trainees every year[92].

In addition, the TiZir Titanium and Iron facility (located at Hardangerfjord on the west coast of Norway) is producing titanium slag and high purity pig iron (HPPI) (NB. the company has recently decided to transition from sulphate to chloride titanium slag). It is the only such facility in Europe and only one of five in the world. The current capacity is 230 ktonnes/y of titanium slag and the titanium slag is predominantly sold to pigment producers[93]. Sales of titanium slag in 2014 and 2015 were ca. 178 ktonnes and 132 ktonnes respectively[94]. Levels of employment at the plant were over 200 employees (2013 and 2014 data suggest 236 and 214 employees respectively[95]).

4.7.2 Impacts on suppliers of feedstock, raw materials and utilities

It is understood that both these Norwegian companies sell the majority of their output to European customers. Thus, the potential reduction in the size of the TiO_2 manufacturing base in the EEA could have adverse repercussions for the profitability of these mining and ore processing operations. Levels of employment might be affected as a result of a Carc Cat 2 classification for TiO_2. A Carc Cat 2 classification for TiO_2 might lead to the following impacts for these upstream stakeholders:

- **Ilmenite concentrate (Titania AS)**: publicly available financial information for the company suggests a turnover of ca. €80-104 million in the period 2013-2015 with earnings before taxes in the region of €23-28 million per year[96]. The majority of profits are assumed to be derived from sales to European customers. If TiO_2 production in the EEA was curtailed or collapsed, the company would naturally aim to find customers overseas. The extent to which this would be

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90 As indicated at http://kronostio2.com/en/manufacturing-facilities/hauge-norway and http://www.ngu.no/sites/default/files/Focus%20nr4_TITANIUM_AND_IRON_TITANIUM%20%20DEPOSITS_IN_NORWAY__v2.pdf (both accessed on 4 November 2016).

91 257 employees in 2015 according to http://www.proff.no/selskap/titania-as/hauge-i-dalane/-/Z0ITENO3/ (accessed on 4 November 2016).

92 Information available at http://kronostio2.com/en/manufacturing-facilities/hauge-norway (accessed on 2 November 2016).

93 Information available at http://www.tizir.co.uk/projects-operations/tyssedal-tio2/ (accessed on 2 November 2016).

94 Multiple sources – Information available at http://www.tizir.co.uk/investors/news-releases/ (accessed on 2 November 2016).

95 Information available at http://www.largestcompanies.com/company/Tizir-Titanium--Iron-AS-275252/closing-figures-and-key-ratios (accessed on 2 November 2016).

96 Information available at http://www.largestcompanies.com/company/Titania-AS-140102/closing-figures-and-key-ratios (accessed on 4 November 2016).

successful and what the economic impacts would be is uncertain – freight costs would make sales to overseas customers potentially uneconomic and there are not that many alternative uses of ilmenite; and

- **Titanium slag (TiZir)**: the 2015 annual reports of TiZir Titanium and Iron suggests total sales of ca. 132 ktonnes in 2015 and ca. 178 ktonnes in 2014[97]. The financial performance of the company in 2015 was worse than the previous years with negative earnings before tax in 2015 down from €4 million in 2014 and €41 million in 2013[98]. It must be noted however that the company produces not only titanium slag but also pig iron and the financial results reflect profits from sales of both products. As for the mining company above, if TiO_2 production in the EEA was curtailed or collapsed, this company would naturally aim to find customers overseas. The extent to which this would be successful and what the economic impacts would be is uncertain.

The majority of feedstock currently used by EEA-based TiO_2 manufacturers is sourced from non-EEA suppliers. The volumes are particularly large. For instance, the relevant IPPC BREF Document notes that sulphate plants may use on average 1.662 tonnes of ilmenite per tonne of TiO_2 pigment products and 0.956 tonne of slag per tonne of TiO_2 pigment produced. If TiO_2 production in the EEA declined by an estimated 15%, the volume of TiO_2 that would not be manufactured would be ca. 160 ktonnes per year. As a consequence, the volumes of feedstock that would no longer be imported into the EEA would be in the range of hundreds of thousands of tonnes. More severe impacts on TiO_2 manufacture would naturally lead to greater impacts upstream.

The volumes of other raw material inputs are similarly large and some calculations can be made to provide an order of magnitude of the volumes of chemicals that would no longer be consumed in the EEA. The majority of these are widely used substances and are likely to be sourced from EEA suppliers. The basis of the calculations are figures provided in the relevant IPPC BREF document (European Commission, 2007) and are reproduced in **Table 4–31**.

Table 4–31: Raw material and energy input to TiO_2 pigment manufacture according to the IPPC BREF Document (excluding feedstock)

Input	Unit	Chloride process	Sulphate process
Chlorine	t/t pigment	0.201	-
Sulphuric acid	t/t pigment	-	3.250 (total, new + recycled)
Coke	t/t pigment	0.366	-
Lime	t/t pigment	0.137	-
Coal	t/t pigment	0.090	-
Oil	t/t pigment	0.005	-
Oxygen	t/t pigment	0.467	-
Silica sand	t/t pigment	0.049	-
Rock salt	t/t pigment	0.016	-
Scrap iron	t/t pigment	-	0.150
Aluminium sulphate	t/t pigment	-	0.021
Hydrogen peroxide	t/t pigment	-	0.012
Calcium hydroxide	t/t pigment	-	0.363
Calcium chloride	t/t pigment	-	0.015
Calcium carbonate	t/t pigment	-	1.380

97 Information available at http://www.tizir.co.uk/wp-content/uploads/2016/04/Tizir-Ltd-Annual-Report-2015.pdf (accessed on 2 November 2016).

98 Information available at http://www.largestcompanies.com/company/Tizir-Titanium--Iron-AS-275252/closing-figures-and-key-ratios?currency=EUR (accessed on 4 November 2016).

Table 4–31: Raw material and energy input to TiO_2 pigment manufacture according to the IPPC BREF Document (excluding feedstock)			
Input	**Unit**	**Chloride process**	**Sulphate process**
Aluminium hydroxide	t/t pigment	-	0.030
Caustic soda	t/t pigment	0.104	0.090
Energy	GJ/t pigment	17-29	23-29 with sulphuric acid neutralisation 33-41 with sulphuric acid re-concentration*
Source: European Commission (2007) * Given different combinations of systems used across the EEA TiO_2 industry for acid neutralisation and/or acid reconcentration, the extreme ranges as in (a) and (b) above apply only as indicative levels for the estimation of the overall energy efficiency in the TiO_2 plant in question			

The split between sulphate and chloride TiO_2 production capacity in the EEA is 55:45 and this is assumed to apply to the actual production volume of 1,100 ktonnes/y. **Table 4–32** summarises the volumes of raw material inputs (excluding feedstock) and energy into EEA-based TiO_2 manufacture.

Table 4–32: Quantified raw material and energy input to TiO_2 pigment manufacture		
Input	**Input**	**Unit**
Feed - Ilmenite	1,540,000	t
Feed - Slag	580,000	t
Chlorine	100,000	t
Sulphuric acid	1,960,000	t
Coke	180,000	t
Lime	70,000	t
Coal	40,000	t
Oil	2,490	t
Oxygen	230,000	t
Silica sand	20,000	t
Rock salt	10,000	t
Scrap iron	90,000	t
Aluminium sulphate	10,000	t
Hydrogen peroxide	10,000	t
Calcium hydroxide	220,000	t
Calcium chloride	10,000	t
Calcium carbonate	830,000	t
Aluminium hydroxide	20,000	t
Caustic soda	110,000	t
Energy	27,100,000	GJ
* Equivalent to ca. 7,500 GWh		

In total, the trade of ca. 4 million tonnes of raw materials would be at stake. If manufacture of TiO_2 in the EEA would decline by only 15%, the amount of TiO_2 production to be lost would be ca. 160-165 ktonnes per year (90 ktonnes/y of the lost volumes would be normally produced via the sulphate process and ca. 75 ktonnes/y of the lost volumes would be normally produced via the chloride process) and the loss of demand for material inputs would be limited to ca. 0.57 million tonnes of chemicals and ca. 1,100 GWh of energy. Some of these losses could be counter-balanced by increased sales to non-EEA customers.

In conclusion, a reduction in the TiO_2 manufacturing base in the EEA (with some plant closures being possible) would result in considerable loss of turnover for the suppliers of feedstock, raw materials, consumables, utilities as well as suppliers of all purchased services required to maintain and operate those manufacturing facilities. Those impacts would be significantly worse if Europe's TiO_2 manufacturing base were to collapse under the burden of lost sales and substantially increase waste management costs.

4.8 Impacts outside the titanium dioxide supply chains

4.8.1 Impacts on industrial minerals that contain titanium dioxide impurities

Relevant industrial minerals and their markets

Introduction

Many industrial minerals contain TiO_2 as a natural impurity up to 4% by weight (TiO_2 is also a common component in soils and marine sands). Examples include:

- Kaolin;
- Bentonite;
- Perlite;
- Mica;
- Diatomite;
- Ball clays;
- Refractory calcined clay (chamotte);
- Calcined bauxite;
- Brown fused alumina;
- Andalusite;
- Zircon (natural zirconium silicate);
- Synthetic mullite;
- Refractory clay; and
- Metal working slags.

TiO_2 in the form of rutile is a widespread accessory mineral in many rocks (magmatic, metamorphic and sedimentary), hence it is also present in industrially used hard rocks (e.g. granite).

A discussion on some of these minerals, including details of their applications and markets is provided below. The combined market value of these minerals is very substantial and the market value of products that rely on them is even greater.

Kaolin

Kaolinite is a clay mineral with the chemical composition $Al_2Si_2O_5(OH)_4$. It is also known as pigment PW19 (Colour Index generic name) / 7004CI (C.I. Constitution number). It is described as "*white clay rock, mostly natural hydrated aluminium silicate with impurities of magnesium, iron carbonates, ferric hydroxide, mica, quartz-sand, etc.*" and the CAS Number 1332-58-7.

Anatase is an impurity in kaolin and the target is to remove the material through industrial beneficiation processes. However, residues remain in kaolin end-products. The presence of TiO_2 in kaolin is **up to 2.5%**, i.e. exceeds the 1% by weight carcinogenicity category 2 classification limit.

Kaolin is used as an extender often to reduce the loading of TiO_2. Due to the presence of TiO_2 impurities in kaolin, however, kaolin would not be a suitable alternative for TiO_2 if the proposed classification for TiO_2 was adopted.

Kaolin currently finds a wide range of applications, including (IMA Europe, undated):

- **Paper**: in the bulk of the paper and to coat its surface. Examples include papers for magazines and brochures, art paper, cartons and boxes, etc.;

- **Ceramics**: whitewares (tableware, sanitaryware, and wall and floor tiles);

- **Fillers**: its whiteness or near whiteness, make it suitable as a filler or pigment;

- **Paint**: calcined kaolins are widely used in satin and matt paints. Kaolin is particularly useful as a partial replacement for TiO_2 pigment, as noted above;

- **Rubber**: used in high value thermoplastic elastomers for a variety of applications and in rubber insulation on high voltage power lines;

- **Plastics**: major application is in PVC cables where its main function is to improve electrical properties. Other important applications include specialty films where it imparts anti-blocking or infrared absorption characteristics. Chemically treated, calcined kaolin is one of the major additives used in the manufacture of automotive parts based on engineering thermoplastics;

- **Refractories**: used to build structures subjected to high temperatures, ranging from simple to sophisticated products, e.g. from fireplace brick linings to re-entry heat shields for the space shuttles. In industry, they are used to line boilers and furnaces of all types-reactors, ladles, stills, kilns and so forth;

- **Fibreglass**: improves the integration of fibres in products requiring strengthened plastics: cars, boats and marine products, sporting goods and recreation products, aviation and aerospace products, circuit board manufacturing, fibreglass insulation, fibreglass air filters, fibreglass tanks and pipes, corrosion resistant fibreglass products, fibreglass building and construction products, etc.; and

- **Cosmetics and pharmaceuticals**: 'British Pharmacopoeia Light Kaolin' (BPLK) is used in both human and veterinary medicinal products, for example, to treat digestion problems and as a constituent of poultices. It can also be used as an excipient in personal care products and in a number of dietary products, plasters, foot-powders and in the specialised treatment of some lung disorders.

The current production volume of kaolin in the EU is 4 million t/y and its consumption is around the same. The market for kaolin in the EU is worth €300 million/y.

Bentonite

Bentonite is an absorbent aluminium phyllosilicate clay consisting mostly of montmorillonite. It contains up to **2%** TiO_2 by weight, i.e. exceeds the 1% by weight carcinogenicity category 2 classification limit. It finds a variety of uses, including (IMA Europe, undated):

- **Foundry**: bonding material in the preparation of moulding sand for the production of iron, steel and non-ferrous casting;

- **Pelletising**: binding agent in the production of iron ore pellets;

- **Construction and civil engineering**: thixotropic, support and lubricant agent in diaphragm walls and foundations, in tunnelling, in horizontal directional drilling (HDD) and pipe jacking. Also used in Portland cement and mortars;

- **Environmental markets**: wastewater purification. Bentonite is the active protective layer of the Geosynthetic Clay Liners;

- **Drilling**: mud constituent for oil- and water-well drilling;

- **Oils / food markets**: removal of impurities in oils where its adsorptive properties are crucial in the processing edible oils and fats (soya / palm / canola oil). In drinks such as beer, wine and mineral water and in products like sugar or honey, bentonite is used as a clarification agent;

- **Agriculture**: animal feed supplement, as a pelletising aid in the production of the animal feed pellets, as well as a flowability aid for unconsolidated feed ingredients such as soy meal. It is also used as an ion-exchanger for improvement and conditioning of the soil. When thermally treated, it can be used as a porous ceramic carrier for various herbicides and pesticides;

- **Pharmaceuticals, cosmetics and medical markets**: filler in pharmaceuticals and antidote in heavy metal poisoning. Personal care products such as mud packs, sunburn paint, baby and face powders, and face creams may all contain bentonite;

- **Detergents**: laundry detergents and liquid hand cleansers/soaps;

- **Paints, dyes and polishes**: thickening and/or suspension agent in varnishes, and in water and solvent paints.

- **Cat litter**;

- **Paper**: used in pitch control, de-inking for paper recycling and the manufacture of carbonless copy paper; and

- **Catalyst**: employed in the alkylation processes to produce fuel additives.

The current production volume of bentonite in the EU is 3 million t/y and its consumption is ca. 2.7 million/y. The market for bentonite in the EU is worth €600 million/y.

Perlite

Perlite is an amorphous volcanic glass that has a relatively high water content, typically formed by the hydration of obsidian. It is naturally occurring and has the unusual property of greatly expanding when heated sufficiently. It is an industrial mineral and a commercial product useful for its light weight after processing. Perlite may contain **0.2%** by weight TiO_2, i.e. it does not exceed the 1% by weight carcinogenicity category 2 classification limit but its market would be impacted if TiO_2 were to be classified as Carc Cat 1B. It finds a variety of uses, including (The Perlite Institute, undated):

- Lightweight formed products;
- High temperature insulation;
- Simulated stone, masonry and wood products;
- Perlite volcanic glass as a hollow microsphere filler;
- Lightweight fillers for glass/reinforced polyester;

- Perlite volcanic glass as a glass flake filler;
- Perlite concrete;
- Filtration (filter aid);
- Non-evacuated cryogenic and low temperature services;
- Well cements; and
- As an absorbent or carrier.

The current production volume of perlite in the EU is 0.65 million t/y and its consumption is around the same. The market for perlite in the EU is worth €120 million/y.

Mica

Mica is a mineral name given to a group of minerals that are physically and chemically similar. They are all silicate minerals, known as sheet silicates (because they form in distinct layers). Micas are fairly light and relatively soft, and the sheets and flakes of mica are flexible. Mica is heat-resistant and does not conduct electricity. There are 37 different mica minerals. The most common include purple lepidolite, black biotite, brown phlogopite and clear muscovite (Minerals Education Coalition, undated). Mica may contain up to **2%** by weight TiO_2, i.e. exceeds the 1% by weight carcinogenicity category 2 classification limit.

It finds wide application, including (IMA Europe, undated):

- **Automotive**: mica is used in the production of bitumen foils that are attached onto the inner vehicle frame structures to dampen vibrations;

- **Brake pads and clutches**: mica is added to frictional systems to impart better heat transfer in conjunction with noise reduction;

- **Decoratives**: mica can be found in various products such as decorative paints, ceramics, decorative concrete, post cards, wallpapers;

- **Drilling**: mica is used as a mud constituent for oil well drilling;

- **Fibre cement**: mica is used in highly engineered fibre cement to impart dimensional stability either in moisturising conditions or in passive fire protection;

- **Fire extinguishers**: mica provides anti-caking & flowability;

- **Foundries**: mica is used for coatings in iron casting and to a limited extent in aluminium production casting;

- **Paints and coatings**: mica is used in external renderings and anti-corrosive paints;

- **Paper coatings**: mica is used in packaging products as it provides protection from the water or grease associated with the food;

- **Plastics**: mica acts as a reinforcing additive in the packaging industry and in the automotive industry;

- **Plasterboard and joint compound**: mica is used primarily as an anti-cracking and reinforcing additive;

- **Pearlescent pigments**: mica can provide a pearlescent effect once it has been coated with TiO_2 or Fe_2O_3;

- **Rubber**: mica is used either as a demoulding agent during the vulcanisation process, or as an anti-sticking powder when several rubber pieces are stacked together; and

- **Welding rods**: mica brings added value both during the rod manufacturing step (easing the extrusion) and the welding itself. During welding, the platy structure acts like a shield protecting the molten steel from ambient air oxidation and moisture.

The current production volume of mica in the EU is 90,000 t/y. The market for mica in the EU is worth €40 million/y.

Diatomite

The term diatomite is applied both geologically and commercially to the nearly pure sedimentary accumulation of diatom frustules—the microscopic skeletons of unicellular aquatic algae belonging to the class of golden brown algae, Bacillariophyceae. The sediments are fine-grained, highly siliceous, and consist primarily of amorphous opaline silica with only minor amounts of organic residue, secondary minerals, and co-deposited non-diatomaceous or crystalline clastic debris. Synonyms in current usage include diatomaceous earth and kieselguhr (Minerals Education Coalition, undated - b). Diatomite may contain up to **0.7%** by weight TiO_2 (i.e. it does not exceed the 1% by weight carcinogenicity category 2 classification limit but its market would be impacted if TiO_2 were to be classified as Carc Cat 1B) and finds a variety of applications, such as (IMA Europe, undated):

- **Filter aids**: because of its high degree of porosity combined with its low density and inertness, diatomite makes an excellent filtration medium, used for antibiotics, beer, chemicals, edible oils and fats, fruit juices, glucose, pharmaceuticals, solvents, sugar, vitamins, water, wine, and many others;

- **Functional mineral additives**: the versatility of diatomite as a functional filler, in part as a result of its unique particle shape, has led to its widespread use in a number of applications such as paints, plastics, paper, insulating bricks, and dental mouldings;

- **Carriers for active Ingredients and diluents**: typical applications include: pesticide carriers and catalyst carriers; and

- **Aggregates**: the aggregates are used as absorbents in a number of applications including floor sweeping, the clean-up of hazardous wastes, oil and grease absorbents, and soil amendments.

The current production volume of diatomite in the EU is 0.1 million t/y and its consumption is 0.13 million t/y. The market for diatomite in the EU is worth €40 million/y.

Ball clays

Ball clay (also known as plastic clay) is an extremely rare mineral found in very few places around the world. Ball clays usually contain three dominant minerals: from 20-80% kaolinite, 10-25% mica, and 6-65% quartz. In addition, there are other 'accessory' minerals and some carbonaceous materials present. The wide variation both in mineral composition and in the size of the clay particles, results in different characteristics for individual clay seams within a deposit (IMA-NA, undated). Ball clays may contain up to **2%** by weight TiO_2, i.e. exceeds the 1% by weight Carc Cat 2 classification limit. Their applications include (IMA Europe, undated):

- **Sanitaryware**: ball clay provides plasticity and workability;
- **Tableware**: ceramic tableware utilises plastic clay to provide high plasticity and a good white-fired colour, combined with kaolin, feldspar and quartz;
- **Wall and floor tiles**: combined with feldspar, kaolin and quartz, plastic clays are utilised for their plasticity and bonding properties;
- **Glazes and slips**: plastic clays are also used in the production of coatings for ceramic products;
- **Refractory clays**: ball clays are used in refractory products such as kiln insulation and furniture;
- **Construction ceramics**: building materials such as bricks, clay pipes and roof tiles all contain plastic clay;
- **Electrical porcelain insulators**: plastic clays are used in the electrical porcelain components that provide insulation from high voltage currents;
- **Chemical applications**: plastic clays are used as fine fillers and extenders in polymers, adhesives, plastics, fertilisers and insecticides; and
- **Sealants**: plastic clays are also widely used for lining landfill waste disposal sites, and for sealing over them once completed.

The current production volume of ball clays in the EU is 12 million t/y and its consumption is around the same. The market for ball clays in the EU is worth €400 million/y.

Vermiculite

Vermiculite is a member of the phyllosilicate, or sheet silicate, group of minerals. It has the unique ability to expand to many times its original volume when heated - a property known as exfoliation. The majority of applications call for vermiculite in its exfoliated form (IMA Europe, undated - b).

Vermiculite contains **0.5%** by weight TiO_2 (i.e. it does not exceed the 1% by weight carcinogenicity category 2 classification limit but its market would be impacted if TiO_2 were to be classified as Carc Cat 1B) and finds a variety of applications including (IMA Europe, undated)

- **Animal feedstuffs**: vermiculite is used as a support and carrying medium for a range of nutrients such as fat concentrates, vitamin preparations and molasses;
- **Bitumen coated screeds**: vermiculite, coated with a bituminous binder, can be used as a dry, lightweight roof and floor screed;
- **Lightweight concretes**: vermiculite concretes may be used for in situ roof and floor screeds and in the fabrication of pre-cast products. Vermiculite concretes can also be used around back boilers and as a fire back support material;
- **Vermiculite plasters**;

- **Loose-fill insulation**: loose-fill vermiculite can be used between joists in lofts for house insulation;

- **Boards, panels and premixed coatings**: these coatings have been used in the petrochemical industry and tunnel construction;

- **Refractory and high temperature insulation**: vermiculite for refractory and high temperature insulation is normally bonded with alumina cements, fire clays and silicates to produce a wide range of vermiculite products which, depending on type and application, can withstand hot face temperatures of up to 1,100 °C;

- **Steelworks and foundries**: vermiculite is used for hot topping molten steel to reduce heat loss from ingots and ladles and generally as a loose-fill insulator;

- **Silicate bonded shapes and blocks**: pressed vermiculite block insulation can be used in high temperature kilns, furnaces, combustion plants, boilers, wood burning stoves and night storage heaters;

- **Automotive industry**: vermiculite is now used extensively in the friction lining industry (e.g. brake and clutch linings) as a safe alternative to asbestos;

- **Horticulture:** vermiculite is well established as a growing medium; and

- **Packaging materials**: exfoliated vermiculite is a useful packaging medium.

Currently, ca. 18,000 tonnes of vermiculite are produced each year in the EU (in Bulgaria) (USGS, 2016b). No data are available on the value of the market in the EU.

Refractory materials

TiO_2 is also present, up to 4%, in a number of naturally occurring minerals that are used in the refractory industry including refractory calcined clay (chamotte), calcined bauxite, brown fused alumina, andalusite, zircon silicate, synthetic mullite, refractory clay, as well as kaolin and bentonites that were discussed above (Cerame-Unie, 2016; German Refractory Association, 2016)[99].

The European Refractory Producers Federation brings together 160 members located in Austria, Belgium, the Czech Republic, France, Germany, Italy, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain and the UK. These companies would be affected by the proposed classification and it is estimated that the proposed classification would impact 40% to 50% of all refractory products (Cerame-Unie, 2016). With regard to the tonnage of potentially impacted refractories, the European Refractory Producers Federation estimates that TiO_2 occurs as an impurity in nearly all silica-based refractories and about 80% of the high alumina refractories. According to statistics held by the Federation, this amounts to 1.3 million t/y manufactured in the EU.

[99] TiO_2 can also be found in metal working slags. A range of 0.5 to 1% is typical in blast furnace slags. Quoted quantities are 35 million t/y for blast furnaces in the EU. Although X-ray fluorescence analysis might detect titanium in a sample which is conventionally reported as TiO_2, in some materials the titanium might be present as titanates. Any classification change needs to be clear on what it applies to.

The value of the EU refractory market in 2014 was ca. €4.8 billion/y; therefore, a simple analogy would suggest that €2-2.5 billion worth might be affected by the proposed classification for TiO_2. In 2014, the industry employed over 17,000 workers[100].

Abrasives

TiO_2 can be present as an impurity in the abrasive grains used in the abrasive industry at a concentration of up to 0.5% by weight (with the exception of pure white fused alumina, which is free of Ti)[101]. According to the Federation of European Producers of Abrasives (FEPA), the abrasives industry represents an annual turnover of €3.5 billion in Europe, of which two-thirds (2/3) are bonded and coated abrasives (€2.3 billion) and 10% are ceramic abrasives (vitrified bonded). There are 150 abrasives production plants in European countries employing ca. 20,000 workers, with 80% involved in the manufacture of bonded and coated abrasives and 30% involved in the manufacture of ceramic abrasives products.

Zircon

Zircon is a mineral belonging to the group of nesosilicates and it is natural zirconium silicate, $ZrSiO_4$. Ilmenite ($FeTiO_3$), rutile (TiO_2) and zircon minerals are mined together as co-products. The downstream processing of zircon, however, leaves TiO_2 as an impurity at **0.1-0.5%** by weight in the zircon. Therefore, the proposed classification for TiO_2 would impact on the industry as classification rules mean that zircon would carry the same classification as TiO_2.

Ceramics account for the single largest share of demand with about 50%[102] as a whitening agent in the body of porcelain tiles, followed by refractory and foundry (30%)[103], followed by zirconia, zirconium chemicals and metal. Minor uses include friction materials, welding rods and zirconium alloys.

There are 10 EU-based companies involved in the marketing of zirconium products in the EU alongside a smaller number of non-EU companies. The most important countries in this market include France, Spain, Italy, Germany and the UK.

The volume of zircon consumed in the EU is estimated at 325 ktonnes/y (according to the USGS, no production takes place in the EU) and has a market value of just over US$300 million (or over €275

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[100] Figures based on a visual assessment of statistics available at http://www.pre.eu/ (accessed on 28 October 2016).

[101] There have also been suggestions that ilmenite or titanium slag may also be used as abrasives.

[102] Information available at http://www.zircon-association.org/Websites/zircon/images/Resources/EICF_160417_presentation_web.pdf (accessed on 28 October 2016).

[103] Foundry applications are mostly relevant to China.

million) per year[104]. It is worth noting that the TiO_2 feedstock demand is the principal driver of zircon supply[105].

