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STUDY OF THE SCOPE OF A BELGIAN NATIONAL REGISTER FOR NANOMATERIALS AND PRODUCTS CONTAINING NANOMATERIALS

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Content

1 Introduction and problem definition

Nanotechnology is considered as one of the key enabling technologies of this century[1] and offers a wide variety of potential uses that that should be considered from the point of view of their economic, health and environmental impacts and applications.

The use of nanomaterials may lead to products with new or improved properties and many nanotechnology enabled products have already been commercialized, ranging from sun-screen (titanium dioxide) over sports equipment (carbon nanotubes) to food packaging (nanoclay).

At the same time, several institutions and stakeholders stress the need for action to address regulatory and knowledge gaps with regards to potential effects of nanomaterials –and products using or containing them– on human health and environment[2,3,4,5]. While there is no indication that all nanomaterials are dangerous, the European Commission[6] highlighted that a substance may present a different danger profile depending on its presence as a nanomaterial or as bulk. Potential risks should therefore be identified at an early stage to be able to develop a culture of sustainable innovation. However, the risk assessment approach could have limits, and it is in that sense that we interpret a statement of Pr. K.A. Dawson[7] at a recent conference organized by the EU Commission, when he highlighted that "the pace of innovation in nanomaterials design far outpaces our capacity to 'be sure' ".

Until now, at the European level, the chemicals industry sees the existing risk assessment paradigm and regulatory framework as a solid basis for ensuring that nanomaterials are produced, used and disposed of in a safe and sustainable way, and highlights particularly the role of REACH (see "Nanomaterials - Safe and Innovative", CEFIC[8]).

The provision of clear and unambiguous criteria to identify nanomaterials for regulatory purposes is a prerequisite for the implementation of any legislation by enabling a coherent cross-cutting reference. In this sense, the recommendation on the definition of a nanomaterial published by the European Commission on 18 October 2011 marked an important step forward[9], and states that a nanomaterials is:

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[1] Hullmann, A. (2006). Who is winning the global nanorace. Nature nanotechnology, 1, 81–83.

[2] E.g. EEA (2013) Late lessons from early warnings: science, precaution, innovation, EEA Report No 1/2013 http://www.eea.europa.eu/publications/late-lessons-2

[3] The existence of the OECD Working Party on Manufactured Nanomaterials (WPMN) is a recognition of the existence of several knowledge gaps. For more information please refer to: http://www.oecd.org/science/nanosafety/

[4] E.g. CIEL-ClientEarth-Bund(2012) - High Time to Act on Nanomaterials: A Proposal for a "Nano Patch" for EU Regulation - http://www.ciel.org/Chem/Nano_EU_13Nov2012.html

[5] E.g. SCENIHR opinions. A summary is presented in De Jong, W.H. (2013), at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/docs/events/nano-rev-ws-jong_en.pdf

[6] Communication from the Commission, "Second Regulatory Review on Nanomaterials", COM(2012) 572 final

[7] See also K.Dawson (2013) Message=we* are gaining a deep confidence. Not at the end, but the end of the beginning?, Technical workshop on the follow-up to the Review of REACH, 27 June 2013, Brussels, at http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index_en.htm#h2-2

[8] http://www.cefic.org/Policy-Centre/Environment--health/Nanomaterials/, consulted on May 2013.

[9] Commission Recommendation of 18 October 2011 on the definition of a nanomaterial. 2011/696/EU.

A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.

By derogation from the above, fullerenes, graphene flakes and single wall carbon nanotubes with one or more external dimensions below 1 nm should be considered as nanomaterials.

Specific provisions on nanomaterials have been introduced at the EU level, for biocides, cosmetics, food additives, food labelling and materials in contact with foodstuff. Although there are no explicit requirements for nanomaterials under REACH or CLP, they meet the regulations' substance definition and therefore their provisions apply.

However, regarding REACH, a number of shortcomings have been reported for nanomaterials. For instance, because most nanomaterials currently on the market are derived from “parent substances” that benfit from a phase-in status, the many nanomaterials currently marketed benefit from delayed registration deadlines[10] in direct contradiction with the “no data, no market” principle underlying REACH[11]. In addition, nanomaterials that are produced or imported at smaller quantities are not subject to registration. And eventually, there are controversial debates surrounding the identification and characterization of nanomaterials. Discussions on the adaptation of REACH annexes to better address nanomaterials are currently on-going.

However, despite this approach and notwithstanding the rapid increase of the market for nanotechnology products, exposure monitoring and assessment is very difficult or impossible at present for nanomaterials as authorities and most enterprises have no means to obtain sufficiently reliable information.

Besides the approach of adapting REACH annexes and other regulations to better address nanomaterials, many EU Member States[12] and the EU Parliament[13] support the introduction of databases or registries for gathering necessary information on (products with) nanomaterials to address current regulatory shortcomings.

In this regard, a number of approaches to reporting, either voluntary or mandatory, have been proposed (including by Belgium) or implemented[14]. Within the European Union, France[15] has become the first country to require manufacturers to identify uses of substances in nanoform in the frame of a mandatory

[10] The next registration deadline is 2018.

[11] CIEL(2012) - Just Out of Reach – at http://www.ciel.org/Publications/Nano_Reach_Study_Feb2012.pdf

[12] http://chemicalwatch.com/11720/dutch-lead-call-for-urgent-eu-action-on-nanomaterials

[13] European Parliament. (2009). European Parliament resolution of 24 April 2009 on regulatory aspects of nanomaterials.

[14] Further information can be obtained from the Nanotechnology Industries Association (NIA) http://www.nanotechia.org/services/databases-reporting-schemes

[15] See https://www.r-nano.fr/

reporting scheme. Various NGO's and companies constituted their own databases, including claims about the exposure risk and possible hazards the nanomaterials may pose for humans and the environment.[16].

Following the stands taken by Belgium during its presidency of the European Council in 2010, the FPS Health, Food Chain Safety and Environment has examined since 2011 the appropriateness of and the resources required for setting up a register for the nanomaterials that are placed on the Belgian market, in coordination with a task force of federal departments and in cooperation with other member states of the European Union. In 2011, an opinion was required from the Belgian Federal Council for Sustainable Development (FCSD) by the Belgian Minister of Environment, about the possible actions to take to improve the existing regulatory framework, including a nanomaterials registry. However divergent opinions between stakeholders impeded the FCSD to adopt an opinion17. The subject of the registries continues to be discussed presently: in January 2013, the European cosmetics industry presented18 its view on nanomaterials registries, highlighting the characteristics that a registry should have, and the actions to take if such an initiative is put in place (define the audience and purpose -information gathering, surveillance/traceability tool, or safety assessment-, comparison with other approaches, resources considerations, harmonized definitions, possibility to focus the scope on certain sectors, advantages of an harmonized approach across the EU). The Commission presented19 its intention to start in 2013 an impact assessment "on the most adequate means to improve transparency", however there is no timeline for a possible implementation and the results of the impact assessment will only be considered by the new Commission (after 2014). In May 2013, a range of Belgian civil society stakeholders20 highlighted the need for a registry and traceability, expressed the citizens right to know and requested that the register considers also safety aspects for workers, consumers and the environment. In interviews conducted by us, industry highlighted the importance of the costs of a registry and the impacts on innovation and SMEs.

