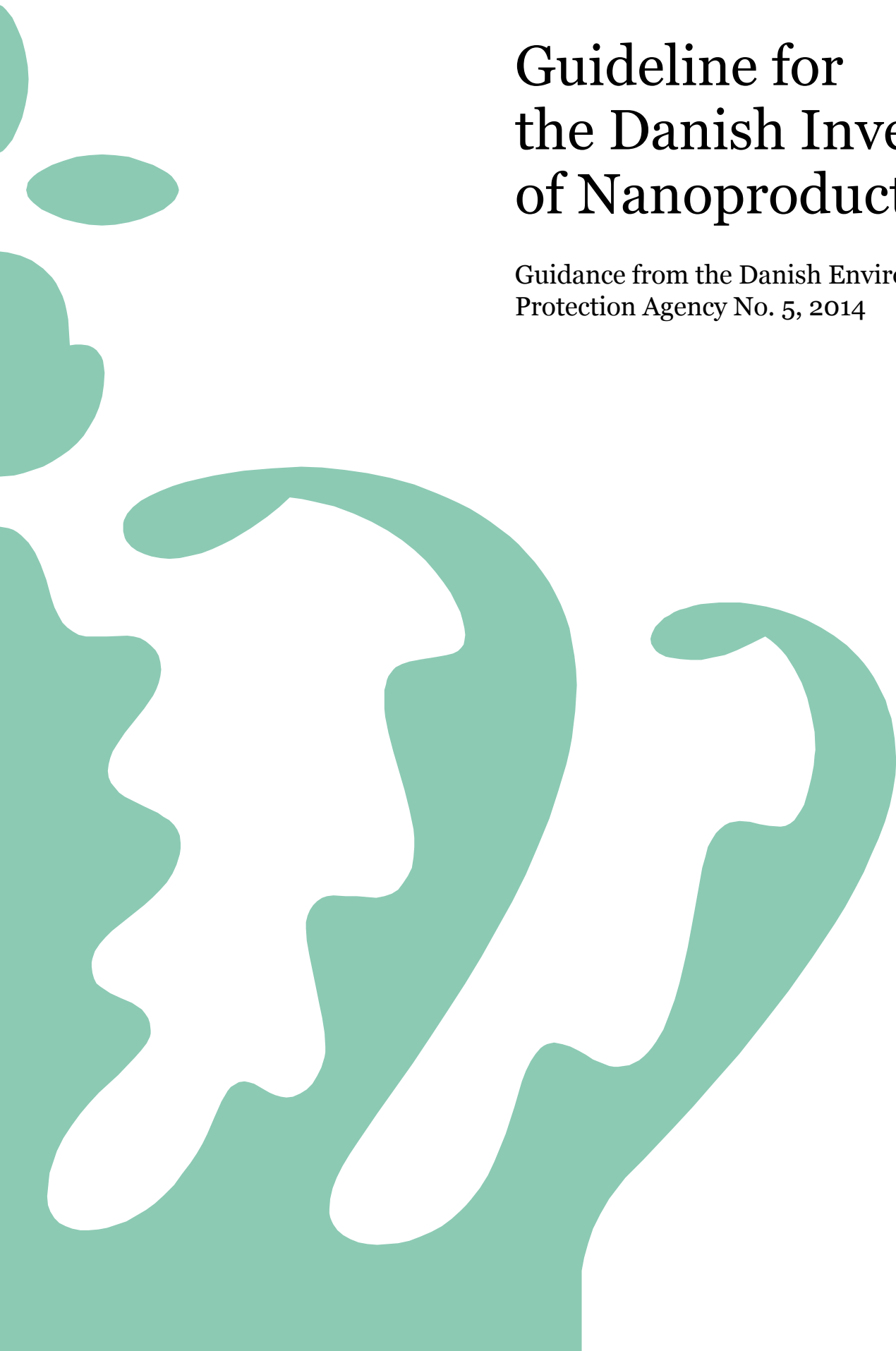




Danish Ministry of the Environment
Environmental Protection Agency

Guideline for the Danish Inventory of Nanoproducts

Guidance from the Danish Environmental
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Guideline for the Danish Inventory of Nanoproducts

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Sources must be acknowledged.

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Preface

The Danish Parliament has decided to establish an inventory of mixtures and products that contain or release nanomaterials. The legal framework for this inventory is described in Statutory Order no. 644 of 13 June 2014 on an inventory of mixtures and products that contain nanomaterials and the duty of manufacturers and importers to report to the inventory (referred to in the following as the Statutory Order on the Inventory of Nanoproducts). As described in this Statutory Order, companies in the Danish market which manufacture or import consumer products containing or releasing nanomaterials must report to the inventory.

These guidelines explain how manufacturers and importers of products for consumers should use the new inventory. The guidelines describe who has a duty to report; which products must be reported; as well as how to collect information and perform the actual reporting to the inventory, see Figure 1.

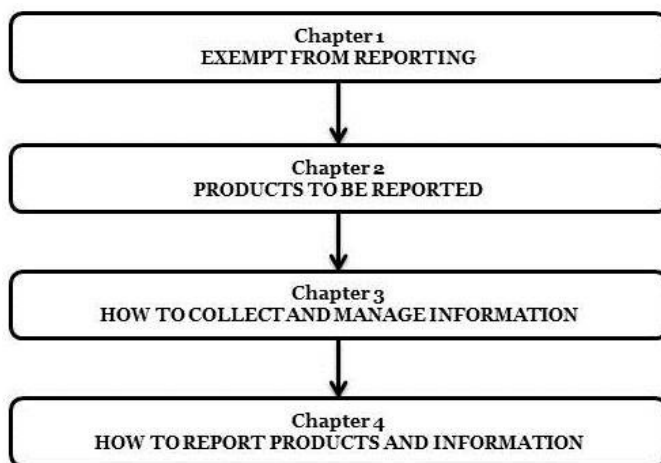


FIGURE 1
THE STRUCTURE OF THESE GUIDELINES REFLECTS THE STRUCTURE OF REPORTING TO THE INVENTORY OF NANOPRODUCTS.

In the event of discrepancies between these guidelines and the Statutory Order on the Inventory of Nanoproducts, the Statutory Order will prevail.

1. Do I have to report my product?

As a company¹, you should be aware that, in a number of areas, products are already covered by regulations which allow the authorities to keep an eye on nanoproducts in the Danish market. If your product is covered by these regulations, it may turn out that you do not have to report this product to the Inventory of Nanoproducts.

By answering a number of questions, you will be able to determine whether your company's products could be covered by the duty to report to the Inventory of Nanoproducts. A flow chart of these questions is in Figure 2 and they are described in more detail below.

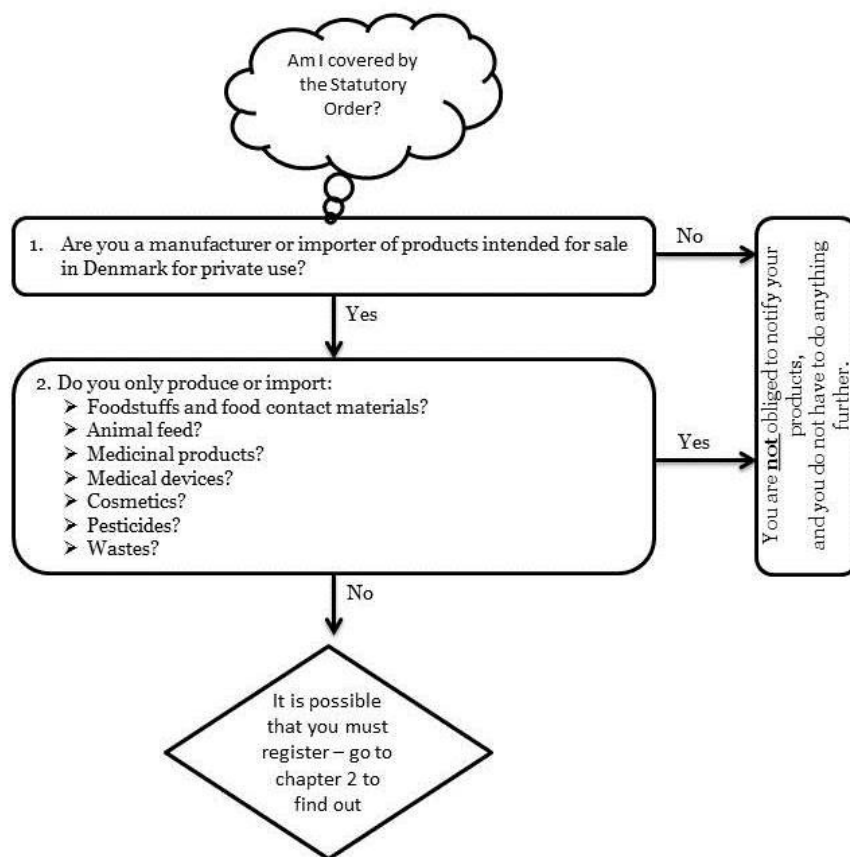


FIGURE 2
ARE YOUR PRODUCTS COVERED BY REGULATIONS ON REPORTING TO THE INVENTORY OF NANOPRODUCTS?

¹ The Statutory Order on the Inventory of Nanoproducts contains a provision (see section 3(2)) which provides that you do not have to report your products if you import or produce a nanoproduct as a private individual and for your own consumption.

1. Are you a manufacturer or importer of consumer products intended for sale in Denmark for private use?
"Importer" refers to the actual importer, i.e. the person or company that owns the product when the product crosses the Danish border. This is regardless of whether or not you have had the product in your physical possession at any given time.
If your product is used solely by professionals (and therefore not by private consumers), you can answer "no" to whether you are selling consumer products intended for sale for private use. This means that your product does **not** have to be reported to the Inventory (see section 2), and you do not have to do anything further.
2. Is your product covered by other regulations?
If you are a manufacturer or importer of only one or more of the following products (mixtures or articles), you are **not** obliged to report these (see section 3), and you do not have to do anything further:
 - 2.1. Foodstuffs and food contact materials
 - 2.2. Animal feed
 - 2.3. Medicinal products
 - 2.4. Medical devices
 - 2.5. Cosmetics
 - 2.6. Pesticides
 - 2.7. Waste.

If you are not exempt from these regulations, read on in the next Chapter to find out whether your products are nanoproducts that need to be reported to the Inventory.

2. Which products must be reported?

Follow the diagram in Figure 3 to decide whether your product must be reported. The diagram helps determine step-by-step whether your products are exempt from reporting. The individual questions are described in more detail in Annex 1. As a further help, this Chapter also contains an overview of fictitious examples of products to illustrate whether different types of product need to be reported. These examples are described in more detail in Annex 2.

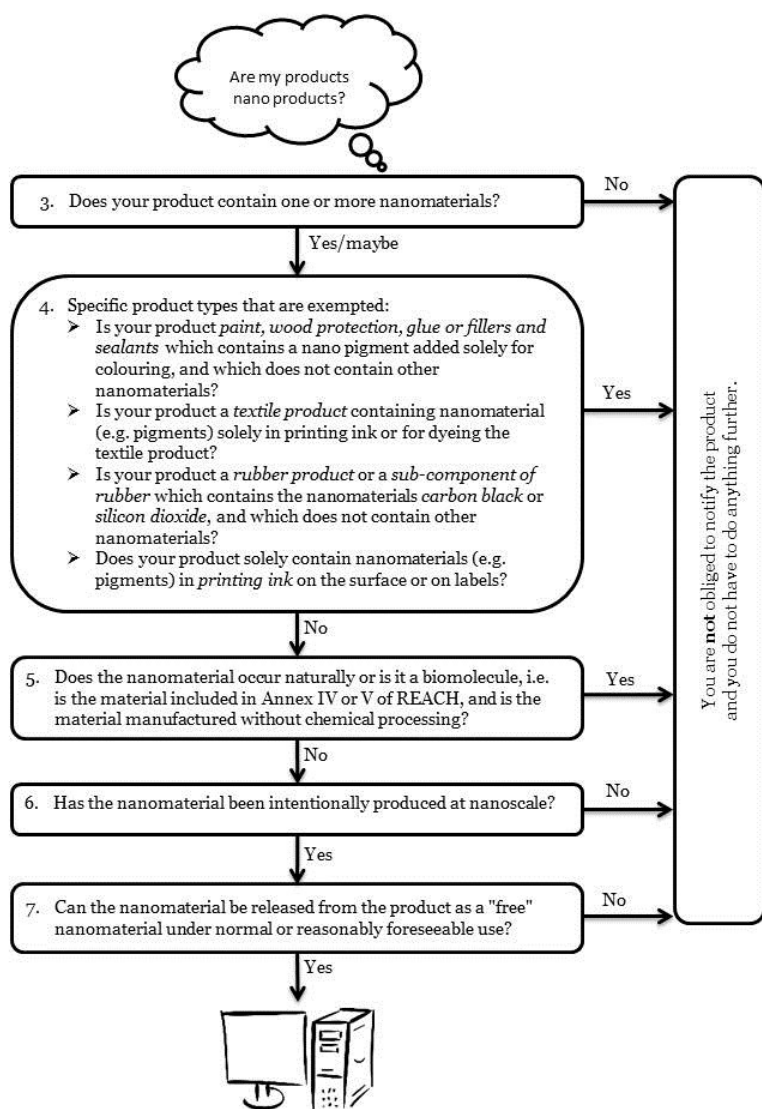


FIGURE 3
ARE MY PRODUCTS NANOPRODUCTS ACCORDING TO THE CRITERIA OF THE STATUTORY ORDER ON THE INVENTORY OF NANOPRODUCTS?