Summary

A summary of the key information on the aforementioned minerals is provided in . The total market value of these minerals and products exceeds €6.2 billion a year but it must be understood that downstream uses of these minerals are of a value much higher than what is shown in this table.

Table 4–33: TiO_2 impurities and markets for selected minerals and products (and scale of impact of TiO_2 classification)

Mineral	TiO_2 impurities (%)	Impacted by TiO_2 classification		EU production (million t/y)	EU market (million t/y)	Value of EU market (€billion/y)
		Carc Cat 2	Carc Cat 1B			
Kaolin	>2.5	✓	✓	4	4	0.3
Bentonite	>2	✓	✓	3	2.7	0.6
Perlite	0.2	×	✓	0.65	0.65	0.12
Mica	<2	✓	✓	0.09	No data	0.04
Diatomite	<0.7	×	✓	0.1	0.13	0.04
Ball clays	<2	✓	✓	12	12	0.4
Vermiculite	0.5	×	✓	0.018	No data	No data
Refractory materials	<4	✓	✓	1.3	No data	>2
Abrasives (ceramic)	0.5	×	✓	No data	No data	2.5
Zircon	0.1-0.5	×	✓	-	0.325	0.275
Total affected by Carc Cat 2	**-**			**>20**	**>18**	**>3.3**
Total affected by Carc Cat 1B				**>21**	**>20**	**>6.2**
Source: consultation						

Impacts from a Carc Cat 2 harmonised classification for titanium dioxide

If TiO_2 were to be classified as Carc Cat 2 (or Carc Cat 1B), several industrial minerals would also have to be classified in the same hazard category if the TiO_2 impurities exceeded the relevant classification limit (1% by weight for Carc Cat 2 and 0.1% by weight for Carc Cat 1B). This could affect their handling, processing, use and waste disposal.

As shown in the table above, on the basis of typical TiO_2 levels present in these minerals, kaolin, bentonite, mica, ball clays and refractory materials would be impacted; these minerals have a combined EU market size of over 18 million tonnes per year and an EU market value of over €3.3 billion. Conversely, minerals such as perlite, diatomite, vermiculite, abrasive grains and zircon would not be affected as their TiO_2 impurities are below the 1% by weight level.

[104] A value per tonne of just below US$1,000 per tonne has been obtained from http://www.zircon-association.org/assets/files/KnowledgeBank/EICF_160417_presentation_web.pdf (accessed on 25 August 2017). An exchange rate of US$1 = €0.917 has been used (as of 28 October 2016).

[105] Information available at http://www.zircon-association.org/Websites/zircon/images/Resources/EICF_160417_presentation_web.pdf (accessed on 28 October 2016).

Impacts would arise as a result of:

- New labelling, which could drive user perception and might have an impact on the cost of handling of the minerals; the presence of the new carcinogen might appear on the safety data sheet which might increase user resistance - even though the TiO_2 is not readily available for inhalation. Contrary to a Carc Cat 1B classification, users would not be obliged by the Carcinogens and Mutagens Directive to actively consider alternatives and strengthen their worker health and safety protection measures; nevertheless, some companies routinely publish and implement black lists of materials to be avoided on grounds that they are CMR; and

- New waste management requirements, as the presence of TiO_2 in concentrations above 1% could render relevant waste streams as hazardous thus requiring different handling and disposal.

4.8.2 Impacts on manufacturers and users of other poorly soluble powders

In its 14 September 2017 opinion, RAC acknowledges that the carcinogenicity profile described for TiO_2 is not exclusively characteristic to TiO_2 but applies to a group of chemicals with similar toxicity profile addressed as "poorly soluble low toxicity (PSLT) particles". As such, the classification of TiO_2 sets a precedent for a subsequent classification of all other PSLT powders regardless of each and every substance's human health carcinogenicity data. Other PSLTs which may be impacted include carbon black, inorganic coloured pigments, iron oxides, cerium oxide, aluminium oxide, magnesium oxide and plastic dusts.

In this context, the ultimate classification for TiO_2 would be a cause of significant problems in two key areas:

- All poorly soluble powders that could replace it (including minerals such as kaolin, chalk, talc, etc.) could be suspected of causing carcinogenicity in humans in a similar manner. As such, the hazard classification of TiO_2 would not offer any discernible additional protection to workers' health as its direct alternatives would have an equivalent carcinogenicity hazard profile; and

- The manufacture, handling, use and disposal of other poorly soluble powders, if similarly classified for carcinogenicity, would become more costly and burdensome in the EEA thus leading to further loss of competitiveness of EEA businesses.

A case study of potential impacts is provided for carbon black (and associated materials) overleaf.

Box 4-3: Case study – Potential impacts on the carbon black industry from the proposed classification for TiO_2

Carbon black (EC No. 215-609-9, CAS No. 1333-86-4) is virtually pure elemental carbon in the form of colloidal particles that are produced by incomplete combustion or thermal decomposition of gaseous or liquid hydrocarbons under controlled conditions. Carbon black is mainly used as a reinforcing agent in tyres and other rubber products. A small percentage is used as a colourant in polymers for indirect food contact use. Carbon black is also in the top 50 industrial chemicals manufactured worldwide, based on annual tonnage, which currently stands at 8.1 million t/y[106].

There are four EU-based companies involved in the manufacture of carbon black and seven companies in total that place carbon black on the EU market. The most important EU Member States within the carbon black market are the Netherlands and Italy as they both host carbon black manufacturing plants. It is estimated that 2,600-3,200 workers are employed in the carbon black industry in the EU.

The EU market for carbon black had a volume of 2 million tonnes in 2014, of which rubber goods (mostly tyres) represented 88% of consumption, followed by plastics (5%), printing inks (4%), coatings and paints (1%) and other small applications such as activated carbon, concrete/bricks, papers/toners and road fillers (collectively accounting or 2%) (Jung & Bouysset, 2015).

As described above, the proposed classification for TiO_2 would potentially pave the way for the classification of carbon black and other substances, for example, fumed alumina (which is used in adhesives, sealants, chemical mechanical planarization and cosmetics)) and activated carbon (which is used in a large variety of uses including as an industrial and consumer filtration medium for potable water and other consumable beverages). Such a classification would have a profound adverse impact on the use of the substances; it would make their handling, use and disposal in the EEA more burdensome and costly and could lead to loss of competitiveness among manufacturers of these substances but also EEA-based downstream users.

If a carcinogenicity classification encouraged users to seek alternatives, impacts on consumer welfare might arise; as the majority of carbon black is used as a reinforcing agent in car and lorry tyres, it imparts important safety properties to the rubber of a tyre, specifically rolling resistance, durability and longevity. Simply stated, consumer and lorry tyres would be less safe and would wear out much sooner (i.e., ca. 10,000 miles lifespan) without the use of carbon black. In another example, activated carbon acts as a filtration medium and removes harmful impurities and unpleasant odours in potable water and other beverages. Its classification might restrict its use in food and beverage processing, possibly compromising food and beverage quality & safety.

Furthermore, given the EU's regulatory influence, this classification could be adopted by other countries and would greatly increase the possibility of product liability legal actions, and worker compensation claims.

Source: information submitted by a leading carbon black manufacturer

4.9 Impacts on the environment

Making the continued use of TiO_2 more burdensome and encouraging the substitution of the substance could have adverse impacts on the environment. This is elaborated with specific examples overleaf.

[106] Information available at http://www.carbon-black.org/index.php/what-is-carbon-black (accessed on 28 October 2016).

Impact category	Relevant applications	Description
Imports of finished articles into the EEA	All	In many applications, cheaper, imported finished articles might replace more expensive EEA-made ones; as a result, there would be an increase in CO_2 emissions from increased transportation of the articles into the EEA.
Alternatives and their impacts on the environment	All	**Obtaining sufficient volumes of alternatives**: the energy required to produce TiO_2 is high and, as such, the ecological footprint of its production is significant. However, the alternatives to TiO_2 are, like TiO_2, based on minerals that are extracted from the earth. A significant new investment and infrastructure would need to be put in place to meet the significantly increased demand for the alternatives. This would have its own significant ecological footprint, which would not be as optimised as has been currently achieved through the 90 years of experience of industrial use of TiO_2. In addition, the current TiO_2 extraction and processing activities (typically outside the EEA) would become redundant and significant volumes of equipment and construction waste from this decommissioning would be generated.
	All	**Adverse effects of alternatives**: some alternatives to TiO_2 are accompanied by an environmental hazard classification (e.g. heavy metals or zinc-based pigments). Substitution of TiO_2 with one of those substances might thus increase ecological pressure on the environment. With specific regard to cosmetics, an increased use of organic UV filters as TiO_2 substitutes would lead to higher volumes of them being released into the environment with potentially long-term adverse effects onto the flora and fauna. Spherical plastic particles that can be used as substitutes are products based on mineral oil and require significant amounts of energy to produce and convert for use and there are concerns about their release to the aquatic environment. Alternatives to TiO_2 would need to be used at higher loadings and TiO_2-free articles would need to be replaced more often. Painting would require larger amounts of TiO_2-free paint thus leading to the generation of increased amounts of waste (empty paint tins). Production of bulkier products (for example, paper products) would impact on packaging and delivery costs, therefore affecting the environmental footprint of some products.

Impact category	Relevant applications	Description
	Adhesives / Fibres / Paper	**Natural vs. petrochemical products**: gelatine glues that contain TiO_2 are based on a by-product from animals and constitute a re-use of otherwise discarded material. The alternative would be hot melts which are more expensive and based on polymers that originate from the petrochemical industry. If these products were replaced, it would be by less environmentally friendly and would result in costlier and less recyclable products. On the other hand, if TiO_2 used in fibres were to be substituted, the poorer quality of the synthetic fibres would cause a shift to natural fibres. The global environmental impact would be much worse due to high land use, increased water and energy consumption, increased use of fertilisers and transport in the context of a projected increase of world population and limited technical closed loop recycling possibilities for natural fibres in comparison with the synthetic ones. Particleboard based furniture often utilises manufacturing residues or reclaimed wood as raw material and therefore the combination of décor paper and particle board contributes to high resource efficiency and the establishment of a circular economy. Décor paper is produced using mainly forest cellulose and TiO_2. The pulp comes from forest managed in a sustainable way (certified by external third parties as FSC and PEFC) and it is a renewable and carbon neutral raw material. Plastic films that could replace this paper are based on fossil fuels.
Durability	All (examples: paints, coatings, plastics)	Because of the superior durability of TiO_2-based paints, coatings, plastics, etc. any alternative would lead to the generation of higher emissions, more waste and the need to re-paint/coat or replace more often. Maintenance of buildings would increase; raw materials would be used more frequently and replacement of wooden parts would become common practice. This would go against the principles of sustainable development.

Impact category	Relevant applications	Description
Air quality	Construction products	**Substitution of TiO_2 would mean loss of photocatalytic applications**: NO_x are one of the most critical groups of air pollutants in urban areas. One of the options to reduce the concentration of these pollutants in the air is to create photocatalytically active surfaces in appropriate locations and TiO_2 is, so far, the only photocatalyst providing the required characteristics. In Directive 2008/50/EC, the European Union set upon local authorities a maximum limit of 40 µg nitrogen dioxide/m^3 in the ambient air at the local authority level and defined potential fines for authorities which fail to meet that limit (as an annual average). In July 2015, the European Commission reprimanded Germany for persistently exceeding the limit for many years[107]. If the federal, state and local governments continue to fail in taking sufficient action to reduce pollution of these harmful gases, there may be proceedings, and following that high fines may also be imposed on individual cities and local authorities (up to €50,000 per day and location is the possible penalty). The use of photocatalysis in TiO_2-containing products leads to environmentally friendly and sustainable decomposition of harmful gases and solids indoors (such as nicotine and tar). Various harmful substances are not simply collected in filter materials (which are often disposed as hazardous waste) but decomposed into harmless compounds. There is currently no comparable technology available. If the increased regulatory burden would impact upon the use of TiO_2 as a photocatalyst, this would bring to the end the widespread use of photocatalysis as an environment-friendly and sustainable technology for air cleaning.
	Fibres	**Automotive applications**: if synthetic fibres for wet laid processes could not be produced any more with a suitable quality due to the elimination of TiO_2 from fibre processing, they would not be available for filter products for the automotive industry. Maintenance intervals/mileages would have to decrease to a level unseen for decades and there would be higher engine oil consumption / material consumption/maintenance costs during a car's life.
	Catalysts	**Impact from loss of catalysts used to prevent atmospheric emissions**: inability to produce SCR catalysts could have adverse environmental impacts and a significant number of these SCR catalysts used globally are manufactured in the EEA. Particularly in countries outside the EEA with lower fuel quality, users would not be able to use SCR technologies for automotive applications and alternative technologies are sensitive to low fuel quality. This might delay the implementation of SCR technologies in such countries for years.

[107] Information available at http://www.fr-online.de/wirtschaft/stickoxid-und-feinstaub--europameister-im-luft-verpesten-,1472780,34274106.html (accessed on 23 October 2016).

Impact category	Relevant applications	Description
Energy consumption, efficiency and management	Paints & coatings, plastics	**Electricity consumption and heating**: if the availability of white and bright architectural paints on the market diminished, a higher consumption of electricity could be expected due to the use of darker colours in the home/office. In relation to exterior coatings, a negative impact would be expected on the heat management of buildings due to reduced light reflectivity. White colours contribute to a global lowering of temperature because of their solar reflectance (cf. temperature of a white roof <50 °C and a dark one >80 °C); reducing the availability of light colours would probably result in more energy-demanding, resource inefficient air conditioning with, ultimately, a potential impact on global warming. In addition, TiO_2 is used to make plastic roofing material and profiles (windows) which reflect light, thus causing buildings to heat up less in hotter climates. This reduces the need for air conditioning. Substitution of this roofing material with less effective material would thus increase energy consumption and the CO_2 footprint. Similarly, the reflectivity of road marking lines would be affected meaning that the white lines might not be as visible thus raising the need for more/better lighting on roads. The potential for a higher number of accidents would mean, apart from increased injuries or deaths, more delays on the roads and, in turn, this increased congestion would also have a negative environmental impact as more vehicles would be running for longer therefore creating more potentially harmful emissions into the atmosphere than would otherwise be produced.
	Inks	**Photovoltaic applications**: photovoltaic modules are covered with white ink films to increase efficiency. Without TiO_2-containing white inks it would not possible to achieve this effect, so efficiency would decline.
	Glass	**Glass applications**: if the EEA industry was discouraged from using TiO_2, there would be costs to the environment, as TiO_2-based glass offers significant benefits in sustainable construction materials – self-cleaning windows reduce maintenance and extend building lifetime, while coatings reduce the need for heating and cooling of buildings which is responsible for a large amount of CO_2 emissions.

Impact category	Relevant applications	Description
Waste management and recycling	Plastics and fibres	**Impacts on plastics recycling**: reclassification of plastic waste as hazardous due to the presence of TiO_2 as a carcinogen would have an effect on the recycling of such waste. Unless a specific exemption is introduced in Annex III of the Waste Framework Directive (on the basis of the critical route of exposure being irrelevant to plastic waste), up to 1.25 million tonnes of recycled plastic products would be at stake. Their recycling prevents the release of an estimated 1.8-2.4 million tonnes of CO_2 equivalents per year, according to the EuPC, through the increased use of virgin resins. Synthetic fibres allow good, proven and effective recycling techniques, such as mechanical recycling of the PP family in the Engineering Plastic sector; mechanical recovery of PET that is applied in fibres production; chemical recycling of polyamide back to feedstock monomer; plus, new innovative techniques currently in progress. A harmonised classification of TiO_2 as a carcinogen could make recycling of fibre waste more difficult, if not impossible if the waste is classified as hazardous. By way of example, using recycled PET polymer from PET bottles for fibres is a sustainable alternative to virgin PET polymer, with just 25% of the carbon footprint compared to virgin polymer use. If regulatory controls on TiO_2 became too burdensome, significant amounts of this high value secondary raw material would have to be exported to operations outside of the EEA. PET (and polyamide) recyclate is slightly discoloured due to the thermal history of the material. This discoloration is masked/reduced by TiO_2. If the continued use of TiO_2 would become unattractive, consumer acceptance for recycled fibre products (for example, in the bedding sector) would be reduced.
	Food packaging	If it was no longer possible to use TiO_2 in food packaging, then some information (which is presently provided by means of printing inks), would be delivered using adhesive paper labels. The mixing of materials would seriously hinder the ability of the current processes to recycle the packaging material. This could result in the growth of the non-recyclable waste fraction (which to date has been decreasing) and an increase in the amount of waste destined for landfill or energy recovery. Furthermore, due to the lower shelf life caused by the lack of TiO_2, increased amounts of packed food will have to be disposed of. If more packaging materials are printed outside the EEA, due to the non-availability of TiO_2 based inks within Europe, then the carbon footprint of the packaging will increase as a result of longer transport routes.

5 Conclusions

5.1 Why and how the proposed classification would impact the EEA

This report has explained that, should the Commission and REACH Committee agree with the RAC's proposal of a Carc Cat 2 harmonised classification for TiO_2, six drivers of impacts on the EEA industry and consumers would come into action:

1. **Restrictions**: there is existing legislation that restricts or otherwise controls the marketing and use of substances that are classified as Carc Cat 2 in specific industry sectors and markets (e.g. cosmetics, food contact materials or toys).

2. **Negative consumer perceptions (especially as a result of labelling)**: industrial/professional user and, primarily, consumer perceptions would play an important role. Irrespective of the route of exposure (which is critical in assessing risks from exposure to TiO_2), presence of a Carc Cat 2 substance in a vast number of industrial processes as well as products placed on the market, many intended for consumer use (e.g. DIY paints, adhesives, sealants, etc. but also food and pharmaceuticals as well as cosmetics) would be perceived by users in a negative way. Consumers would not be able to understand the fundamental difference between a Carc Cat 1B and a Carc Cat 2 classification or in any way be able to evaluate the importance of the exposure route.

3. **Increased administrative burden from and costs of waste management**: this report has shown than in many sectors several waste streams which are currently classified as non-hazardous, may be re-classified as hazardous following the introduction of the Carc Cat 2 harmonised classification due to a TiO_2 content that exceeds 1.0% by weight. Waste management cost increases would particularly impact the manufacturers of the pigment given the very large volumes of potentially relevant waste streams generated at each manufacturing location.

4. **Damage to the EEA manufacturing base**: the direct impact of a Carc Cat 2 harmonised classification would be the loss of up to an estimated 15% of the EEA market for TiO_2; this, combined with losses from sales of ancillary products and the increased cost of waste management would jeopardising the viability of (at least some) EEA-based TiO_2 manufacturing plants. Looking at the downstream supply chains for TiO_2-containing formulations and articles, these are particularly long and diverse; for instance, paints containing TiO_2 are applied to myriads of surfaces/articles which, in turn, find their way into vast numbers of different complex end products. Manufacturing outside the EEA, where the carcinogenicity classification for TiO_2 would not apply, could become more competitive and thus more attractive, and whilst it may be impossible to quantify all impacts that would arise along the supply chains, it is clear that adverse impacts would magnify as the scope and the value of markets increases along those chains.

5. **Lack of technically feasible alternatives**: there is a lack of feasible alternatives for TiO_2 for the vast majority of its uses therefore substitution could not be a feasible solution to an increased regulatory burden associated with the continued use of the substance. More specifically:

    a. There is no alternative on the market with technical properties, e.g. brilliance, colour strength, opacity, pearlescence and price-performance ratio, similar to TiO_2. The range of colour shades achievable (e.g. in paints) without TiO_2 is very narrow compared to the present range. Bright opaque colours available today would be unachievable.

b. No known alternative can demonstrate the weatherability of TiO_2. This is based on TiO_2's exceptional stability to heat, light and weathering plus its ability to absorb UV radiation, a critical property in the field of cosmetics, packaging and construction e.g. by preventing degradation of paint films and embrittlement of plastic articles.

c. No known alternative holds approvals for use in certain consumer applications where authorisation of additives is required before use. Only approved white colours can be used in food and pharmaceuticals and TiO_2 is the only white pigment which is approved for use as a colouring agent in food and pharmaceutical applications.

d. Some applications must use TiO_2. No other substance could replace TiO_2 as a raw material in the production of Complex Inorganic Coloured pigments (e.g. rutile pigments). In its use as a photocatalyst, no real alternative exists with the same performance.

Overall, there are no viable alternatives for delivering whiteness to polymeric or synthetic materials (paints, plastics, paper) as effectively or efficiently as TiO_2. Some potential alternatives may pose a hazard to human health and/or the environment. Importantly, if TiO_2 is classified as a Carc Cat 2 substance, other less white pigments (being poorly soluble powders themselves) would also meet the requirements for the same hazard classification, if they were to be tested to the same level as TiO_2.

6. **Adverse side-effects on unrelated supply chains**: the classification of TiO_2 would pave the way to the potential classification of other substances, either because they are themselves poorly soluble (see Point 5 above) or because they contain TiO_2 impurities at a level that exceeds 1.0% by weight. This would generate adverse impacts along the respective supply chains.

5.2 Impacts on the manufacture and supply of titanium dioxide in the EEA

In total, there are 17 TiO_2 manufacturing plants in the EU plus one in Norway (as well as two known manufacturers in Ukraine). Germany, the United Kingdom, and Finland combined represent over 60% of EEA production capacity for TiO_2.

EEA production represents almost 20% of the total worldwide production and amounts to ca. 1,100 ktonnes/y. Of this, 67-68% is sold in the EEA and the rest is sold to customers outside the EEA. The total value of the TiO_2 manufactured in EU plus Norway is estimated at ca. €3 billion and the **Gross Value Added to the EEA economy is estimated at ca. €560 million**. The breakdown of TiO_2's applications shows that paints, coatings, inks, plastics and paper account for 98% of total demand for the substance, with paints and coatings accounting for more than half of the total – importantly, exposure of the end users of these products is non-existent. The remaining 2% covers a wide range of minor but specialist applications (with each one still potentially accounting for the consumption of thousands of tonnes of TiO_2).

The range of impacts resulting from a Carc Cat 2 classification for TiO_2 manufacturers in the EEA include:

- **Capacity underutilisation**: this report estimates a significant direct impact on downstream uses of TiO_2 from a harmonised classification of Carc Cat 2 corresponding to the loss of 10-15% of total TiO_2 demand in the EEA. This impact would arise from a combination of regulatory pressures and negative user perceptions. Loss of demand, and the introduction of this harmonised classification, would not result in a corresponding increase in consumer and worker health protection. Due to the high fixed costs in the manufacture of the substance, a substantially high capacity utilisation is required to ensure profitability for each plant. Capacity utilisation in recent years has generally been low and any further decrease would jeopardise the economic viability of at least some TiO_2 manufacturing plants in the EEA;

- **Loss of production of ancillary products**: TiO_2 manufacturing plants also produce co-products such as titanium chemicals, iron salts, sulphates, inorganic acids, aluminium substances, etc. If demand for, and production of, TiO_2 declined, production (and associated sales) of these by-products would also be affected. Moreover, certain co-products (iron filter salts) also happen to contain more than 1.0% TiO_2 impurities by weight, meaning that they would also be classified as carcinogenic when placed on the market and this would impact upon their use for a number of their established uses; and

- **Higher cost of waste management**: if wastes with a TiO_2 content above 1.0% by weight were to be classified as hazardous, the cost and complexity of their waste management would dramatically increase. There are several waste streams generated at the TiO_2 manufacturing sites which amount to several thousand tonnes per year. Whilst these are currently disposed of as non-hazardous, the Carc Cat 2 harmonised classification might lead to them being classified as non-hazardous given their volumes, risk for exposure to TiO_2 by inhalation and the possibility of EEA Member States opting to make use of Article 7(2) of the Waste Framework Directive which permits Member States to classify waste as hazardous even if it does not appear as such on the LoW (as far as can be ascertained, this option does not appear to have found any/wide use so far). Moreover, red gypsum would be very unlikely to continue finding useful downstream applications as an industrial raw material leading to loss of sales which currently support the profitability of TiO_2 production. The excess cost associated with waste management could be in the range of **hundreds of millions of Euros**.

Overall, loss of demand for and sales of TiO_2 and co-products would have a severely detrimental effect on the EEA TiO_2 manufacturing base. If those impacts were to be accompanied by changes to waste management costs, the EEA might experience a (partial) collapse of its TiO_2 manufacturing base.

The TiO_2 manufacturing industry in the EA currently employs an estimated **8,150 workers** and is responsible for the **creation of ca. 22,800 support jobs** within the domestic economies of the relevant EEA Member States. These jobs would be at risk if TiO_2 plants were to shut down due to them no longer being economically viable. It can be envisaged that TiO_2 manufacturing activities outside the EEA would be expanded in order to meet global demand for the pigments thus, effectively, transferring jobs from the EEA to non-EEA locations.

5.3 Impacts on the supply of feedstock and raw materials and energy to titanium dioxide manufacture in the EEA

There is no mining of titanium ore in the EU, yet there is an ilmenite mine in Norway as well as an ore processor generating TiO_2 slag, also in Norway. These two companies are understood to currently sell most of their outputs to European customers. Adverse impacts to TiO_2 market in the EEA from the adoption of a Carc Cat 2 harmonised classification could have notable negative consequences for the two companies which would be forced to seek customers outside the EEA. The rest of the significant volumes of feedstock required by EEA manufacturers of TiO_2 are sourced from overseas suppliers.

As far as suppliers of other raw materials and energy are concerned, a total annual trade of ca. 4 million tonnes of chemicals and an annual demand for over 7,500 GWh of energy would be place in jeopardy with the scale of impacts depending on the scale of reduction in EEA-based TiO_2 manufacturing operations. Closure of TiO_2 manufacturing plants in the EEA would result in significant loss of turnover for the suppliers of feedstock, raw materials, consumables, utilities as well suppliers of all purchased services required to maintain and operate those manufacturing facilities.

5.4 Impacts on downstream users of titanium dioxide in the EEA

There are four main areas where impacts may arise for downstream users:

- Compliance with horizontal legislation (primarily relating to labelling and to waste management);
- Restrictions on the marketing and use of formulations and products that contain substances classified as Carc Cat 2;
- Adverse market, supply chain and competition dynamics; and
- Employment impacts.