In this context, FPS is developing a scope regarding the nanomaterials and products containing nanomaterials that is aimed at setting the appropriate boundary conditions for the introduction of a Belgian register (product meaning here substances, mixtures and articles).

This report presents an exploration of potential options for a Belgian registry (BNR), based on the best current knowledge about what is on the market presently, and taking into account the uncertainties in this domain.

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[16] E.g. Woodrow Wilson database (The Project on Emerging Nanotechnologies) , ANEC-BEUC inventory of consumer products containing nanomaterials, database of German Environmental NGO 'BUND' (Friends of the

Earth Germany). See also the more recent database from the Danish Consumer Council and the Danish Ecological Council, build in cooperation with DTU Environment: http://nano.taenk.dk as well as the nanowerk database at http://www.nanowerk.com/nanotechnology_databases.php

[17] CFDD(2011) - Rapport annuel 2011 - http://www.frdo-cfdd.be/DOC/pub/jv_ra/Rapport%20annuel%202011.pdf, p.34.

[18] Cosmetics Europe (2013) - The view of the cosmetics industry on nanomaterial registries: The nano-specific regulatory requirements for cosmetic products – learnings from the implementation of the nano-notification - http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/docs/events/nano-rev-ws-schellauf_en.pdf

[19] http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/docs/events/nano-rev-ws-linher_en.pdf

[20] Open letter by various Belgian NGO's and workers associations, May 2013, http://m.crioc.be/index.php?mode=document_crioc&id_doc=6880

This is done through:

- the development of a knowledge base for the analysis;
- a clarification of the priorities and aims of the registry by a dialog with the authorities and stakeholders;
- the development of the options;
- a concise socio-economical balance of the options.

Based on these results, recommendations are made to improve the pragmatic implementation of the register to ensure its objectives are achieved.

2 Building the knowledge base: Where can we fInd Nanomaterials?

Nanomaterials (NM) are found in many original products[21] (i.e. final products) and in intermediate products along the supply chain. A two-part method (see Figure 1) was utilised to determine the amount of products containing NMs that are on the market in Belgium, encompassing the entire supply chain from primary chemicals to intermediate products to original products:

1) Identification of economic activities (grouped according to NACE codes[22]) likely to use or contain NMs;

2) Estimation of the number of unique products likely to contain NMs in the supply chain, categorized per economic sector. A unique product is here a product anywhere along the supply chain, placed on the Belgian market, and that has its own product identifier (e.g. different coloured paints are unique products).

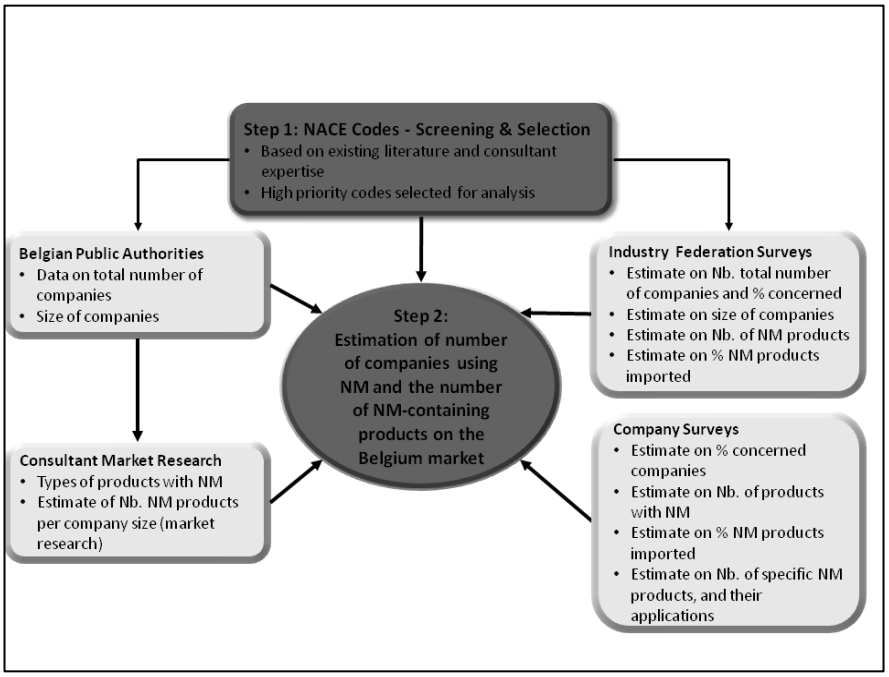

Figure 1 Overview of the methodology to estimate the number of NM-containing products on the BM.

[21] An original product is product that is no longer altered with the exception of packaging or labelling.

[22] European Commission.2008. *Statistical Classification of Economic Activities in the European Community, Rev. 2 (2008) (NACE Rev. 2)*.

2.1 Step 1: NACE Code Analysis and the Forming of Sectors

In order to perform a comprehensive study on the effects of a BNR, an analysis of economic sectors (classified according to NACE codes) was conducted. This consisted of integrating a bottom-up approach (identification of a set of substances in nanoforms and their uses) with a top-down approach (categorization of economic activities -NACE codes- according to the likelihood of usage of products containing or using substances in nanoform).

Substances in nanoform that have high production volumes and/or are widely dispersed in different products were collated; some of these include: carbon black, synthetic amorphous silica (SAS), precipitated calcium carbonate (PCC), aluminium oxide, titanium dioxide, zinc oxide, nanosilver, and pigments. Carbon black and SAS represent by far the largest volume[23] of nanomaterials currently on the market (almost 85% and 12% of total nanomaterial on the market, respectively)[24].

In order to assist in classifying products for the purpose of a register, products were categorised according to the REACH product types: substances, preparations, and articles[25]. For pragmatic purposes, and in agreement with the main focus of the register on manufactured nanomaterials as expressed by the Belgian authorities, natural[26] NMs and incidentally produced NMs are excluded from the estimation. For example, ground flour is not considered a NM. Furthermore, it rapidly appeared that a pragmatic definition of incidentally produced NM was required to omit materials that – if not omitted, it could be that very many powders would be considered a NM in the analysis and which is not the aim of the potential register. Classification of a NM as incidental was based, in this study, on available particle size distributions and consultation with experts: e.g. ground calcium carbonate with a median volume-based particle size of around 5µm is considered incidental (even if the definition of a NM as proposed by the European Commission is met), while precipitated calcium carbonate is considered a NM.