The questions follow a logical order which takes into account the relevance of the questions, asking the easiest questions first, as well as the questions that can quickly determine if your product is *not* covered by the obligation to report. This means that the last questions are the most difficult. However, you should note that, in some cases, the difficult questions will appear fairly early in the process. If this is the case, you can skip the question and assess whether your product is exempt from reporting on the basis of the remaining questions.

2.1 Examples of products

To assist you in interpreting and understanding the Statutory Order, Annex 2 contains examples of products which are subject to reporting as well as products which are not. The table below groups these examples of products in the same order as in figures 2 and 3.

Point	Examples
1. Products for export	1: Products for export
3. Does the product contain nanomaterials?	2: Coloured marker pens 3: Cleaning agents 4: Cleaning sponges 5: Laptops
4. Is the product covered by the exemption from reporting?	6: Self-cleaning paints 7: Paints 8: Car tyres
5. Does the nanomaterial appear naturally in the product?	9: Cement
6. Has the nanomaterial been intentionally manufactured?	9: Cement
7. Can the nanomaterial be released?	10: Self-cleaning windows 11: Self-cleaning roof tiles, other tiles/bricks etc. 12: Antimicrobial door handles 13: Marker pens (I) and (II) 14: Car polish 15: Antimicrobial cleaning cloths 16: Sports equipment 17: Painted fences 18: Drills

TABLE 1
EXAMPLES OF NANOPRODUCTS (SEE DETAILED OVERVIEW IN ANNEX 2).

3. Collecting data and documentation

The obligation to report entered into force on 20 June 2014. From this date, you must start to collect information about your nanoproducts so that you will be ready on 20 June 2015 to report to the Inventory for the year 2014. Reporting must take place once a year and no later than on 30 August.

3.1 How to collect information and data

In most situations, it will be easiest to collect the required data on the nanomaterials and your product continuously over the year, and preferably as you purchase your raw materials, sub components or your product.

In some situations, you will be able to get the required information from reading the safety data sheets on your raw material, sub component or product. If the safety data sheet does not contain the required information, you can contact your supplier for the information needed for your reporting. For example, you may send the covering letter and a form (see Annex 3) to your supplier to tell him which information you need.

You must keep a continuous check on the data and information that you collect. You can do this, for example, by entering this into a form so that you keep an account of each product that needs to be reported to the Inventory of Nanoproducts. It might be a good idea to register the data and information that you collect in a form that will allow you to directly insert them as answers to the Inventory's reporting parameters described in Annex 6.

In addition to keeping a check on the actual information, you also have the possibility of entering the reporting parameters in the Inventory of Nanoproducts on a continuous basis over the year as described in Chapter 4.

3.2 What should I do if I can't obtain the mandatory information?

There may be situations in which you, not for lack of trying, are unable to provide the mandatory information needed for your reporting. You can omit to report *some* mandatory information to the Inventory if it has proven impossible to obtain this information - or if the cost of obtaining the information is disproportionately high. However, you are required to document why it is impossible or disproportionately expensive to obtain the information, see section 5(5) of the Statutory Order on the Inventory of Nanoproducts.

3.2.1. What information can be omitted if it cannot be obtained?

The following information can be omitted:

- The name of the nanomaterial.
- How the nanomaterial is incorporated in the product.
- Whether the nanomaterial, or the substance from which the nanomaterial is made, is registered under REACH and, if so, whether there is information which the European

Chemicals Agency has approved as confidential pursuant to the confidentiality rules laid down in the REACH Regulation.

- The name of the chemical compound (IUPAC name).
- CAS number.
- EU number (EINECS/ELINCS/INCI).
- The formula.

It is not possible to omit reporting *all* of the above information. You *have to* report some of it.

An example of impossibility is when you have to obtain the information from a foreign supplier of a raw material, sub component or product, and your supplier refuses to pass on the information because he considers it a trade secret.

An example of disproportionately high costs of obtaining the information is when it requires very expensive analyses. The Statutory Order on the Inventory of Nanoproducts only includes an obligation to communicate information; not an obligation to perform analyses.

3.2.2. Documentation that the information could not be obtained

For each piece of information that you have omitted, you have to document that it is impossible, or associated with disproportionately high costs, for you to obtain the information. This means that you have to submit documentation for your efforts to obtain the information when you report.

This documentation could, for example, be attached copies of your letters, e-mails, follow-up on orders etc. to your suppliers in which you request information about possible nanomaterials - along with the replies from these suppliers declining to supply the information.

Whether this documentation is adequate or whether you could have done more to obtain the information will be subject to specific assessment by the Danish EPA. Amongst other things, the following aspects will be important for this assessment:

- The date you ordered the raw material, sub component or product from the supplier. If the order date is after entry into force of the regulations on reporting of nanoproducts, you ought to have included in your order to the supplier your questions about possible nanomaterials in the raw material, sub component or product. On the other hand, it may be difficult to obtain the information from the supplier about nanomaterials if the articles had already been ordered, paid for, produced and possibly even shipped before entry into force of the regulations.
- Whether you only have one order with the supplier in question, which means that your dealings with the supplier ended upon submission of the order, or whether you have ongoing collaboration with your supplier and receive a fixed range of products from him.
- If, on the other hand, you market the product as a nanoproduct, you are expected to report all of the required information to the Inventory. This is also the case if you have published product information about the nano-properties of your product on your website, or about the chemicals in your product in general.

3.2.3. Agreement with the supplier that the supplier can report information on your behalf in complete confidentiality

In order to ensure confidentiality, you can allow a supplier from abroad to report to the Inventory. You have to notify the Danish EPA that the reporting will be carried out by your foreign supplier. The supplier can then contact the Danish EPA through the website (www.mst.dk). The supplier will thus contact the Danish EPA directly (see also Chapter 4.5).

3.3 Reporting products in groups

If several products subject to reporting have the same application and the same nanomaterial(s) which make(s) them subject to reporting, then these products may be reported together as a group (group reporting). Different colours of self-cleaning paints are an example of such a group. Each of the individual paints is subject to reporting because of its contents of nanoscale titanium dioxide,

however, because of the possibility of group reporting, all of the paints can be reported together as a group.

Group reporting is described in more depth in Chapter 4.4.

3.4 Products that are already registered in the Danish Product Registry

Some of the information that needs to be reported to the Inventory of Nanoproductions overlaps with information that is already registered in the Danish Product Registry². If you know the registration number from the registration of your product in the Product Registry (the PR number), you can omit to provide the information already available to the authorities in the Product Registry. You do this by entering a copy of the reporting page which contains a field for reporting the PR number but which does not contain fields for reporting the information that is already in the Product Registry. The missing information will later be transferred from the Product Registry to the Inventory of Nanoproductions.

If you do not know the reporting number for the Product Registry, your supplier may be able to provide you with the reporting number.

3.5 Managing business secrets

Both the mandatory and the optional information that you report can be business secrets that require protection.

Normally, the Danish EPA considers the following information as business secrets, without you having to state separately that you consider it to be business secrets, see section 8(2) of the Statutory Order on the Inventory of Nanoproductions.

- Detailed information about the full composition of a mixture.
- The precise application or function of a nanomaterial or mixture.
- The precise quantity of the mixture manufactured or marketed.
- The relationship between a producer or importer and his distributors.

If there is other information that you consider a business secret, you have the option of stating this in connection with your reporting. Tick off the confidentiality field by the relevant piece of information. You must provide reasons in the comments field for why you consider the information a business secret, see section 8(1) of the Statutory Order on the Inventory of Nanoproductions.

Business secrets will be protected as follows:

- There is no public access to the Inventory. The Inventory and the employees with access to the Inventory are subject to security procedures.
- Only named employees in the Danish EPA and the Danish Working Environment Authority have direct access to the Inventory.
- Other authorities etc. may request information from the Inventory where appropriate for their work. In such events, the authorities in question will be made familiar with the security procedures applying to the Inventory Researchers etc. may be imposed with a duty of confidentiality by the Danish Public Administration Act and must moreover sign a statement of confidentiality in order to have access to the information.

² For further information on the Danish Product Register see on <http://engelsk.arbejdstilsynet.dk/en/Produktregistret.aspx>

The summary of the reported information that is published annually will not contain confidential information.

The Statutory Order on the Inventory of Nanoproducts does, however, allow for the publication of confidential information in situations that require immediate action to protect the environment or human health or safety, for example in an emergency situation.

In the event of a request for right of access to the Inventory, the Danish EPA must make a concrete assessment about passing on the requested information, however, subject to the provisions on protection of business secrets in the Danish Access to Public Administration Files Act, the Danish Public Administration Act and the Danish Environmental Protection Act.

3.6 Where can I find more help?

These guidelines are meant as guidance for manufacturers and importers to understand the Statutory Order on the Inventory of Nanoproducts, as well as a practical guide to reporting to the Inventory. In the event of discrepancies between the wording in these guidelines and the Statutory Order, the Statutory Order will apply at all times.

If you need more assistance or information about what and how to report, or about where and how to obtain the information needed for the reporting, from autumn 2014 there will be a help desk service available on the Danish EPA's website, just as there will be an FAQ.

4. How to register your product at virk.dk

Registration in the Inventory of Nanoproducs is through www.virk.dk. You log in with your employee signature. From here, you can find the reporting page of the Inventory of Nanoproducs by selecting the authorities tab (in Danish: *Myndigheder*). Having selected this tab, under "Stat" you will find the Danish EPA (in Danish: *Miljøstyrelsen*) under which you will find the Inventory (in Danish: *Nanoproduktregister*). You now have access to the IT system for reporting in the Inventory of Nanoproducs.

As long as you have not submitted your information, you will be able to resume a current reporting, edit already entered data, and copy data from earlier reporting.

The system indicates with a red asterisk (*) the information that is mandatory and which you are therefore required to fill in (read more in Chapter 3.2).

Guiding text explaining the individual reporting parameters will appear if you move your mouse over the text by the individual reporting field.

Figure 4 shows the entrance page to the system on virk.dk. The page has three overall sections (tabs) that can be accessed through the topmost menu bar:

- The **Start** tab contains a brief description of the Inventory, and here you will also find references to the Statutory Order on the Inventory of Nanoproducs and these guidelines.
- Under the **Registrant** tab, you must provide basic information about your company and enter one or more contact persons (see more in Chapter 4.1).
- Under the **Reporting** tab, you can begin reporting product or a group of products. Here you can also edit or delete products that have already been entered.

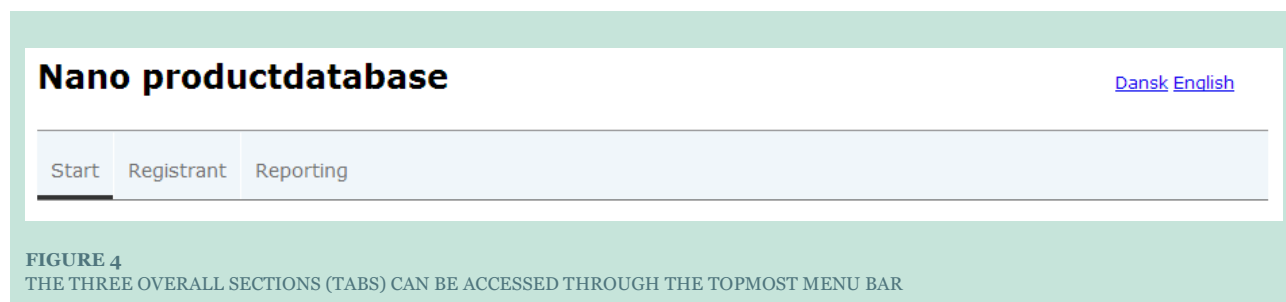


FIGURE 4
THE THREE OVERALL SECTIONS (TABS) CAN BE ACCESSED THROUGH THE TOPMOST MENU BAR

To exemplify the registration process, this Chapter shows screen dumps from registration of the fictitious product *Cleanly outdoor wood paint*. This is a self-cleaning paint (see example 6 in Annex 2), which contains titanium dioxide nanoparticles (AEROXIDE P25). AEROXIDE P25 is what gives this product its self-cleaning property.