5.4.1 Costs arising from compliance with horizontal legislation

The key legislative instruments of relevance to the use of a Carc Cat 2 substance include the CLP Regulation and the Waste Framework Directive 2008/98/EC and associated instruments. Specific impacts include the following:

- **Labelling requirements**: following the classification of the substance, there would be a need for replacing existing labels on TiO_2 and mixtures that contain the substance in concentrations exceeding 1.0% by weight to reflect its new harmonised classification. Existing labelling stocks would need to be disposed of and new labels printed and applied to packaging materials. Logistic complexities for those trading both within and outside the EU might arise. The associated costs cannot be estimated but based on past experience and given the ubiquitous nature of TiO_2, costs can reasonably be anticipated to rise to the range of millions of Euros;

- **Poison Centre notifications**: according to the newly introduced Annex VIII to the CLP Regulation, before placing mixtures on the market, submitters (i.e. importers and downstream users placing on the market mixtures for consumer/professional/industrial use) shall provide information (product identification, hazard identification, composition information and toxicological information) relating to mixtures classified as hazardous on the basis of their health or physical effects to their national Poison Centres. Importers and downstream users of mixtures which are currently not classified as hazardous but contain TiO_2 in concentrations above 1.0% will become obliged to provide information to Poison Centres over the period 2020-2024, depending on whether those mixtures are used by consumers, professional users or industrial users. This new obligation will generate an additional administrative burden and cost, which, again, cannot be quantified at present;

- **Waste management costs**: there is a wide variety of waste streams which contain over 1.0% TiO_2 and are generated during the use of the substance as a raw material but also at the end of the useful life of products/mixtures. Some may already be classified as hazardous due to the presence of other hazardous components (e.g. solvents) and their management might not be affected by the harmonised classification, but this will not always be the case. Others, however, may currently be handled as non-hazardous and can be disposed of in non-hazardous landfills; such waste streams would require segregation, separate storage and more specialised management after the introduction of the substance's Carc Cat 2 harmonised classification. Notably, the implementation of the Waste Framework Directive does not appear to be uniform across the EU Member States and the approach they take to allocating waste streams to the most relevant entries in the European LoW may vary. A few companies have provided estimates of the costs involved in establishing systems for the segregation and separate management of waste that contains more or less than 1.0% TiO_2. These range from **a few thousand Euros** per company to potentially **millions of Euros** (for instance, separation of TiO_2-containing sludge at a paper mill and separate treatment would increase the cost of treating the sludge by €200 per tonne. This would translate into an additional cost €2-3 million per year, while no additional protection to human health would be achieved, as TiO_2 in sludge cannot be inhaled). Perhaps, however, the greatest threat from the classification of waste as hazardous would be the potential impacts on reuse and recycling of waste. Any impacts on the recycling of post-consumer plastic waste would have a very damaging effect on the circular economy while impacts on the ability of companies to recycling scrap that contains TiO_2 would have a very detrimental effect on production economics. For example, the manufacture of polyamide yarns would be severely impacted if fibre manufacturers could not sell their TiO_2-containing waste (amounting to 10% waste for each kg of yarn production) as an input material for engineering plastics;

- **Implications arising from the REACH Regulation**: under Article 31 of the REACH Regulation, the provision of SDS would apply creating an additional administrative burden.

Notably, the use of TiO_2 in the form of slurry with the aim of eliminating exposure to powders would result in a higher raw material cost as the price of slurry is **€200-250/tonne higher** compared to powder.

5.4.2 Market losses due to regulatory and voluntary restrictions on the use of titanium dioxide

There are particular industry sectors where the use of a Carc Cat 2 substance is subject to restrictions either due to the existence of relevant EEA-wide regulation, or due to national provisions or voluntary initiatives by relevant industry organisations (e.g. CEPE). In some cases, exemptions and derogations are possible as described below:

- **Use of TiO_2 in toys**: Carc Cat 2 substances are not permitted to be used in toys placed on the EEA market, but possibilities for exemptions exist on the basis of (a) concentration, (b) (in)accessibility of the substance. The SCCS would review the use of the substance and would conclude as to whether it might be appropriate to list it to Appendix A of the Toy Safety

Directive (List of CMR substances and their permitted uses). Notably, for a Carc Cat 2 substance, it will not be necessary to demonstrate that there are no suitable alternative substances or mixtures available. Therefore, there is a realistic likelihood that toy use of TiO_2-based based could be allowed to continue. However, the continued presence of the substance in toys could cause reputational damage to the toy manufacturers and thus they may put pressure on paint manufacturers to reformulate their products to substitute TiO_2. A restriction on the use of TiO_2 in toys could create an anomaly in the market due to similar products being classified as toys or not. For instance, the use of TiO_2 in colour pencils, felt tip pens, wax crayons used in non-artistic applications would be banned, while the substance could well be present in very similar products placed on the shelves for artistic use or even gel pens and elaborate colouring and painting articles which could well be accessible to children[108];

- **Use of TiO_2 in cosmetics**: the main use in cosmetics is as a colourant and UV filter. The situation is similar to toys in that the use of Carc Cat 2 substances is not permitted and would be subject to an evaluation by the SCCS (without a requirement to demonstrate the unavailability of feasible alternatives) which may result in the substance being approved (or not) for use in cosmetics (including cosmetic pencils, printing inks on cosmetic product containers and toy cosmetics). It is to be noted that such exemptions are not granted in a procedural or (semi-)automatic manner but on a case by case basis, with the outcome potentially varying from that of other substances classified as Carc Cat 2. In case an exemption would not be granted, a very large number of cosmetic products would be impacted and a very useful, safe ingredient would be lost. Only two minerals UV-filters are on the positive list for use in cosmetics, TiO_2 and ZnO and elimination of one would limit the options available to cosmetics manufacturers;

- **Use of TiO_2 as a food additive**: although TiO_2 was recently re-evaluated by EFSA as safe, a carcinogenicity harmonised classification might lead to the review of the evaluation result. However, given the extremely low probability of exposure by inhalation through food and the lack of feasible substitutes of equivalent performance, it may be presumed that an approval for the continued use of TiO_2 would be secured;

- **Use of TiO_2 in pharmaceuticals**: according to the European Medicines Agency, the use of any excipient with a known potential toxicity, and which could not be avoided or replaced, would only be authorised if the safety profile was considered to be clinically acceptable in the conditions of use, taking into account the duration of treatment, the sensitivity of the target population and the benefit-risk ratio for the particular therapeutic indication. As such, the harmonised classification would result in a risk assessment evaluation. It is assumed that this evaluation will take into account the evaluation of the safety of the substance as a food additive. It can also be assumed that due to the lack of exposure via inhalation, approval for continued use could be secured;

- **Use of TiO_2 in food contact materials**: relevant CoE Resolutions on coatings, paper/board and food packaging inks do not distinguish CMR categories and national legislation implementing said resolutions might have an impact on the use of TiO_2 upon its classification as Carc Cat 2. In general, there is a trend towards more stringent requirements on additives for food contact materials;

[108] See guidance on the applicability of the Toys Safety Directive to colouring and painting articles, writing and drawing articles and stationery items, available here: http://ec.europa.eu/DocsRoom/documents/5852/attachments/1/translations/en/renditions/native (accessed on 24 October 2017).

- **Use of TiO_2 in tobacco-related products**: Directive 2014/40/EU on the manufacture, presentation and sale of tobacco and related products does not distinguish between Carc Cat 1B and Carc Cat 2 substances, and as such the harmonised classification would need to be taken into account in the generation of an enhanced report for the TiO_2 and might have an indirect role in making the substance more susceptible to future regulatory action (a ban);

- **Use of TiO_2 in products awarded with a label under a recognised ecolabel scheme**: TiO_2 could no longer be used in products that hold an ecolabel, such as the EU Ecolabel, the German Blue Angel and the Nordic Swan, which lists CMR properties under their exclusion criteria. Classification of TiO_2 as Carc Cat 2 would also mean that textiles currently awarded the OEKO-TEX® certification could no longer attain this. Loss of those awards would make the impacted products less attractive to consumers who value these schemes and consider such ecolabel schemes important in making purchasing decisions. In addition, the harmonised classification could trigger substitution of TiO_2-containing products in public procurement (infrastructure, public building, supplies for public administration) processes (EEA Member States may run their own Green Public Procurement initiatives). The harmonised classification would have an effect in the context of green building certification schemes such as BREEAM (Building Research Establishment Environmental Assessment Method), which have relied on an eco-label approach to point scoring; and

- **Use of TiO_2 in articles intended for use in the automotive industry**: under the Global Automotive Declarable Substance List (GADSL) a Carc Car 2 substance would not be "Prohibited" but would be "Declarable", thus making it less appealing for automotive manufacturers and less marketable by paint manufacturers.

It is worth noting that even where an exemption or derogation can be obtained, measuring the bioavailability of TiO_2 with the aim of establishing that risks to consumers are acceptably low could be costly. For instance, if testing were to be undertaken to demonstrate that the TiO_2 in the polyamide and polyester yarn is completely bound and strongly encapsulated in the polymer, making its inhalation impossible, the cost of commissioning such testing by specialist laboratories has been estimated to be €1-1.5 million.

On the other hand, even where the existing legislative framework allows the continued use of a Carc Cat 2 substance, market and consumer perceptions and pressures might lead to attempts at substitution or product withdrawal from the market, as is elaborated below.

5.4.3 Market losses due to negative market and consumer perceptions of the safety of titanium dioxide

The Carc Cat 2 harmonised classification would unavoidably raise doubts on the part of buyers, users and consumers, about the safety of TiO_2 as a raw material and of products and mixtures that contain it.

As far as consumer uses are concerned, under the CLP Regulation, TiO_2-based formulations would be accompanied by appropriate hazard labelling including a pictogram, a signal word, a hazard statement and several precautionary statements. The labelling requirements for Carc Cat 2 would be very similar to the non-expert consumer eye to those of Carc Cat 1B. In any case, a pictogram of an 'exploding person', and the terms "Warning" and "Suspected of causing cancer", even if the inhalation exposure route was to be specified, would cause alarm among users. Companies placing TiO_2-containing mixtures on the market would not be free to choose what they include in the labels affixed to their products and may only label according to the CLP Regulation.

In certain countries in particular, e.g. France, there is a ban on self-service in stores for potentially carcinogenic formulations which could physically prevent consumer access to these products. Consumer uses that would be particularly vulnerable to the development of negative perceptions among users would include formulations such as paints, inks, adhesives, sealants, detergents as well as products which consumers have significant exposure to and for which safety aspects play a critical role, such as food (and its packaging which may contain TiO_2 through a multitude of routes: coatings, inks, labels, container material), pharmaceuticals, cosmetics and textiles. In addition, mixtures and articles intended for use by children (toys, school paints, inks, etc.) might also attract negative publicity because they contain TiO_2. Precisely to avoid such negative publicity, industrial users of TiO_2 might opt for substituting TiO_2 (where feasible) or removing products from the market, which could lead, for example, to the vast majority of paints no longer being available for use by school children.

Even for professional and industrial users, the presence of hazard labelling for TiO_2 could cause unwillingness to handle and (potentially) be exposed to the pigment and its formulations and could encourage employers to seek alternative pigments. From a different perspective, as TiO_2 would be stigmatised, some brand owners would likely put significant pressure on the upstream supply chain to replace TiO_2. This would also attract negative publicity and undue attention from the media, NGOs, professional users and the end consumer (even where the TiO_2 inhalation risk is zero), thus adding further pressure towards the avoidance of use of TiO_2-based products even where such action is unnecessary as there is no risk of exposure via inhalation.

5.4.4 Feasibility and cost of substituting titanium dioxide

TiO_2 concentrations of 1.0% by weight could not achieve the desired technical characteristics in its formulations and past attempts at finding alternatives to the substance have failed. For example, concerted efforts have been made towards the replacement of TiO_2 in paint formulations in response to its high market price. Those efforts failed as it was only possible to substitute a small proportion of the overall TiO_2 loading if performance standards were to be met. Substitution of TiO_2 is technically infeasible with the exception of very small niche markets for which TiO_2's brightness and effectiveness are not a priority. Only a very small percentage of colour shades can be achieved without TiO_2.

For applications where TiO_2 is an indispensable raw material, e.g. the manufacture of Complex Inorganic Pigments, its replacement is de facto impossible. For certain other applications, e.g. as a UV filter in cosmetics and the packaging for pharmaceuticals, and as a white food colourant and a pharmaceutical excipient, there are no approved alternatives that could match the technical performance and efficiency of TiO_2.

TiO_2 is used in a vast number of products. By way of a single example, TiO_2 is used in the great majority of coloured pharmaceutical and dietary supplement tablets and capsules, either as a sole colourant or in combination with other pigments to produce a range of colours. Reformulation to remove TiO_2 would clearly be an enormous (and very costly) task.

Downstream users of TiO_2 consulted for this study have, therefore, consistently argued that reformulation to technically feasible TiO_2-free products is not possible. If the technical characteristics of the new formulations were to be disregarded, the time required for reformulation would in any case be significant[109] and the costs would be very large due to the testing and trialling

[109] Examples from consultation: (a) consumer paints: 5-10 years; (b) industrial paints: 5-20 years; (c) consumer inks: 2-5 years; (d) printer toners: 2-10 years; (e) industrial inks: 5 years; (f) cosmetics: 3-8 years; (g) fibres: over 2 years.

required (for pharmaceuticals alone, testing the stability of the formulations would necessitate an unprecedented volume of tests), the increased volumes of less efficient pigments needed (e.g. 20-50% higher for ZnS) and the need for new additives (e.g. new UV absorbers/blockers in construction plastics)[110].

In conclusion, reformulation is not a realistic proposition in the vast majority of TiO_2's applications. If, however, reformulation was pursued under pressure from regulation and from the supply chain, (a) it would lead to a greyer world and (b) the cost of manufacturing would increase as a result of the investment cost of reformulation (see details above) and the lower efficiency of alternative pigments. Small companies in particular could not easily absorb the costs of reformulation so would need to pass these on to customers, thus rendering their products more expensive and their market position less competitive. Furthermore, replacement of TiO_2 would result in poorer quality products which would affect the faith of customers in the TiO_2-free products.

5.4.5 Increases to operating costs and associated loss of competitiveness and competition

Following from the discussion above, it is to be expected that operating costs of downstream users of TiO_2 would increase due to:

- Increased costs of waste management;
- Increased administrative burden (provision of SDS, provision of information to Poison Centres); and
- Losses of economies of scale if some products are removed from the market.

If EEA-made products were to become costlier to manufacture, it would be unavoidable for them to become less competitive relative to non-EEA made products sold both within and outside the EEA market. For bulk producers, price sensitivity is key and the proposed classification could severely harm them. In addition, and for obvious reasons, the manufacture of finished articles outside the EEA would become less costly and burdensome and thus more economically appealing.

Although relocation of the production of important TiO_2-containing products, such as DIY and professional architectural paints, might not appeal across the board as it is mainly a regional activity, over time and under the constant pressure of market needs, a shift of the value chain to locations outside the EEA could be expected, for reasons of proximity and integration with suppliers (unless non-EEA jurisdictions quickly follow the EEA example and introduce their own similar hazard-based limitations on the use of TiO_2).

Within the EEA, the increased regulatory burden could also drive consolidation in the industry, leading to less competition. SMEs would be most vulnerable in the face of such a trend. SMEs have limited capabilities (in terms of R&D, marketing, equipment) for protecting their workers and formulating feasible alternatives. Large companies producing a wide range of products would be better placed to cope with a loss of TiO_2-containing products compared to smaller businesses which concentrate on smaller product portfolios.

Finally, it should be understood that adverse impacts would not only affect the users of TiO_2 but would permeate the supply chain. Many examples can be provided here, e.g. DIY stores could see

[110] Quantified estimates from consultation: (a) paints: up to €60 million; (b) plastics: €4-10 million; (c) consumer inks: €0.05-5 million; (d) industrial inks: €5 million; (e) pigments: €0.05-4 million; (f) fibres: €0.5-2 million.

their sales to DIY enthusiasts coming under pressure; or packaging manufacturers would be forced to redesign packaging structures (which could impair established recycling processes).

5.4.6 Conclusion on economic impacts

In general, the manufacture of TiO_2-containing mixtures and articles and their use in the EEA would become more complex and thus costlier, without delivering any contribution to the protection of human health. This would impact upon the competitiveness of supply chains based in the EEA, although, unlike a Carc Cat 1B classification, a Carc Cat 2 harmonised classification would not offer substantial incentive for companies to relocate outside the EEA as its implications on worker health protection would not be as direct.

Changes to the consumer market as a result of restrictions under sectoral legislation and shifting consumer opinions and perceptions on the safety of TiO_2-based formulations would affect the EEA market for the end products and such market losses could translate upstream to attempts to substitute TiO_2, increased production costs and loss of market share and profits. This could result in some (parts of) supply chains in the EEA becoming less competitive vis-à-vis their non-EEA counterparts.

Based on data collected as part of this study and assumptions presented in this report, it would be reasonable to expect that a decline in demand for TiO_2 combined with adverse effects on consumer and user perceptions would mean **the loss of a proportion of overall current demand for TiO_2 in the EEA, which can be tentatively estimated at 10-15%**. This would not be accompanied by a corresponding improvement in consumer health protection as inhalation exposure to TiO_2 in its free, powder form is non-existent.

5.4.7 Impacts on employment

It is not possible to quantify the potential impacts on employment in the EEA. However, it is clear that the number of workers potentially affected is particularly large. For instance, 110,000 workers are involved in the manufacture of paints and printing inks in the EEA and the number of workers involved in the application of paints (at construction sites, industrial production lines, etc.) is estimated to be around 1 million. In the plastics sector, 1.5 million workers are involved in the manufacture of plastics with an estimated 4.5 million workers handling and using the plastics further downstream. Based on the assumption that between 10% and 15% of EEA demand for TiO_2 might be lost following the adoption of the proposed classification, the number of jobs potentially lost could be of the order of thousands across the EEA.

5.5 Impacts on actors outside the titanium dioxide supply chains

Many industrial minerals contain TiO_2 as a natural impurity up to 4% by weight with most containing more than 1.0%. This means that if TiO_2 were to be classified as Carc Cat 2, several industrial minerals would also have to be classified as Carc Cat 2. This would affect their handling, processing and use. Information available suggests that EEA markets for minerals of **a combined volume that exceeds 20 million tonnes per year and a combined market value of over €3.3 billion per year** would potentially be impacted. In addition, TiO_2 manufacturing plants not only produce TiO_2, they also are capable of generating several by-products. A scale back in the manufacture (and sales) of TiO_2 would also mean a reduction in the volumes of ancillary products and by-products produced (and sold). Moreover, some of these products (such as iron filter salts) contain TiO_2 as an impurity in concentrations that exceed 1% by weight. As such, they would need to be classified and labelled as suspected carcinogens when placed on the EEA market.

The Carc Cat 2 harmonised classification for TiO_2, if adopted, would set a precedent for the subsequent hazard classification of other poorly soluble powders regardless of each and every substance's human health carcinogenicity data. This would (a) effectively render the known alternative white pigments unsuitable as replacements for TiO_2, and (b) make the manufacture, handling and use of such poorly soluble powders more costly and burdensome in the EEA, thus leading to further loss of competitiveness of EEA businesses along the relevant supply chains.

5.6 Impacts on consumers

Given that TiO_2 is present in a multitude of products that surround consumers in their daily lives, the potential impacts from the Carc Cat 2 harmonised classification would be significant and far-reaching but would critically depend on (a) existing regulatory requirements, and (b) the extent and success of reformulation efforts instigated by the harmonised classification:

- **Loss of consumer choice and reduction of product availability**: the market presence of several other regulated products such as cosmetics, toys, food and its packaging, pharmaceuticals, but also 'green' products that currently hold ecolabels (ranging from paints to textiles) would be placed under threat. Where attempts were to be made to substitute TiO_2, the result could also be the removal of products from the market. If one takes the NCS catalogue[111] as an example, out of the 1950 NCS colours in total only 125 are currently produced without TiO_2. Many consumer articles (e.g. plastics) would become costlier to manufacture in the EEA and the impact on their pricing could lead to their production being scaled back, relocated outside the EEA or discontinued;

- **Increased costs and loss of performance**: reformulated products would be costlier and the reduced durability of painted/pigmented products would increase the maintenance and replacement costs for the individual consumer, the public sector, local authorities, housing associations and national health systems (due to the increase in the cost of pharmaceuticals). With particular regard to the use of TiO_2-containing DIY products, the presence of a suspected carcinogen could disincentivise consumers from undertaking DIY activities themselves and thus becoming more reliant on professionals, increasing the cost of undertaking repairs and maintenance around the home. By way of example, a member of the public may currently purchase the DIY paint needed for painting the walls and ceiling of a 120-130 m^2 apartment for, say, €50. A professional painter would charge €500, if not more, to do the painting. This cost increase would be particularly detrimental and with notable social consequences for consumers on low incomes;

- **Loss of satisfaction and welfare**: EEA consumers would face the potential loss of a great proportion of the colour palette, poorer aesthetics, duller home and office interiors and exteriors, and the worsening of the quality, durability and performance in several products. For instance, TiO_2-free alternative DIY paints, coatings and construction products would have neither the durability nor the 'brilliant white' appearance of existing paints. Higher paint thicknesses would be required to achieve the same opacity / hide the paint that is being painted over. In addition, paint would probably need to be applied in three or four layers, not the current one to two applications. Painted walls would need to be refurbished more regularly due to damage and

[111] NCS is an international colour system for design, architecture, production, research and education.

discolouration given that other white pigments cannot display TiO_2's ability to absorb UV radiation. Thus, painting jobs would take longer, would need to be done more often, and homeowners and tenants would be disappointed with the final results compared with what can currently be achieved with TiO_2-based paints. Due to the cost associated with hiring a professional decorator (see above), the standard of decoration in homes across the EEA could decline and this would mostly affect people on low incomes. This impact would not result in improved protection of human health, as consumers/users are not exposed to TiO_2 by inhalation when painting a room, or living or sleeping in a room that has been painted.

DIY work, use of recreation/school art products are popular activities for the public, including children, across the EEA. The message that the Carc Cat 2 harmonised classification of TiO_2 would convey is that if such activities involve white and bright colours they might potentially be causing harm and thus should be curtailed or avoided. This would impact upon the creativity of children and adults alike.

Certain cosmetic formulations would also deliver an inferior performance to that which consumers are used to. Sunscreens would require increased dosages of alternatives (e.g. ZnO) to achieve the same protection against the sun, thus their formulation would cost more, and the products would be undesirably whiter on the skin when applied. Without TiO_2 as whitening pigment, make-up products and other cosmetics would be less efficient and/or appealing for consumers;

- **Adverse effects on public health**: elimination of TiO_2 from certain products could have adverse effects on public health. Examples of this include bright safety coatings for the road marking industry, display information on packaging that is important to the consumer (e.g. food ingredients, safety), UV filters used in the packaging of foodstuffs, cosmetics and light-sensitive pharmaceuticals, and intumescent products and coatings. Of particular importance is the use of TiO_2 as a UV filter in sunscreens. Under the Cosmetic Products Regulation there are only two mineral UV filters authorised: TiO_2 and ZnO. ZnO contributes mainly to UVA protection and has poorer performance against UVB radiation, in contrast to TiO_2 which is a major contributor to high SPFs (sun protection factors).

5.7 Impacts on the environment

Restricting or making the continued use of TiO_2 more complex, burdensome and costly could have adverse impacts on the environment. The key underlying reasons include:

- The large volumes of alternatives that would be theoretically required for the substitution of TiO_2 across the board (other white pigments such as zinc oxide and lithopone have a global market ca. 15-23 times smaller than TiO_2) – the extraction of alternatives would be accompanied by an increased environmental footprint;

- The adverse environmental hazard profile of certain alternatives (see Annex 2);

- The unrivalled efficiency of TiO_2 and the durability of TiO_2-containing products – use of alternatives would result in the generation of higher emissions, generation of larger volumes of waste and the need to re-paint/coat or replace articles more often;

- The unique catalytic and photocatalytic properties of TiO_2 which allow for environment-friendly and sustainable technologies for indoor and outdoor air cleaning;

- The contribution of TiO_2 to better energy efficiency and management in the fields of construction and photovoltaics and the role of white and bright paints and coatings in a lighter and brighter living and work environment;

- The likely increase of imports of finished TiO_2-containing articles into the EEA following the adoption of the Carc Cat 2 harmonised classification, which would lead to increased releases of greenhouse gases from transportation; and

- The adverse impacts on the circular economy from making the re-use and recycling of materials such as plastics and packaging more difficult due to the presence of a suspected carcinogen in concentrations greater than 1.0% by weight.

5.8 Potential benefits to health from the proposed classification for titanium dioxide

As a final point in this analysis, it is appropriate to juxtapose the extensive adverse impacts from the adoption of the Carc Cat 2 harmonised classification against the likely benefits to human health that might arise.

Numerous epidemiological studies of more than 24,000 workers handling TiO_2 demonstrate no correlation between long-term exposure to TiO_2 and lung tumours, and this is supported by two large case-control studies that included over 2,000 lung cancers. Therefore, the adoption of the Carc Cat 2 hazard classification would not result in a discernible improvement to the health of workers who handle TiO_2 beyond what is achieved as a result of compliance with the existing legislative framework across the EEA. Indeed, the hazard classification might encourage substitution of TiO_2 by other poorly soluble powders which could essentially pose similar carcinogenicity hazards through the inhalation route.

Furthermore, as TiO_2 is typically embedded in matrices (in the wider sense of the term, i.e. paints, coatings, plastics, fibres, pigment preparations, ceramic articles, enamels, elastomers, etc.), any concern over worker inhalation exposure should largely be confined to the handling and use of the substance in its powder form, i.e. at the stage of manufacture and where TiO_2 is used in powder form as a raw material, and the very limited occurrences of exposure of the workers to dusts or aerosols that contain TiO_2 (e.g. spraying of a (powder) coating). The proposed classification specifically notes that carcinogenicity is suspected via the inhalation route only and not by any other route. However, all other legislation which comes into effect once a harmonised classification is decided disregards this distinction and would apply regardless of whether it is impossible or improbable to inhale TiO_2 as a powder or within a matrix. As such, the proposed harmonised classification would cause adverse economic impacts on EEA industry without any distinct benefit to workers' health.

On the other hand, as regards consumer exposure to TiO_2, possibilities for inhalation exposure to TiO_2 are remarkably narrow:

- The substance is not available to consumers (or indeed professional users) in the form of free powder (although some TiO_2-containing recreation/artists colours might come in a dry form);

- Exposure to dusts that contain TiO_2 is infrequent and TiO_2 may not be present in a free form. For instance, exposure to dust generated during the removal and disposal of products that contain TiO_2 (for example, when sanding old paint) is sporadic and with normal respiratory protection, the presence of TiO_2 should not raise a health concern (although consumers may erroneously perceive this differently if the Carc Cat 2 harmonised classification was adopted); and

- Similarly, inhalation of aerosols might theoretically also occur in some very limited cases (e.g. spraying of liquid products such as paints) but normal risk management measures a low exposure frequency substantially reduce exposure to TiO_2 which again is embedded into a 'matrix'.

In all cases, inhalation exposure is infrequent and the levels of potential exposure are likely to be very low. On this basis, the proposed classification would not contribute towards the improved protection of consumer health.

Taking the above into account and considering the unintended adverse consequences that would arise for the supply chains of both TiO_2 and of other poorly soluble powders, as well as for consumers in the EEA, it can be concluded that the proposed classification would lead to a scale of socio-economic impacts entirely disproportionate to (a) any suspected risk to human health, and (b) any human health benefits that could theoretically be attributed to result from the Carc Cat 2 harmonised classification. Workplace measures dictated by existing legislation on occupational safety and health provide a more cost-efficient and proportionate approach to controlling risks to worker health. Taking this approach would also be consistent with the requirements and aspirations of the EU's 'better regulation' agenda. The harmonised classification would go beyond what is necessary to achieve the human health protection objective satisfactorily and it would cause disproportionate costs for economic operators and citizens due to its unforeseen consequences under a variety of regulatory regimes that link to and depend on the classification of substances under the CLP Regulation.