The following is a list of just <u>some</u> substances considered as manufactured nanomaterials, and their potential applications:

- Pigments of different types and size ranges depending on their application, e.g.: plastics, paints, inks, textiles, ceramics, etc.
- Carbon Black as reinforcing filler in tyres and other rubber products, or pigment in inks, coatings, plastics, ceramics, etc., as well as various miscellaneous applications.
- Synthetic Amorphous Silica (SAS) for biocidal properties, as reinforcing filler in rubber, anti-caking agent, or as an abrasive agent.
- Precipitated Calcium Carbonate (PCC) as a filler or additive (coated or un-coated) in plastics and paper products, opacifier or extender in coatings & inks, mineral base for food or pharmaceutical products, etc.
- Titanium dioxide for photocatalytic properties.
- Carbon Nanotubes (CNT) for antistatic properties or increasing strength-weight ratio of sports equipment.

[23] 9.6 million tonnes (carbon black) and 1.5 million tonnes (synthetic amorphous silica)

[24] European Commission. (2012). *Types and uses of nanomaterials, including safety aspects.*

[25] REACH definitions can be found here: http://www.reach-compliance.eu/english/REACH-ME/engine/sources/definitions.html

[26] For the purpose of the study, natural nanomaterials were defined according to REACH Article 3(39),

- Nanosilver for antimicrobial properties.
- Rare earth metals for catalysis.
- Boehmite for abrasion resistance in coatings, etc.

As is evident from the above list, this implies that products containing fillers or pigments (e.g. some rubber products, plastic products, paper products, and textiles) or are coated with a preparation containing NMs (e.g. painted furniture or machinery) are considered to be NM-containing products. On this basis, economic activities (NACE codes) were categorized according to the likelihood of usage of products containing NMs:

- Group I very high likelihood for the use of NM
- Group II use of NM cannot be excluded
- Group III use of NM is very unlikely

In total, 985 datasets were analyzed, corresponding to

- 21 NACE Sections
- 88 NACE Divisions
- 272 NACE Groups
- 604 NACE Classes

In view of the results obtained, economic activities as defined by NACE were categorized thematically into sixteen sectors, including only NACE categories belonging to Group I (very high likelihood for the use of NM):

1. Substance Manufacturers
2. Cosmetics
3. Health Care
4. Food & Feed
5. Coatings & Inks
6. Cleaning & Disinfection
7. Tyres & other Rubber Products
8. Plastic Products
9. Building & Construction
10. Textiles
11. Paper Products
12. Wood Products
13. Sporting Goods
14. Electronics
15. Complex Objects
16. Miscellaneous

Each sector contained the entire supply chain where possible; manufacturing (intermediary and original products), wholesale, and retail. Only retailers potentially selling to a professional user[27] (e.g. paint to a painting firm) are considered in the analysis, according to the priorities set to this study by the FPS.

2.2 Step 2: Estimation of number of companies using NM and the number of NM-containing products on the Belgium market

As indicated in Figure 1, the number of total companies per sector was obtained from the Belgian public authorities and allocated according to enterprise size defined as in the Commission definition based on the number of employees[28]: micro (0-9), small (10-49), medium (50-249), and large (>250). The

[27] Where a professional user is a company with a registration number from the official Belgian database “Banque-Carrefour des Entreprises”, see http://economie.fgov.be/en/entreprises/BCE/#.UaYTQayf6hk

[28] http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/sme-definition/

(i) percentage of companies using NMs per sector and (ii) the number of unique products (UP) containing NMs per company using NMs were estimated by integrating the results of three independent groups of sources:

1. Own research: market research on approximately 10 companies in the sector to evaluate if they place NM-containing products on the market. Of those companies using NMs, the range of unique products containing NMs was quantified according to company size (micro, small, medium, large) for each sector.
2. Company surveys and interviews: an online survey for companies with approximately 70 responses provided an indication of the percentage of companies per sector that put NM-containing products on the market. The respondents also provided their company size. In addition, the respondents provided an estimated range of the number of products they place on the BM containing NMs;
3. Industry Federations surveys and interviews: where possible, industry federations in relevant sectors provided estimates on the percentage or the total number of companies using NMs. Furthermore, where possible, industry federations provided a range of the total number of unique products containing NMs per sector or a range for the number of unique products containing NMs per company.

From each of the three sources of information stated above, two values were obtained for each identified sector: the lower range and the upper range in terms of percentage of companies using NMs per sector. The fractional values for the lower and upper range (min and max) of companies using NMs were then integrated to form representative values for the lower and upper range for each sector; the integration was based on the comparison of the obtained values and the authors own evaluation of quality of the value (e.g. if values from two sources were close and the third source was very different, the outlier is neglected). For some sectors, all three sources of information was not available, and therefore only 2 sources of information were used, and in very few cases only one source of information was available.

The range of companies putting products with NMs on the market was estimated by multiplying the (i) total number of companies per sector by (ii) the lower and upper fraction of companies using NMs per sector obtained by the aforementioned integration of the three different sources; the total number of companies for each sector was obtained using the Belgian public authorities databases and categorized according to economic activities (NACE) as previously described.

For all sectors evaluated, the number of companies placing a NM-containing product on the market was estimated to be between 35,000-45,000 enterprises. This represents approximately 15-20% of all the enterprises in Belgium according to 2011 data from the Belgian National Social Security Office[29].

The total number of unique products (UP) containing NMs placed on the market in Belgium was estimated analogous to the method used to calculate the number of companies using NMs in the following steps:

Step A: Estimation of number UP containing NMs per company using NMs in each sector (results summarised in Figure 2). For each of the three sources listed above, a minimum and maximum value of

[29]http://www.onssrszlss.fgov.be/sites/default/files/binaries/assets/statistics/employment/Employment_valAANTALW_NL_2011 4.xlsx

UP containing NM per company using NMs for each sector was obtained. Each of the three sources were critically compared amongst themselves and integrated to form a range (min and max) representing the number of UP containing NMs per company in each sector.

Step B: Estimation of the total number of NMs in each sector. The number of UP containing NMs per company in each sector (Figure 2) was multiplied by the number of companies in using NMs in each sector (as outlined in the previous paragraph).

In general, the estimations from the three independent sources, where available, were within 25% of one another.