4.1 Reporting registrant information

Under the registrant tab, most of the information about your company will be filled in automatically. Therefore, you only have to provide information about the size of your company in the topmost part of this tab. In the bottom part of the tab (see Figure 5) you can create, edit or delete one or more contact persons. You must provide a name and an e-mail address for each contact person. There has to be at least one contact person. When you have finished entering the information, click the save button and continue to the reporting tab.

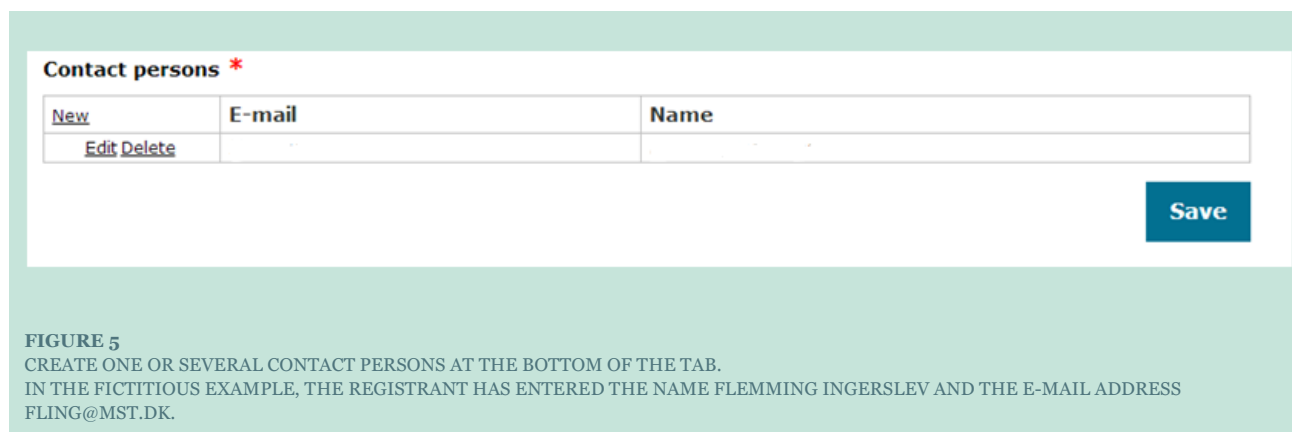


FIGURE 5
CREATE ONE OR SEVERAL CONTACT PERSONS AT THE BOTTOM OF THE TAB.
IN THE FICTITIOUS EXAMPLE, THE REGISTRANT HAS ENTERED THE NAME FLEMMING INGERSLEV AND THE E-MAIL ADDRESS FLING@MST.DK.

4.2 Reporting nanoproducts

Under the reporting tab, you state the information about your product(s) and the nanomaterials contained within each of them. This tab contains a number of subpages as illustrated in Figure 6. First, you gain access to an overview of the products you have already reported. For each product you have reported you have access to a product information tab. From here you have access to three sub tabs where you can enter information on the nanomaterials in your products.

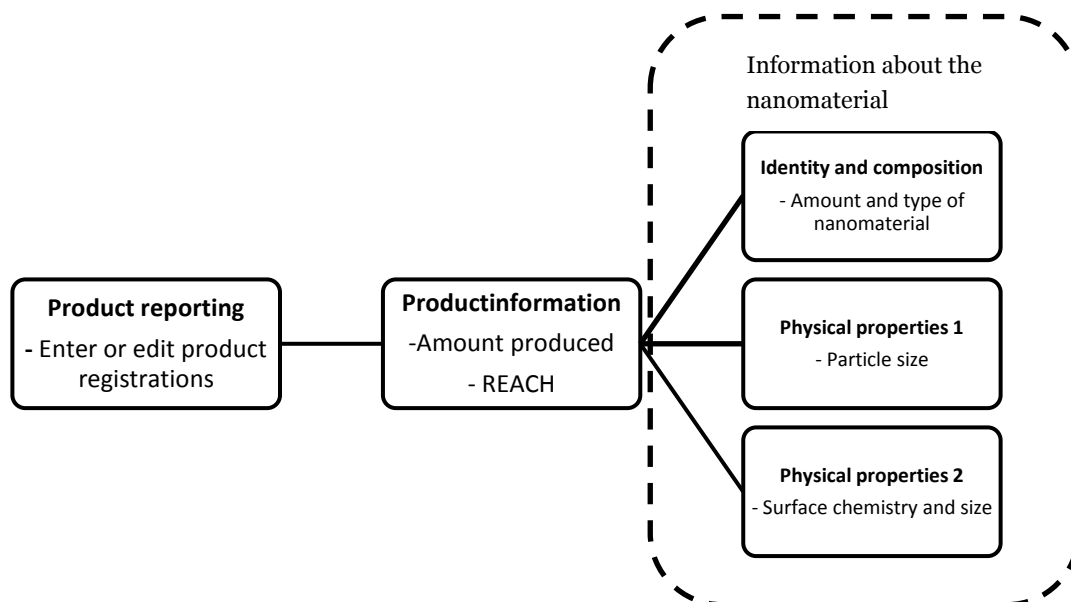


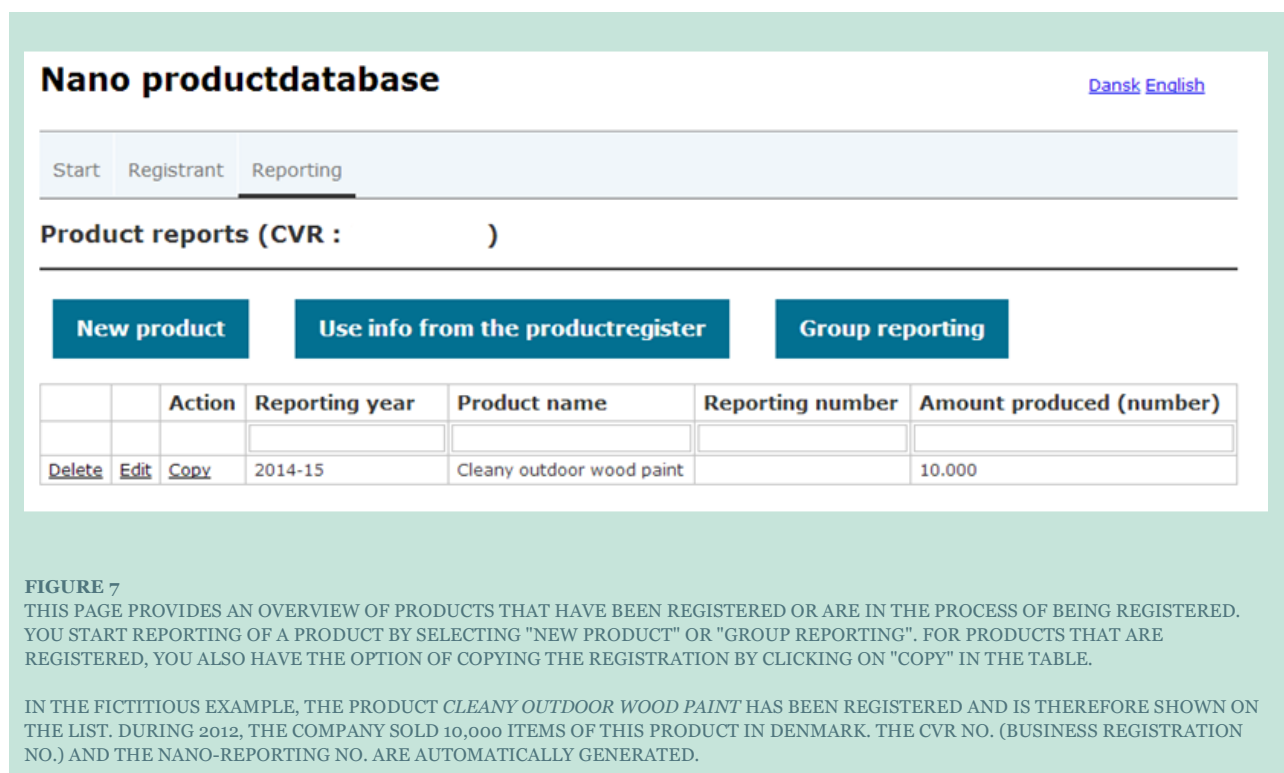
FIGURE 6
OVERVIEW OF THE REPORTING TAB.

4.2.1 Add, remove and edit reported products

From the product reporting tab, you can begin reporting a product or you can edit products that you are in the process of registering. Moreover, you can set up copies of products that have already been

reported. You can also perform group reporting. See how to report products in groups in Chapter 4.4. and in Annex 7.

If you select "New product" or "Edit" in the table (see Figure 7), you are automatically moved on to the product information sub page.



4.2.2 Reporting product information

At the product reporting tab you must enter general information about your product (see Figure 8). To the right is a check box which you can tick off to indicate whether the information is confidential. The information will then be treated as business secrets (read more about business secrets in Chapter 3.5). You are asked to add comments in the comments field to explain why you want the information to be kept confidential.

Reporting parameters are divided into two categories: a) The mandatory information **required** for each product that is covered by the obligation to report, and b) the optional information that **may** be submitted. The mandatory information is marked by a red asterisk (*).

Information about the nanomaterials contained in the product is registered by selecting "New" at the bottom of the table (see Figure 8). From here you will automatically be led to the "Information on the nanomaterial" sub page (see more on this in Chapter 4.2.3). If your product contains several nanomaterials, you will have to repeat this action several times. As long as you have not yet submitted the information, you can edit or delete information by selecting "Edit" or "Delete".

When you have entered the required information, you can save this by selecting "Save". Your data will not be registered in the inventory of Nanoproducts until you have clicked "Submit" (read more in Chapter 4.3).

Start Registrant **Reporting****Product reporting**

		Confident
Reporting year	2014-15	
Reporting number		
Product name *	Cleany outdoor wood paint	<input type="checkbox"/>
Produced amount (number of products) *	10.000	<input type="checkbox"/>
Professional use (Y/N) *	Yes	<input type="checkbox"/>
Produced or imported product	The product is imported to Denmark	<input type="checkbox"/>
Description of use *	Outdoor paint	<input type="checkbox"/>
Chemical category (REACH/PC)	Adhesives, sealants	
Environmental Release category (REACH/ERC)	Wide dispersive outdoor use of long-lif	
Process category (REACH/PROC)	Roller application or brushing	
Article category (REACH/AC)		

Content of nanomaterial in product

New	Delete	Edit	Chemical name	CAS number	Name of the nanomaterial	Amount of nanomaterial in product (gram)
			titanium dioxide	13463-67-7	Aeroxide TiO ₂ P25	

Register**Save****FIGURE 8**

YOU MUST ENTER GENERAL INFORMATION ABOUT YOUR PRODUCT IN THE REPORTING SUB TAB. THE MANDATORY INFORMATION IS MARKED BY A RED ASTERISK (*). TO THE RIGHT IS A CHECK BOX WHICH YOU CAN TICK OFF IF THE INFORMATION IS CONFIDENTIAL. THE TABLE AT THE BOTTOM OF THE PAGE SHOWS AN OVERVIEW OF THE NANOMATERIALS YOU HAVE ENTERED FOR THE SPECIFIC PRODUCT. THE TABLE ALLOWS YOU TO REGISTER A NEW NANOMATERIAL BY SELECTING "NEW" OR EDIT A NANOMATERIAL ALREADY SHOWING ON THE LIST.

IN THE FICTITIOUS EXAMPLE, THE INFORMATION ABOUT CLEANY OUTDOOR WOOD PAINT HAS BEEN ENTERED AND THE NANOMATERIALS CONTAINED IN THE PRODUCT HAVE ALREADY BEEN REGISTERED AND ARE THEREFORE SHOWN IN THE TABLE. CLEANY OUTDOOR WOOD PAINT CONTAINS NANOSCALE TITANIUM DIOXIDE, WHICH HAS CAS NO. 13463-67-7. THE TRADE NAME OF THE TITANIUM DIOXIDE APPLIED IS AEROXIDE TiO₂ P25, AND CLEANY OUTDOOR WOOD PAINT CONTAINS 50G OF THIS NANOMATERIAL.