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7 Annex 1: Legislation of relevance to hazard classifications under consideration

7.1 EEA-wide legislative requirements

7.1.1 Classification and labelling

Table 7–1: Key parameters of relevant legislation – Classification & labelling

Key parameters		Details
Relevant legislative instruments		Regulation 1272/2008/EC
Description of potential impact	Carc Cat 1B classification	It would affect the labelling of TiO_2 as placed on the market and products containing TiO_2. It would require changes to labelling and SDS of mixtures. Packaging may need to be changed and new information needs to be provided to national Poison Centres. The CLP Regulation does <u>not</u> apply to cosmetics, food and feed additives, medical devices, human and veterinary medicinal products. Labelling provision: • Pictogram:  • Signal word = **Danger** • Hazard statement and code = H350 may cause cancer (state exposure route if it has been conclusively proven that no other routes of exposure cause the hazard) • Precautionary statement: prevention P201, P202, P281; response P308, P313; storage P405; disposal P501. Generic concentration limit for mixture classification as carcinogenic ≥0.1%. Requirements for the packaging of mixtures would also arise under Article 35 of the CLP Regulation. • The packaging shall be designed and constructed so that its contents cannot escape, except in cases where other more specific safety devices are prescribed; • The materials constituting the packaging and fastenings shall not be susceptible to damage by the contents, or liable to form hazardous compounds with the contents; • The packaging and fastenings shall be strong and solid throughout to ensure that they will not loosen and will safely meet the normal stresses and strains of handling; and • Packaging fitted with replaceable fastening devices shall be designed so that it can be refastened repeatedly without the contents escaping. Earlier in 2017, a new Regulation was introduced on emergency health response (Poison Centres), Regulation (EU) 2017/542 which introduced a new Annex, Annex VIII to the CLP Regulation. According to this, before placing mixtures on

Table 7–1: Key parameters of relevant legislation – Classification & labelling		
		the market, submitters (i.e. importers and downstream users placing on the market mixtures for consumer/professional/industrial use) shall provide information (product identification, hazard identification, composition information and toxicological information) relating to mixtures classified as hazardous on the basis of their health or physical effects to their national Poison Centres. A universal submission format shall be used across the EU. When mixture components are classified under the CLP Regulation as Carc Cat 1B (or Cat 2), their concentration in a mixture shall be expressed as a range; as an alternative, exact percentages may be provided. Importers and downstream users placing on the market mixtures for consumer, professional and industrial use shall comply from 1 January 2020, 1 January 2021 and 1 January 2024 respectively. Importers and downstream users having submitted information relating to hazardous mixtures to Poison Centres before the dates of applicability mentioned above and which are not in accordance with Annex VIII, shall for those mixtures not be required to comply with this Annex until 1 January 2025
	Carc Cat 2 classification	Labelling provision: • Pictogram:  • Signal word = **Warning** • Hazard statement and code = H351 suspected of causing cancer (state exposure route if it has been conclusively proven that no other routes of exposure cause the hazard) • Precautionary statements are the same as for category 1B. Generic concentration limit for mixture classification as carcinogenic ≥1.0%. If at concentration greater than 0.1%, then SDS should be provided free of charge upon request (only for non-consumer use mixtures i.e. those not intended for sale to the general public). Tactile warning of danger label = raised equilateral triangle (to EN ISO 11683). Requirements on packaging are the same as under Carc Cat 1B (where a mixture is classified as hazardous, generally this being the case as TiO_2 concentrations exceed 1.0% by weight). Requirements on information submission to national Poison Centres are the same as under Carc Cat 1B (where a mixture is classified as hazardous, generally this being the case as TiO_2 concentrations exceed 1.0% by weight).
Applicability (multiple sectors vs. single sector)		Multiple
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/P
Driver of impact on society	Hazard	✓
	Risk (incl. availability of alternatives)	
Immediacy of potential impact		As soon as harmonised classification is adopted and CLP Regulation is updated. This could take 18 months or more

Table 7–1: Key parameters of relevant legislation – Classification & labelling		
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Possible but unlikely – but it would increase compliance costs
	Carc Cat 2 classification	Possible but unlikely – but it would increase compliance costs
Comparison of impacts between Carc Cat 1B and Carc Cat 2		Given the typical concentration of TiO_2 in its formulations, the labelling requirement would remain with the same pictogram. **Overall: essentially same provisions but less burdensome or with fewer criteria to be met**

7.1.2 Carcinogens at work

Table 7–2: Key parameters of relevant legislation – Carcinogens at Work

Key parameters		Details
Relevant legislative instruments		Framework Directive - Council Directive 1989/391/EEC Directive 2004/37/EC – Carcinogens and Mutagens at Work
Description of potential impact	Carc Cat 1B classification	**Directive 2004/37/EC**: employers should consider the use of alternative substances. If the substance cannot be replaced, closed systems should be used. Where this is not possible exposure should be reduced. Employers have to make certain information available to the competent authority if requested (activities, quantities, exposures, number of exposed workers, preventive measures)
	Carc Cat 2 classification	Not applicable to Category 2 carcinogens
Applicability (multiple sectors vs. single sector)		Multiple (incl. manufacture)
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/P
Driver of impact on society	Hazard	
	Risk (incl. availability of alternatives)	✓ If no alternatives available, use of TiO_2 could continue with improved worker health protection measures (as/where necessary)
Immediacy of potential impact		As soon as harmonised classification is adopted and CLP Regulation is updated. Industry may have some time before the official adoption of the CLH to conduct risk assessments
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Only if technically feasible safer alternatives could be identified; this is not the case with TiO_2. However, adherence to requirements would be burdensome
	Carc Cat 2 classification	No explicit provisions restricting use
Comparison of impacts between Carc Cat 1B and Carc Cat 2		**Overall: Carc Cat 2 is not relevant**

7.1.3 Waste

Table 7–3: Key parameters of relevant legislation – Waste Framework		
Key parameters		**Details**
Relevant legislative instruments		Directive 2008/98/EC Regulation 1357/2014 Decision 2000/532/EC (as amended by Decision 2014/955/EU) Basel Convention
Description of potential impact	Carc Cat 1B classification	**Directive 2008/98/EC**: the properties that render wastes hazardous are defined in Annex III to Directive 2008/98/EC. According to Annex III, when a waste contains a substance classified as a carcinogen under CLP and exceeds or equals one of the concentration limits shown in Table 6 to the Annex, the waste shall be classified as hazardous by HP 7. The criteria of Annex III of the Framework Directive would apply only to 'mirror' entries in the List of Waste (LoW) established by Decision 2000/532/EC, not the entries classified as 'absolute non-hazardous' or 'absolute hazardous'. A Carc. Cat 1B classification for TiO_2 would mean that a concentration that exceeds 0.1% would render any TiO_2-containing waste hazardous. However, under Article 7(3) of Directive 2008/98/EC, where a Member State has evidence to show that specific waste that appears on the list as hazardous waste does not display any of the properties listed in Annex III, it may consider that waste as non-hazardous waste. The Member State shall notify the Commission of any such cases without delay and shall provide the Commission with the necessary evidence. In the light of notifications received, the list shall be reviewed in order to decide on its adaptation. It is worth noting that in October 2016 the Industry, Research and Energy Committee (ITRE) of the European Parliament voted in favour of amendments to the Directive including the addition of the following to Article 9, "- *reduce the content of hazardous substances in materials and products by setting targets and encourage communication about hazardous substances in the supply chain*". **Regulation 1357/2014**: concentrations for the definition of waste as hazardous are as above. This Regulation outlines the update from DSD and DPD to CLP The transboundary movement of wastes that contain TiO_2 (if classified as Carc Cat 1B and falling under UN Class 9) would also become more complex under the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal
	Carc Cat 2 classification	**Directive 2008/98/EC & Regulation 1357/2014**: same provisions apply as above, except that the concentration at which the waste is considered hazardous is 1%. NB. virtually all products manufactured, certainly in paints and ink sectors, contain more than 1% TiO_2
Applicability (multiple sectors vs. single sector)		Multiple (incl. manufacture)
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/P/(C)

Table 7–3: Key parameters of relevant legislation – Waste Framework		
Key parameters		**Details**
Driver of impact on society	Hazard	✓
	Risk (incl. availability of alternatives)	
Immediacy of potential impact		As soon as an article or mixture becomes waste after the harmonised classification is adopted and CLP Regulation is updated
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Uncertain whether regulatory burden would be so high as to lead to TiO_2 being abandoned, especially if an exemption can be secured
	Carc Cat 2 classification	Uncertain whether regulatory burden would be so high as to lead to TiO_2 being abandoned, especially if an exemption can be secured
Comparison of impacts between Carc Cat 1B and Carc Cat 2		Given the typical concentration of TiO_2 in its formulations, LoW 'mirror' entry waste would still be classified as hazardous **Overall: same provisions for both classification categories**

7.1.4 Industrial Emissions

<table>
<tr><th colspan="3">Table 7–4: Key parameters of relevant legislation – Industrial Emissions</th></tr>
<tr><th colspan="2">Key parameters</th><th>Details</th></tr>
<tr><td colspan="2">Relevant legislative instruments</td><td>Directive 2010/75/EC – Industrial Emissions (IPPC)
Regulation 1357/2014
Decision 2000/532/EC</td></tr>
<tr><td rowspan="2">Description of potential impact</td><td>Carc Cat 1B classification</td><td>The list of polluting substances in Annex II includes “Substances and mixtures which have been proved to possess carcinogenic or mutagenic properties or properties which may affect reproduction via the air”
Member States shall ensure that the permit includes all measures necessary for compliance with the requirements of Articles 11 and 18. Those measures shall include among others:
(a) emission limit values for polluting substances listed in Annex II, and for other polluting substances, which are likely to be emitted from the installation concerned in significant quantities, having regard to their nature and their potential to transfer pollution from one medium to another</td></tr>
<tr><td>Carc Cat 2 classification</td><td>Whilst there is no substitution requirement, Annex II does not distinguish between Carc Cat 1B and Carc Cat 2 carcinogens, when referring to non-vapour emissions into water</td></tr>
<tr><td colspan="2">Applicability (multiple sectors vs. single sector)</td><td>Multiple (incl. manufacture)</td></tr>
<tr><td colspan="2">Potential adverse impact on:
- Industry (I)
- Professionals (P)
- Consumers (C)</td><td>I</td></tr>
<tr><td rowspan="2">Driver of impact on society</td><td>Hazard</td><td>✓</td></tr>
<tr><td>Risk (incl. availability of alternatives)</td><td>(✓)</td></tr>
<tr><td colspan="2">Immediacy of potential impact</td><td>Depends on speed at which installation emission permits are updated</td></tr>
<tr><td rowspan="2">Realistic potential for a restriction on the use of TiO_2</td><td>Carc Cat 1B classification</td><td>Unlikely</td></tr>
<tr><td>Carc Cat 2 classification</td><td>Unlikely</td></tr>
<tr><td colspan="2">Comparison of impacts between Carc Cat 1B and Carc Cat 2</td><td>No explicit provisions restricting use, but emissions to water are treated the same
Overall: Carc Cat 2 comes with less onerous provisions</td></tr>
</table>

7.1.5 REACH Regulation

Table 7–5: Key parameters of relevant legislation – REACH Restrictions for consumer products

Key parameters		Details
Relevant legislative instruments		Regulation 1907/2006/EC – Annex XVII
Description of potential impact	Carc Cat 1B classification	Annex XVII to Regulation (EC) No 1907/2006, in its entries 28 to 30, prohibits the sale to the general public of substances that are classified as CMR categories 1A or 1B or of mixtures containing them in a concentration above specified concentration limits. The substances concerned are listed in Appendices 1 to 6 to Annex XVII (through a Commission Regulation following the procedure laid down by Articles 68(2) ad 133(4) of REACH). Section 4.1 of the main part of the report has explained the process and uncertainties surrounding the listing of a newly classified TiO_2 in Appendix 2 of REACH Annex XVII. REACH Article 68(2) also allows a 'fast-track' restriction procedure which applies not only to substances and mixtures but also articles. Article 68(2) stipulates that for a substance on its own, in a preparation or in an article which meets the criteria for classification as carcinogenic, mutagenic or toxic to reproduction, category 1A or 1B, and could be used by consumers and for which restrictions to consumer use are proposed by the Commission, Annex XVII shall be amended in accordance with the procedure referred to in Article 133(4). Under this procedure, the European Commission has published a preliminary list of CMR Cat. 1A and 1B substances it proposes to restrict for use in textile consumer articles. The list contains 286 chemicals potentially present in textile articles and clothing, including phthalates, flame retardants and pigments. Following a period of consultation, the latest information suggests that the European Commission will aim to limit the scope to articles that may come into direct contact with the skin and include the substances from the list of the CMRs subject to the public consultation that are most relevant for such articles. A wider scope and inclusion of additional CMRs will be considered in a second step. The Commission is going to establish 4 lists of CMR 1A/1B substances (European Commission, 2016): - Substances that are potentially present in clothing and are relevant for the restriction; - Substances that are less likely to be present in clothing or less likely to be released, to be further assessed in a second step; - Substances that are not present in clothing; and - Substances that were not present in the initial list, suggested during the public consultation, to be further assessed in a second step. Articles to be considered in a second step might include floor coverings, carpets, upholstery, clothing accessories and leather articles. It is also understood that the Commission is looking to present a proposal to "fast-track" a restriction of CMR substances in construction products. Restrictions under Annex XVII of REACH do not apply to (a) medicinal or veterinary products; (b) cosmetic products, (c) certain fuels and oil products; and (d) artists' paints covered by Regulation (EC) No 1272/2008
	Carc Cat 2 classification	No restriction (but national rules may vary)

Table 7–5: Key parameters of relevant legislation – REACH Restrictions for consumer products		
Key parameters		**Details**
Applicability (multiple sectors vs. single sector)		Multiple
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/C
Driver of impact on society	Hazard	✓
	Risk (incl. availability of alternatives)	✓ Lack of suitable alternatives, exposure conditions and socio-economic aspects may be considered in granting derogations
Immediacy of potential impact		When substances receive a harmonised classification for the first time as CMR or are re-classified and are included in an ATP of the CLP Regulation, the European Commission prepares a draft amendment to include these substances in the Appendices of REACH Annex XVII. The amendment then has to be adopted in accordance with Articles 68(2) and 133(4) of REACH, before the new substances are covered by entries 28-30. Typically, transferral from CLP Annex VI to REACH Annex XVII takes 18 months, however significant delays have recently occurred. In addition, there is a possibility that the European Commission might choose to investigate issues of exposure pathways and risks before adding the substance to Appendix 2 of REACH Annex XVII (see discussion in Section 4.1 of the main report). (NB. inclusion to the list of 286 chemicals potentially present in textile articles and clothing may be avoided if exposure can be ruled out on technical grounds)
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	In principle, yes, for the substance and its mixtures (>0.1% wt.)
	Carc Cat 2 classification	No
Comparison of impacts between Carc Cat 1B and Carc Cat 2		No scope for EU-wide restriction on consumer uses **Overall: Carc Cat 2 is not relevant**

Table 7–6: Key parameters of relevant legislation – REACH provisions on Safety Data Sheets (SDS)		
Key parameters		**Details**
Relevant legislative instruments		Regulation 1907/2006/EC – Article 31
Description of potential impact	Carc Cat 1B classification	The supplier of a substance or a mixture shall provide the recipient of the substance or mixture with a safety data sheet compiled in accordance with Annex II: (a) where a substance or mixture meets the criteria for classification as hazardous in accordance with Regulation (EC) No 1272/2008 (…) The supplier shall provide the recipient at his request with a safety data sheet compiled in accordance with Annex II, where a mixture does not meet the criteria for classification as hazardous in accordance with Titles I and II of Regulation (EC) No 1272/2008, but contains: (a) in an individual concentration of ≥1 % by weight for non-gaseous mixtures (…) at least one substance posing human health or environmental

Table 7–6: Key parameters of relevant legislation – REACH provisions on Safety Data Sheets (SDS)		
Key parameters		**Details**
		hazards; or (b) in an individual concentration of ≥0.1 % by weight for non-gaseous mixtures at least one substance that is Carc Cat 2 (…) The safety data sheet need not be supplied where hazardous substances or mixtures offered or sold to the general public are provided with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor. Following the introduction of the proposed classification, for all professional or industrial mixtures containing more than 0.1% of TiO_2 by weight, a SDS will have to be provided, free of charge. A SDS shall be provided to a downstream user or distributor upon request. (NB. for mixtures which are not classified as hazardous but which contain certain hazardous substances, an SDS should be provided if requested by downstream users or distributors; however, given the typical concentrations of TiO_2 in its mixtures this scenario is unlikely to arise). Also under Article 33, information is to be provided on substances on the Candidate List but this is not considered here
	Carc Cat 2 classification	Same provisions apply, given the typical concentration of TiO_2 in its mixture (it exceeds 1% by weight)
Applicability (multiple sectors vs. single sector)		Multiple
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/P/(C)
Driver of impact on society	Hazard	✓
	Risk (incl. availability of alternatives)	
Immediacy of potential impact		The SDS should be updated without delay if new information becomes available on the hazards
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Possible, but not outright; industry input possible
	Carc Cat 2 classification	No potential for a restriction
Comparison of impacts between Carc Cat 1B and Carc Cat 2		Given the typical concentration of TiO_2 in its formulations, requirements under REACH Article 31 would be the same **Overall: same provisions for both classification categories**

Table 7–7: Key parameters of relevant legislation – REACH Restrictions for non-consumer products		
Key parameters		**Details**
Relevant legislative instruments		Regulation 1907/2006/EC – Annex XVII
Description of potential impact	Carc Cat 1B classification	Harmonised classification as Carc Cat 1B opens up possibilities for future proposals for restrictions to be submitted by Member States or ECHA (European Commission) following a Risk Management Options Assessment (RMOA)
	Carc Cat 2 classification	Likelihood of restrictions proposals is much lower than under Carc Cat 2
Applicability (multiple sectors vs. single sector)		Multiple
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/P/(C)
Driver of impact on society	Hazard	
	Risk (incl. availability of alternatives)	✓ Restrictions proposals need to consider alternatives and balance of benefits vs. costs
Immediacy of potential impact		Depends on timing of restrictions proposals; unclear as to whether interested Member States (or the Commission) would first wait for the official update to the CLP Regulation
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Possible, but not outright; industry input possible
	Carc Cat 2 classification	Very unlikely
Comparison of impacts between Carc Cat 1B and Carc Cat 2		Realistically, no scope for EU-wide restriction on TiO_2 uses **Overall: Carc Cat 2 is not relevant**

Table 7–8: Key parameters of relevant legislation – REACH Authorisation		
Key parameters		**Details**
Relevant legislative instruments		Regulation 1907/2006/EC – Annex XIV
Description of potential impact	Carc Cat 1B classification	Possible future proposal for inclusion to Candidate List, following a Risk Management Options Assessment (RMOA). Potential subsequent listing in Annex XIV requires that continued use beyond the sunset date receives an Authorisation (unless use is specifically exempt)
	Carc Cat 2 classification	A Carc cat 2 substance cannot be proposed for inclusion to the Candidate List and subsequent listing in REACH Annex XIV
Applicability (multiple sectors vs. single sector)		Multiple
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/P/(C)

Table 7–8: Key parameters of relevant legislation – REACH Authorisation		
Key parameters		**Details**
Driver of impact on society	Hazard	✓ Listing on the Candidate List focuses on hazard profile
	Risk (incl. availability of alternatives)	✓ Prioritisation, scope of Applications for Authorisation and outcome of applications will depend on existence of alternatives and balance of benefits vs. costs
Immediacy of potential impact		Depends on timing of (a) SVHC proposal, (b) prioritisation of the substance into Annex XIV, (c) granted Sunset/latest Application Dates. The process does allow for a considerable amount of time for generating an Application. However, the mere listing of the substance on the Candidate List could result in negative perceptions along the supply chain
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Possible, but not outright; industry can make inputs to the process and has control over the contents of Applications
	Carc Cat 2 classification	Not possible to be listed on REACH Annex XIV
Comparison of impacts between Carc Cat 1B and Carc Cat 2		No scope for the substance to be subject to Authorisation if classified as Carc Cat 2 **Overall: Carc Cat 2 is not relevant**

7.1.6 Cosmetics

Table 7–9: Key parameters of relevant legislation – Cosmetics		
Key parameters		**Details**
Relevant legislative instruments		Regulation 1223/2009/EC, as amended
Description of potential impact	Carc Cat 1B classification	**Regulation 1223/2009/EC**: TiO_2 is included in three 'positive lists' of the Cosmetics Regulation: - Annex IV (List of colourants allowed in cosmetic products), entry 143; and - Annex VI (List of UV filters allowed in cosmetic products) entries 27 and 27a with a concentration limit of 25%. According to Article 15 substances classified as CMR substances of category 1A, 1B, or 2 under Part 3 of Annex IV to Regulation (EC) No 1272/2008 are banned for use in cosmetic products. Exceptions to this general rule are possible where all of the following are fulfilled: <u>Category 1A or 1B</u> - They comply with the food safety requirements as defined in Regulation (EC) No 178/2002; - There are no suitable alternative substances available, as documented in an analysis of alternatives; - The application is made for a particular use of the product category with a known exposure; and - They have been evaluated and found safe by the Scientific Committee on Consumer Safety (SCCS) for use in cosmetic products. This must take into account exposure to these products, overall exposure from other sources and vulnerable population groups. <u>Category 2</u> - They have been evaluated and found safe by the Scientific Committee on Consumer Safety (SCCS) for use in cosmetic products. This must take into account exposure to these products, overall exposure from other sources and vulnerable population groups. Specific labelling in order to avoid misuse of the cosmetic product shall be provided in accordance with Article 3 of this Regulation, taking into account possible risks linked to the presence of hazardous substances and the routes of exposure. The Commission shall amend the Annexes to this Regulation within 15 months of the inclusion of the substances concerned in Part 3 of Annex VI to Regulation (EC) No 1272/2008. **SCCNFP Opinion 0005/98**: the SCCNFP is of the opinion that TiO_2 is safe for use in cosmetic products at a maximum concentration of 25% in order to protect the skin from certain harmful effects of UV radiation. This opinion concerns crystalline (anatase and/or rutile) TiO_2, whether or not subjected to various treatments (coating, doping, etc.), irrespective of particle size, provided only that such treatments do not compromise the safety of the product. The SCCNFP proposes no further restrictions or conditions for its use in cosmetic products. **SCCS Opinion 1516/13 (22 April 2014)**: in April 2014, the SCCS concluded that the use of nano-scale TiO_2 with the characteristics as indicated below, at a concentration up to 25% as a UV-filter in sunscreens, can be considered to not pose any risk of adverse effects in humans after application on healthy, intact or sunburnt skin. This, however, does not apply to applications that might lead to inhalation exposure to TiO_2 nanoparticles (such as powders or sprayable products) (Scientific Committee on Consumer Safety, 2014). As of November 2016, two further TiO_2-related opinions are pending, one on coatings for nano-scale TiO_2 used as a UV

Table 7–9: Key parameters of relevant legislation – Cosmetics		
Key parameters		**Details**
		filter in dermally applied cosmetic products (SCCS positive draft opinion published and submitted to public consultation – the SCCS considers that the use of the three TiO_2 nanomaterials coated with either cetyl phosphate, manganese dioxide or triethoxycaprylylsilane, can be considered safe for use in cosmetic products intended for application on healthy, intact or sunburnt skin. This, however, does not apply to applications that might lead to exposure of the consumer's lungs to the TiO_2 nanoparticles through the inhalation route (such as powders or sprayable products) (Scientific Committee on Consumer Safety, 2016)) and another on nano-scale TiO_2 when used as UV-filter in sunscreens and personal care spray products at a concentration up to 5.5%
	Carc Cat 2 classification	Carc Cat 2 substances are prohibited for use in cosmetic products. A derogation may be granted and is based on an opinion on safe use from the SCCS only; the remaining provisions (e.g. an analysis of alternatives) would not apply
Applicability (multiple sectors vs. single sector)		Single
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/P/C
Driver of impact on society	Hazard	
	Risk (incl. availability of alternatives)	✓ SCCS needs to assess new information and decide on fate of substance
Immediacy of potential impact		At the September 2016 meeting of the cosmetics working group of the European Commission it was clarified that CMR substances are not automatically banned for use in cosmetic products, if they have a mandatory classification as such under the CLP Regulation. A ban on the use of a CMR substance in cosmetics must be implemented by a specific act amending the relevant annexes of the Cosmetics Regulation[112]. Following the introduction of the harmonised classification, a risk management procedure would be initiated and might result in a ban on the use of the substance. In the case of a CMR 1B classification, the Commission would need to start amending the Annexes of the Cosmetic Regulation within maximum 15 months of the application of the CLP regulation. The SCCS risk assessment is itself based on the submitted evidence by the cosmetic industry. Preparing of a dossier to support a request for an exemption can only be prepared after the RAC opinion on the CLH proposal and, in the case of a CMR 1B classification, can only be submitted after the other exemption criteria are fulfilled (compliance with food safety requirements, no suitable alternatives, application for particular use only). The SCCS process can be long with several iterations (and the opinion may become available only after the date of entry into application of the harmonised CMR classification under the CLP Regulation), however TiO_2 is a substance with a large body of scientific and toxicological evidence that is familiar to the Committee

[112] See Chemwatch article, https://chemicalwatch.com/50071/cmr-substances-not-automatically-banned-in-cosmetics (accessed on 19 January 2017).

Table 7–9: Key parameters of relevant legislation – Cosmetics		
Key parameters		**Details**
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Probable – industry needs to demonstrate that exposure of consumers is sufficiently low and provide information on absence of suitable alternatives
	Carc Cat 2 classification	Probable – industry needs to demonstrate that exposure of consumers is sufficiently low
Comparison of impacts between Carc Cat 1B and Carc Cat 2		Use of TiO_2 would still be reviewed by the SCCS and may or may not lead to a restriction; however, no additional criteria would have to be met **Overall: essentially the same impact under either classification but with fewer criteria to be met for Carc Cat 2**

7.1.7 Toy Safety

<table>
<tr><th colspan="3">Table 7–10: Key parameters of relevant legislation – Toy Safety</th></tr>
<tr><th colspan="2">Key parameters</th><th>Details</th></tr>
<tr><td colspan="2">Relevant legislative instruments</td><td>Directive 2009/48/EC
European Standard EN71-3:2013</td></tr>
<tr><td rowspan="2">Description of potential impact</td><td>Carc Cat 1B classification</td><td>Directive 2009/48/EC: CMR substances shall not be used in toys but exceptions exist:
(a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;
(b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2);
(c) a decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A to Annex II (which lists permitted uses of CMR substances).
That decision may be taken if the following conditions are met:
(i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure;
(ii) there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives; and
(iii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.
A Carc. Cat 1B harmonised classification would affect the use of the substance in toys, including in toy cosmetics – see the Cosmetics Regulation

EN71 Standard: sets out requirements toys must meet in order to be sold in the EU. Included in these requirements are extraction limits for metals in toys and toy components, but extraction limits are not provided for individual raw materials used in the manufacturing of toys or their components, such as titanium dioxide. The manufacturer of any toy product has the responsibility to ensure that the finished article complies with the Standard including the migration limits relevant to the intended condition of use. The standard defines three different toy categories, and migration limits for 19 elements are specified for each category. Titanium is not listed.