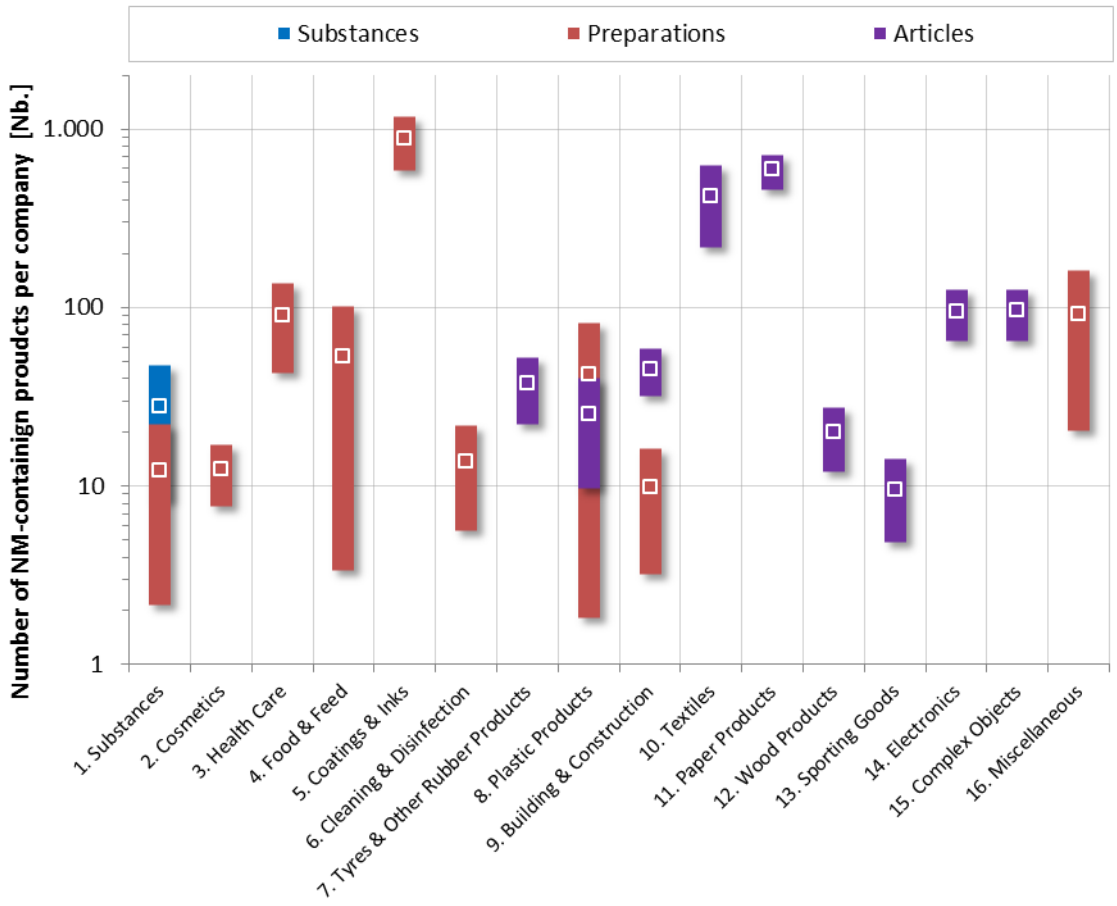

Figure 2. Overview of the number of NM-containing unique products per company containing NMs according to product type (substance, preparation, article) within each sector. The range represents the min and max, while the white box represents the mean of the min and max values. Note: y-axis is logarithmic. The companies in each sector without products containing NMs are omitted from this calculation.

In Figure 2, the number of unique NM-containing products per company using NMs (categorized as substances, preparations, and articles) are broken down according to sector. The companies in the sectors coatings & inks, textiles, and paper products have the highest number of unique NM-containing products per company since pigments and some filler materials (e.g. SAS, PCC) are considered NMs. The sectors electronics (e.g. computers, radios, electrical parts, etc.) and complex objects (e.g. cars, refrigerators, furniture, etc.) also have many products containing NMs, especially due to coatings (e.g. on machinery) and also filler materials in rubber and plastic components.

In general, for the entire supply chain, the number of unique products is as follows: there are around 2000-5000 unique substances, 80,000-160,000 unique preparations, and 800,000-1,300,000 unique articles containing NMs[30].

Ranges in Figure 2 are aggregated values for the entire sector and does not represent the minimum and maximum range of each NACE code constituting each sectors: meaning, within each sector, subgroups can have declarations per company values higher or lower than in Figure 2. It is also important to note that due to the interconnected nature of the present world economy, a majority of products are imported from outside of Belgium, therefore leading to non-linear, fragmented supply chain.

3 A registry, but a registry of what? For which purpose? And what are the priorities?

The Introduction of a Belgian national register of nanomaterials and products containing nanomaterials (BNR) has been discussed as a tool to support Competent Authorities in:

1. ensuring sustainability of this innovative technology ;
2. providing confidence and transparency towards the general public and towards workers ;
3. ensuring traceability and hence, making effective government intervention possible in case of hazard for public health, for workers or for the environment;
4. acquiring a better knowledge of the market, of the features of those materials and of their potential exposure risks;
5. setting up a knowledge database which may be necessary for national or European regulatory evolutions later on.

Within the options that are considered by the Belgian authorities, the registry is not foreseen as a publically accessible database. All submitted information shall be confidential. The data can be used by the Public Authorities to monitor innovation, perform risk assessments, or to publish *aggregate* data in national or international reports for the general public.

Amongst the options that are considered by the authorities, there is the possibility to focus on 3 different types of products that contain nanomaterials (NM): substances, preparations and articles (as identified in the preceding section). Given that the requirements regarding declaration might be different for each type, it is therefore necessary to first delineate the nature of each product.

3.1 Products that might be declared: the scope

The Belgian authorities are considering the possibility to register the production with the purpose of placing on the Belgian market, and placing on the Belgian market for professional users[31], including

[30] The aim here is to determine the number of unique marketed substances, preparations and articles. It must thus be noted that a single NM may be sold as separate substances (UP) according to their characteristics and qualities (e.g. carbon black), and this is reflected in the numbers here. In addition, preparations and articles with an identical chemical composition, being sold under different brand names are considered “unique” products.

[31] Where a professional user is a company with a registration number from the official Belgian database “Banque-Carrefour des Entreprises”, see http://economie.fgov.be/en/entreprises/BCE/#.UaYTQayf6hk

importation on the BE territory, of the following substances, preparations and articles are subject to a declaration:

1. Manufactured substances in a nanoform, defined as substances containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm, with the exclusion of natural or incidentally formed substances. Fullerenes, graphene flakes and single wall carbon nanotubes with one or several external dimensions smaller than 1 nm are also to be considered as substances in a nanoform and must be declared.
2. Preparations containing one or several substances in a nanoform likely to be extracted or released during normal or reasonably foreseeable conditions of use including disposal.
3. Articles for which there is a possibility of exposure to humans either directly or indirectly through the environment. At this stage the question of end-of-life aspects is not considered in this report, because authorities are still considering the possible legal basis. For the purpose of identifying the articles subject to a declaration, the following criteria is under consideration by the FPS (as a proxy to the likelihood of exposure from articles):
    - Articles for which substances in a nanoform are used during their manufacturing process (at whatever stage)
    - or containing those substances,

    AND at the same time for which,

    - the substances in a nanoform are present in a loose state,
    - or the substances in a nanoform are incorporated in any other phase than solid (in suspension in liquids, gels or in gases, mesophases, etc),
    - or the substances in a nanoform are incorporated at the surface (alone or in any type of mixture and phase - including solid).

Whereas the Belgian authorities are considering defining a natural substance according to REACH Article 3(39), at this point there is no commonly agreed upon definition for incidentally formed nanomaterials.