4.2.3 Reporting information about the nanomaterial

The "Information on the nanomaterial" sub page contains three tabs (see Figure):

- "Identity and composition"
- "Physical properties 1"
- "Physical properties 2"

You can jump between the various tabs. This means you don't have to enter the information in a specific order. To the right is a check box which you can tick off to indicate whether the information is confidential. The information will then be treated as business secrets (read more about business secrets in Chapter 3.5). When you indicate that the information is to be kept confidential, a

comments field appears in which you are asked to explain why you want the information to be kept confidential.

Nano productdatabase [Dansk](#) [English](#)

Start | Registrant | Reporting

Information on the nanomaterial

Click on the headings below to give informations under each category:

<u>Identity and composition</u>	Physical properties 1	Physical properties 2
Name of the nanomaterial * <input style="width: 90%;" type="text" value="Aeroxide TiO2 P25"/>	<input type="checkbox"/> Not available	<input type="checkbox"/>
Is the substance registered under REACH? * <input style="width: 90%;" type="text" value="No"/>	<input type="checkbox"/> Not available	<input type="checkbox"/>
REACH registration number <input style="width: 90%;" type="text"/>		<input type="checkbox"/>
How that nanomaterial is in the product * <input style="width: 90%;" type="text" value="Liquid"/>	<input type="checkbox"/> Not available	<input type="checkbox"/>
Amount of nanomaterial in product (gram) <input style="width: 90%;" type="text"/>		<input type="checkbox"/>
Amount of nanomaterial in product (%) <input style="width: 90%;" type="text" value="1"/>		<input type="checkbox"/>
Chemical name <input style="width: 90%;" type="text" value="titanium dioxide"/>		<input type="checkbox"/>
CAS number * <input style="width: 90%;" type="text" value="13463-67-7"/>	<input type="checkbox"/> Not available	<input type="checkbox"/>
IUPAC name * <input style="width: 90%;" type="text" value="dioxotitanium"/>	<input type="checkbox"/> Not available	<input type="checkbox"/>
EINECS number (EU-number) * <input style="width: 90%;" type="text" value="236-675-5"/>	<input type="checkbox"/> Not available	<input type="checkbox"/>
Chemical formula * <input style="width: 90%;" type="text" value="TiO2"/>	<input type="checkbox"/> Not available	<input type="checkbox"/>

Save

FIGURE 9

THE "INFORMATION ON THE NANOMATERIAL" SUB PAGE IS SPLIT INTO THREE GROUPS. THE MANDATORY INFORMATION IS MARKED BY A RED ASTERISK (*). TO THE RIGHT IS A CHECK BOX WHICH YOU CAN TICK OFF IF THE INFORMATION IS CONFIDENTIAL.

IN THE FICTITIOUS EXAMPLE, THE INFORMATION UNDER "IDENTITY AND COMPOSITION" HAS BEEN ENTERED. CLEANY OUTDOOR WOOD PAINT CONTAINS THE NANOMATERIAL AEROXIDE TiO₂ P25 WITH THE CHEMICAL NAME *TITANIUM DIOXIDE*, CAS NO. 13463-67-7, IUPAC NAME *DIOXOTITANIUM* AND EINECS NO. 236-675-5. CLEANY OUTDOOR WOOD PAINT CONTAINS 50G OF THE NANOMATERIAL, CORRESPONDING TO 1% OF THE TOTAL MASS OF THE PRODUCT (5L).

4.3 Submitting data

As long as you have not submitted your information, you will be able to resume a current reporting, edit already entered data and copy data from earlier reporting. You finalise your reporting by selecting "Submit", and until you have done so, you are able to change, add and delete your data in www.virk.dk. Note that you can only submit your reported information if all of the mandatory fields (marked by a red asterisk) have been completed.

Once you have submitted your data, you will see a confirmation that data has been submitted and your registration number will be provided. This same confirmation will be sent to the e-mail adresse(s) you have stated under your contact information. **Once data has been submitted, it**

can no longer be changed. Only the Danish EPA can change data following a request from the company.

4.4 Group reporting

If you have many products or if you have products that are almost identical, you may want to use the group reporting function. With this function you can create an XML file with all the relevant information and then upload this file to the system. A technical description of how this works is given in Annex 7.

4.5 Reporting the confidential information of foreign manufacturers/suppliers

There may be situations in which a foreign manufacturer or supplier of a product does not want to pass on all information about the product to the Danish vendor, because some of the information constitutes business secrets. In these situations, the Danish company may make arrangements for the foreign manufacturer/supplier itself, or its representative in the EU, to report the information directly to the Inventory of Nanoproducts. In this case, the Danish company must inform the Danish EPA that the foreign manufacturer/supplier will report the information in question directly to the Inventory. The manufacturer/supplier must then approach the Danish EPA and report the information which it wants to keep secret.

Annex 1: Detailed review - Which products must be reported?

This Annex contains details about the questions asked in Chapter 2. Chapter 2 explains how to assess whether your product is a nanoproduct. The enumeration of the headings below matches the enumeration of questions in Figure 3.

3. Does your product contain one or more nanomaterials (see section 2 of the Statutory Order)?

Whether or not you need to report your product depends primarily on whether it contains nanomaterials. This is not always an easy question to answer, but in many cases answering this question can exclude a large number of products from the duty to report. This means that if you are certain right away that no nanomaterials are contained in your product, you do not have to do anything further.

In popular terms, nanomaterials are tiny particles that may have been added to your product in the same way that many other types of substance are added to a product to achieve new or improved properties. A formal definition of a nanomaterial is given in the box below. In simple terms, this definition means that if your product contains a material in particle form and if half of these particles are of a size that is less than 100nm, then your product is a nanoproduct. The duty to report has no minimum limit for the percentage the nanomaterial represents of the total product.

The European Commission's recommended definition of nanomaterial

Nanomaterial (implemented by section 4, no. 1, of the Danish Statutory Order on the Inventory of Nanoproducts)

'Nanomaterial' means a natural, incidental or manufactured material containing particles, in a free 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 1nm-100nm.

'Particle', 'agglomerate' and 'aggregate' are defined as follows: (implemented by section 4, nos. 2-4 of the Danish Statutory Order on the Inventory of Nanoproducts)

- (a) 'particle' means a minute piece of matter with defined physical boundaries;
- (b) 'agglomerate' means a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components;
- (c) 'aggregate' means a particle composed of strongly bound or fused particles.

COMMISSION RECOMMENDATION of 18 October 2011 on the definition of a nanomaterial (2011/696/EU)

Please note that the definition is based on the number size distribution. This means that if 50% or more of the number of particles contained in the material are at nanoscale, the material will, by this definition, be a nanomaterial. Particle size is often measured by either volume or weight, but these measures cannot be applied here. Because the definition is based on number of particles rather than on volume or weight, a far greater number of materials actually fall within the definition of a nanomaterial.

As a matter of fact, quite a lot of chemical substances fall within this definition, including substances that are widely used today and that have not previously been considered nanomaterials. These include a great number of colouring agents (pigments), fillers and extenders in paints and much more. It contains descriptions of a number of widely applied nanomaterials. Several of these are used both in large form and in nano-form, so although the material is on the list, the version of it in your product is not necessarily a nanomaterial.

The box below lists the most common aspects that you need to be aware of when you assess whether there are nanomaterials in your products. Examples are given. For example, a nanomaterial is a solid substance, that is, not droplets or micelles, and nanostructured materials are therefore not considered nanomaterials if the surface or the particle is greater than 100nm. However, if your product contains a solid material which has one or more dimensions that are less than 100nm, then this material is a nanomaterial and you should therefore move on to question 4 in Figure 3.

Examples of nanomaterials and examples of substances that are not nanomaterials

Only solid materials can be nanomaterials. This means, for example, that **the following are considered nanomaterials:**

- Powders with nano-objects, i.e. with nanoparticles, nano-flakes, nanofibres, or aggregates and agglomerates of nano-objects (e.g. fillers and extenders in cement and mortar products).
- Nanosuspensions, i.e. solid nano-objects in a liquid (e.g. pigments in paints).
- Nano-aerosols, i.e. solid nano-objects in an aerosol or an aerosol with solid nano-objects in the droplets of liquid (e.g. pigments in spray products).
- Nanocomposites, i.e. a solid material with nano-objects distributed in the matrix (e.g. fillers, extenders and/or pigments in plastic products).

Examples of materials that are **not considered nanomaterials:**

- Internally nanostructured particles larger than 100nm (e.g. core-shells and capsules).
- Nanostructured surfaces, nanoporous materials and nanofoam (e.g. the nanostructured surface of a computer chip).

4. Specific product types exempt from reporting

Specific products that meet certain specific criteria are exempt from the Inventory. These include:

Paints, wood preservatives, adhesives, fillers and sealants (section 3(1), no. 13) which contain nanoscale pigments. If the pigments have been added solely to apply colour to the product, then the product is exempt from reporting. However, if there are other nanomaterials in the product which are not pigments, or which were added for other reasons than to apply colour (for example nanoscale fillers or nanoscale titanium dioxide added for photocatalytic properties), then the product cannot be exempted and you should move on to the next question.

Textile products (section 3(1), no. 12) are exempt if the nanomaterial is used as a printing ink or to

dye the textile. The typical materials exempted here are pigments. If the fabric contains other nanomaterials, or if the purpose of the material is not solely to add colour to the surface of the fabric or to dye it, then you must report the product.

Rubber products or products with rubber sub components (section 3(1), no. 14) are exempt if the only nanomaterials in the products are carbon black or silicon dioxide. A rubber product could be an O-ring, a membrane, a tyre or a rubber tube, while a rubber sub component could be the same products, however, included as sub components in another product. For example, an O-ring in a vacuum pump is a *rubber sub component* in the pump. Similarly, a bicycle tyre or a bicycle inner-tube are *rubber sub components* of a bicycle.

These are specific relationships that can influence whether your product is exempt or not.

Therefore, you should ask your supplier whether your product specifically contains:

- carbon black with EINECS no. 215-609-9, or
- silicon dioxide with the EINECS nos. 231-545-4, 262-373-8, 238-455-4, 238-878-4 and 239-487-1 or the CAS nos. 13778-37-5, 13778-38-6 and 17679-64-0.

If the product of rubber, or with a rubber sub component, contains other nanomaterials than these specific ones, then it is not exempt from reporting and you should move on to the next item.

Products with a nanomaterial (e.g. pigment) in the printing ink on the surface of the product or on the label on the product (section 3(1), no. 11) are exempt from reporting. Printing inks and other printing materials often contain nanoscale pigments, however magazines and newspapers can often be exempted if they only contain nanomaterials in the printing ink. If the paper itself is coloured, then the product is not exempt and must be reported to the Inventory. This also applies to packaging materials, for example. Packaging material products must be reported if the material itself is coloured, however if it is only the print on the surface of the material that contains a nanomaterial, or a label on the packaging, then the product is exempt and does not have to be reported.

If your product is not exempt from reporting due to one of the above conditions, then you should move on to item 5.

Remember that your product will not be exempt from reporting if it contains other nanomaterials than those specifically stated above as leading to exemption. So, if this is the case, you should also move on to the next item.

5. Products with nanomaterials that are naturally occurring or biomolecules

A naturally occurring nanomaterial or biomolecule means a nanoscale material which is listed in Annexes IV and V of the REACH Regulation 3 (see the box below). Nanomaterials modified through chemical treatment or processed in some other way (for example refined titanium dioxide (sulphate or chloride process) or surface-treated particles) are not considered naturally occurring or biomolecules.⁴ Products that contain these chemically modified nanomaterials therefore have to be reported to the Inventory. Materials that have been mechanically processed (for example grinding, screening, centrifuging, floatation, etc.) are exempt, because these are not chemical processes and because the nanomaterial is therefore still considered the same naturally occurring material or biomolecule.

³"Substances which occur in nature" means "a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means" (Article 3(39) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)).

⁴"Not chemically modified substance" means "a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities" (Article 3(40) of the REACH Regulation of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)).

Natural substances which, as a general rule, are exempted from REACH

Annex IV: Biomolecules, inert gases etc.

Annex IV contains a long list of substances that are exempted from the obligation to report. These substances can be divided into the following overall groups: Triglycerides, fatty acids, fatty acid methyl esters (FAME), water, monosaccharides, disaccharides, starch and inert gases.