Note that children's paints fall under toys (while artists' paints fall under paints and coatings)</td></tr>
<tr><td>Carc Cat 2 classification</td><td>Carc Cat 2 substances are prohibited in toys, in components of toys or in micro-structurally distinct parts of toys.

Derogation conditions are the same as Carc Cat 1B, except for the requirement to demonstrate in an analysis of alternatives that there are no suitable alternative substances or mixtures available, as documented</td></tr>
<tr><td colspan="2">Applicability (multiple sectors vs. single sector)</td><td>Multiple</td></tr>
<tr><td colspan="2">Potential adverse impact on:
- Industry (I)
- Professionals (P)
- Consumers (C)</td><td>I/C</td></tr>
</table>

Table 7–10: Key parameters of relevant legislation – Toy Safety		
Key parameters		**Details**
Driver of impact on society	Hazard	
	Risk (incl. availability of alternatives)	✓ The Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) needs to assess new information and decide on fate of substance
Immediacy of potential impact		The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and at the latest every five years from the date that a decision in accordance with Article 46(3) was taken. SCHEER must provide their opinion on the use of CMR in toys following the same rules of procedure as the SCCS (in cosmetics document). Under Article 46(3) the formal decision on the authorisation of CMRs in toys is taken by the Commission after they have been evaluated by the relevant scientific committee. These measures are adopted in accordance with the regulatory procedure with scrutiny referred to in Article 47(2). The timeframe for SCHEER opinion is decided upon by the Chairman of the Committee and so is not a standard. The EN Standard might take some time before it is amended to potentially include TiO_2
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Possible – industry needs to demonstrate that exposure of children is sufficiently low/zero
	Carc Cat 2 classification	Possible – industry needs to demonstrate that exposure of children is sufficiently low/zero
Comparison of impacts between Carc Cat 1B and Carc Cat 2		**Overall: Use of TiO_2 would still be subject to restriction but the burden of proving safe use would be lower**

7.1.8 Food contact materials

Table 7–11: Key parameters of relevant legislation – Food Contact Materials		
Key parameters		**Details**
Relevant legislative instruments		Framework Regulation (EC) No 1935/2004 – Food Contact materials Regulation (EC) No 2023/2006 - Good Manufacturing Practice for Materials and Articles intended to come into Contact with Food Plastics - Regulation EU/10/2011 - Plastics in Materials and Articles Plastics - Regulation 282/2008/EC - Recycled Plastic Materials and Articles Active and Intelligent Materials - Regulation (EC) No 450/2009 - Active and intelligent materials and articles
Description of potential impact	Carc Cat 1B classification	**Framework Regulation 1935/2004**: according to its Article 3, materials and articles, including active and intelligent materials and articles, shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food in quantities which could: (a) endanger human health; or (b) bring about an unacceptable change in the composition of the food; or (c) bring about a deterioration in the organoleptic characteristics thereof. For the groups of materials and articles listed in Annex I and, where appropriate, combinations of those materials and articles or recycled materials and articles used in the manufacture of those materials and articles, specific measures may be adopted or amended in accordance with the procedure referred to in Article 23(2). Annex I includes the following materials and articles (in bold those potentially relevant to TiO_2): 1. Active and intelligent materials and articles **2. Adhesives** **3. Ceramics** 4. Cork **5. Rubbers** **6. Glass** 7. Ion-exchange resins 8. Metals and alloys **9. Paper and board** **10. Plastics** **11. Printing inks** 12. Regenerated cellulose **13. Silicones** **14. Textiles** 15. **Varnishes and coatings** (e.g. can coatings) 16. Waxes 17. Wood **Regulation 2023/2006 (GMP)**: this Regulation lays down rules on good manufacturing practice for materials and articles intended to come into contact with food. It introduces general rules for all business operators in the supply chain, and specifies that quality assurance and control systems are established and implemented. All printing inks intended for use on food packaging are in the scope of this Regulation. Its Annex introduces detailed rules, which relate to processes involving the application of printing inks to the non-food contact side of a material or article. **Regulation EU/10/2011 (Plastics Regulation incorporating the Union List)**:

Table 7–11: Key parameters of relevant legislation – Food Contact Materials		
Key parameters		**Details**
		according to Recital 27, substances that are classified as carcinogenic should not be used in food contact materials without previous authorisation and should therefore not be covered by the functional barrier concept. ***Plastic multi-layer materials and articles***: substances not listed in the Union list or provisional list may not be classified as a carcinogen in accordance with the criteria in sections 3.6 of Annex I of the CLP Regulation. ***Multi-material multi-layer materials and articles:*** substances classified as a carcinogen in accordance with the criteria in Section 3 of Annex I of the CLP Regulation cannot be listed in the Union list or provisional list. Coated and printed plastic materials and articles are covered by the scope of the Plastics Regulation. Plastics held together by adhesives are also covered by its scope. However, substances used only in **printing inks, adhesives and coatings** are not included in the Union list because these layers are not subject to the compositional requirements of the Plastics Regulation. The only exceptions are substances used in coatings which form gaskets in closures and in caps. The requirements for printing inks, adhesives and coatings are intended to be set out in separate specific Union measures. Until such measures are adopted, they are covered by national law[113]. If a substance used in a coating, a printing ink or an adhesive is listed in the Union list, the final material or article has to comply with the migration limit of this substance, even if the substance is used in the coating, printing ink or adhesive only. Even though **colourants** fall under the definition of additives, they are not covered by the Union list of substances. Colourants used in plastics are covered by national measures. Certain colourants, in particular, cadmium pigments, are regulated by EU legislation on chemicals and listed in Annex XVII of the REACH Regulation. They have to comply with the general safety requirements of Article 3 of the Framework Regulation (EC) No 1935/2004 and are subject to risk assessment in line with Article 19 of the Plastics Regulation. TiO_2 is currently an authorised substance, under entries 610, 805 and 873 in Table 1 of Annex I, for use as an additive or polymer production aid. No TiO_2-specific migration limits are provided hence, in accordance with Article 11, a generic specific migration limit of 60 mg/kg applies and in accordance with Article 12 an overall migration limit for plastic materials of 10 milligrams of total constituents released per dm^2 of food contact surface (mg/dm^2) applies. Article 15 (3) states that when new scientific data are available the declaration of compliance shall be renewed; however, the new classification (based on pre-existing toxicological data) may not qualify as 'new scientific data'. **Regulation 282/2008/EC**: only authorised monomers and additives should be added to the recycled plastics and their migration limits should also be respected by recycled plastic food contact materials. Use of TiO_2 in recycled plastic would be unlikely to be authorised, if no longer on the Union List. **Regulation (EC) No 450/2009**: the Regulation defines active materials and

[113] A brochure by Chemours provides a useful overview of relevant national legislation (Chemours, 2016c).

Table 7–11: Key parameters of relevant legislation – Food Contact Materials		
Key parameters		**Details**
		articles as those which may deliberately incorporate substances, which are intended to be released into food. On the other hand, intelligent packaging systems provide the user with information on the conditions of the food and should not release their constituents into the food. Only substances which are included in the 'Community list' of authorised substances may be used in components of active and intelligent materials and articles. Under Article 5(2)(c)(i), CMR substances cannot be used in such materials and packaging even if not in direct contact with food or the environment surrounding the food and even if they are separated from the food by a functional barrier. Annex II (point 10) further requires that, "*The written declaration (…) shall be renewed when substantial changes in the production bring about changes in the migration or when new scientific data are available*". **Notes**: in relation to ceramic materials used for food contact, Directive 84/500/EEC (as amended by Directive 2005/31/EC) applies. However, this specifically regulates the migration of lead and cadmium from ceramic food contact materials and does not include provisions relevant to carcinogens in general. Consultation suggests that this Directive may be subject to revision and replacement by a Regulation in the future. Another food contact material that is regulated in the EU is regenerated cellulose film intended to come into contact with foodstuffs which is subject to provisions of Directive 2007/42/EC. According to Article 3, regenerated cellulose films shall be manufactured using only substances or groups of substances listed in Annex II to the Directive subject to the restrictions set out therein. Substances other than those listed in Annex II may be used when these substances are employed as colouring matter (dyes and pigments) or as adhesives, provided that there is no trace of migration of the substances into or onto foodstuffs, detectable by a validated method. Consultation and research has not confirmed the relevance of these food contact materials to TiO_2
	Carc Cat 2 classification	**Framework Regulation 1935/2004**: any difference between classification categories are not noted in this Regulation and can be found in the material specific Regulations. **Regulation EU/10/2011 (Plastics Regulation incorporating the Union List)**: same provisions apply as for Carc Cat 1B substances. **Regulation 282/2008/EC**: same provisions apply to those for Carc Cat 1B substances as they are in reference to Reg. (EU) 10/2011. **Regulation (EC) No 450/2009**: same provisions apply as for Carc Cat 1B substances
Applicability (multiple sectors vs. single sector)		Multiple
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/C

Table 7–11: Key parameters of relevant legislation – Food Contact Materials		
Key parameters		**Details**
Driver of impact on society	Hazard	
	Risk (incl. availability of alternatives)	✓ The European Food Safety Agency (EFSA) needs to assess new information and decide on whether to authorise the continued use of the substance
Immediacy of potential impact		Classification of TiO_2 as a carcinogen may trigger a re-evaluation of an authorisation. Such re-evaluation may be initiated under Article 11(5) or Article 12 (1) of the Framework Regulation by the business operator using an authorised substance, the Commission, a Member State or the European Food Safety Authority under Article 12 (3). In this context, it should be stressed that Article 11(5) of the Regulation obliges a business operator using an authorised substance or materials or articles containing the authorised substance to "*immediately inform the Commission of any new scientific or technical information, which might affect the safety assessment of the authorised substance in relation to human health*"
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Unclear – inhalation exposure would appear to be irrelevant. It is understood that national legislation may be in place (for instance on paper, board, coatings) and action may be taken under national rules. Council of Europe Resolutions, the CEPE Code of Practice and EuPIA's Exclusion Policy would also apply (see Sections 8.2.1-8.2.3 below)
	Carc Cat 2 classification	EU-wide regulations are largely the same as for Carc Cat 1B substances, but role of national rules is important. The CEPE Code of Practice would apply but EuPIA's Exclusion Policy would not apply
Comparison of impacts between Carc Cat 1B and Carc Cat 2		**Overall: largely, same provisions for both classification categories**

7.1.9 Food and feed additives

Table 7–12: Key parameters of relevant legislation – Food Additives

Key parameters		Details
Relevant legislative instruments		Regulation 1333/2008 Regulation 1129/2011 Regulation 738/2013 Regulation 231/2102
Description of potential impact	Carc Cat 1B classification	**Regulation 1333/2008**: only food additives included in the Community list in Annex II may be placed on the market and used in foods under the conditions of use specified therein. Only food additives included in the Community list in Annex III may be used in food additives, in food enzymes and in food flavourings under the conditions of use specified therein. Food additives must comply with the specifications outlined in Article 14. A food additive may be added to the Community list where it meets the following conditions: • It does not, on the basis of available scientific evidence, pose a safety concern to the health of the consumer at the level of use; • There is reasonable technological need that cannot be achieved by other economically and technologically practicable means; • It does not mislead the consumer. Only food colours listed in Annex II may be used for the purpose of health marking, or for the decorative colouring or stamping of eggshells. The last Commission Regulation to introduce new food categories where use of TiO_2 (E171) is permitted was new food categories where E171 is allowed was Commission Regulation (EU) No 738/2013. This notes that TiO_2 is not liable to have an effect on human health, it is not necessary to seek the opinion of the European Food Safety Authority. Nevertheless, TiO_2 has been re-evaluated by EFSA in accordance with Commission Regulation (EU) No 257/2010 (European Food Safety Authority, 2016). The conclusion has been that available toxicological data do not indicate adverse effects via oral ingestion. While EFSA was unable to set an Acceptable Daily Intake (ADI) for TiO_2 because of data limitations, using the margin of safety approach, they concluded that dietary exposure does not pose health concerns. The experts highlighted, however, the need for new research to fill data gaps on potential effects of titanium dioxide on the reproductive system (European Food Safety Authority, 2016b). A Carc. Cat. 1B classification may lead to the review of the evaluation and potentially the removal from the list of approved food additives or the setting of a stringent ADI. **Regulations 1129/2011 & 738/2013**: in the EU, TiO_2 (E171) is listed in Annex II of Regulation 1333/2008/EC as a permitted colour in foodstuff at *quantum satis* and it is presumed to be safe **Regulation 231/2102**: this Regulation specifies purity criteria
	Carc Cat 2 classification	**Regulation 1333/2008**: same provisions apply as for Carc Cat 1B substances **Regulation 231/2102**: at present, the same applies as for Carc Cat 1B substances

Table 7–12: Key parameters of relevant legislation – Food Additives		
Key parameters		**Details**
Applicability (multiple sectors vs. single sector)		Single (but with indirect links to cosmetics and pharmaceuticals)
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/C
Driver of impact on society	Hazard	
	Risk (incl. availability of alternatives)	✓
Immediacy of potential impact		Timing would depend on the completion of the review of the new scientific data
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Possible but unlikely – only calcium carbonate (chalk, E170) is an approved white colourant and it cannot meet the performance of TiO_2. Also, inhalation exposure risks are clearly limited
	Carc Cat 2 classification	Possible but unlikely – only calcium carbonate (chalk, E170) is an approved white colourant and it cannot meet the performance of TiO_2. Also, inhalation exposure risks are clearly limited
Comparison of impacts between Carc Cat 1B and Carc Cat 2		**Overall: same provisions for both classification categories**

<table>
<tr><th colspan="3">Table 7–13: Key parameters of relevant legislation – Additives in Animal Feed Additives</th></tr>
<tr><th colspan="2">Key parameters</th><th>Details</th></tr>
<tr><td colspan="2">Relevant legislative instruments</td><td>Regulation 1831/2003</td></tr>
<tr><td rowspan="2">Description of potential impact</td><td>Carc Cat 1B classification</td><td>No feed additive can be placed on the market, processed or used if it is not authorised in accordance with this Regulation and the conditions for use and labelling are met.
Conditions for authorisation are that the feed additive must not:
• Have an adverse effect on animal health, human health or the environment;
• Be presented in a manner which may mislead the user; or
• Harm the consumer by impairing the distinctive features of animal products or mislead the consumer with regard to the distinctive features of animal products.
TiO_2 is currently listed in Annex I under Category 2 (colourants), Functional Group a with the entry: “Titanium dioxide (anatase & rutile structure) as colouring agents authorised for colouring foodstuffs by Community rules [Dogs; Cats]”
An authorisation may be revoked if the Commission decide, on the basis of an opinion by the Authority, that it no longer meets the criteria for authorisation</td></tr>
<tr><td>Carc Cat 2 classification</td><td>The hazard classification of a substance is not given as a condition for authorisation within the legal text. It is not apparent whether or not it is taken into account in the EFSA authorisation</td></tr>
<tr><td colspan="2">Applicability (multiple sectors vs. single sector)</td><td>Single</td></tr>
<tr><td colspan="2">Potential adverse impact on:
- Industry (I)
- Professionals (P)
- Consumers (C)</td><td>I/C</td></tr>
<tr><td rowspan="2">Driver of impact on society</td><td>Hazard</td><td></td></tr>
<tr><td>Risk (incl. availability of alternatives)</td><td>✓</td></tr>
<tr><td colspan="2">Immediacy of potential impact</td><td>Timing would depend on the completion of the review of the new scientific data for food additives</td></tr>
<tr><td rowspan="2">Realistic potential for a restriction on the use of TiO_2</td><td>Carc Cat 1B classification</td><td>Possible but unlikely – no other white pigment appears to be listed</td></tr>
<tr><td>Carc Cat 2 classification</td><td>Possible but unlikely – no other white pigment appears to be listed</td></tr>
<tr><td colspan="2">Comparison of impacts between Carc Cat 1B and Carc Cat 2</td><td>Overall: uncertain differences between the two classification categories</td></tr>
</table>

7.1.10 Colouring matters for medicinal products

<table>
<tr><th colspan="3">Table 7–14: Key parameters of relevant legislation – Colouring matters for Medicinal Products</th></tr>
<tr><th colspan="2">Key parameters</th><th>Details</th></tr>
<tr><td colspan="2">Relevant legislative instruments</td><td>Directive 2001/83/EC
Regulation 1901/2006
Directive 2009/35/EC
Regulation 1333/2008 (see above)</td></tr>
<tr><td>Description of potential impact</td><td>Carc Cat 1B classification</td><td>Directive 2001/83/EC: It is a legal requirement according to Directive 2001/83/EC on the Community code relating to medicinal products for human use as amended that excipients which are used must comply with the relevant European Pharmacopoeia (Ph Eur) monograph.
Carcinogenic potential is included in toxicological and pharmacological tests.
Testing required:
• In respect of substances having a close chemical analogy with known carcinogenic or carcinogenic compounds;
• In respect of substances which have given rise to suspicious changes during long-term toxicological tests; and
• In respect of substances which have given rise to suspicious results in the mutagenic-potential tests or in other short-term carcinogenicity tests.

Regulation 1901/2006: Regulation 1901/2006 on medicinal products for paediatric use includes a Commission Statement with which the Commission requested the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency to draw up an opinion on the use of these categories of substances as excipients of medicinal products for human use, on the basis of Articles 5(3) and 57(1)(p) of Regulation (EC) No 726/2004.
The CHMP delivered its opinion in October 2007; this states, “In the event that CMR toxicity has been identified for an excipient, the rule is to avoid and replace this excipient. In the rare cases where this would not be possible, the use of such CMR excipients in a medicinal product would only be considered after careful evaluation of the benefits of the medicinal product in the target patient population versus the potential risks (…) any risk identified for an excipient and in particular a CMR substance, would be acceptable only on condition that this excipient cannot be substituted with a safer available alternative, or that the toxicological effects in animal models are considered not relevant for humans (e.g. species specific, very large safety ratio), or where the overall benefit/risk balance for the product outweighs the safety concern with the product. Overall, the use of any excipient with a known potential toxicity, and which could not be avoided or replaced, would only be authorised if the safety profile was considered to be clinically acceptable in the conditions of use, taking into account the duration of treatment, the sensitivity of the target population and the benefit-risk ratio for the particular therapeutic indication” (European Medicines Agency, 2007)[114].</td></tr>
</table>

[114] Interestingly, the opinion also states, “*For non-genotoxic rodent carcinogens (which are known to be around 50% of molecules tested in life span rodent carcinogenicity studies) only those for which the mechanism of tumorigenesis (including the route of administration) has been identified as relevant for man, should be carefully considered before a decision is taken to include them in a pharmaceutical product. It is important to highlight that many of the substances positive in the carcinogenicity studies are specific rodent*

Table 7–14: Key parameters of relevant legislation – Colouring matters for Medicinal Products

Key parameters		Details
		Directive 2009/35/EC: colouring matters used to colour medicinal products for human and veterinary use must abide by the rules on colouring matters in Annex II to Regulation (EC) No. 1333/2008 and Regulation 231/2012 (that has repealed Directive 95/45/EC) laying down the specific purity criteria concerning colours for use in foodstuffs apply to medicinal products. A Carc. Cat 1B classification would result in the review and potential de-authorisation of TiO_2
	Carc Cat 2 classification	**Directive 2001/83/EC**: no differentiation between carcinogenic category in the legal text but this may be taken into account in the carcinogenic-potential testing. **Regulation 1901/2006**: there may be a possibility that it could be easier to obtain an authorisation with a category 2 carcinogen as the evidence for classification as carcinogenic category 2 is considered to "limited". This is not a guarantee. **Directive 2009/35/EC**: the same rules should apply for Category 2 Carcinogens as this Regulation is based on Reg. 1333/2008 and Regulation 231/2012
Applicability (multiple sectors vs. single sector)		Single
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/C
Driver of impact on society	Hazard	
	Risk (incl. availability of alternatives)	✓
Immediacy of potential impact		Depends on the type of variation required for the existing Authorisation dossiers (European Commission, 2013): - A replacement of the excipient would require a variation Type IAIN which requires immediate notification; - Qualitative or quantitative changes in one or more excipients that may have a significant impact on the safety, quality or efficacy of the medicinal product requires a major variation Type II; or - A reduction of the shelf life of the finished product as packaged for sale would require a variation Type IAIN which requires immediate notification. It would also be dependent on food additives legislation. Timing would depend on the completion of the review of the new scientific data for a removal of TiO_2 from the Annex of Regulation 1333/2008

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carcinogens with no relevance to humans. In addition, the 'safety ratios' (e.g. the relation between the exposures that were tumorigenic in rodents and those to be reached in patients) should be taken into consideration" (European Medicines Agency, 2007).

Table 7–14: Key parameters of relevant legislation – Colouring matters for Medicinal Products		
Key parameters		**Details**
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Possible but might be unlikely – only calcium carbonate (chalk, E170) is an approved white colourant and it cannot meet the performance of TiO_2. Also, inhalation exposure risks are clearly limited (while calcium from $CaCO_3$ would be absorbed by ingestion).
	Carc Cat 2 classification	Same as for Carc Cat 1B substances
Comparison of impacts between Carc Cat 1B and Carc Cat 2		**Overall: same provisions for both classification categories (but with uncertainties)**

7.1.11 Medical devices

Table 7–15: Key parameters of relevant legislation – Medical Devices

Key parameters		Details
Relevant legislative instruments		Medical Devices Regulation (EU) 2017/745
Description of potential impact	Carc Cat 1B classification	The text for the new medical devices Regulation includes a 0.1% concentration limit for category 1A and 1B CMRs and endocrine disrupting chemicals (EDCs) in devices that: - Are invasive and come into direct contact with the body; - (Re)administer, transport or store medicines, body liquids or other substances, including gases, to/from the body; or - Transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body. Devices would only be permitted to contain such substances, at a level above this limit, if a justification is provided. This would have to be based on: - An analysis and estimation of potential patient or user exposure; - An analysis of alternative substances, materials or designs; - Arguments to justify why any possible substitutes or design changes are "inappropriate to maintain the functionality, performance and the benefit-risk ratios of the product"; and - Where applicable and available, the latest scientific committee guidelines Information on use must explain the precautions related to materials incorporated into the device that are carcinogenic. According to Annex I (paragraph 10.4.5) to the new Medical Devices Regulation, these devices *"shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging, with the list of such substances…."*
	Carc Cat 2 classification	There are no concentration limit provisions nor labelling/information requirements for Carc Cat 2 substances
Applicability (multiple sectors vs. single sector)		Multiple
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/(C)
Driver of impact on society	Hazard	
	Risk (incl. availability of alternatives)	✓
Immediacy of potential impact		As soon as harmonised classification is adopted and CLP Regulation is updated, unless justification for ongoing use is submitted (timing uncertain)
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Possible but unlikely – lack of alternatives and inhalation exposure risks are clearly limited
	Carc Cat 2 classification	Carc Cat 2 substances are outside the scope of the regulation
Comparison of impacts between Carc Cat 1B and Carc Cat 2		**Overall: Carc Cat 2 is not relevant**

7.1.12 Construction products

Table 7–16: Key parameters of relevant legislation – Construction products		
Key parameters		**Details**
Relevant legislative instruments		Construction Products Regulation (EU) 305/2011
Description of potential impact	Carc Cat 1B classification	In line with Article 4(1) of the Regulation, the manufacturer must draw up a Declaration of Performance (DoP) when placing on the market a construction product which is covered by a harmonised standard, or for which a European Technical Assessment has been issued. A copy of the DoP must be further supplied with every product which is made available on the market. The Regulation also provides in Article 6(5) that the information referred to in Article 31 (requirements for safety data sheets), or Article 33 (duty to communicate information on substances in articles), of the REACH Regulation shall be provided together with the DoP but more should be further investigated in line with CLP Regulation, Regulation 528/2012, Directive 2000/60/EC and Directive 2008/98/EC. This information therefore accompanies the construction product in all steps of the supply chain till the final end user (contractor, worker and consumer). Article 3(3) also allows the Commission to decide for which essential characteristics manufacturers shall declare the performance of the product and the Commission can also determine threshold levels. This is not applied today, but could be in the future. Combined with Article 6(5), this may have the effect to exclude some products from the market. Its recital No. 25 also stresses that "*the specific need for information on the content of hazardous substances in construction products should be further investigated*", which may influence any future revision of the Regulation. The classification of TiO_2 as a Carc. Cat. 1B would mean that safety data sheets would need to be supplied for mixtures that contain more than 0.1% TiO_2. Also, if the substance is named as a Substance of Very High Concern or ends up in Annex XIV, information will also need to be provided to users of construction articles that contain TiO_2 in a concentration above 0.1% by weight
	Carc Cat 2 classification	If a Category 2 Carcinogen is present in a mixture at a concentration ≥0.1% then a SDS must be available upon request (as per Note 1 under Table 3.6.2 of the CLP Regulation)
Applicability (multiple sectors vs. single sector)		Construction products
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/(P)/(C)
Driver of impact on society	Hazard	✓
	Risk (incl. availability of alternatives)	
Immediacy of potential impact		As soon as harmonised classification is adopted and CLP Regulation is updated (mixtures) and after the adoption of TiO_2 as a SVHC (articles). Any future extension of the REACH Regulation to cover new substances will automatically apply also to the obligation of construction products manufacturers to disseminate the relevant information, thus keeping pace with scientific progress

Table 7–16: Key parameters of relevant legislation – Construction products		
Key parameters		**Details**
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Unlikely
	Carc Cat 2 classification	Unlikely
Comparison of impacts between Carc Cat 1B and Carc Cat 2		Given the typical concentration of TiO_2 in its formulations, the requirement for SDS preparation would still apply (but provision of the SDS would not be mandatory) **Overall: Carc cat 2 classification is accompanied by less onerous provisions**