No declaration of the above mentioned substances, preparations and articles is required for a company that places on the market a total amount of less than 100 g of substances annually as such, or in preparations or articles. Furthermore, a simplified declaration is foreseen to be required for placing a product on the market for a scientific research and development activity.

3.2 Potential declaration procedure

A product which is classified as falling under the scope must be declared if it is transferred on the Belgian Market (BM) from one Professional User (PU) to another PU. Exported products do not require a declaration. In principle, according to the latest discussions, the declaration process and communication along the supply chain can be summarized as follows:

- One single declaration number is awarded to every declaration made[32]. This number is communicated by the authorities only to the declarant. The declaration is made annually and submitted through a secure web site.
- When the declarant puts on the market a substance, preparation or article for a professional user, he hands him down the declaration number corresponding to the substance, preparation or article.

3.3 Potential contents of the declaration

For every substance, preparation, or article declared, it is foreseen that the following information be submitted:

1. Declarant information
2. Substance identification, including:
    a. Chemical identification of concerned substance(s), chemical name, CAS number.
    b. Particle characteristics including median particle size, particle size distribution, form and shape characteristics, state of aggregation and agglomeration
3. Amount of substance(s) placed on the market, specifying type of product (substance, preparations, article)
4. Uses and claimed properties of the substance in nanoform
5. Identification of professional users to whom the declarant has transferred the property to.

If the declarant does not alter the particle characteristics with respect to the ones received from his supplier, the declarant may mention the declaration number(s) that was passed on to him instead of the particle characteristic information specified above (2.b of the preceding list).

4 Baseline and Options for a registry

The baseline is the present situation, without a BNR, meaning that although no direct additional costs for industry and government will be incurred, the various important reasons for implementing a BNR will be unmet and could eventually present large indirect costs (e.g. traceability in the case of hazard for public health or workers, compensation payments). On the other hand, requiring all products (substances, preparations, articles) containing NMs to be declared is not a realistic option since that could potentially result in around 3 to 5 million declarations and affect between 35,000 to 45,000 companies. **Therefore, the following options are proposed with the aim to develop a pragmatic BNR that helps the Belgian authorities achieve its stated goals with respect to NM-containing products**[33].

Option 1: BNR excluding products that are already regulated for NM. Products containing NM that are already regulated by existing regulations (i.e. cosmetics, biocide, novel food) will be exempted. Since these regulations are European, the data collected by European Authorities may not be communicated with Belgian Authorities and will not be incorporated in the BNR.

[32] This means that the declaration number is different for each professional user and for each declaration, and thus that only authorities have access to the traceability along the entire supply chain.

[33] All BNR options are variations based on proposed scope presented in Section 3.1

Option 2: BNR excluding pigments and fillers in preparations and articles. This option excludes all preparations and articles containing only pigments and/or fillers and no other NMs, where fillers are specified here as SAS and PCC. All substances must still be declared. This implies that many coatings & inks, textiles, paper products, plastic parts will be excluded. However, many complex objects (e.g. cars) could potentially still be required to be declared since it is likely they contain additional NM in at least one article comprising the object. There are specific issues that may arise for this option: for example, there are many different types of pigments – some organic, some inorganic, some manufactures intentionally in a specific range between 1-100nm (e.g. LCD pigments), some pigments post-processed to grow the primary particles to larger aggregates to improve opacity in paints. Grouping all pigments together would be arbitrary (e.g. why should iron-oxide based pigments be exempted and not iron-oxide additives, even if they have the same range of primary particles?) and not fulfil some objectives of the proposed register.

Option 3: BNR excluding specific supply chain actors. A large share of the companies affected would be retailers who sell to other professional users and wholesalers (i.e. distributors of original products). Most of these actors are micro and small enterprises and would normally be required to declare a very high number of products considering the size of their company (e.g. potentially several hundred depending on the sector) and the majority of their products would be imports, thereby leading to high declaration costs. These actors are at the end of the supply chain and do not modify the products and experience the same exposure as the consumer. To minimize the burden on micro and small enterprises, all retailers are exempted from declaring. In addition, micro and small enterprises distributing original products are also exempted from declaring. These actors are however, obligated to pass any BNR declaration number they receive associated with a product along to the downstream PU. Since the highest volume of unique products are distributed by medium and large wholesalers, and these actors are still obligated to declare, effective traceability will still be achieved.

Option 4: BNR with a positive list of products to be declared. This option is another way to limit the impacts of establishing a mandatory BNR in a selective way. As such it incorporates all the costs and benefits that the inclusion of a negative list also entails with one addition, innovative products are not automatically required to register. New products would have to be detected on the market and a new decision would have to be made for whether or not to include them in the register.

Option 5: BNR with a possibility to avoid declaration based on scientific evidence (including non-testing methods). Because of the possibility to waive the declaration with the aid of non-testing methods (akin to REACH) large parts of product groups might be not subject to declaration anymore over time thus generating large monetary benefits. As not all companies would have to test individually but could argue to waive the declaration based on similarity of a given product with another product where waiving was approved, the monetary benefits could scale significantly in some sectors. The non-testing methods are not arbitrary but do introduce a certain degree of uncertainty into the declaration portfolio. It is foreseen that the Belgian Authorities will release a set of guidelines and examples detailing which products can be excluded as a starting point for industry.

Option 6: BNR with an exemption list for selected pigments and fillers, selected supply chain actors, the possibility to avoid declaration based on scientific evidence, and a rollout phase for implementation. Quickly summarized, it includes of the following:

- Option 2 modified: Preparations and articles containing only fillers and/or selected pigments and no other NMs (where fillers are specified here as SAS and PCC) are exempted from obligatory

declaration. All substances must still be declared if they fulfil the NM definition. It proposed that pigments be appropriate classified, potentially according to end use or properties, and only selected groups of pigments shall be exempted. This will make the number of declarations more manageable while still fulfilling the main objectives of the BNR.

- Option 3: Retailers and (classified according to NACE code) are exempted from obligatory declaration. Wholesalers of original products (classified according to NACE code) defined as either micro or small enterprises are exempted from obligatory declaration. They are however obligated to pass the received declaration number along to the next downstream PU. This will make the number of declarations more manageable while still fulfilling the main objectives of the BNR.
- Option 5: The possibility to avoid declaration based on scientific evidence (including non-testing methods). It is foreseen that the Belgian Authorities will release a set of guidelines and examples detailing which products can be excluded as a starting point for industry.
- A rollout phase for substances, then preparations, and finally articles. Within this rollout phase, there is a sub-rollout phase envisioned: Professional users who are the first to place a product category (e.g. substances) on the BM must declare first, followed by all other professional users (see following figure):
    - This will allow the implementation to run smoother, provide more certainty for stakeholders, generate an accurate database, allow optimization of the procedure, permit time for scientific knowledge and measurement techniques to advance in step with the registry, and result in less total costs.
    - For all phases, it is recommended that stakeholder meetings occur and guidance documents be prepared well in advance of each rollout phase.