For the complete list of see COMMISSION REGULATION (EC) No 987/2008 (<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:268:0014:0019:EN:PDF>).

Annex V: Substances which occur in nature and which are not chemically modified

Annex V contains a list of naturally occurring substances such as minerals, ores, ore concentrates, raw and processed natural gas, crude oil and coal.

Minerals have been assessed to be of primary relevance for exemption from reporting to the Inventory of Nanoproducts. Minerals are solid, inorganic substances that can vary in composition from pure chemical elements over simple salts to very complex silicates.

For a more in-depth explanation, see the European Chemicals Agency's (ECHA) "Guidance for Annex V Exemptions from the obligation to register" from November 2012 (http://echa.europa.eu/documents/10162/13632/annex_v_da.pdf).

6. Has the nanomaterial been intentionally manufactured at nanoscale?

Section 3(1), no.9, of the Statutory Order on the Inventory of Nanoproducts exempts products from reporting if the nanomaterial contained in the product has not been intentionally manufactured. Therefore, the next step is to determine whether this is the case for your nanomaterial(s) (item 6, figure 3). First, you must find out whether your nanomaterial(s) is/are intentionally produced in the nanoscale size, in order to give the material special properties.

You should apply an interpretation corresponding to the approach in ISO for defining "engineered nanomaterials" when determining whether your nanomaterials have been intentionally manufactured. According to this interpretation, materials that achieve new or significantly improved properties when used in nano-form (i.e. properties which the material does not have when used as larger objects) are considered to have been intentionally manufactured.

The new or improved properties could be transparency, enhanced colouring/dyeing power, enhanced dispersibility, and antimicrobial properties. Some of these properties are achieved exclusively because of the high surface-to-volume ratio of the nanomaterial. The effect is therefore greater when you use nanoparticles than microparticles, for example.

A material can have been *unintentionally* manufactured at nanoscale, for example through ordinary grinding processes. In this case the material does not obtain special properties due to its size and is therefore exempt from reporting. However, a material will have been *intentionally* manufactured at nanoscale if it is purified or in some other way separated according to size or weight, etc. Products containing this type of material will be covered by the obligation to report, because the intention of using the particles is to achieve the specific properties of the nanoparticles.

7. Are nanomaterials released to the environment or consumers under normal conditions of use?

Section 2 of the Statutory Order on the Inventory of Nanoproducts states that a product must be reported to the Inventory if:

- (i) the nanomaterial is released during normal or reasonably foreseeable use of the mixture or article, and/or
- (ii) the nanomaterial itself is not released but may release substances in soluble form that are classified as CMR substances or as hazardous substances.

The release of the nanomaterial can be a part of the function of the product (for example, the colour pigment from a marker pen), however the release can also be from wear and other foreseeable events or if the product is broken. By (i) is meant that the nanomaterial added to/contained within the product can be released from the product. If the product contains free nanoparticles which may be released during use, wash, wear, or if the product accidentally breaks, then the product is covered by the obligation to report. However, if the product can only release the nanomaterials with part of the matrix (for example, with a carrying material, so that the nanomaterials are bound in another material), or if nanomaterials are released which originate from the matrix but which are not the originally added nanomaterials, then this is not considered a release of the originally added nanomaterial, see section 2 of the Statutory Order on the Inventory of Nanoproducts, and the product is therefore not covered by the obligation to report. For example, this applies to varnished surfaces (both with and without added nanomaterials) where sanding of the varnish results in sanding dust. However, because the sanding dust consists of the paint matrix (not just the added nanomaterials as free particles), then the painted product does not have to be reported. On the other hand, liquid products with nanomaterials must be reported, because the nanomaterials are not bound in the liquid matrix and can therefore be released during handling and use of the product.

Sentence (ii) refers to specific nanomaterials which cause the release of a substance from the product that is classified as environmentally hazardous in Acute Category 1 or Chronic Categories 1-4, or as a CMR substance. This could be an antimicrobial product with nanosilver or nano-zinc which releases silver or zinc ions. For more on how chemical substances in general are classified, go to the following fact sheet: <http://eng.mst.dk/topics/chemicals/legislation-on-chemicals/fact-sheets/fact-sheet-classification-labelling-and-packaging-the-clp-regulation/> .

Annex 2: Examples of products

Below are examples of products, including descriptions of whether the product needs to be reported or not, and why.

1 - Products for export

Example of product

You are the manufacturer of a product that contains nanomaterials. The product is produced exclusively for export.

Considerations

Because your product is exclusively being exported and therefore is not traded in Denmark, the product need **not** be reported to the Inventory of Nanoproducts.

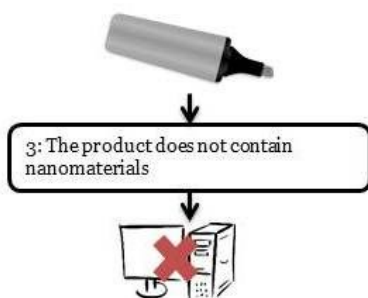
2 - Coloured marker pens

Example of product

You are the importer of a coloured marker pen with a felt tip.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine whether your product contains nanomaterials that cause your product to be covered by the obligation to report, and you should move on to Figure 3 in these guidelines.



Item 3. After having studied the safety data sheet and been in contact with your supplier, you have ascertained that your coloured marker pen contains a soluble colouring agent. This means the definition of a nanomaterial has not been met.

For this reason, you need **not** report your product to the Inventory of Nanoproducts, and therefore you do not have to do anything further.

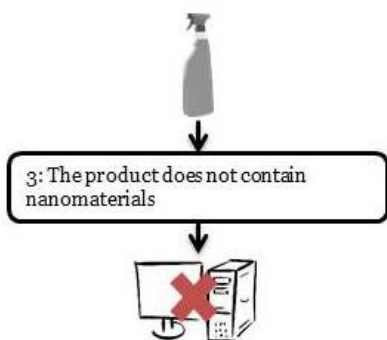
3 - Cleaning agent

Example of product

You are the importer of a liquid cleaning agent.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine



whether your product contains nanomaterials that cause your product to be covered by the obligation to report, and you should move on to Figure 3 in these guidelines.

Item 3. Your supplier has informed you that your cleaning agent is an emulsion with nanodroplets. Nanoemulsions are not considered nanomaterials according to the definition (see Table 1), because the droplets are liquid objects.

For this reason, you need **not** report your product to the Inventory of Nanoproducts, and therefore you do not have to do anything further.

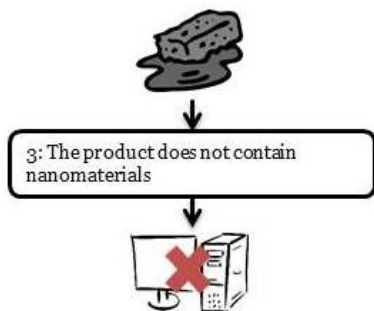
4 Cleaning sponge

Example of product

You are the importer of a cleaning sponge with a nanostructured surface.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine whether your product contains nanomaterials that cause your product to be covered by the obligation to report, and you should move on to Figure 3 in these guidelines.



Item 3. The cleaning sponge has a surface with structures at nanoscale. This is a nanostructured surface which does not fall within the definition of a nanomaterial (see Table 1).

For this reason, you need **not** report your product to the Inventory of Nanoproducts, and therefore you do not have to do anything further.

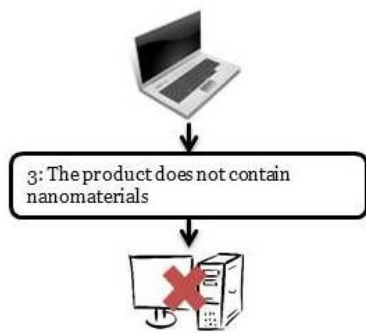
5 - Laptop

Example of product

You are the importer of a portable computer.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine whether your product contains nanomaterials that cause your product to be covered by the obligation to report, and you should move on to Figure 3 in these guidelines.



Item 3. After having studied the product specifications (and possibly also having received confirmation from your supplier), you have ascertained that your laptop contains a 32-nanometer processor with a nanostructured surface. Nanostructured surfaces are not covered by the definition.

For this reason, you need **not** report your product to the Inventory of Nanoproducts, and therefore you do not have to do anything further.

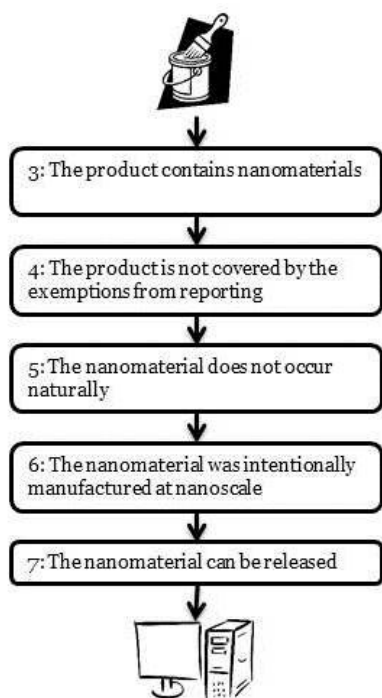
6 - Self-cleaning paint

Example of product

You are the importer or manufacturer of a paint product with self-cleaning and dirt-repellent properties. Buyers of your product can use the paint to treat a wall, a brick wall or woodwork, etc. The product is sold to both private consumers and professionals.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine whether your product contains nanomaterials that cause your product to be covered by the obligation to report (i.e. Figure 3).



Item 3. After having been in contact with your supplier, you have found out that your product contains nanoscale titanium dioxide with an anatase crystal structure that meets the definition of a nanomaterial in the Statutory Order on the Inventory of Nanoproducts (see the EU's recommended definition of a nanomaterial), and that it is the titanium dioxide which gives your product its self-cleaning properties. The supplier also informed you that your product does not contain any other nanomaterials. You have now determined that the product contains a single nanomaterial, which means you can answer "Yes" to item 3 in Figure 3.

Item 4. The nanoscale titanium dioxide was not added exclusively to give colour to the paint product; it was also added to provide it with self-cleaning properties. Furthermore, the other provisions regarding textile products, printing inks and rubber products are not relevant. Therefore, your product does not fall within the range of specific product

types that are exempt from reporting, and you should move on to the next item.

Item 5. The titanium dioxide was manufactured through a chemical process, and the titanium dioxide used can therefore not be said to be naturally occurring.

Item 6. The titanium dioxide is assessed to have been intentionally manufactured at nanoscale in order to achieve as large a surface area as possible and thus enhance the self-cleaning properties. You should therefore continue to the next item.

Item 7. Your paint product is liquid upon application. If consumers get paint on their skin while applying the paint, they are exposed to the nanomaterial through direct contact with the skin and, therefore, it cannot be ruled out that the nanomaterial can be released during normal use of the product.

The overall conclusion is that this product **must be reported** to the Inventory of Nanoparticles. Read about how to obtain and manage information and how to report it in Chapter 3.

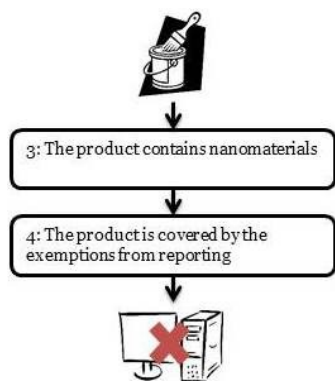
7 - Paint

Example of product

You are the manufacturer of a paint product with pigments. Buyers of your product can use the paint to treat a wall, a brick wall or woodwork, etc.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoparticles (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoparticles. You therefore have to determine whether your product contains nanomaterials that cause your product to be covered by the obligation to report (i.e. Figure 3).



Item 3. After having been in contact with your supplier, you have ascertained that one or more of the pigments meet the definition of a nanomaterial. The paint contains no fillers, extenders or other components at nanoscale which occasion an obligation to report the product. You should continue to the next item.

Item 4. The added pigments have been added exclusively to colour the product and there are no other nanomaterials in your product. Because paint products with added nanoscale pigments exclusively to colour the paint are specifically exempt from reporting,

your paint does not have to be reported to the Inventory of Nanoparticles.

For this reason, you need **not** report your product to the Inventory of Nanoparticles, and therefore you do not have to do anything further.

8 - Car tyres

Example of product

You are the importer of car tyres containing carbon black.