7.1.13 Biocides

Table 7–17: Key parameters of relevant legislation – Biocides		
Key parameters		**Details**
Relevant legislative instruments		Regulation EU/528/2012
Description of potential impact	Carc Cat 1B classification	Active substances classified as Carc. Cat 1B shall not be authorised unless they meet one of the criteria set out in Article 5 (2): (a) the risk to humans, animals or the environment is negligible; (b) the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or (c) not approving the active substance would have a disproportionate negative impact on society. Substances classified as a Carc Cat 1B are exclusion criteria and so prevent active substance approval. Derogation is available if at least one of the following conditions is met: • The risk to humans, animals or the environment from exposure to the active substance in a biocidal product, under realistic worst-case conditions of use, is negligible, in particular where the product is used in closed systems or under other conditions which aim at excluding contact with humans and release into the environment; • It is shown by evidence that the active substance is essential to prevent or control a serious danger to human health, animal health or the environment; or • Not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance. The availability of suitable and sufficient alternatives should be taken into account when granting a derogation. Biocidal products shall not be authorised for making available on the market for use by the general public if it has been classified as a Carc Cat 1B. Substances that are classified as a Carc Cat 1B are considered to be candidates for substitution
	Carc Cat 2 classification	Category 2 Carcinogens are not within the scope of the restrictions prescribed by the Regulation
Applicability (multiple sectors vs. single sector)		Multiple
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/C
Driver of impact on society	Hazard	
	Risk (incl. availability of alternatives)	✓
Immediacy of potential impact		The Biocidal Products Committee (BPC) has to make their decision 270 days after the receipt of the eMSCA evaluation

Table 7–17: Key parameters of relevant legislation – Biocides		
Key parameters		**Details**
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Unlikely – TiO_2 is not a biocide itself; lack of alternatives and inhalation exposure risks are clearly limited
	Carc Cat 2 classification	Not possible
Comparison of impacts between Carc Cat 1B and Carc Cat 2		**Overall: Carc Cat 2 is not relevant**

7.1.14 Electrical and electronic equipment

Table 7–18: Key parameters of relevant legislation – WEEE and RoHS		
Key parameters		**Details**
Relevant legislative instruments		Directive 2011/65/EU Directive 2012/19/EU
Description of potential impact	Carc Cat 1B classification	The RoHS Directive prescribes that where scientific information has become available, taking into account the precautionary principle, the restriction of hazardous substances, including nanomaterials which may be hazardous due to properties relating to their size or structure, and their substitution by more environmentally friendly alternatives which ensure at least the same level of protection of consumers should be examined. Review and amendment of Annex II should be coherent and maximise synergies with work carried out under other Union. Following a Carc. Cat 1B classification for TiO_2, particularly, if regulatory activities ensue under the REACH Regulation, there may be a possibility that a Member State may submit a proposal for including the substance in Annex II of the RoHS Directive
	Carc Cat 2 classification	It is unclear whether or not a Carc Cat 2 would be subject to the same provisions as there is no definition of "hazardous" or differentiation between hazard class categories. It is noted that the aim of the Directive is to protect the environment and human health via the environmental release of hazardous substances. It would be at the discretion of Member States if any action were to be taken
Applicability (multiple sectors vs. single sector)		Multiple
Potential adverse impact on: - Industry (I) - Professionals (P) - Consumers (C)		I/C
Driver of impact on society	Hazard	
	Risk (incl. availability of alternatives)	✓
Immediacy of potential impact		Timing would depend on how soon a proposal for an Annex II entry is submitted by a Member State
Realistic potential for a restriction on the use of TiO_2	Carc Cat 1B classification	Possible but inhalation exposure risks are clearly limited
	Carc Cat 2 classification	Possible but inhalation exposure risks are clearly limited
Comparison of impacts between Carc Cat 1B and Carc Cat 2		**Overall: uncertain differences between the two classification categories**

7.1.15 Tobacco products

<table>
<tr><th colspan="3">Table 7–19: Key parameters of relevant legislation – Tobacco products</th></tr>
<tr><th colspan="2">Key parameters</th><th>Details</th></tr>
<tr><td colspan="2">Relevant legislative instruments</td><td>Directive 2014/40/EU
Decision (EU) 2016/787</td></tr>
<tr><td rowspan="2">Description of potential impact</td><td>Carc Cat 1B classification</td><td>Directive 2014/40/EU: the Directive sets out additional enhanced reporting obligations for additives included in a priority list in order to assess, inter alia their toxicity, addictiveness and CMR properties, including in combusted form. Manufacturers or importers need to prepare reports on the available scientific literature on the effects of each listed additive. The information received shall assist the Commission and Member States in taking the decisions pursuant to Article 7, including a prohibition on the marketing of tobacco products containing additives that have CMR properties in unburnt form or increase the CMR properties of a tobacco product at the stage of consumption to a significant or measurable degree.

Decision (EU) 2016/787: the Decision sets out the priority list of additives and includes TiO_2 into the list. The Decision applies from 1 January 2017 and manufacturers and importers will be required to submit enhanced reports in respect of the first set of identified additives by 1 July 2018.

It can be envisaged that the proposal for a harmonised classification of Carc Cat 1B would need to be taken into account in the generation of the enhanced report for the TiO_2 and might have an indirect role in making the substance more susceptible to future regulatory action (a ban)</td></tr>
<tr><td>Carc Cat 2 classification</td><td>Directive 2014/40/EU: there is no distinction between hazard class categories and so it is unclear whether there may be different obligations. It appears that it is based on a carcinogenic classification and so the provisions may apply to category 2 carcinogens as well.

Decision (EU) 2016/787: Same provisions may apply to category 2 carcinogens as no distinction is made between hazard class categories</td></tr>
<tr><td colspan="2">Applicability (multiple sectors vs. single sector)</td><td>Single</td></tr>
<tr><td colspan="2">Potential adverse impact on:
- Industry (I)
- Professionals (P)
- Consumers (C)</td><td>I/C</td></tr>
<tr><td rowspan="2">Driver of impact on society</td><td>Hazard</td><td></td></tr>
<tr><td>Risk (incl. availability of alternatives)</td><td>✓
Enhanced report will need to look into both hazard and exposure to estimate the risk of tobacco smokers</td></tr>
<tr><td colspan="2">Immediacy of potential impact</td><td>By 1 January 2018 the enhanced report will need to be submitted; the CLH process will not have finished before then</td></tr>
<tr><td rowspan="2">Realistic potential for a restriction on the use of TiO_2</td><td>Carc Cat 1B classification</td><td>Only a potential indirect effect</td></tr>
<tr><td>Carc Cat 2 classification</td><td></td></tr>
<tr><td colspan="2">Comparison of impacts between Carc Cat 1B and Carc Cat 2</td><td>Overall: same provisions for both classification categories (but with uncertainties)</td></tr>
</table>

7.1.16 Summary and conclusions

Summary

Table 7–20, presents the applicability of the different pieces of legislation to the general TiO_2 application areas identified earlier in this document. Red colour indicates relevance, while orange colour indicates potential relevance (if certain conditions are met) or specific areas where particularities exist; for instance, the CLP Regulation and the Authorisation provisions of the REACH Regulation apply to chemical inputs to food preparation and pharmaceuticals manufacture but not to the marketing and use of foodstuffs or medicines.

Comparison between Carc Cat 2 an Carc Cat 1B classification implications under EU law

Table 7–21 shows the different legislation areas grouped by differences in their provisions between Carc Cat 1B and Carc Cat 2 substances. Five groups can be distinguished:

- **Group 1 (red) – no change in provisions**: here, Carc Cat 2 substances are treated the same as Carc Cat 1B substances. This group includes waste, food contact materials, food additives, medicinal products and tobacco additives;

- **Group 2 (light red) – theoretically less onerous but, in practice, potentially similar provisions**: here, Carc Cat 2 substances are treated less stringently than Carc Cat 1B ones but in practical (and economic) terms manufacturers and downstream users would essentially need to meet very similar requirements. This group includes the labelling provisions of the CLP Regulation, cosmetics and toy safety;

- **Group 3 (yellow) – less onerous provisions**: here, Carc Cat 2 substances are treated less stringently than Carc Cat 1B ones. This group includes industrial emissions and construction products and the REACH Regulation (are regards the provision of SDS, not Annexes XVII or XIV);

- **Group 4 (green) – no provisions**: here, Carc Cat 2 substances fall outside the scope of the relevant legislation. This group includes the Carcinogens and Mutagens at Work Directive, medical devices and biocides; and

- **Group 5 (grey) – differences are uncertain**: here, it is unclear how the carcinogenicity category of a substance is taken into account. This group include feed additives and restriction of substances in electrical and electronic equipment.

There are some important differences between the provisions of the existing regulatory framework. Crucially, Carc Cat 2 substances are outside the scope of the Carcinogens and Mutagens Directive and REACH Regulation's Annexes XVII (and XIV). This, however, would not mean that a classification of Carc Cat 2 would not be accompanied by significant impacts as, in several cases, the provisions of EEA-wide regulation for Carc Cat 2 substances are the same (or practically the same) as for Carc Cat 1B ones as shown in **Table 7–21**.

Table 7–20: Relevance of different regulatory instruments to the applications of TiO_2 following a harmonised classification of Carc Cat 1B

Relevant legislation	Type	Number	Manufacture and import of TiO_2	Paints	Plastics	Paper	Inks	Construction materials	Fibres	Catalysts	Food, feed and food contact materials	Pharmaceuticals	Cosmetics	Elastomers	Pigment and pigment preparations *	Ceramics	Glass	Medical devices	Detergents	Biocides
CLP	Regulation	1272/2008/EC																		
Carcinogens and Mutagens at Work	Directive	1989/391/EEC																		
	Directive	2004/37/EC																		
Waste Framework	Directive	2008/98/EC																		
	Regulation	1357/2014																		
	Decision	2000/532/EC																		
Industrial Emissions	Directive	2010/75/EC																		
REACH	Regulation Annex XVII	1907/2006/EC																		
	Regulation Annex XIV	1907/2006/EC																		
	Regulation Article 31	1907/2006/EC																		
Cosmetics	Regulation	1223/2009/EC (as amended)																		
Toy Safety	Directive	2009/48/EC																		
	European Standard	EN71-3:2013																		

Table 7–20: Relevance of different regulatory instruments to the applications of TiO_2 following a harmonised classification of Carc Cat 1B

Relevant legislation	Type	Number	Manufacture and import of TiO_2	Paints	Plastics	Paper	Inks	Construction materials	Fibres	Catalysts	Food, feed and food contact materials	Pharmaceuticals	Cosmetics	Elastomers	Pigment and pigment preparations *	Ceramics	Glass	Medical devices	Detergents	Biocides
Food Contact Materials	Regulation on Food Contact Materials	1935/2004																		
	Regulation Plastics in Materials and Articles	EU/10/2011																		
	Regulation Recycled Plastic Materials and Articles	282/2008/EC																		
	Regulation	(EC) No 450/2009																		
Food Additives	Regulation	1333/2008/EC																		
	Directive	94/36/EEC																		
	Regulation	231/2102																		
	Regulation	1831/2003/EC																		

Table 7–20: Relevance of different regulatory instruments to the applications of TiO_2 following a harmonised classification of Carc Cat 1B

Relevant legislation	Type	Number	Manufacture and import of TiO_2	Paints	Plastics	Paper	Inks	Construction materials	Fibres	Catalysts	Food, feed and food contact materials	Pharmaceuticals	Cosmetics	Elastomers	Pigment and pigment preparations *		Ceramics	Glass	Medical devices	Detergents	Biocides
Medicinal Products	Directive	2001/83/EC																			
	Regulation	1901/2006																			
	Directive	2009/35/EC																			
	Directive	94/36/EC																			
Construction Products	Regulation	305/2011																			
Biocides	Regulation	EU/528/2012																			
Medical Devices	Regulation	2017/745																			
Restriction of hazardous substances in electrical and electronic equipment	Directive	2011/65/EU																			
	Directive	2012/19/EU																			
Tobacco additives	Directive	2014/40/EU																			
	Decision	(EU) 2016/787																			
Other				✓	✓		✓	✓	✓		✓										

* the left-hand side column refers to manufacture while the right-hand side refers to pigment and pigment preparation use

Table 7–21: Grouping of EEA-wide legislation areas where differences between Carc Cat 1B and Carc Cat 2 exist		
Group	**Legislation area**	**Conclusion on differences in regulatory provisions**
Key: red – same provisions; light red – essentially same provisions but less burdensome or with fewer criteria to be met; orange – less onerous provisions; green – no provision/impact; grey – unclear		
1	Waste framework	Given the typical concentration of TiO_2 in its formulations, LoW 'mirror' entry waste would still be classified as hazardous
	Food contact materials	Same provisions would apply (also see discussion on national regulations)
	Food additives	Same provisions would apply
	Medicinal products	Same provisions would probably apply (but with uncertainties)
	Tobacco additives	Same provisions would probably apply (but with uncertainties)
2	CLP - Labelling	Given the typical concentration of TiO_2 in its formulations, the labelling requirement would remain with the same pictogram
	Cosmetics	Use of TiO_2 would still be reviewed by the SCCS and may or may not lead to a restriction; however, no additional criteria would have to be met
	Toy safety	Use of TiO_2 would still be subject to restriction but the burden of proving safe use would be lower
3	Industrial emissions	No explicit provisions restricting use, but emissions to water are treated the same
	Construction products	Given the typical concentration of TiO_2 in its formulations, the requirement for SDS preparation would still apply (but provision of the SDS would not be mandatory)
	REACH	Article 31 of REACH Regulation on SDS provision would still apply; however, there would be no scope for an EU-wide restriction on consumer uses and no likelihood for Authorisation requirements (Annexes XVII and XIV)
4	Carcinogens and mutagens at work	No explicit provisions restricting use
	Medical devices	No explicit provisions restricting use (with some small uncertainty)
	Biocides	No explicit provisions restricting use
5	Feed additives	Uncertain differences between the two hazard classification categories
	Restriction of hazardous substances in electrical & electronic equipment	Uncertain differences between the two hazard classification categories

Of particular importance are the implications of the labelling provisions of the CLP Regulation as they would impact nearly all TiO_2 formulations (with content above 1% w/w) and most critically the most important application of TiO_2, paints. Because paints always contain over 1% of TiO_2 by weight they would have to carry the same pictogram on their label as for the Carc Cat 1B classification, which would have severe consequences on public perception (see discussion elsewhere in this document). In addition, implementation of the waste regulations that disregards the importance of the exposure pathway specified in the hazard classification (by inhalation) could cause very extensive problems to the management of waste and recycling activities.

It is important to point out that several pieces of relevant legislation would certainly impose a regulatory burden on the TiO_2 supply chain and the outcome of such efforts made cannot be predicted with any certainty. There are application areas where a Carc Cat 2 hazard classification could cause major problems but where rapid, successful action by interested parties could mitigate impacts. Typical examples are the cosmetics, toys, food, pharmaceuticals applications where a risk assessment would need to be undertaken to take into account the new classification. For instance, for cosmetics, securing derogations could be a challenging task as there are only 15 months between the CLH being added to Annex VI of the CLP and the Cosmetics Regulation annexes being updated with a review of the existing authorisations for TiO_2 (as a colourant and UV filter) by the SCCS. Therefore, the time for obtaining an SCCS opinion on safe use is very short. It is understood that it can take up to 2 years to prepare an SCCS dossier. If cosmetics companies would be interested in safeguarding the use of TiO_2, they would need to prepare a dossier for the SCCS opinion as soon as possible.

More widely, a carcinogenic classification of any kind for a substance would still have significant implications in retail / consumer, professional and industrial settings even if the use of the substance is not restricted by legislation.

7.2 Other regulatory provisions

7.2.1 National Health and Safety at Work and Consumer Safety Legislation

Assessing impacts under national legislation has been outside the scope of this project. As such it cannot be certain what impacts would arise on the national level but it is reasonable to assume that some requirements and controls would apply to a Carc Cat 2 substance.

In relation to workers, the new classification might result in a tightening of national Occupational Exposure Limits (OELs). For instance, it has been suggested that the current OEL in the UK is set at 10 mg/m^3 but following the classification of the substance as a carcinogen, it might be reviewed and might become an order of magnitude lower. This would have an impact on use of dry TiO_2 pigment in member facilities in terms of LEV and PPE provision, and in terms of monitoring worker exposure. Downstream users might be required to implement additional measures to manage the risks to workers of exposure to TiO_2 dust.

In relation to consumers, a relevant example is national French legislation according to which a CMR 2 classified formulation has to be stored under lock (this provision should shortly be amended to storage in a place not accessible to the public), hence such formulation would still be stigmatised as potentially unsafe. In Germany, past legislation would ban the marketing of paints classified as Carc Cat 2 to consumers, but this will no longer be the case through an amendment of the legislation in early 2017.

7.2.2 Food contact materials

Regulatory provisions outside the harmonised framework

Introduction

EFSA is responsible for "*risk assessment of food contact materials (FCMs) and articles (FCAs)*" for which it has received a mandate from the European Commission, and that mandate does not cover all food contact materials and articles. Risk assessment for non-harmonised FCMs and FCAs is carried out by the CoE/EDQM whilst drafting a new resolution, or by the national authorities whilst preparing new national provisions. The European Commission is responsible for "*risk management*" of harmonised food contact materials and articles while national authorities are responsible for non-harmonised FCMs/FCAs whilst relying in most cases on CoE/EDQM resolutions.

Framework Regulation (EC) No. 1935/2004 includes a long list of materials and articles in its Annex I but, in practice, so far specific rules have been set out for a few of them. The following rules on food contact materials and articles apply:

- **Harmonised rules** on active and intelligent materials under Regulation (EC) No 450/2009, and plastics under Regulation 10/2011 (NB. as shown in **Table 7–11**, there is legislation on ceramics and regenerated cellulose film but these do not have a direct relevance to TiO_2);

- **Council of Europe (CoE) Resolutions on coatings, paper and board, and printing inks**. Although these CoE Resolutions are guidelines, they are used by most national competent authorities to check compliance of non-harmonised food contact materials and articles with Article 3 of the EU Framework Regulation. Several of these Resolutions are under review. This review work is confidential and it is understood that there is also a confidential draft CoE/EDQM Framework Resolution that concerns the use / presence of CMRs food contact materials and articles. The existing Resolutions are presented below; and

- **National rules on a variety of food contact materials and articles**. Pending the adoption of more specific EU measures, food contact materials must also comply with any relevant national legislation in different EU Member States. Literature suggests that specific pieces of national legislation on different types of materials are currently in place in 19 EU Member States (Baughan, 2015). Member States such as Finland and the Netherlands, for example, maintain national requirements for paper and board, while Germany has established Recommendations concerning paper and board for different end-uses (e.g., baking and filter papers). On 25 September 2016, the Belgian Federal Public Service (FPS) Public Health and Safety of the Food Chain and Environment released a Royal Decree on varnishes and coatings intended to come into contact with foodstuffs, which was planned to come into force on 1 January 2017. According to the decree, the following substances can be used intentionally to make coatings intended for food contact: those substances listed on the Annex I to Regulation (EU) No 10/2011 on plastics, those approved by a Member State, those approved by the European Food Safety Authority, those that do not migrate to a detectable amount in the food, and those that are not classified as CMR, and are not in nano-form (Food Packaging Forum, 2016).

  More generally, national regulations may include positive lists for substances, impurity specifications, and sanctioned test methods. For Member States without specific requirements for paper and board (e.g., the United Kingdom, Denmark, and Sweden), such materials are required to be safe, which can be established through references to national positive listings, EU Directives, evaluations by the EU Scientific Committee on Food (now the European Food Safety Agency), clearances in other jurisdictions (e.g., clearances under the U.S. Food and Drug Administration's food additive regulations), and CoE Resolutions (Misko, 2004).

CoE Resolution on coatings

In relation to coatings in food packaging, there is a Council of Europe (CoE) Resolution, namely, Framework Resolution ResAP(2004)1 on coatings[115] intended to come into contact with foodstuffs. The Resolution is not legally binding and applies to coatings which in the finished state are intended to come into contact or which are brought into contact with foodstuffs and are designed for that purpose. The following types of coating are covered (CoE, 2004):

[115] Coatings are defined as the finished material prepared mainly from organic materials applied to form a layer/film on a substrate in such a way as to create a protective layer and/or to impart certain technical performance.

- Coatings for metal packaging;
- Flexible packaging coatings; and
- Heavy-duty coatings.

In accordance with the Resolution, coatings should meet the following conditions:

- They comply with the requirements of the EU Framework Regulation;
- They are manufactured in accordance GMP;
- They do not transfer their constituents to foodstuffs in quantities exceeding 10 mg/dm^2 of surface area of material or article (mg/dm^2) (overall migration limit). However, this limit is 60 mg of the constituents released per kg of foodstuff (mg/kg) in the following cases:

  - Articles which are containers or are comparable to containers or which can be filled, with a capacity of not less than 500 ml and not more than 10 litres;
  - Articles which can be filled and for which it is impracticable to estimate the surface area in contact with foodstuffs; and
  - Caps, gaskets, stoppers or other similar devices for sealing;

- They do not transfer migrating components not listed in "Technical document No. 1 – List of substances to be used in the manufacture of coatings intended to come into contact with foodstuffs" which have MW < 1000 D in quantities which could endanger human health. These non-listed substances of MW < 1000 D should be subjected to appropriate risk assessment, taking into account dietary exposure as well as toxicological and structure activity considerations.

TiO_2 is listed in 'List 1 of additives' as an additive not subject to any restriction of specification. On the other hand, 'Silver chloride (20% w/w) coated onto titanium dioxide (80% w/w)' is listed in the Appendix to the 'List 1 of additives' and a restriction or specification for it are pending (CoE, 2009).

It should be noted that this Resolution as well as those discussed below apply to the States members of the Partial Agreement in the Social and Public Health Field; these include: Austria, Belgium, Cyprus, Denmark, Finland, France, Germany, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CoE Resolution on paper and board

Of relevance to paper and board is Council of Europe Resolution AP (2002)1. As above for coatings, the Resolution is not legally binding but serves as an important reference and applies to all food contact paper, including coated board and paper layers in multilayer materials, but excluding non-wovens. Paper that is used in food contact articles but that is separated from the food by a functional barrier is outside the scope of the Resolution (Baughan, 2015). According to the Resolution, paper and board used for all food contact applications under normal or foreseeable conditions of use should meet the following conditions (CoE, 2002):

- Comply with the requirements of the EU Framework Regulation;
- Be manufactured in accordance with GMP;
- Be of suitable microbiological quality;
- Not release substances which have an antimicrobial effect on foodstuffs; and
- Comply with restrictions on the migration of lead, cadmium, mercury and pentachlorophenol.

Technical Document No. 1 contains the lists of additives which may be used in the manufacture of paper and board materials and articles intended to come into contact with foodstuffs. TiO_2 is present in List 1, the list of additives assessed, without any restriction or specification but rather with the indication “Acceptable” (CoE, 2009b).

CoE Resolution on printing inks

In 2005, the CoE Committee of Ministers of the Partial Agreement in the Social and Public Health Field adopted the Resolution ResAP (2005)2 on “Packaging Inks Applied to the Non-Food Contact Surface of Food Packaging”. CoE Resolutions are not legally binding, but are considered as statements of policy for national policy makers of the Partial Agreement member states. The Resolution imposes the following requirements (CoE, 2005):

- Printed materials and articles intended to come into contact with foodstuffs, should not, in their finished state and under normal and foreseeable conditions of use, transfer their constituents to foodstuffs in quantities which could endanger human health or bring about an unacceptable change in the composition of the foodstuffs or a deterioration in the organoleptic characteristics thereof, in accordance with Article 3 of Regulation (EC) No. 1935/2004;

- The substances in packaging inks should be selected in conformity with the requirements for the selection of packaging ink substances as set out in Technical Document No.1;

- The packaging inks should be manufactured in accordance with the guides for good manufacturing practice;

- The packaging inks should be applied in accordance with converters’ good manufacturing practices;

- The printed or overprinted varnished layer of finished printed material or article should not come into direct contact with food;

- Global and specific migration from the finished printed material or article should not exceed the relevant limits; and

- There should be no, or only negligible, visible set-off or migration from the printed or varnished non-food contact layer to the food contact surface.

Technical Document No.1 (CoE, 2007) includes among its exclusion criteria CMR 1A/1B/2 substances. Substances which, however, are classified as category 1A, 1B, or 2 but are evaluated by (a) Scientific Committee(s) and as a result can be used under the specified conditions, are admitted. No restriction is currently imposed on TiO_2.

Impacts from a harmonised hazard classification for titanium dioxide

Impacts from a Carc Cat 1B classification

If TiO_2 were to be classified as Carc Cat 1B, it would fail the exclusion criteria for printing inks. As far as coatings and paper/board are concerned, the listings of TiO_2 might be reviewed as a consequence of its new hazard classification.

However, consultation for the purposes of this analysis has suggested that a Draft CoE/EDQM General Resolution is in preparation which will (once approved) stay above all existing Coe/EDQM resolutions and guides. According to consultees, Article 3.3 of the Draft General Resolution, titled “General concentration threshold for non-evaluated substances, measured in food (or simulants)”, prescribes that, "*Non-evaluated substances shall only be used in the manufacture of food contact materials and articles if migration or release into food is not detectable. A general concentration threshold of 0.01 mg/kg foodstuff of a given substance is applied to demonstrate absence, with the exception of carcinogenic, mutagenic or toxic for reproduction (CMR), or substances in nano-form, including their impurities that shall not be transferred at all*".

Impacts from a Carc Cat 2 classification

As the details of national legislation across 31 EEA Member States are not known, it cannot be certain how the provisions for different carcinogenicity classification categories would vary. The CoE Resolution on printing inks covers all CMR categories, therefore classification of Carc Cat 2 would affect the use of TiO_2 in printing inks in the same way as a Carc Cat 1B one. In addition, no specific reference to hazard categories is made in the CoE Resolutions on coatings and paper/board and as such, a Carc Cat 2 classification, similarly to a Carc Cat 1B one, could potentially lead to the listings (approvals) of TiO_2 being reviewed.

7.2.3 CEPE Code of Practice for coated articles where the food contact layer is a coating

In the absence of harmonised regulations for coatings in direct contact with foodstuffs (beyond the general provisions of Article 3 of the Framework Regulation 1935/2004/EC), CEPE, the trade association for paints, printing inks and artists' colours in Europe, has taken the initiative to develop a Code of Practice which describes how compliance with the Framework Regulation can be demonstrated for direct food contact coatings (CEPE, 2009). The Code of Practice is of a voluntary nature and applies to the food contact surfaces of the following:

- Coated light metal packaging up to a volume of 10 litres;
- Coated metal pails and drums with volumes ranging from 10 to 250 litres;
- Coated articles with volumes 250 to 10,000 litres;
- Heavy duty coated articles having a volume >10,000 litres;
- Coated flexible aluminium packaging; and
- Printing inks and coatings in direct food contact.

TiO_2 is currently listed under Annex III (Incomplete List of Additives, an appendix to List C) without any limitation on migration or other use condition; this list reflects the substances authorised under Framework Regulation (EC) No. 1935/2004 under which TiO_2 is authorised by virtue of its listing under Regulation EU/10/2011 (the Union List). The Code of Practice does not incorporate a mechanism for exemptions being granted for the use of specific substances; it rather allows the use of intentionally added CMR substances if they have been reviewed in accordance with its Articles 4 and 5. According to Article 5 of this Code of Practice, additives which have been evaluated by SCF/EFSA, classified in list SCF 0-4 and used in compliance with specific migration limits or other restrictions can be used in such coatings, even if they are CMR substances. Thus, EFSA can authorise a substance classified as a CMR and hence the CEPE Code of Practice would then authorise its use as well. In other words, the actions of EFSA following the implementation of the proposed classification for TiO_2 would dictate whether TiO_2 remains an authorised additive under the CEPE Code of Practice or not.