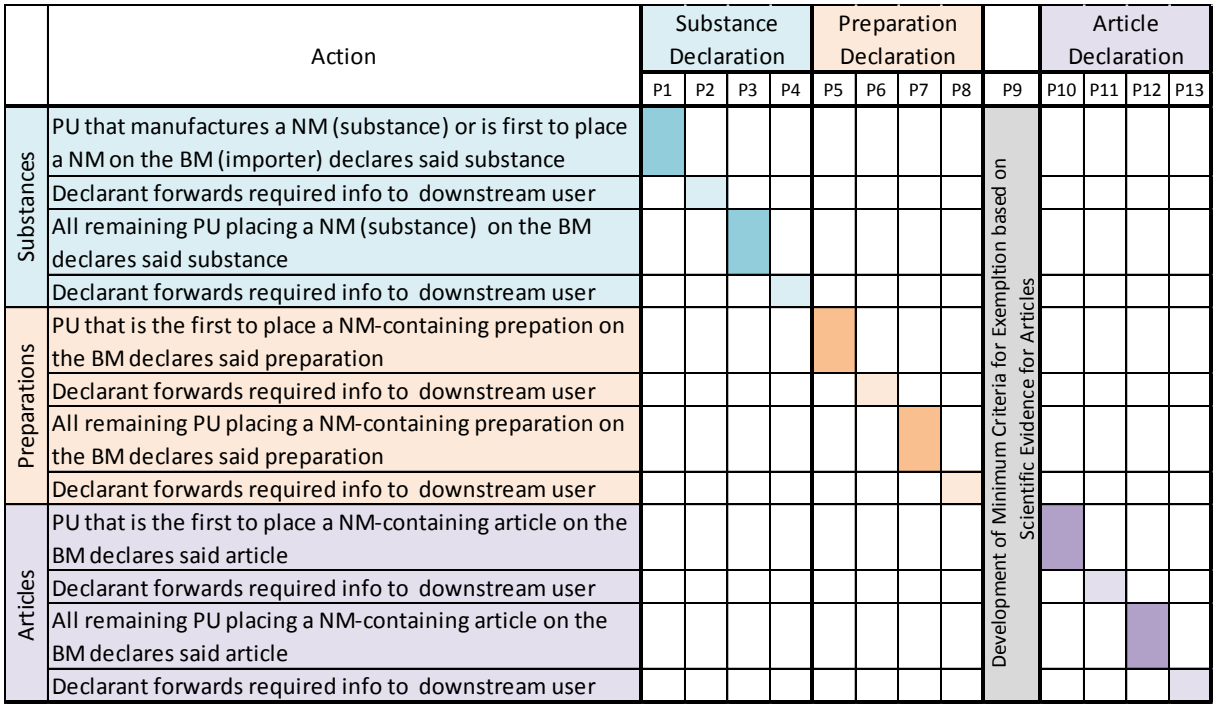

Figure 3: Proposed rollout phase for implementation of the BNR. Note that the length of each period is not specified and must not be equal

An alternative to a BNR is a European Register for NM-containing products. The analysis of a European Register is outside the scope of this study. However, the concept of a European Register for NM-

containing products has been voiced repeatedly as an alternative to the BNR during stakeholder consultations and expert interviews during this study. Such a European register would be especially useful for the purposes of pooling data already collected on nanomaterials by different regulations, minimize the overall administrative burden, facilitate information gathering and submittal of declarations for legal entities importing products, and improve the overall quality of submitted data.

5 Socio-economic comparison of considered options

The afore-mentioned options are compared according to a socio-economic balance in order to compare and propose a recommended option. The benchmarks for comparison include the objectives of the BNR:

1. providing confidence and transparency towards the general public and towards workers;
2. ensuring traceability and hence, making effective government intervention possible in case of hazard for public health, for workers or for the environment;
3. acquiring a better knowledge of the market, of the features of those materials and of their potential exposure risks for human health and environment;
4. setting up a knowledge database which may be necessary for national or European regulatory evolutions later on

And the additional benchmarks:

5. Impacts on the European internal market
6. Effectiveness of the BNR: respect to ease of implementation and quality of the data obtained
7. Time to implement the option fully and acquire a fully functional dataset
8. Total direct costs to industry

For the purpose of this social-economic balance, the cases where the implementation of options proves beneficial, options are marked with a plus sign (“+), while options associated with negative effects are marked with a minus sign (“-“) and “+/-“ means mixed effects relative to the baseline. An example of a mixed effect is the effect of option 4 (a positive list) on confidence and transparency; it is positive since some NMs will be registered but it is also negative since it the positive list might not be representative of NM on the market and full transparency would not be achieved. In order to specify the total directs costs for industry, a rating from 1-5 is employed: 1 = little to no costs incurred; 3 = moderate costs incurred; 5 = high costs incurred).

The costs incurred by companies consist of implementation costs and recurring administrative costs. The implementation costs are split into two categories: a) base implementation costs associated with first setting up the system to deal with the BNR, and b) administrative implementation costs that account for the collating (collection) and entering of the data required for the first declaration. Administrative recurring costs refer to the administrative effort required to check the validity of the existing declaration and update the entries with new values as required.

The development of a full cost assessment model was out of reach in the time framework of the study. However, notwithstanding this issue, an important amount of data has been collected (e.g. estimates on implementation and recurring costs, depending on the position of a PU in the supply chain) that allows for a relative comparison of the costs of the different options, as presented also here below.

Table 1 Relative comparison of costs resulting from the implementation of different options. See text here above and description of the options for details.

	Benchmark	Base line and evaluated Options					
		1	2	3	4	5	6
1	Confidence and transparency	+	+/-	+	+/-	+	+/-
2	Traceability and intervention in case of hazard	+	+	+	+	+	+
3	knowledge of the market, potential exposure risks on human health and environment	+	+/-	+	-	+	+
4	Knowledge database for national or European regulator evolutions	+	+	+	+/-	+	+
5	Impact on European internal market	-	-	-	-	-	-
6	Effectiveness of implementation, quality of obtained data	-	+/-	+	+	+/-	+
7	Time to fully implement option	+	+	+	+	+/-	+/-
8	Total direct costs to industry	4	3	3	--[a]	3-4	2

6 Uncertainties, Costs/risks and benefits of inaction, open questions

The analysis of the presence of nanomaterials on the Belgian market and the comparison between options is partially based on the input from stakeholders as well as estimations on the number of companies potentially affected and the number of products that would be declared according to the different options presented. In general, there is little to no publically available information on the number of unique NM-containing products on the market. The estimates in this study are based on extensive work with the Belgian Authorities and Belgium companies manufacturing NMs, companies using NMs in their products, and industry federations of sectors that most commonly use NM. Despite these sources, it is difficult to obtain very accurate data on the total number of products on the market containing NM since: a) it is unclear to many stakeholders what qualifies as a NM, and b) aggregate sectoral data is normally collected on volume of sales, not number of products.