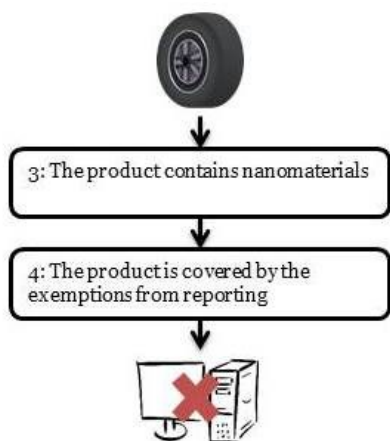
Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine

whether your product contains nanomaterials that cause your product to be covered by the obligation to report, and you should move on to Figure 3 in these guidelines.

Item 3. After having studied the safety data sheet and been in contact with your supplier, you have ascertained that the carbon black applied meets the definition of a nanomaterial. The supplier also informed you that your product does not contain any other nanomaterials, and therefore you should continue to the next item.

Item 4. Your product is a rubber product which only contains the nanomaterial carbon black. Because rubber products with added nanoscale carbon black are specifically exempt from reporting, the tyre does not have to be reported to the Inventory of



Nanoproducts.

For this reason, your product need **not** be reported to the Inventory of Nanoproducts, and you do not have to do anything further.

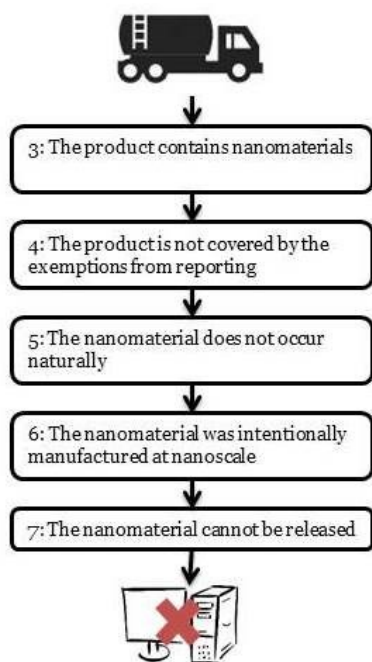
9 - Cement

Example of product

You are the importer of a cement product in powder form.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine whether your product contains nanomaterials that cause your product to be covered by the obligation to report, and you should move on to Figure 3 in these guidelines.



Item 3. After having been in contact with your supplier, you have ascertained that the product contains the fillers calcium carbonate and silicon dioxide, and that both of these materials meet the definition of a nanomaterial. The supplier also informed you that your product does not contain any other nanomaterials, and therefore you should continue to the next item.

Item 4. Because your product does not fall within any of the mentioned product groups, you should continue to the next item.

Item 5. Calcium carbonate is a naturally occurring mineral. Calcium carbonate is included in Annex V of the REACH Regulation, and since the calcium carbonate applied in your product was manufactured through an ordinary grinding process and was not subsequently chemically processed, then this material is exempt from reporting. This means that the content of calcium carbonate in your cement product does not have to be

reported to the Inventory of Nanoproducts.

Item 6. Nanoscale silicon dioxide has been used in cement for decades, and this material was not added to your product because of its nano-form but because of other properties that the material possesses, even when it is not in nano-form. The applied silicon dioxide was therefore not intentionally manufactured at nanoscale, which means the content of silicon dioxide in your cement product does not have to be reported to the Inventory of Nanoproducts.

For this reason, your product need **not** be reported to the Inventory of Nanoproducts, and you do not have to do anything further.

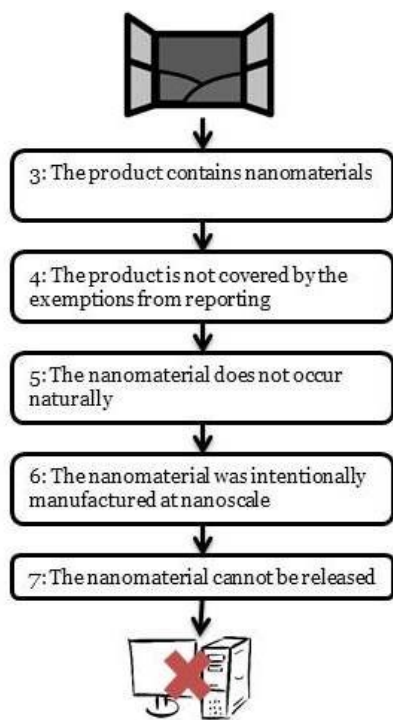
10 - Self-cleaning windows

Example of product

You are the importer of a window or glazing with self-cleaning properties. The product is marketed to private consumers.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine whether your product contains nanomaterials that cause your product to be covered by the obligation to report, and you should move on to Figure 3 in these guidelines.



Item 3. After having been in contact with your supplier, you have ascertained that the self-cleaning property of your product is due to a titanium dioxide surface, and that nanoparticles were used to make this surface, which means the definition of a nanomaterial has been met. The supplier also informed you that your product does not contain any other nanomaterials, and therefore you should continue to the next item.

Item 4. Because your product does not fall within any of the mentioned product groups, you should continue to the next item.

Item 5. The titanium dioxide was manufactured through a chemical process, and the titanium dioxide used can therefore not be said to be naturally occurring.

Item 6. The titanium dioxide is assessed to have been intentionally manufactured at nanoscale in order to achieve as large a surface area as possible and thus enhance the self-cleaning properties. The nanomaterial was therefore intentionally manufactured at nanoscale.

Item 7. Processing of the window means that the titanium dioxide is bound in a layer on the surface of glazing. The nanomaterial is therefore not likely to be released from the product during use or if it breaks.

For this reason, you need **not** report your product to the Inventory of Nanoproducts, and therefore you do not have to do anything further.

11 - Self-cleaning roof tiles, other tiles/bricks etc.

If you are the manufacturer or importer of self-cleaning construction products, such as roof tiles or similar with self-cleaning properties based on titanium dioxide, you should follow the self-cleaning-window example above which follows the same outline. Because the nanomaterial giving the product its self-cleaning properties is bound in a solid matrix in the surface, the product is exempt from reporting (see the detailed description of item 7 in Section 7 of Annex 1).

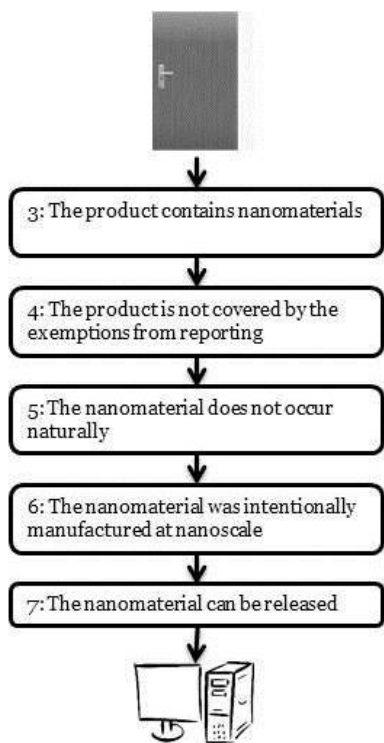
12 - Antimicrobial door handles

Example of product

You are the importer of an antimicrobial door handle, the antimicrobial properties of which stem from a coating which contains silver.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine whether your product contains nanomaterials that cause your product to be covered by the obligation to report, and you should move on to Figure 3 in these guidelines.



Item 3. After having been in contact with your supplier, you have ascertained that the silver used meets the definition of a nanomaterial. The supplier also informed you that your product does not contain any other nanomaterials, and therefore you should continue to the next item.

Item 4. Because your product does not fall within any of the mentioned product groups, you should continue to the next item.

Item 5. The silver used has been purified and manufactured in a chemical process and is therefore not a naturally occurring material.

Item 6. The silver used is assessed to have been intentionally manufactured at nanoscale in order to achieve as large a surface area as possible and thus enhance the antimicrobial properties. The silver was therefore intentionally manufactured at nanoscale.

Item 7. The antimicrobial properties stem from silver ions that are released from the surface of the product. Silver ions are among the substances in soluble form that have been classified, and you should therefore continue

to the next item.

For this reason, your product **must be reported** to the Inventory of Nanoproducts. Read about how to obtain and manage information and how to report it in Chapter 3.

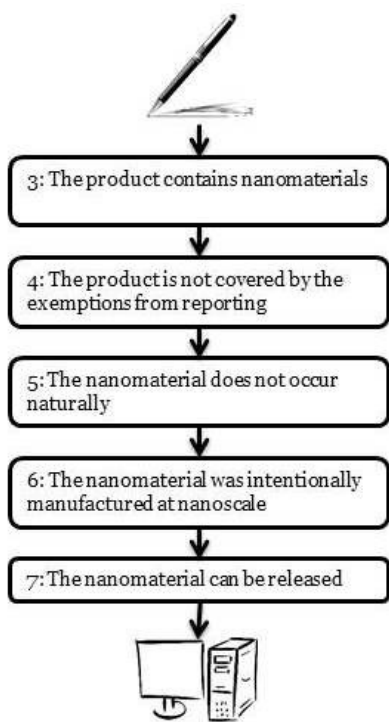
13 - Marker pens (I)

Example of product

Your are the importer of a marker pen.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine whether your product contains nanomaterials that cause your product to be covered by the obligation to report, and you should move on to Figure 3 in these guidelines.



Item 3. After having studied the safety data sheet and been in contact with your supplier, you have ascertained that your marker pen contains a nanoscale pigment (carbon black), which means the definition of a nanomaterial has been met and you should continue to the next item.

Item 4. Because your product does not fall within any of the mentioned product groups, you should continue to the next item.

Item 5. Carbon black is not a naturally occurring material and it is therefore not included in the Annexes to the REACH Regulation. You should therefore continue to the next item.

Item 6. Carbon black nanopigments are used to improve dispersion of the colour pigments in the liquid ink, and the carbon black in your product was therefore intentionally manufactured at nanoscale.

Item 7. Because the pigments are transferred from the marker pen to a surface, the nanomaterial can be released during normal

use of the product.

For this reason, your product **must be reported** to the Inventory of Nanoproducts. Read about how to obtain and manage information and how to report it in Chapter 3.

Marker pens (II)

Your product is a marker pen similar to the product under Marker pens (I). However, in this example, your marker pen also contains a nanoscale pigment in the plastic part of the pen, which could cause your product to be subject to reporting.

The review of the carbon black in the ink of your pen follows the same outline as in the example above, however the carbon black in the plastic part of the pen must be reviewed separately. Because the pigment in the plastic cannot be released (item 7), this pigment does not have to be reported. This does not affect the conclusion from the example under Marker pen (I), and you must report your product and provide information about the carbon black pigment in the ink, however not about the pigment in the plastic.

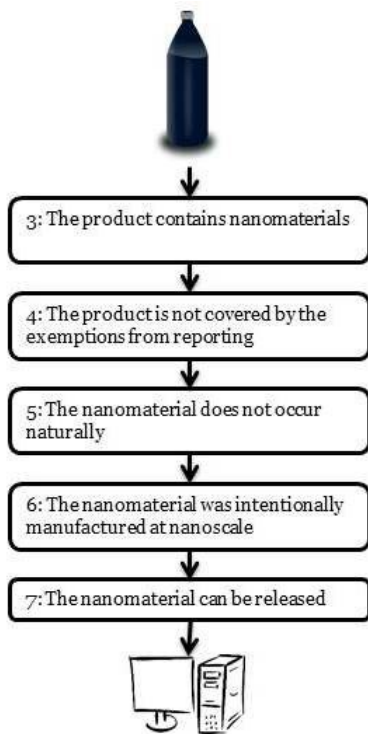
14 - Car polish

Example of product

You are the importer of a polishing agent that is used to treat lacquered surfaces on cars.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine whether your product contains nanomaterials that cause your product to be covered by the obligation to report, and you should move on to Figure 3 in these guidelines.



Item 3. After having studied the safety data sheet and been in contact with your supplier, you have ascertained that your product contains carbon black nanoscale pigments, which means the definition of a nanomaterial has been met. The supplier also informed you that your product does not contain any other nanomaterials, and therefore you should continue to the next item.

Item 4. Because your product does not fall within any of the mentioned product groups, you should continue to the next item.

Item 5. Carbon black is not a naturally occurring material and it is therefore not included in the Annexes to the REACH Regulation. You should therefore continue to the next item.

Item 6. The polishing agent must be non-abrasive, and nanoscale carbon black has been added to achieve this exact property. The nanomaterial was therefore intentionally manufactured at nanoscale.

Item 7. Because your product is liquid, the nanomaterial can be released during normal

use of the product.