The trade associations listed below are recommending this Code of Practice to their member companies (CEPE, 2009):

- APEAL – The Association of European Producers of Steel for Packaging;
- CEFIC FCA – The CEFIC Food Contact Additives Panel;
- CEPE – The European Council of Paint, Printing Ink and Artists' Colours Industry;
- FoodDrinkEurope – The confederation of the food and drink industries of the EU (formerly CIAA);
- European Aluminium – The European Aluminium Association (formerly EAA);
- EMPAC – The European Metal Packaging Association;
- EPRA – The European Phenolic Resins Association;
- EWF - The European Wax Federation;
- CEFIC HARRPA – The CEFIC Hydrocarbon and Rosin Resins Producers Association; and
- PlasticsEurope Epoxy Resins Committee.

In summary, the role of the voluntary Code of Practice following the classification of TiO_2 as a carcinogen would depend on whether the relevant scientific bodies (e.g. EFSA) would continue to consider TiO_2 safe for use or not. Moreover, the Code of Practice covers the intentional use of all CMR substances (Cat 1 and 2). As such a classification of Carc Cat 2 would not have any material difference to a Carc Cat 1B one as far as the use of TiO_2 in coatings for food contact materials is concerned. Notably, national initiatives are also known to exist.

7.2.4 EuPIA Exclusion Policy for printing inks and related products

The European Printing Ink Association (EuPIA) could not support the aforementioned CoE Resolution as adopted, because it was believed not to be practicable. The substance inventory lists were not sufficiently comprehensive, and did not provide protection for consumer health or reflect current practices (EuPIA, 2012).

Independent of these legal initiatives and in the absence of specific EU legislation, EuPIA developed a Guideline setting out a mechanism for the selection of raw materials for food packaging inks. Raw materials are selected in accordance with the "Selection scheme for packaging ink raw materials" of the EuPIA Guideline and with specific purity requirements. The inks are formulated and manufactured taking into account many individual and varying parameters relating to the substrate, application and end use in order to minimise the potential for migration of ink components into food and to allow the final package to comply with the legal requirements of Regulation (EC) No 1935/2004 and other existing regulations. Packaging inks are formulated and manufactured in accordance with the EuPIA Good Manufacturing Practices (EuPIA, 2016).

EuPIA has established an Exclusion Policy (which evolved from an earlier Exclusion List). The EuPIA Exclusion Policy applies to the manufacture and supply of <u>all types</u> of printing inks and related products, for use in any application and <u>on any substrate</u>. Although the EuPIA Exclusion Policy does not impose any legal obligations, it has the full support of all EuPIA members. Printing ink manufacturers who are not members of EuPIA are also invited and encouraged to apply the criteria of the Exclusion Policy (EuPIA, 2016b).

Raw materials excluded by the Policy, and which must therefore be avoided in the formulation of printing inks, are those substances or mixtures classified in one or more of the CLP hazard classes/categories listed in Group A and Group B on the following page. CMR 1A/1B are to be found in Group A. Furthermore, the substances in Groups C to G (listed in Annex 1 of the Policy) are excluded regardless of whether or not they fall under the hazard criteria of Group A or B.

For specific technical and performance reasons it may be necessary, in an individual ink, to use a raw material that contains a substance classified according to Group A or B. This exception may only be applied where the concentration of the substance in the raw material is below the limits at which the raw material will be classified and labelled. A decision to use such a raw material should be made only:

- If no suitable alternative raw materials are available;
- After an appropriate risk assessment has been carried out on the ink manufacturing process;
- After a risk assessment has been carried out, in conjunction with the converter, on the application and end use of the printed product.

When a raw material currently used becomes included in one of the categories in this Exclusion Policy by reason of re-classification, by default EuPIA members are expected to substitute this material as soon as practicable. A time frame of six months is normally regarded as appropriate.

If, after technical investigation, it is found not to be possible to replace a raw material in the short term for a specific application, an exemption from substitution can be granted according to the following rules:

- For hazards listed in Group A, the explicit approval of the EuPIA Technical Committee is required. A list of exemptions approved under this procedure is provided in Annex 2 to the Policy; and

- For hazards listed in Group B (only), it shall be the responsibility of the individual member company to conduct a risk assessment and to demonstrate that safe use is assured (in their own manufacturing, in customers' operations and/or in the final printed product as appropriate).

Importantly, a classification of Carc Cat 2 would mean that the substance would fall outside the scope of the exclusion criteria, thus its use would not be prohibited.

7.2.5 Global Automotive Declarable Substance List

The Global Automotive Declarable Substance List (GADSL) needs also be considered. The GADSL covers declaration of certain information about substances relevant to parts and materials supplied by the supply chain to automobile manufacturers. The information is applicable to the use of these parts or materials in the production of a vehicle up to its usage and relevant to the vehicle's re-use or waste disposal.

The GADSL provides a definitive list of substances requiring declaration with the target to minimise individual requirements and ensure cost-effective management of declaration practice along the complex supply chain. The scope is to cover declarable substances in the flow of information relevant to parts and materials supplied throughout the automotive value chain, from production to the end of life phase. The GADSL only covers substances that are expected to be present in a material or part that remains in the vehicle or part at point of sale and shows which substances are regulated. This is a voluntary industry initiative designed to ensure integrated, responsible and sustainable product development by automobile manufacturers and their supply chain. Its purpose is to minimise individual requirements and ensure cost effective management of declaration practice along the large and complex global supply chain[116].

If TiO_2 were to be classified as Carc Cat 1B, automotive OEMs via the GADSL would require that the substance is not contained in products supplied to them. On the other hand, classification of TiO_2 as Carc Cat 2 would render the substance a "Declarable" one but it would be unlikely to make it a candidate for a "Prohibited" substance classification.

[116] Additional information is available at http://www.gadsl.org/.

7.2.6 CE marking

Implications of a Carc Cat 1B harmonised classification

Those products which are subject to a CE mark have to undergo a conformity assessment which assesses the products characteristics and whether they meet EU harmonised standards before an EC Declaration of Conformity is issued. The CE mark will be given if the product meets the conformity assessment under the legislation it is subject to. Whilst there is no general rule for carcinogens for CE markings, the classification of TiO_2 as Carc Cat 1B would mean that some products might not be able to attain a CE mark. Relevant affected products may include:

- **Toys**: Directive 2009/48/EC on toy safety specifies in detail the essential requirements to be fulfilled by manufacturers, importers or distributors, to prove that their product complies with EU regulations and finally, to be able to affix the CE marking. Annex II to the Directive specifies the safety requirements products have to comply with. In accordance with this Annex, substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys (although derogations can be granted); and

- **Ecodesign of energy related products**: the Ecodesign Directive (2009/125/EC) is a framework Directive that sets the ecodesign requirements related to the environmental parameters that manufacturers have to meet in order for their products to carry the CE marking. The Directive calls for particular attention to the use of substances classified as hazardous to health and/or the environment according to Council Directive 67/548/EEC, the precursor to the CLP Regulation.

The new Regulation (EU) 2017/745 on Medical Devices also makes some generic references to chemical risks but no specific requirement on CMR substances in relation to the CE marking is made.

Implications of a Carc Cat 2 harmonised classification

For toys, provisions for a Carc Cat 2 substance would appear to be same as Carc Cat 1B, except that there is a slight difference in derogation criteria which means that the use of a Carc Cat 2 substance might be granted a derogation where Carc Cat 1B would not and the generic concentration limit is 1% up from 0.1%. For ecodesign of energy related products, CE marking provisions would appear to be the same for both hazard classification categories.

7.2.7 Ecolabelling schemes

Implications of a Carc Cat 1B harmonised classification

Article 6(6) of Regulation (EC) No 66/2010 on the EU Ecolabel stipulates that the EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, CMR, in accordance with the CLP Regulation, nor to goods containing substances referred to in Article 57 of the REACH Regulation. The EU Ecolabel is awarded to many categories of products, including:

- Personal care products;
- Cleaning products;
- Clothing and textiles;
- Footwear;
- Paints and varnishes;

- Electronic equipment;
- Coverings;
- Furniture and bed mattresses;
- Gardening products
- Household appliances;
- Lubricants;
- Certain household items (sanity tapware and flushing toilets and urinals); and
- Paper products.

For instance, Commission Decision 2014/312/EU establishing the ecological criteria for the award of the EU Ecolabel for indoor and outdoor paints and varnishes prescribes that the final product formulation, including all intentionally added ingredients present at a concentration of greater than 0.010%, shall not, unless expressly derogated in its Appendix, contain substances or mixtures classified as toxic, hazardous to the environment, respiratory or skin sensitisers, or carcinogenic, mutagenic or toxic for reproduction in accordance with the CLP Regulation.

National and regional ecolabelling schemes may also include exclusion criteria that relate to carcinogenicity properties. For instance, ready-to-use paints (wall paints) cannot be awarded the German Blue Angel ecolabel if they contain CMR substances (Blue Angel, 2015). Similarly, for an indoor paint or varnish to be awarded the Nordic Swan, the mixture cannot be classified as CMR 1 or 2 (Nordic Ecolabelling, 2015).

Implications from a Carc Cat 2 harmonised classification

There appears to be no difference between Carc Cat 1B and Carc Cat 2 in the known schemes, as provisions on carcinogens are based on a carcinogenicity classification in general (H350 or H351).

7.2.8 OEKO-TEX® Standard

Implications of a Carc Cat 1B harmonised classification

The OEKO-TEX® Standard 100 is a worldwide consistent, independent testing and certification system for raw, semi-finished, and finished textile products at all processing levels, as well as accessory materials used. The central focus of the OEKO-TEX® Standard 100 has been the development of test criteria, limit values and test methods on a scientific basis. Among the limit values, there is a list for dyestuffs and pigments classified as carcinogenic and this list would likely include TiO_2 following its proposed classification.

On the issue of TiO_2 in the textile sector, it has also been noted by stakeholders that in the spinning process of man-made fibres there is always some amount of waste generated which contains TiO_2 (used for delustering of the fibres). This type of waste is largely used in EU (and worldwide) as an input material for other industries (e.g. engineering plastics and composite materials) and can be applied in automotive industry, machinery, household appliances, etc. The potential classification of TiO_2 as Carc Cat 1B consequently means a complete change of evaluation of the above goods by the final consumers.

Implications from a Carc Cat 2 harmonised classification

There appears to be no difference between Carc Cat 1B and Carc Cat 2. There is at least one Carc Cat 2 substance already listed under colourant.

7.2.9 Other provisions

The presence of a ubiquitous substance classified as a suspected carcinogen in a multitude of products could also have a bearing on risk-based materials declaration systems or other initiatives which focus on hazardous substances. Consultation has for instance referred to:

- IEC 62474, the international standard for the management of declaration of materials and substances in E&E products;

- ISO TS 16949, in the future IATF 16949, is a standard aimed at the development of a quality management system that provides for continual improvement, emphasising defect prevention and the reduction of variation and waste in the automotive industry supply chain; and

- VinylPlus, the voluntary commitment of the European PVC producers, which, among other things, promotes the recycling of PVC waste. The recycling of PVC products which often contain TiO_2 such as window profiles, floorings might be affected by the classification of TiO_2 as a Carc Cat 2 substance. This could impact upon VinylPlus' ability to meet its recycling targets.

8 Annex 2: Alternatives for titanium dioxide

8.1 Technical feasibility of alternatives

TiO_2 is used primarily as a pigment to scatter light, because it absorbs almost no incident light in the visible region of the spectrum. This pigment scatters light by three mechanisms: reflection from the surface of a crystal, refraction within a crystal, and diffraction, whereby light is bent as it passes near a crystal. Reflection and refraction are maximised by increasing the difference between the refractive index of the pigment and that of the polymer matrix or other material in which it is dispersed (Gázquez, et al., 2014).

TiO_2 (also known as Pigment White 6 or PW6) is the universal choice for white pigments. It is suitable for almost every usage and requirement; compared to TiO_2 all other white pigments have indisputable disadvantages or they are limited in their applicability.

A list of white pigments is presented in **Table 8–2**. Among them, zinc compounds such as zinc oxide, and zinc sulphide (within lithopone) as well as carbonates and other mineral powders (kaolin, talc) find extensive use. However, TiO_2 has the highest refractive index among all known white pigments, as shown in **Table 8–1**. Rutile TiO_2 has a refractive index that exceeds 2.7, while other popular white pigments such as zinc oxide (ca. 2), lithopone, kaolin, chalk and talc (all less than 2) have much lower index numbers. The high refractive indices of rutile and anatase TiO_2 result in high light scattering properties; as a result, relatively low levels of TiO_2 pigment are required to achieve a white opaque coating, in comparison to alternative white pigments.

Table 8–1: Density and refractive indices of selected white pigments

CI numbers	Pigment	Density	Refractive Index
PW1	Lead white	6.70-6.86	1.94 - 2.09
PW3	Lead sulphate	6.12-6.39	1.878; 1.883; 1.895
PW4	Zinc oxide	5.47-5.65	2.00 - 2.02
PW5	Lithopone	4.3	2.3 (ZnS); 1.64 ($BaSO_4$)
PW6 – Rutile	Titanium dioxide	3.75-4.3	2.71 - 2.72
PW6 – Anatase	Titanium dioxide	3.9	2.54 - 2.55
PW10	Barium carbonate	4.3	1.529; 1.676; 1.677
PW11	Antimony trioxide	5.67-5.75	2.18 - 2.35
PW12	Zirconium oxide	2.40	2.16
PW18	Chalk	2.7-2.95	1.486 (1.510); 1.645
PW18	Magnesite	3.0	1.508; 1.510; 1.700
PW19	Kaolin (Speswhite)	2.16-2.63	1.558; 1.565; 1.564
PW20	Mica	1.58-1.61	1.56 - 1.60/61
PW21 – PW22	Barytes	4.3-4.6	1.636; 1.637; 1.648
PW24	Aluminium hydroxide	2.42-2.45	1.568 - 1.587
PW25	Gypsum	2.32-2.36	1.520; 1.523; 1.530
PW26	Talc	2.5-2.8	1.539; 1.589; 1.589
PW27	Silica/Quartz	2.2-2.65	1.40 - 1.55

Sources: http://cameo.mfa.org/images/c/cd/Download_file_536.pdf (accessed on 18 August 2016), ASTM (1995); Zorll (2000); https://refractiveindex.info/?shelf=main&book=ZrO2&page=Wood (accessed on 21 August 2017); https://www.emsdiasum.com/microscopy/products/preparation/mica.aspx (accessed on 21 August 2017)

Table 8–2: Overview of white pigments							
Colour Index generic name	**C.I. Common or Historical Name**	**C.I. Constitution Number**	**Chemical Composition**	**Colour Description**	**Opacity 1 = opaque 4 = trans.**	**Light Fastness I = excellent IV=Fugitive**	**Hazard classification**
PW1	Lead white	77597	Basic lead carbonate CAS No: 1319-46-6	Silvery white	1-2	I	**Not harmonised** Acute Tox. 4 (H302) Acute Tox. 4 (H332) Repr. 1A (H360) STOT RE 2 (H373) Aquatic Chronic 1 (H410)
PW2	Lead sulphate white	77633	Basic lead sulphate CAS No: 12397-06-7	Greyish to white	2	I	**Not classified** (but likely to have a profile similar to other lead pigments)
PW3	Basic lead sulphate white	77630	Lead sulphate CAS No: 7446-14-2	Greyish to white	2	I	**Not harmonised** Acute Tox. 4 (H302) Acute Tox. 4 (H332) Repr. 1A (H360) STOT RE 2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
PW4	Zinc oxide white	77947	Zinc oxide CAS No: 1314-13-2 CAS No: 91315-44-5	Translucent white	2	I	**Harmonised** Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
PW5	Lithopone	77115	Barium sulphate (28 - 30%) and zinc sulphide (68 - 70%) with trace amounts of zinc oxide CAS No: 7727-43-7 CAS No: 1314-98-3	White	1-2	I	7727-43-7: **Not classified** 1314-98-3: **Not classified**
PW6	Titanium white	77891	Titanium dioxide: CAS No: 13463-67-7	Purest white	1	I	**Not classified**
PW7	Zinc sulphide white	77995 77975	Zinc sulphide CAS No: 1314-98-3	White to yellowish	1-2	I	**Not classified**

Table 8–2: Overview of white pigments							
Colour Index generic name	**C.I. Common or Historical Name**	**C.I. Constitution Number**	**Chemical Composition**	**Colour Description**	**Opacity 1 = opaque 4 = trans.**	**Light Fastness I = excellent IV=Fugitive**	**Hazard classification**
PW8	Strontium sulphide	77847	Strontium sulphide CAS No: 1314-96-1	Phosphorescent	-	-	**Not harmonised** Met. Corr. 1 (H290) Acute Tox. 3 (H301) Skin Corr. 1A (H314) Eye Dam. 1 (H318) Aquatic Acute 1 (H400)
PW10	Barium carbonate	77099	Barium carbonate CAS No: 513-77-9	Powder white	3	-	**Harmonised** Acute Tox. 4 (H302)
PW11	Antimony white	77052	Diantimony trioxide CAS No: 1309-64-4	Powder white	1	I	**Harmonised** Carc. 2 (H351)
PW12	Zirconium oxide	77990	Zirconium oxide CAS No: 1314-23-4	-	-	-	**Not classified**
PW13	Barium tungstate	77128	Barium wolframate CAS No: 7787-42-0	White	-	I	**Not harmonised** Acute Tox. 4 (H302) Acute Tox. 4 (H332)
PW14	Bismuth oxychloride	77163	Bismuth chloride oxide CAS No: 7787-59-9	Silvery white with pearlescent or iridescence properties	-	-	**Not classified**
PW15	Tin oxide	77861	Tin dioxide CAS No: 18282-10-5	White to grey with slight pearlescent sheen	1	I	**Not classified**
PW16	Lead silicate	77625	Lead monosilicate CAS No: 10099-76-0	White	**1**	-	**Not classified** (but likely to have a profile similar to other lead pigments)

Table 8–2: Overview of white pigments							
Colour Index generic name	**C.I. Common or Historical Name**	**C.I. Constitution Number**	**Chemical Composition**	**Colour Description**	**Opacity 1 = opaque 4 = trans.**	**Light Fastness I = excellent IV=Fugitive**	**Hazard classification**
PW17	Bismuth subnitrate	77169	Basic bismuth nitrate CAS No: 1304-85-4	Pearlescent white; Microcrystalline powder	1	II	**Not classified**
PW18	Chalk	77220 + 77713	Natural calcium carbonate with magnesium carbonate as an impurity CAS No: 471-34-1 CAS No: 546-93-0	White to cream/blue/ grey off white	1-4	I	471-34-1: **Not classified** 546-93-0: **Not classified**
PW18	Precipitated chalk	77220	Pure calcium carbonate CAS No: 471-34-1	White	1-4	I	**Not classified**
PW18: 1	Dolomite	77220:1 + 77713:1	Calcium magnesium carbonate CAS No: 83897-84-1	White to pale pink to yellowish white	1-4	I	**Not harmonised** Skin Irrit. 2 (H315) Eye Dam. 1 (H318) STOT SE 3 (H335)
PW19	Kaolin	77004 77005	White clay rock, mostly natural hydrated aluminium silicate with impurities of magnesium, iron carbonates, ferric hydroxide, mica, quartz-sand, etc. CAS No: 1332-58-7	Bright white; can have blue, green, red, orange or brown undertones	1-4	I	**Not classified**
PW20	Mica	77019	Hydrous aluminium potassium silicate CAS No: 12001-26-2	Translucent pearlescent or shimmering off-white	4	I	**Not classified**
PW21	Barium sulphate (synthetic)	77120	Synthetic barium sulphate CAS No: 7727-43-7	White	2-3	I	**Not classified**

Table 8–2: Overview of white pigments							
Colour Index generic name	**C.I. Common or Historical Name**	**C.I. Constitution Number**	**Chemical Composition**	**Colour Description**	**Opacity 1 = opaque 4 = trans.**	**Light Fastness I = excellent IV=Fugitive**	**Hazard classification**
PW22	Barytes (natural barium sulphate)	77120	Natural barium sulphate CAS No: 7727-43-7	White to off white	2-3	I	**Not classified**
PW23	Alumina blanc fixe	77122	Aluminium hydrate, barium sulphate; coprecipitate of ca. 25% aluminium hydroxide and 75% barium sulphate CAS No: 21645-51-2 CAS No: 7727-43-7	White Crystalline powder	-	I	21645-51-2: **Not classified** 7727-43-7: **Not classified**
PW24	Aluminium hydroxide	77002	Aluminium hydroxide CAS No: 21645-51-2	Translucent white powder	3-4	I	**Not classified**
PW24	Gibbsite (natural form of aluminium hydroxide)	-	Natural aluminium hydroxide with varying amounts of basic aluminium sulphate CAS No: 21645-51-2	Brown tinted Translucent Flakes	4	I	**Not classified**
PW25	Gypsum	77231	Hydrated calcium sulphate CAS No: 91315-45-6 CAS No: 10101-14-4	White	1-3	I	**Not classified** (calcium sulphate, CAS No: 7778-18-9 is also not classified)
PW26	Talc	77718 + 77019	Mixed hydrated silicate of magnesium with varying impurities of calcium, iron and other compounds CAS No: 14807-96-6 CAS No: 8005-37-6	Slightly off white to light grey	1-3	I	14807-96-6: **Not classified**
PW27	Silica	77811	Two types: Hydrous = diatomaceous earth; Anhydrous = silica Silicon dioxide CAS No: 7631-86-9	White to off white	1-4	I	**Not classified**

Table 8–2: Overview of white pigments							
Colour Index generic name	**C.I. Common or Historical Name**	**C.I. Constitution Number**	**Chemical Composition**	**Colour Description**	**Opacity 1 = opaque 4 = trans.**	**Light Fastness I = excellent IV=Fugitive**	**Hazard classification**
PW28	Calcium silicate	77230	Calcium metasilicate; Calcium silicate; CAS No: 10101-39-0 CAS No: 10101-41-4 CAS No: 13397-24-5 CAS No: 26499-65-0	White to light cream	2-3	I	10101-39-0: **Not classified**
PW28	Hydrated calcium silicate	77230	Hydrated calcium silicate	Bright White	4	I	As above
PW 30	Lead phosphate	77622	Trilead bis(orthophosphate) CAS No: 7446-27-7	-	-	-	**Harmonised** Repr. 1A (H360Df) STOT RE 2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
PW32	Zinc phosphate	77964	Trizinc bis(orthophosphate) CAS No: 7779-90-0	White	1	I	**Harmonised** Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)
PW33	Calcium sulpho-aluminate	77235	Calcium sulphoaluminate	-	-	-	**Not classified**
Source: http://www.artiscreation.com/white.html#ci_pigment_white (accessed on 18 August 2016); ECHA C&L Inventory, https://echa.europa.eu/information-on-chemicals/cl-inventory-database (accessed on 18 August 2016)							

According to comments made by I&P Europe on the French proposal for the harmonised classification of TiO_2[117], "*to obtain the same effect in pigmented materials with alternative substances such as zinc oxide, aluminium oxide or barium sulphate, 4 to 6 times as much pigment (ZnO) or 10 to 14 times as much pigment (Al_2O_3 and $BaSO_4$) would need to be added, amounts which are so high that the high pigment concentration results at one hand in a loss again in scattering properties because of 'crowding' at the percolation point and at the other in a loss in physical performance of the product (due to loss in mechanical strength of the pigmented matrix or viscosity increased or solidification of liquid products)*" (see also **Figure 8–1** also reproduced from I&P Europe's submission to the public consultation).

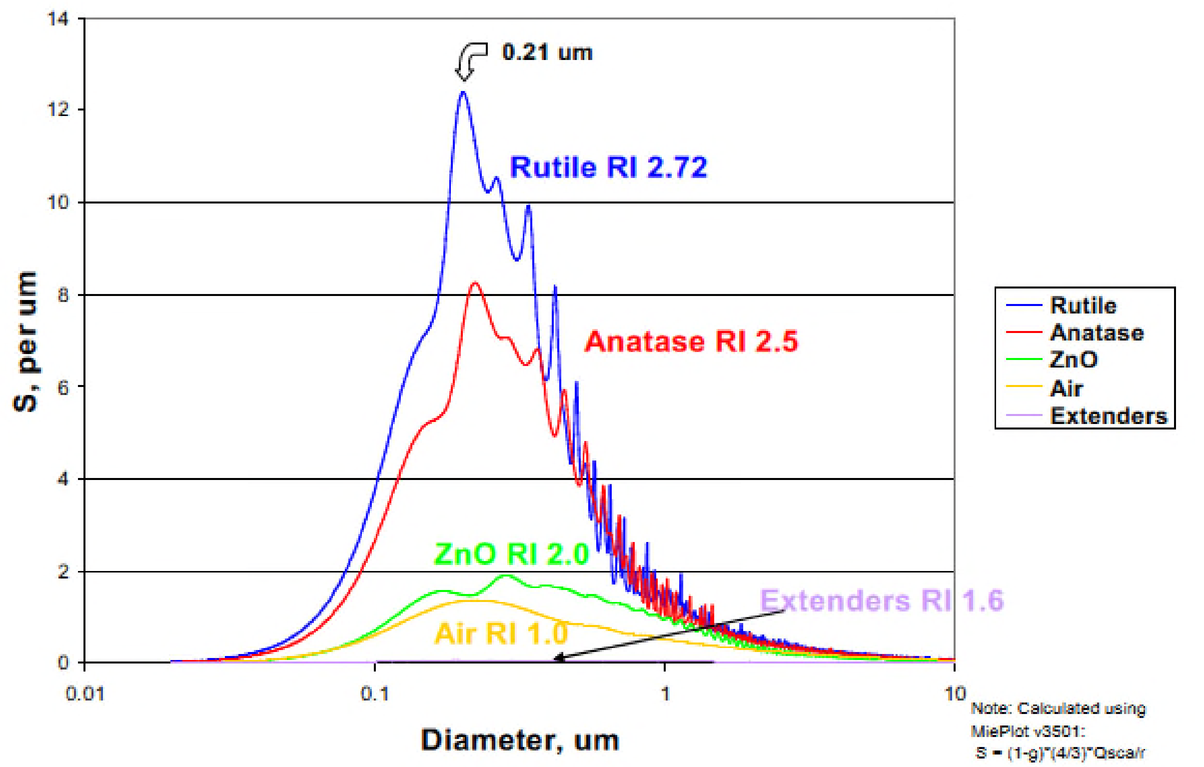

Figure 8–1: Pigment scattering coefficients of TiO_2 and selected alternatives
Source: (Crowther & Johnson, undated)

An important measure of a pigment's potential hiding power can be determined by a simple test whereby it is tinted with a standard black pigment, and assessed using an arbitrary scale. The tinting strength values for rutile titanium pigments range between 1550 and 1850 and for anatase between 1150 and 1350. The best of the other white pigments listed in **Table 8–1**, zinc sulphide, is only half as powerful as rutile (Gázquez, et al., 2014).