The relative effect of the different options on sectors that deal with substances and preparations have low to moderate uncertainties due to the extensive stakeholder cooperation. In addition, the estimates for the various options for some article-based sectors such as Paper Products, and Textiles possess low uncertainty since it is fairly clear which NM are most commonly used in these sectors and what would occur if these NM were exempted. However, high uncertainty exists for the articles in the sector Complex Objects which consists of hundreds of components, many being imported, and the composition unknown.

Furthermore, uncertainty exists for the options with the possibility to avoid declaring based on scientific evidence, as it is difficult to predict what justifies as adequate scientific evidence.

Some benchmarks presented in the previous table can be easily evaluated when comparing the present situation (the base line) with the options previously presented: direct costs for industry are reduced to zero, as well as the implementation time, and the impact on the European internal market.

Regarding transparency, the level suggested as necessary is different between stakeholders, having civil society[34] calling for the right to know and industry[35] pledging for a better dialogue and communication and highlighting the existence of confidential business information, publication of toxicological test reports on their websites, and existing voluntary or regulatory programs to generate and increase information sharing, transparency and communication. While it appears that the proposed options increase the level of transparency in some aspects, the evaluation of the necessary level of transparency is an intrinsically political decision.

Regarding confidence, there is also a diversity of opinions, having NGO's and workers associations linking confidence aspects with the availability of information, while industry often indicates that requiring a disproportionate level of information and transparency may trigger unjustified fears and distrust on a technology that is promising, without a clear scientific evidence that such measures are necessary. Presently the level of knowledge of the public regarding nanomaterials is rather low, but probably increasing as indicated by the recent publication of articles about nanomaterials in newspapers, even at the Belgian level[36]. Bonny (2003) examined the GMO's case and presented various factors explaining the distrust of part of the public: potential risks, the extensive publicity given to them, coupled with the inadequacy of answers to these diverse criticisms, and a drawing up of an unfavourable risk-benefit balance (particularly regarding a perceived unequal distribution of the risks and advantages between various actors). She pointed also that that various fears and objections to the evolution of agriculture and to the functioning of society (i.e. limited trust in institutions and firms) appear to be crystallized around GMOs. Distrust may represent high costs both for authorities and industry. For the case at end, if a registry enters into force, the confidence issue depends amongst others on a proportionate level of transparency associated with a carefully balanced communication about the meaning and purpose of the database content, and about nanomaterials in general, in a long term open dialogue with the various stakeholders.

However, EEA (2001)[37] states that

> *The costs of preventive actions are usually tangible, clearly allocated and often short term, whereas the costs of failing to act are less tangible, less clearly distributed and usually longer term, posing particular problems of governance. Weighing up the overall pros and cons of action, or inaction, is therefore very difficult, involving ethical as well as economic considerations […]*

[34] See e.g. Open letter by various Belgian NGO's and workers associations, May 2013, http://m.crioc.be/index.php?mode=document_crioc&id_doc=6880

[35] CEFIC(2011) - Risk Assessment of nanomaterials from an industry perspective at http://ec.europa.eu/health/nanotechnology/docs/ev_20110329_co12_en.pdf

[36] See e.g. "Nanoparticules, macro soucis", La Libre Belgique, 24/04/2013, and "Nanomaterialen schaden uw gezondheid", De Morgen, 15/05/2013.

[37] EEA(2001) - Late lessons from early warnings: the precautionary principle 1896–2000, Environmental

issue report No 22, European Environment Agency.

This is particularly true when considering the potential health, workers and environmental risks of nanomaterials in a context of very fast innovation, with expected numerous new substances or nanoforms of the same substance, lack of standard methods, scattered data of non-uniform quality[38] and mixed messages about the data obtained for nanomaterials so far e.g. through REACH (early results from June 2013 indicate that only four nanomaterials were registered by 2013 REACH deadline[39]). Moreover scientific evidence suggests that a case-by-case approach is needed for risk assessment: while there is no indication that all nanomaterials are dangerous, the European Commission[40] highlighted that a substance may present a different danger profile depending on its presence as a nanomaterial or as bulk.

For that reason, introducing a benchmark in Table 1 that quantifies potential future health, environment and workers effects is currently not possible. Modeling approaches for overcoming this problem, like those suggested by EEA (2013)[41] for accounting for the health and environment costs of inaction seems hardly feasible presently, as show also by the difficulties encountered by F. Gottschalk et al (2011)[42] when estimating water exposure through modeling due to a lack of data on nanomaterials on products, their concentrations, and their production:

> *If one wanted to improve [the model], a distinction would be necessary among the quantities of ENM produced, imported and exported. Ensuring that such data from industry (apart from commercially confidential information) becomes publicly available would be crucial for improving the simulations of ENM environmental concentrations and the subsequent risk assessment.*

The same difficulty may be encountered about the assessment of the benefits of traceability. It is expected that various presented options have the potential to establish a traceability. While having a traceability gives authorities the means for taking focused actions in case of a withdrawal, the fact that the potential number and extent of withdrawal cases in the future is hard to predict do not allows a quantified approach of the expected cost/benefits balance for that withdrawal aspect.

What is clear however is the present lack of information and the positive contribution of various of the presented options to improve it. Moreover, in the presented options, there is a link between traceability and the gathering of information: less information will be collected without traceability, and the data validation will be more difficult. From that point of view, the cost of inaction can be translated in the cost of having an incomplete view of the nanomaterials on the market, and in cost of market studies that are necessary for palliate to that information gap, which in its turn influences on the quality of the conclusions of scientific studies that are lacking such an information, and on the quality of the analysis of the necessity or not to improve and update regulations.

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[38] JRC(2013) - Addressing needs for information on nanomaterials - Workshop on the Second Regulatory Review on Nanomaterials, 30 January 2013, Brussels, at http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/docs/events/nano-rev-ws-maruszewski_en.pdf

[39] ECHA conference press, 3/6/2013, cited by NIA at http://www.nanotechia.org/news/news-articles/early-results-indicate-only-4-nanomaterials-registered-2013-reach-deadline
which states also that “the representative did indicate that this is “a very preliminary number” and that full details would be revealed in early September 2013”.

[40] Communication from the Commission, “Second Regulatory Review on Nanomaterials”, COM(2012) 572 final

[41] EEA (2013) Late lessons from early warnings: science, precaution, innovation, EEA Report No 1/2013 http://www.eea.europa.eu/publications/late-lessons-2

[42] Gottschalk et al (2011) - Engineered nanomaterials in rivers e Exposure scenarios for Switzerland

at high spatial and temporal resolution - Environmental Pollution 159 (2011) 3439e3445.