For this reason, your product **must be reported** to the Inventory of Nanoproducts. Read about how to obtain and manage information and how to report it in Chapter 3.

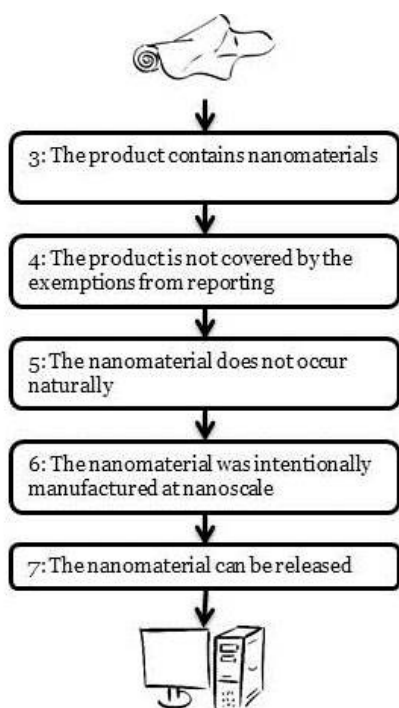
15 - Antimicrobial cleaning cloth

Example of product

You are the importer of a cleaning cloth with nanosilver.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine whether your product contains nanomaterials that cause your product to be covered by the obligation to report, and you should move on to Figure 3 in these guidelines.



Item 3. After having studied the product specifications (and possibly also having received confirmation from your supplier), you have ascertained that the cloth contains nanosilver which meets the definition of a nanomaterial, and you should therefore continue to the next item.

Item 4. Because your product does not fall within any of the mentioned product groups, you should continue to the next item.

Item 5. The silver used has been purified and manufactured in a chemical process and is therefore not a naturally occurring material.

Item 6. The silver used is assessed to have been intentionally manufactured at nanoscale in order to achieve as large a surface area as possible and thus enhance the antimicrobial properties of the product.

Item 7. The antimicrobial properties stem from silver ions that are released from the surface of the product. Silver ions are among the substances in soluble form that have been classified and that require reporting.

For this reason, your product **must be reported** to the Inventory of Nanoproducts. Read about how to obtain and manage information and how to report it in Chapter 3.

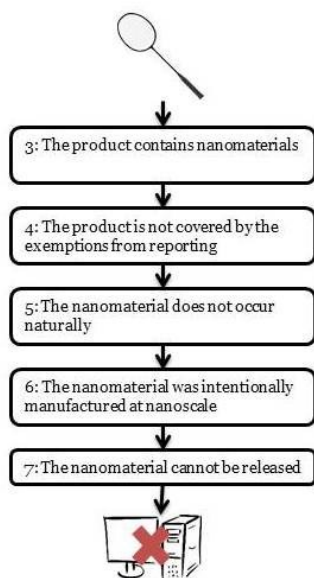
16 - Sports equipment

Example of product

You are the importer of a badminton racket.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine whether your product contains nanomaterials that cause your product to be covered by the obligation to report, and you should move on to Figure 3 in these guidelines.



Item 3. After having been in contact with your supplier, you have ascertained that the racket contains carbon nanotubes to make the racket lighter, as well as stronger and more flexible. Carbon nanotubes meet the definition of a nanomaterial. The supplier also informed you that your product does not contain any other nanomaterials, and therefore you should continue to the next item.

Item 4. Because your product does not fall within any of the mentioned product groups, you should continue to the next item.

Item 5. The carbon nanotubes were manufactured through a chemical process and can therefore not be said to be naturally occurring.

Item 6. The carbon nanotubes are assessed to have been intentionally manufactured at nanoscale in order to achieve as large a

surface area as possible and thus enhance the effect of the material. The nanomaterial was therefore intentionally manufactured at nanoscale.

Item 7. Carbon nanotubes are a part of the racket frame and it is assessed they cannot be released from the product during normal use.

For this reason, you need **not** report your product to the Inventory of Nanoproducts, and therefore you do not have to do anything further.

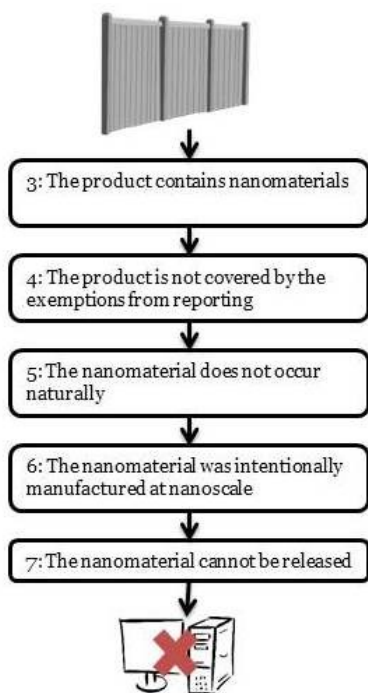
17- Painted fences

Example of product

You are the importer of a fence panel treated with self-cleaning paint.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine whether your product contains nanomaterials that cause your product to be covered by the obligation to report, and you should move on to Figure 3 in these guidelines.



Item 3. After having been in contact with your supplier, you have found out that the paint used contains nanoscale titanium dioxide with an anatase crystal structure that meets the definition of nanomaterial in the Statutory Order on the Inventory of Nanoproducts (see the EU's recommended definition of nanomaterial), and that it is the titanium dioxide which gives your product its self-cleaning properties. The supplier also informed you that your product does not contain any other nanomaterials. You have now determined that the product contains a single nanomaterial, which means you can answer "Yes" to item 3 in Figure 3.

Item 4. The nanoscale titanium dioxide was not added exclusively to give colour to the paint product; it was also added to provide it with self-cleaning properties. Furthermore, the other provisions regarding textile products, printing inks and rubber products are not relevant. Therefore, your product does not fall within the range of specific product

types that are exempt from reporting, and you should move on to the next item.

Item 5. The titanium dioxide was manufactured through a chemical process, and the titanium dioxide used can therefore not be said to be naturally occurring.

Item 6. The titanium dioxide is assessed to have been intentionally manufactured at nanoscale in order to achieve as large a surface area as possible and thus enhance the self-cleaning properties. The nanomaterial was therefore intentionally manufactured at nanoscale.

Item 7. Scientific studies have shown that nanomaterials added to paint are not released from painted surfaces (NANOKEM 20125). The added nanomaterial is therefore not released from your product.

For this reason, you need **not** report your product to the Inventory of Nanoproducts, and therefore you do not have to do anything further.

18 - Drill

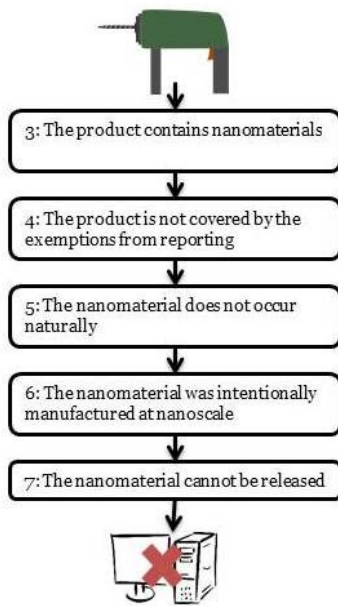
Example of product

You are the importer of a drill.

Considerations

Because your product is marketed to private consumers (Figure 2 item 1), and because your product is not covered by other regulations concerning nanoproducts (Figure 2 item 2), your product is covered by the Statutory Order on the Inventory of Nanoproducts. You therefore have to determine whether your product contains nanomaterials that cause your product to be covered by the obligation to report, and you should move on to Figure 3 in these guidelines.

⁵ Saber, A. T., H. Wallin, et al. (2011). NANOKEM. Nanoparticles in the paint and lacquer industry - exposure and toxic properties.



Item 3. After having studied the product specifications (and possibly also having received confirmation from your supplier), you have ascertained that the plastic parts of the drill contain a nanoscale pigment which meets the definition of a nanomaterial, and you should therefore continue to the next item.

Item 4. Because your product does not fall within any of the mentioned product groups, you should continue to the next item.

Item 5. The pigments used have been purified and subsequently processed and are therefore not a naturally occurring material.

Item 6. The pigments used are assessed to have been intentionally manufactured at nanoscale in order to enhance their colour effect.

Item 7. The pigments are bound in the solid plastic matrix. The nanomaterial can

therefore not be released from the product during use or if it breaks.

For this reason, you need **not** report your product to the Inventory of Nanoproducts, and therefore you do not have to do anything further.

Annex 3 Example of covering letter and supplier statement

This annex will as soon as possible be completed with a proposal for a letter that Danish companies can use when they contact foreign suppliers in order to get information needed for registration of nanoproducts.

Annex 4: Widely applied nanomaterials

Only a few nanomaterials account for the majority of nanomaterials used in nanoproducts. Below is a brief outline of the most widely used nanomaterials. Although your product contains one of the materials listed below, the material does not necessarily meet the definition of a nanomaterial in *your* product, as a majority of the materials are also available as larger particles. On the other hand, the list below is not exhaustive, so your product may contain materials at nanoscale which are not mentioned here.

Carbon black

Carbon black is particles used primarily as reinforcement in tyres and other rubber products, as well as to a lesser extent as a colourant in black paint, plastic products, etc. Carbon black has been used in products for many years and in 2007 approx. 9500 substances and mixtures containing carbon black were registered in the Danish Product Registry.

Titanium dioxide

Titanium dioxide is used in a broad range of products, however in particular in paints, plastics and in products for impregnation of construction materials. Titanium dioxide occurs in two crystal forms, anatase and rutile, of which the first is more photoreactive than the second. Anatase titanium dioxide nanoparticles are used primarily for photocatalytic purposes, for example in self-cleaning paint, while rutile titanium dioxide particles are used as white pigments in paints, plastics, food and paper, where the majority of particles are expected to be microparticles. However, most often a certain amount of nanoparticles will be present.

Pigments

Pigments are used in a broad range of products, however in particular in paints and plastics. As much as 50% of all pigments are used in ink for graphic printing; 25% are used in paints; and less than 20% are used in plastic products such as toys.

Silica/Silicon dioxide

These compounds are used due to their self-cleaning, antimicrobial and structural/rheological properties in an increasing number of products, including paints and wood preservatives, coatings, other construction materials and food, and they are used as nanocrystals in electronic equipment.

Metals and their compounds

In the coating industry in particular, metals and their compounds (such as metal oxides) are used at nanoscale for surface treatment (as described above). Furthermore, they are found in catalytic converters, as nanocrystals in electronic equipment, etc. **Nanosilver**, for example, is used in a range of products for its antimicrobial properties.

Other examples of nanomaterials, which are however not as widely applied, include carbon nanotubes, fullerenes, silicates and various metals and metal oxides.

Annex 5: Product groups that can contain nanomaterials

This Annex contains a list of examples of products and product groups which are considered most relevant with regard to assessing whether they contain nanomaterials. It should be stressed that these types of product are not necessarily nanoproducts or contain nanomaterials. The list is meant as guidance in the preliminary phase to identify relevant products to assess for whether or not they are nanoproducts subject to reporting. It should also be stressed that the products listed are not necessarily nanoproducts and that you yourself have to assess and determine whether your products need to be reported to the Inventory of Nanoproducts.

Products with self-cleaning surfaces

- Windows
- Roof tiles
- Other tiles/bricks
- Roofing felt
- Various paints
- Products painted with paint that contains certain nanomaterials (e.g. nanosilver).

Remember the following exemptions:

- *Products that do not release nanoparticles*
- *Products painted with paint that contains certain nanomaterials, e.g. in the form of pigments*

Antimicrobial products (with nanosilver, nano-copper, etc.)

- Fabrics (socks, sports clothing, mattresses)
- Paint with nanosilver and/or titanium dioxide
- Disinfectant products (e.g. cloths)
- Products painted with paint that contains certain nanomaterials (e.g. nanosilver).
- Wood preservatives and impregnated wood
- White goods for non-food uses (e.g. tumble dryers that release silver ions).