Lower hiding powder exhibited by pigments other than TiO_2 could also be counterbalanced by deposition of thicker layers, but these layers are then more difficult / impossible to dry or cure, nor will they perform any longer the required functionalities. This could be particularly important in processes such as printing, but also more widely would impact upon the efficiency of any coating operation.

[117] Available at: https://echa.europa.eu/documents/10162/48252319-d727-42aa-8b3e-bb97cb218f0e (accessed on 22 August 2016).

Other important features of TiO_2 pigments are excellent resistance to chemical attack, good thermal stability and resistance to ultraviolet (UV) degradation. Rutile pigment is more resistant to UV light than anatase, and is preferred for paints, plastics, especially those exposed to outdoor conditions, and inks. On the other hand, anatase pigment has a bluer tone than the rutile type, is less abrasive and is used mainly in indoor paints and in paper, ceramics, rubber and fibre manufacture. Both rutile and anatase pigments can be made more resistant to photodegradation by coating the pigment particles, which also improves their dispersibility, dispersion stability, opacity and brightness (Gázquez, et al., 2014).

As a result, there is no white pigment that can match the opacity, hiding power, cost-efficiency, inertness and weatherability of TiO_2. It is important to note that several of the pigments identified above are mineral fillers widely considered to be suitable as extender pigments. Such pigments can be (and in some cases, have been) used to partly replace TiO_2 in formulations, primarily for cost reasons. Their performance however cannot match that of TiO_2 as they have a relatively low refractive index of ca. 1.5. When the surrounding medium is air with a refractive index of 1.0, the difference in the two index values produces substantial light scattering, so that extender pigments appear white. However, when such alternative pigments are dispersed in other media, e.g. a paint binder which itself has a refractive index of ca. 1.5, they scatter light very poorly and appear much more transparent. Considering matrices such as paints, extender pigments may also have an adverse effect on other physical properties such as consistency, gloss (Zorll, 2000), stability and scrub resistance (film toughness) (Karakaş, et al., 2015). Whilst, on a case-by-case basis, TiO_2 might be technically possible to replace, particularly where technical requirements are not stringent, in order for opacity and hiding power to be acceptable, increased loadings of the alternatives may need to be used, thus imparting poor cost-efficiency on the alternatives.

A more recently developed technology is that of organic pigments, effectively opaque polymer systems. These have been used in interior and exterior coatings as hollow-sphere polymeric pigment that allow paint manufacturers to reduce the raw material cost (i.e. the cost of TiO_2) of their formulations. For instance, such a commercial product claims to offer "*significantly increased light scattering efficiency while maintaining paint performance*", "*greater cost savings while providing equal hiding*", and "*a comparatively low binder demand* [so that] *the total PVC* [Pigment Volume Concentration] *can be slightly increased without sacrificing paint performance*" (Dow, 2010)[118]. However, this is not a solution if complete elimination of TiO_2 from the formulations is required; also, the integrity of the hollow spheres plays a significant role in the performance of such products (NB. products from other companies are available, the above is only one example).

8.2 Hazard profile of alternatives

Table 8–2 presented an overview of the hazard classification of alternative white pigments. It is acknowledged that other alternative systems may exist but, in terms of hazard profiles, the focus here is on alternative substances rather than materials.

The list of alternative white pigments includes several heavy metal compounds. Lead-based pigments in particular are far more hazardous than TiO_2; they currently find very little use, if any, as they have been replaced by TiO_2. Zinc oxide and zinc phosphate have unfavourable environmental hazard profiles.

118 The specific product referred to here is claimed to be "*non-toxic in single acute oral, dermal, and inhalation exposure tests. Without proper safety precautions, it can be a mild skin and eye irritant*" (Dow, 2010).

Importantly, we must consider the mechanism through which the supposed toxicity of TiO_2 is manifested. As the carcinogenic effect in animal testing discussed in the French CLH proposal is not substance-specific but characteristic of respirable poorly soluble dusts, this can be expected to occur with most, if not all potential alternative substances too. Therefore, if it were accepted that TiO_2 is a carcinogen, all poorly soluble powders that could replace it (including minerals such as kaolin, chalk, talc, etc.) could be considered to exert carcinogenicity in a similar manner. This would especially be true if the substances in question were not so widely used as TiO_2 so that there is only limited experience with them. Consequently, at least every other organic and inorganic pigment would be a candidate for such a measure, especially fine particle sized pigment grades (Winkler, 2016). Overall, substitution of TiO_2 motivated by its classification as a Carc Cat 2 substance by inhalation would not result in a discernible benefit to workers' health.

8.3 Availability of alternatives

Availability is another key concern over the vast majority of potential alternative pigments. Few pigments have a global consumption higher than TiO_2. Other white pigments such as zinc oxide and lithopone have a global market ca. 15-23 times smaller than TiO_2. In other words, there would simply be insufficient quantities of many of the alternative white pigments if TiO_2 were to be substituted in the EEA. **Table 8–3** presents an overview of the REACH registration status of the alternative white pigments. With the notable exceptions of zinc oxide, zinc sulphide, barium carbonate, and a number of naturally occurring minerals, the remaining pigments are registered in tonnage ranges far lower than TiO_2.

Table 8–3: Registration tonnages for alternative white pigments

Colour Index generic name	C.I. Common or Historical Name	Chemical composition	REACH registration tonnage (t/y)
PW1	Lead white	Basic lead carbonate CAS No: 1319-46-6	10-100
PW2	Lead sulphate white	Basic lead sulphate CAS No: 12397-06-7	Not registered
PW3	Basic lead sulphate white	Lead sulphate CAS No: 7446-14-2	Intermediate only
PW4	Zinc oxide white	Zinc oxide CAS No: 1314-13-2 CAS No: 91315-44-5	 100,000 – 1,000,000 Not registered
PW5	Lithopone	Barium sulphate (28 - 30%) and zinc sulphide (68 - 70%) with trace amounts of zinc oxide CAS No: 7727-43-7 CAS No: 1314-98-3	 10,000 – 100,000 100,000 – 1,000,000
PW6	Titanium white	Titanium dioxide: CAS No: 13463-67-7	1,000,000 – 10,000,000
PW7	Zinc sulphide white	Zinc sulphide CAS No: 1314-98-3	100,000 – 1,000,000
PW8	Strontium sulphide	Strontium sulphide CAS No: 1314-96-1	10,000 – 100,000
PW10	Barium carbonate	Barium carbonate CAS No: 513-77-9	100,000 – 1,000,000
PW11	Antimony white	Diantimony trioxide CAS No: 1309-64-4	10,000+

Table 8–3: Registration tonnages for alternative white pigments			
Colour Index generic name	**C.I. Common or Historical Name**	**Chemical composition**	**REACH registration tonnage (t/y)**
PW12	Zirconium oxide	Zirconium oxide CAS No: 1314-23-4	10,000 – 100,000
PW13	Barium tungstate	Barium wolframate CAS No: 7787-42-0	Not registered
PW14	Bismuth oxychloride	Bismuth chloride oxide CAS No: 7787-59-9	Not registered
PW15	Tin oxide	Tin dioxide CAS No: 18282-10-5	1,000 – 10,000
PW16	Lead silicate	Lead monosilicate CAS No: 10099-76-0	Not registered
PW17	Bismuth subnitrate	Basic bismuth nitrate CAS No: 1304-85-4	100 – 1,000
PW18	Chalk	Natural calcium carbonate with magnesium carbonate as an impurity CAS No: 471-34-1 CAS No: 546-93-0	1,000,000 – 10,000,000 1,000+
PW18	Precipitated chalk	Pure calcium carbonate CAS No: 471-34-1	1,000,000 – 10,000,000
PW18:1	Dolomite	Calcium magnesium carbonate CAS No: 83897-84-1	100,000 – 1,000,000
PW19	Kaolin	White clay rock, mostly natural hydrated aluminium silicate with impurities of magnesium, iron carbonates, ferric hydroxide, mica, quartz-sand, etc. CAS No: 1332-58-7	100,000 – 1,000,000
PW20	Mica	Hydrous aluminium potassium silicate CAS No: 12001-26-2	Annex V exemption
PW21	Barium sulphate (synthetic)	Synthetic barium sulphate CAS No: 7727-43-7	10,000 – 100,000
PW22	Barytes (natural barium sulphate)	Natural barium sulphate CAS No: 7727-43-7	10,000 – 100,000
PW23	Alumina blanc fixe	Aluminium hydrate, barium sulphate; coprecipitate of ca. 25% aluminium hydroxide and 75% barium sulphate CAS No: 21645-51-2 CAS No: 7727-43-7	1,000,000 – 10,000,000 10,000 – 100,000
PW24	Aluminium hydroxide	Aluminium hydroxide CAS No: 21645-51-2	1,000,000 – 10,000,000
PW24	Gibbsite (natural form of aluminium hydroxide)	Natural aluminium hydroxide with varying amounts of basic aluminium sulphate CAS No: 21645-51-2	1,000,000 – 10,000,000
PW25	Gypsum	Hydrated calcium sulphate CAS No: 91315-45-6 CAS No: 10101-14-4	Annex V exemption
PW26	Talc	Mixed hydrated silicate of magnesium with varying impurities of calcium, iron and other compounds CAS No: 14807-96-6 CAS No: 8005-37-6	Annex V exemption

Table 8–3: Registration tonnages for alternative white pigments			
Colour Index generic name	**C.I. Common or Historical Name**	**Chemical composition**	**REACH registration tonnage (t/y)**
PW27	Silica	Two types: Hydrous = diatomaceous earth; Anhydrous = silica Silicon dioxide CAS No: 7631-86-9	Annex V exemption
PW28	Calcium silicate	Calcium metasilicate; Calcium silicate; CAS No: 10101-39-0 CAS No: 10101-41-4 CAS No: 13397-24-5 CAS No: 26499-65-0	Annex V exemption
PW28	Hydrated calcium silicate	Hydrated calcium silicate	Annex V exemption
PW 30	Lead phosphate	Trilead bis(orthophosphate) CAS No: 7446-27-7	Not registered
PW32	Zinc phosphate	Trizinc bis(orthophosphate) CAS No: 7779-90-0	10,000 – 100,000
PW33	Calcium sulphoaluminate	Calcium sulphoaluminate	No data

Finally, availability also needs to reflect the approval status of the different pigments. TiO_2 holds approvals which other pigments may not. For instance, TiO_2 is the only white pigment which is allowed for use as a colouring agent in pharmaceuticals. For foodstuff, the only other approved colourant is calcium carbonate (E170) but is used in different applications to TiO_2 (see also discussion below as well as in Section 4.4.3); any other alternative pigment, if there is one to be found, would have to go through a long authorisation process for food additives. This process would take years. Similarly, TiO_2 has specific approvals for use in cosmetic products[119] and packaging (plastic) materials.

8.4 Information from consultation

Table 8–4 summarises information on specific alternatives that has been collected during the first round of consultation with downstream users. This information confirms that no alternative appears to be feasible as a substitute for TiO_2. The table also includes some information available on the ECHA website from the public consultation on the proposed classification for TiO_2. It is worth noting that an assessment of alternatives specific relevant to plastics has been provided by EuPC and has been incorporated into Section 4.5.2.

[119] Zinc oxide is approved for use in UV sun screens but it contributes mainly to UVA protection in contrast to TiO_2 which protects against UVB radiation and is a major contributor to high Sun Protection Factors (SPF).

Table 8–4: Overview of characteristics of potential alternatives identified through consultation		
Potential alternative	**Assessment of the alternatives**	**Example applications**
Zinc oxide (ZnO) *EC / List no.: 215-222-5* *CAS no.: 1314-13-2*	ZnO can be, and indeed is, used in paints but not as a general replacement for TiO_2 it tends only to be considered for 'niche' applications, such as hobby and artistic use or cosmetics. However, from a technical, economic and efficiency perspective it may not be considered a feasible alternative by users of TiO_2, as explained below. **Technical feasibility**: - ZnO has worse refractive index and durability, thus a much higher amount is needed due to lower covering ability and opacity (opacity is 5 times lower); a paint layer with TiO_2 would probably need to be replaced by 4 layers of a ZnO-containing formulation. An increased ZnO concentration could affect opacity power and scrub resistance; - ZnO has worse weatherability and stability against yellowing (in plastics) due to lack of UV stability compared to TiO_2; - ZnO can cause thickening when used in water based paints; - In sun-care products nano ZnO is permitted now in the EU and in some other regions around the world but is not as easy to formulate with and fewer grades are available. ZnO contributes mainly to UVA protection (in contrast to TiO_2 which is a major contributor to the SPF) and has poorer performance against UVB radiation; sunscreens would require increased dosages thus their formulations would cost more, and would be undesirably whiter on the skin; - In other cosmetics, ZnO is not as good for coverage of the skin and it cannot produce pearl effect pigments; only TiO_2 can be used for such applications **Economic feasibility**: - ZnO is lower cost but less efficient than TiO_2, thus not cost effective; - ZnO's price depends on zinc price and this can be volatile; **Availability**: - ZnO is readily available but in tonnages far lower than TiO_2; **Risk reduction**: - Harmonised classification of H400/H410 (aquatic toxicity 1, acute and chronic) means that it has been replaced by TiO_2 in many applications (however, solubility of ZnO from matrices such as plastic is low); - Zinc is subject to migration limits under Annex II of the Plastics Regulation 10/2011, and can therefore not be used in unlimited quantities	Cosmetics Plastics Paints Coil coatings Sealants Wallcoverings

Table 8–4: Overview of characteristics of potential alternatives identified through consultation		
Potential alternative	**Assessment of the alternatives**	**Example applications**
Zinc sulphide (ZnS) *EC / List no.: 215-251-3* *CAS no.: 1314-98-3*	In a very few applications ZnS is used instead of TiO_2, whenever the abrasion of TiO_2 is too high. However, it is accompanied by several disadvantages: **Technical feasibility**: - ZnS cannot match TiO_2's whiteness and opacity properties and is not suitable for thin film applications (such as 1-3 µm in printing inks); - ZnS requires higher dosages; - ZnS degrades upon exposure to UV light, leading to darkening of the pigment (in plastics it causes "zinc burn"); and - ZnS shows poor weathering properties (hydrolysis) **Availability and economic feasibility**: - As there is only one producer in the world, the whiteness and opacity are lower and the price is several times higher, ZnS is no alternative for the majority of TiO_2 applications. Price would likely rise further if TiO_2 became unavailable **Risk reduction**: - According to notifications provided by companies to ECHA during REACH registration, no hazards have been classified, but there are concerns over releases of zinc to the environment; - ZnS may be undesirable due to the presence of sulphur. It is also known to display biocidal (antimicrobial) properties on the nano-scale - Zinc is subject to migration limits under Annex II of the Plastics Regulation 10/2011, and can therefore not be used in unlimited quantities	Wallcoverings Paints & coatings Printing inks Plastics
Barium sulphate ($BaSO_4$) *EC / List no.: 231-784-4* *CAS no.: 7727-43-7*	$BaSO_4$, as well as other fillers such as talc and kaolin (see below), can replace certain amounts of TiO_2 in formulations, but never the entire loading of TiO_2. **Technical feasibility**: - $BaSO_4$ produces a good white shade, but has very poor opacity. Similarly, limestone fillers are brighter white than the average quarried product, but cannot approach the impact of TiO_2; - $BaSO_4$ has a very high specific gravity and has a tendency to form a hard settlement in (paint) cans; **Economic feasibility**: - It is less costly than TiO_2 but due to poor hiding power a higher dosage is required thus resulting in a higher cost than TiO_2 (a ten-times higher loading is required to obtain a nearly comparable result); **Availability**: - Market availability is good but still far lower than TiO_2; **Risk reduction**: - According to notifications provided by companies to ECHA during REACH registration, no hazards have been classified. However, it contains a heavy metal which industry is generally moving away from (still, $BaSO_4$ has a low water solubility); - Barium is subject to migration limits under Annex II of the Plastics Regulation 10/2011, and can therefore not be used in unlimited quantities	Paints Road marking paints Plastics masterbatches

Table 8–4: Overview of characteristics of potential alternatives identified through consultation		
Potential alternative	**Assessment of the alternatives**	**Example applications**
Lithopone: mixture of barium sulphate and zinc sulphide ($BaSO_4/ZnS$) *EC / List no.: 231-784-4/ 215-251-3* *CAS no.: 7727-43-7/ 1314-98-3*	Also known as C.I. Pigment White 5, lithopone is a mixture of inorganic compounds, widely used as a white pigment powder. It is composed of a mixture of barium sulphate and zinc sulphide. **Technical feasibility**: - Lithopone is essentially an extender. It can be used as cheaper alternative, but only for low cost end products; - Lithopone offers only $^2/_3$ of TiO_2's opacity/hiding power and not the same level of whiteness; - It is unsuitable for exterior use (paints) due to relatively poor weatherability; - It offers no resistance to UV radiation and thus does not match the lightfastness of TiO_2; **Economic feasibility**: - It is moderately expensive; **Availability**: - Market availability is good but still far lower than TiO_2; **Risk reduction**: - Components not classified for hazards, but there are concerns over releases of zinc and heavy metals to the environment	Paints Coil coatings Wallcoverings
Kaolin (white clay or China clay, $Al_2Si_2O_5(OH)_4$) *EC / List no.: 310-194-1* *CAS no.: 1332-58-7*	As discussed for $BaSO_4$ above, kaolin can replace certain amounts of TiO_2 in a formulation, but never the whole amount of TiO_2. **Technical feasibility**: - Lower technical performances (opacity), i.e. less whitening capacity compared to TiO_2; - White dispersions contain a reduced amount of TiO_2, but also contain glycols and reduce the solids content leading to shrinkage (in sealants); - Dispersions need agitation to prevent settling; - Calcined kaolin has improved whiteness but still can only be used as a TiO_2 extender rather than a full replacement; - In gelatine glues, it is possible to use kaolin. This, however, gives different colour, rheology and viscosity. Especially where colour and viscosity are key, TiO_2 should be used. In dispersion glues (which are similar to paints), TiO_2 gives a form of white colour so it can be used as a base for colouring. Neither kaolin nor any other alternative can be used in that regard; **Economic feasibility**: - No data; **Availability**: - No data (but see discussion on the wide availability of this mineral); **Risk reduction**: - According to the classification provided by companies to ECHA in CLP notifications this substance causes serious eye irritation and causes skin irritation	Paper & board Rubber Adhesives Sealants Paints & coatings Road marking paints

Table 8–4: Overview of characteristics of potential alternatives identified through consultation		
Potential alternative	**Assessment of the alternatives**	**Example applications**
Calcium carbonate ($CaCO_3$) and Precipitated Calcium Carbonate (PCC) *EC / List no.: 207-439-9* *CAS no.: 471-34-1*	Calcium carbonate is used as TiO_2 extender to reduce, but not eliminate, the presence of TiO_2. **Technical feasibility**: - Lower technical performance (opacity is 5 times lower), i.e. lower whitening capacity compared to TiO_2, it may be used in isolation to form a rudimentary white paint; - Calcium carbonate also tends to be greyish white versus TiO_2 which is a bright white; - Poor application properties (especially for thin layers, e.g. in printing inks), low gloss and poor wet and dry hiding characteristics; - No UV resistance performance; - Low stability in the presence of acids (see also food applications below); - $CaCO_3$ is not easy to spray on capsules as the spray solution becomes very thick / viscous and clogs up the equipment; - Calcium carbonate (E170) is also authorised under the EU Additives Regulation (EC) No 1333/2008 at Annex II for use as a Group II food colour which may be used in most foods at *quantum satis* and it is considered to be safe. However its value as a food colour is limited because it has poor or no functionality in many food applications: (a) as well as being a much less effective white colour than TiO_2, it will readily react with any acids present in foods to generate carbon dioxide and a (possibly soluble) calcium salt with no white colouring properties; (b) it could not be used as a colour in any foods with low pH as it would neutralise the acid present, adversely affecting the product flavour, quality and possibly shelf life; (c) it also could not be used as a white colour in cake batters, scone doughs, etc. since it would interfere with the raising agent system; (d) calcium carbonate could not be used as a replacement to produce white glitter powders since E555 (Potassium aluminium silicate - mica) is only authorised for use as a carrier for TiO_2 (and E172 iron oxides which produce red/brown colour glitter powders); (e) it is normally used in foods to function as an acidity regulator, anticaking agent, stabiliser or nutrient source (of dietary calcium) rather than as a colour. It is also used as a firming agent in many canned or bottled vegetable products; **Economic feasibility**: - Less costly than TiO_2; **Availability**: - Widely available in quantities larger than TiO_2; **Risk reduction**: - According to the classification notified by REACH registrants, this substance causes serious eye damage, skin irritation and may cause respiratory irritation; - The use of $CaCO_3$ also has a potential health impact since the calcium would contribute to the total intake of calcium in a day (through foodstuff, food supplements or pharmaceuticals). Some individuals are affected adversely by increased calcium intake. TiO_2 is not absorbed in the gastrointestinal tract, so has no adverse health impact via food consumption	Decorative paints Flooring and wall paints Paper & board Rubber Cosmetics Food Pharmaceuticals

<table>
<tr><th colspan="3">Table 8–4: Overview of characteristics of potential alternatives identified through consultation</th></tr>
<tr><th>Potential alternative</th><th>Assessment of the alternatives</th><th>Example applications</th></tr>
<tr><td>Trilead bis(carbonate) dihydroxide (white lead $2PbCO_3 \cdot Pb(OH)_2$)
EC / List no.: 215-290-6
CAS no.: 1319-46-6</td><td>White lead was used in the past, but is no longer used because of its heavy metal content.
Technical feasibility:
- It is an effective white pigment with excellent whiteness and opacity;
Economic feasibility:
- No data;
Availability:
- Very low;
Risk reduction:
- According to the classification notified by REACH registrants, this substance may damage fertility or the unborn child, is very toxic to aquatic life with long lasting effects, is harmful if swallowed, is harmful if inhaled and may cause damage to organs through prolonged or repeated exposure</td><td>Paints
Wallcoverings</td></tr>
<tr><td>Zirconium oxide (ZrO_2)
EC / List no.: 258-784-7
CAS no.: 53801-45-9</td><td>ZrO_2 can be used as opacifying agent in frits.
In paints, ZrO_2 would require a fourfold increase in film thickness</td><td>Frits
Paints</td></tr>
<tr><td>Cerium Oxide (CeO)
EC / List no.: 234-374-3
CAS no.: 11129-18-3</td><td rowspan="2">Both are less efficient and more expensive as heat stabilisers with limited availability</td><td rowspan="2">Silicone rubber</td></tr>
<tr><td>Carbon black (C)
EC / List no.: 215-609-9
CAS no.: 1333-86-4</td></tr>
<tr><td>Antimony oxide (Sb_2O_3)
EC / List no.: 215-175-0
CAS no.: 1309-64-4</td><td>Technical feasibility:
- Good opacity and hiding power but worse than TiO_2. The substance is also expensive and quite soft, making it unsuitable for areas prone to wear and tear;
Risk reduction:
- According to the harmonised classification and labelling (CLP00) approved by the European Union, this substance is suspected of causing cancer (H351)</td><td>Paints
Coil coatings</td></tr>
<tr><td>Aluminium oxide (Al_2O_3)
EC / List no.: 215-691-6
CAS no.: 1344-28-1</td><td>Al_2O_3, like TiO_2, may be used in SCR catalysts. Compared Al_2O_3, TiO_2 has the technical advantage that it is a sulphur-resistant carrier material. In addition, process efficiency would drop dramatically (by a factor of 4 or 5). Significant investments would be required to maintain current production levels</td><td>Catalysts</td></tr>
<tr><td>Aluminium hydroxide ($Al(OH)_3$)
EC / List no.: 244-492-7
CAS no: 21645-51-2</td><td>Much lower opacity than TiO_2 or almost full transparency (depending on binder system)</td><td>Pigment formulations</td></tr>
</table>

Table 8–4: Overview of characteristics of potential alternatives identified through consultation		
Potential alternative	**Assessment of the alternatives**	**Example applications**
Bismuth chloride oxide (BiClO) *EC / List no. : 232-122-7* *CAS no.: 7787-59-9* Tin oxide (SnO_2) *EC / List no.: 242-159-0* *CAS no.: 18282-10-5*	Only suitable for special applications such as hobby colours and artistic use	Artists' paints
Magnesium oxides	Magnesium oxides can be used in aerospace and vehicle ceramics	Ceramics
Organic UV filters	TiO_2 could be replaced in sunscreens by organic filters (avobenzone, EHT, Tinosorb® S and others). However, there is currently no guarantee that they are suitable alternatives that are technically and economically feasible with the same efficiency as TiO_2. **Technical feasibility**: - Unstable to light and can complex leading to a reduction of UV protection; - Their efficacy is not as good as TiO_2 (or ZnO); **Economic feasibility**: - Organic UV filters are costly; **Availability**: - Only a few manufacturers of these ingredients exist	Cosmetics
Optical brighteners	The paper industry uses optical brighteners in order to reduce (but not eliminate) the consumption of TiO_2; however, optical brighteners are not feasible alternatives when opacity is the target. They do also have limitations regarding their use in food contact material applications in several jurisdictions; the German Federal Institute for risk assessment (BfR) imposes limitations while the US FDA restricts the use of optical brighteners (by imposing conditions of use by food type, conditions of use) and China prohibits their use	Paper & board
Alternative photocatalytic materials	**Semiconductors**: there are known semiconductors which show certain photocatalytic activities too, but they are much costlier and they would show similar health risks due to their similar chemical and physical structures **Air clearing devices**: photocatalytic surfaces containing TiO_2 might be replaced by air clearing devices; they come with a cost for acquisition, electricity and filter media, operating noise and waste generation (e.g. used filter media) **More frequent cleaning**: as to the self-cleaning properties of TiO_2-based surfaces, these might be replaced by cleaning materials and frequent cleaning efforts, with the disadvantages of running costs and potential environmental pollution **Biocides**: as to the prevention against algae and mould, TiO_2-based products might be replaced by several biocides with harmful components, with the disadvantage of costs for application and maintenance, and environmental pollution	Photocatalysts
Opaque Polymer Systems	Widely marketed as TiO_2 extenders under various trade names, these are easy to handle, relatively cost effective, and have little impact on application properties. They are not capable of delivering an opaque paint system in isolation or in combination with any of the above technologies, thus they do not allow the complete replacement of TiO_2	Paints

Table 8–4: Overview of characteristics of potential alternatives identified through consultation		
Potential alternative	**Assessment of the alternatives**	**Example applications**
Steel	Steel is relevant to the hot water tank industry: all tanks are internally coated with porcelain enamel for water contact. Enamelled tanks might be replaced by steel tanks; however, the use of stainless steel would be unaffordable	Porcelain enamels

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