Another aspect of the cost of inaction is that so far the Belgian government, using the existing legal instruments, could not get an overview of workplaces where workers can be exposed to nanomaterials or products containing them. The fact that many producers of intermediate and final products do not know whether or not the products they use contain nanomaterials probably plays an important role. Hence, the accumulation of knowledge and mapping of such workplaces could be used as an indicator for the progress of a database development. Moreover, a legislation calling for the reporting of the numbers of workers that can be exposed to nanomaterials has not yielded adequate results. It was concluded that this is partially due to lack of knowledge about the presence of nanomaterials in articles or preparations that are being used. Nanomaterial traceability illustrated above is not only about tracing products or recording information; it also plays into health and safety surveillance. It can deliver specific objectives like supporting manufacturers who take responsibility to protect their workers: the information obtained can be used to better perform the obligatory workplace risk analysis, and, consequently, to take more adequate preventive measures. Responsible nanotechnology innovation involves putting enforcement into practice.

Other potential costs of inaction were mentioned by stakeholders and/or authorities: an increase of confusion with the presence of various scattered and/or unvalidated databases, and the difficulty for struggling against false claims.

7 Additional recommendations for improving a potential BNR

Based on stakeholder input and our own analysis, the following recommendations are made to improve the effectiveness of the potential BNR with respect to its stated goals:

With respect to products to be declared:

- that all substances in nanoform that are manufactured or imported on Belgium territory, regardless if they are only manufactured for the purpose of export, be subject to declaration to improve traceability and to monitor innovation[43]. Substances for the purpose of scientific R&D and product development are exempt.
- that, in support of option 5 and 6 (exclusion of products based on scientific evidence), a “nanoclassifier” system based on physio-chemical properties could potentially be used to classify NMs in order to put them on or take them off of an exemption list.
- that all preparations containing substances in nanoform (substances to be declared) and placed on the BM should be declared to ensure traceability for intermediate and transferred products even if there is no exposure at this specific point in the supply chain. Another alternative is to not require the PU to declare but oblige the PU to communicate the received declaration information to the next downstream PU.
- that, in support of option 5 & 6 (exclusion of products based on scientific evidence), a set of pragmatic guidelines and criteria be developed to for articles defining where exposure can and cannot be excluded.

[43] There are some substances produced in Belgium but only for export and return in a final product. Requiring all substances to be declared allows to capture these substances proactively.

With respect to the procedural specifics of the BNR:

- that a clear and concise set of harmonised information requirements and definitions should be provided to ensure the establishment of an effective and functional register well in advance of implementation of the BNR. In particular, it is recommended that the following be explicitly specified:
    - the definition of incidentally formed nanomaterials (could be based volume based thresholds) or any other definition or criteria that allows to discard substances like ground calcium carbonate (as opposed to precipitated calcium carbonate) from the scope.
    - the definition of natural nanomaterials (could be based on REACH definitions)
    - the required data for the characterisation of substances (e.g. provision of guidance on measurement methods, number of measurements for standard deviation, level of justification required)
    - the specifications regarding the obligations of importers in case no information can be obtained from its exporter
    - the format of specific provisions of the declaration. (e.g. provision of the identities of customers could be uploaded as text files)
    - guidelines for declaring complex objects which potentially contain multiple different articles and preparations
    - the declaration information that must be communicated to the next downstream user. For example, in order for a downstream declarant to be able to declare the amount of substance(s) contained in its products that are placed on the market, it must have receive specific information from its supplier.
        - It is recommended that the that FPS should prepare and provide a document (a certificate) to declarants that contains all relevant information that should be communicated with downstream users (e.g. declaration number, chemical identity, concentration of NM in preparation, amount of NM per articles, etc.)
- that only information that changes should be updated in the annual declaration (e.g. amount of substance(s) placed on the market, identity of customers)
- that the declaration system does not require declarants to obtain new declaration numbers in case the chemical composition of an existing declared product is changed; only if a new product is created. Introduction of such a system should reduce the administrative burden significantly for all downstream users. The declarant is however required to communicate the changes in chemical composition to its customers.
- that companies should not be obliged to mention registration numbers in trading and accountancy documents to avoid an disproportionate administrative burden (in particular to SMEs) and that professional users decide themselves how to best communicate the declaration number and the required associated chemical information (or the declaration certificate received from the FPS which could be communicated).
- that a simplified declaration process be introduced for nanomaterials and NM-containing products put on the market for scientific research and development and product development activities.

8 Conclusion

The data collected from individual companies through surveys and interviews, experts, industry federations, in addition to our own market research has shown that nanomaterials, as defined according to the COM definition, are present on the Belgian market in a large variety of products within many economic sectors and along the entire supply chain, and that declaring all of them, and to trace them all along their lifecycle would result in costs that are considered too high.

Therefore, it is necessary to consider options for a streamlined scope that meets the BNR goals (e.g. traceability, confidence and transparency, data necessary for exposure scenarios, etc.). Six options were considered including various restrictions of the scope were analysed and compared with one another with respect to the BNR objectives and the direct costs for industry.

For the case of a BNR, option 6 is recommended: BNR with an exemption list for selected pigments and fillers, selected supply chain actors, the possibility to avoid declaration based on scientific evidence, and a rollout phase for implementation as this option achieves the register objectives in the most effective manner – in respect to the direct costs incurred by industry and also the amount of relevant data obtained per the number of declarations that could be used for e.g. exposure and risk assessments. Furthermore, it is suggested that the recommendations outlined in the previous section be adopted to effectively implement a pragmatic BNR.

The analysis did reveal that in many sectors there was difficulty in obtaining very accurate information on nanomaterials in products mainly because in many cases the information simply does not exist and the knowledge along the supply chain diminishes the farther away from the substance manufacturer a professional user is; this effect is compounded for importers that receive products from outside Belgium and in particular outside of the EEC. Furthermore, there is the issue of exposure: many professional users claim that they do not have nanomaterials because the substance is part of a matrix and there is no risk of exposure. Even with the active cooperation of some industry federations and companies from certain sectors, it is difficult to get a very accurate estimation of the number of NM-containing products, the number of potential companies affected, and the direct costs because the data is not available in an aggregated form and the extrapolation of individual company data to an entire sector creates uncertainty. Furthermore, the lack of a pragmatic definition of exposure for articles, created confusion for complex objects and led to high uncertainty in these estimations.

Costs, risks and benefits of inaction where briefly considered: while there are clearly identified costs and benefits of inaction for certain aspects (direct costs for industry, no impact on the EU internal market, the costs of the lack of better information, and the costs in establishing the information), the costs of failing to act in other aspects are better considered either from the political point of view (the required/accepted level of transparency) or in a strategic risk analysis and communication perspective (communication, dialogue, transparency, and their relations to the risk of the potential high costs of public distrust). It is highlighted that scientifically the present information gaps are to be translated into uncertainties in e.g. large scale exposure assessments or combined exposures from multiple products. Other potential costs of inaction were mentioned: potential confusion resulting from the presence of various scattered and/or databases that are not officially validated, difficulties with enforcement inspections, difficulties in health and safety surveillance, and when performing the compulsory workplace risk analysis, and also the difficulty for struggling against false claims.

The trends and relative comparison of the options outlined in this study are to the best of our knowledge valid. In order to improve the results of similar studies in the future, it is recommended that several possible scopes being presented, upon which a basic analysis is performed and selecting for example two major options to which the methodology employed in this study is applied.