Remember the following exemptions:

- *Disinfectant products that do not include nanomaterials (e.g. based on alcohol)*
- *Plasters and other medical devices, refrigerators and food containers with nanosilver*
- *Products painted with paint that contains certain nanomaterials, e.g. in the form of pigments*

Spray products

- Protective and preservative/impregnation sprays for surface treatment
- Sprays for various forms of coating

Remember the following exemption:

- *Spray products that form aerosols which consist exclusively of liquids; deodorant sprays with nanoparticles.*

Products with colours

- Products of dyed plastic (providing nanoparticles are released from the plastic)
- Products and packaging of dyed cardboard/paper

- Coloured marker pens
- *Remember the following exemptions:*
 - *Coloured fabrics, labels, newspapers or books dyed with printing ink, paints, wood protectors, lacquers and joint fillers/sealants.*

Automobile industry

- Various lubricants (e.g. with graphite)
- Car waxes
- Window care products
- *Remember the following exemptions:*
 - *Car tyres*
 - *Rubber components in cars*

Building components

- Quick-drying cement
- Floor-levelling products
- Self-cleaning concrete products
- Roof tiles

Toys

- Products of dyed plastic (providing nanoparticles are released from the plastic)
- Marker pens, crayons, etc.

Annex 6: Description of all the parameters that can be reported to the Inventory of Nanoproductions

This Annex contains detailed explanations for the reporting fields on the reporting page. Some of the fields are explained separately, while others are explained collectively because they cover the same parameters.

The reporting parameters are divided into two categories: a) The mandatory information **required** for each product that is covered by the obligation to report (listed in Annex 1 of the Statutory Order on the Inventory of Nanoproductions), and b) the optional information that **may** be submitted (in Annex 2 of the Statutory Order on the Inventory of Nanoproductions). Just as on the reporting page itself, in the following the information which is mandatory is marked by an asterisk, *.

Product information	
Product name *	<i>The trade name of the product</i>
Produced amount (number of products) *	<i>Manufacturers should state the amount produced and importers should state the amount of products imported and sold to private consumers in the Danish market.</i>
Professional use (Y/N) *	<i>Is the product also being used commercially/by professionals?</i>
Description of use *	<i>Describe what the product is used for, and if relevant also how it is used.</i>
Chemical category (REACH/PC)	<i>State the chemical category corresponding to the REACH registration. You can find this information on the safety data sheet of the product, for example. The chemical categories must be determined as described in "Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system" available on the website of the European Chemicals Agency.</i>
Environmental release category (REACH/ERC)	<i>State the environmental release category corresponding to the REACH registration, i.e. ERC1, ERC2, etc. You can find this information on the safety data sheet of the product, for example. The environmental release categories must be determined as described in "Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system" available on the website of the European Chemicals Agency.</i>
Process category (REACH/PROC)	<i>State the process category corresponding to the</i>

	<i>REACH registration, i.e. PROC1, PROC2, etc. You can find this information on the safety data sheet of the product, for example. The process categories must be determined as described in "Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system" available on the website of the European Chemicals Agency.</i>
Article category (REACH/AC)	<i>State the article category corresponding to the REACH registration, i.e. AC1, AC2, etc. You can find this information on the safety data sheet of the product, for example. The article categories must be determined as described in "Guidance on information requirements and chemical safety assessment, Chapter R.12: Use descriptor system" available on the website of the European Chemicals Agency.</i>
Information on the nanomaterial	
Name of the nanomaterial*	<i>State trade name and any other names of the nanomaterial in your product in the free-text field, for example "P25 TiO2 nanoparticles". If you are the importer, your supplier/supply chain should be able to inform you about the name.</i>
REACH registration number	<i>If the nanomaterial is registered under REACH, then you must state its REACH registration number. If you are the importer, your supplier/supply chain should be able to inform you about the number. If the REACH registration number does not exist or cannot be identified, you must state this by ticking off the "Not available" box</i>
How the nanomaterial is incorporated in the product.	<i>Describe how the nanomaterial is included in the product. For example, it could be included in a solid matrix/in a composite material, or in a dispersion, an aerosol or similar.</i>
Amount of nanomaterial in product (%)	<i>State the mass percentage of the nanomaterial per product. If the nanomaterial is only included in a sub component of the product, then you should state the content of the material in this sub component.</i>
Amount of nanomaterial in product (grams)	<i>State the total mass (in grams; g) of the nanomaterial per product.</i>
Chemical name	<i>State the chemical name of the nanomaterial, if you know it. For example, titanium dioxide. Often the chemical name is the same as the name you state under the IUPAC name below.</i>
CAS number *	<i>State the unique CAS number of the nanomaterial which is used in connection with procurement of the nanomaterial and which will therefore be known by the buyer. The CAS number includes three parts separated by hyphens, like this: YYYYYY-XX-X , of which the first part may consist of 3 to 6 digits; e.g. 13463-67-7 for titanium dioxide. If you do not know the CAS number, your supplier/supply chain should be able to inform you about the number.</i> <i>If the CAS number does not exist or cannot be</i>

	<i>identified, you must state this by ticking off the "Not available" box</i>
IUPAC name *	<i>The IUPAC nomenclature is a naming system for chemical compounds. Write the chemical name of the nanomaterial (see IUPAC) in the free-text field, e.g. dioxotitanium. If you are the importer, your supplier/supply chain should be able to inform you about the IUPAC name.</i>
EINECS number (EU number)*	<i>State the EU number of the nanomaterial, i.e. either its EINECS, ELINCS or INCI number. The EU number must be stated on the labels of hazardous substances according to EU legislation. The seven-digit EU number includes three parts separated by hyphens, like this: XXX-XXX-X; e.g. 236-675-5 for titanium dioxide. If you are the importer, your supplier/supply chain should be able to inform you about this number. If the EU number does not exist or cannot be identified, you must state this by ticking off the "Not available" box .</i>
Chemical formula *	<i>State the molecular formula of the nanomaterial, e.g. TiO₂. If you are the importer, your supplier/supply chain should be able to inform you about this number.</i>
Upload file with documentation that data is not available	<i>This field is only available if you have marked that data is unavailable. Here you can upload a file with documentation that you have not been able to obtain the required data.</i>

Physical properties 1

Particle size (nm)

State the volume-based average particle size (in nanometers; nm) of the nanomaterial. You must also state which of the following methods you have used to measure the particle size of the nanomaterial.

1. Transmission Electron Microscopy
2. MEB
3. Atomic Force Microscopy
4. Other

If the method used is not listed, you can choose "Other", and you can then state which method was used in the "Other determination method" field. You can also state which test guidelines have been used. For example, EN Standards or ASTM Standards. Finally, you can upload a file with your documentation for particle size.

Number size distribution

Here you can state which of the following methods you have used to measure the particle number size distribution of the nanomaterial.

1. DLS
2. Laser diffraction
3. Gravimetric sedimentation
4. Differential centrifugal sedimentation
5. Raman spectroscopy
6. Other

If the method used is not listed, you can choose "Other method used", and you can then state which method was used in the "Other methods" field. You can also state which test guidelines have been used. For example, EN Standards or ASTM Standards. Finally, you can also upload a file with data

for the number size distribution (typically, this will be a graph showing the number size distribution).

Aggregation and agglomeration

State the average size of the aggregates and the agglomerates (in nanometers; nm) in the nanomaterial. By aggregation is meant that the material clumps up/grows together and is difficult to separate again, e.g. in a liquid dispersion. By agglomeration is meant that the material clumps up, but that the clumps can be separated again and dispersed e.g. in a liquid through stirring or other simple effect.

State which method was used to measure the size of the aggregates and agglomerates in the nanomaterial. You can also state which test guidelines have been used. For example, EN Standards or ASTM Standards. Finally, you can also upload a file with data for the size of the aggregates and agglomerates in the nanomaterial (typically, this will be a graph showing the number size distribution).

Physical properties 2

Form

State how many of the dimensions of the nanomaterial are smaller than 100nm, as well as which of the options give the best qualitative description of their shape. You can also provide a supplementary description, e.g. of whether the particles are spherical, flaky, rods, fibres, films etc. In other words, you must also state which of the following methods was used to determine the shape of the nanomaterial.

1. Transmission Electron Microscopy
2. MEB
3. Atomic Force Microscopy
4. Other

If the method used is not listed, you can choose "Other method used", and you can then state which method was used in the "Other methods" field. You can also state which test guidelines have been used. For example, EN Standards or ASTM Standards. Finally, you can upload a file with your documentation for the shape of the nanomaterial.

Specific surface area

State the average size of the specific surface area (in square meters per gram; m²/g). You must also state which of the following methods you have used to measure the specific surface area of the nanomaterial.

1. BET using nitrogen
2. TEM/EM calculation
3. SAXS
4. Other

If the method used is not listed, you can choose "Other", and you can then state which method was used in the "Other method used" field.

Crystalline surface

State whether information is available about the crystalline surface of the nanomaterial, including whether the nanomaterial occurs in a mixture, as well as information about the trivial name for the crystalline shape of the nanomaterial (e.g. general terms such as anatase or rutile titanium dioxide or the specific Bravais crystal structure). You can also state which of the listed crystalline forms the nanomaterial exists in. You can also state which test guidelines have been used. For example, EN Standards or ASTM Standards. Finally, you can upload a file with your documentation for the crystalline surface of the nanomaterial.

Surface chemistry

State whether the nanomaterial is surface treated/coated and which of the following coatings was used:

1. Organic (e.g. polyols, esters and siloxanes)
2. Inorganic (e.g. silicon dioxides, metals and metal oxides)
3. Other

You can also specify which of the following coatings was used:

1. Hydrophilic organic coating
2. Hydrophobic organic coating
3. Hydrophilic inorganic coating
4. Hydrophobic inorganic coating
5. Other

If the coating used is not listed, you can choose "Other", and you can then state which coating was used in the "Additional qualitative specification of coating" field.

Surface charge

State the average surface charge of the material (its zeta potential), as well as the pH value and the medium applied (e.g. "-35mV at pH 7 in demineralised water"). You can also state which test guidelines have been used. For example, EN Standards or ASTM Standards. Finally, you can upload a file with your documentation for the surface charge of the nanomaterial.

Annex 7: Group reporting

The reporting module at virk.dk also allows you to report your nanoproducts as an XML file. In this way you can provide information about several products at once.

The procedure for group reporting includes the following steps:

1. Retrieve an empty XML file at xxxxx and save it somewhere appropriate on your computer.
2. The file can be opened using an XML editor (e.g. Microsoft's XML Notepad 2007, which can be searched and downloaded free of charge on the internet).
3. You enter information in the file for the product(s) that need(s) to be uploaded to the system (for more about the structure of the file see xxx) .
4. Save the file under a new name.
5. On the reporting page at virk.dk, click the group reporting button under the reporting tab.
6. Click on the select file button to access your file for upload.
7. Select your file and click on "Open" to open it.
8. Click on "Group reporting"

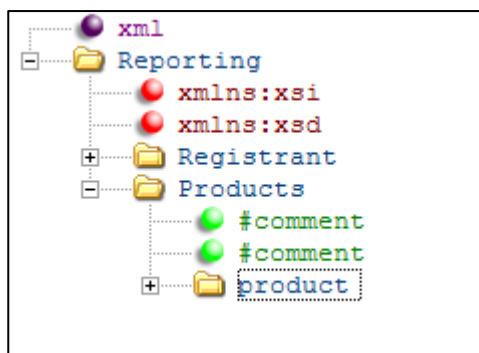
Your nanoproducts have now been uploaded to the reporting page of the Inventory of Nanoproducts. You can view the information in the system and you can edit individual data and delete products as you would otherwise do in the system.

Note: All products that have been uploaded to the system from an Xml file must be submitted before they have been registered in the nanoproducts database.

DESCRIPTION OF XML FILE

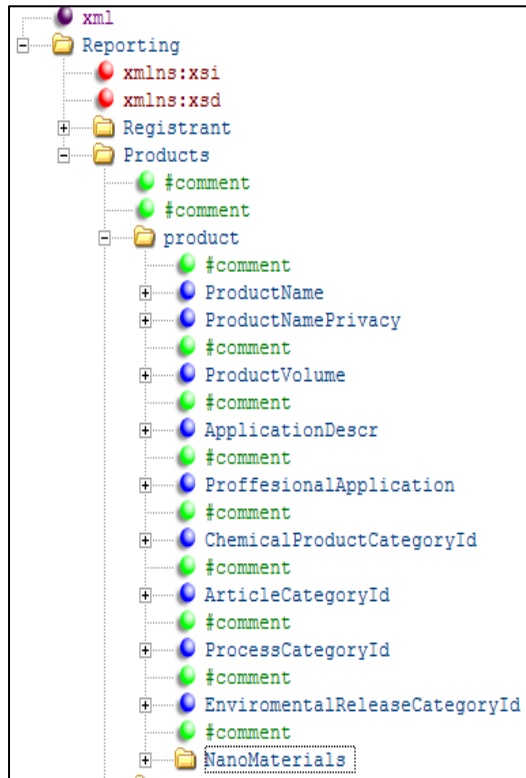
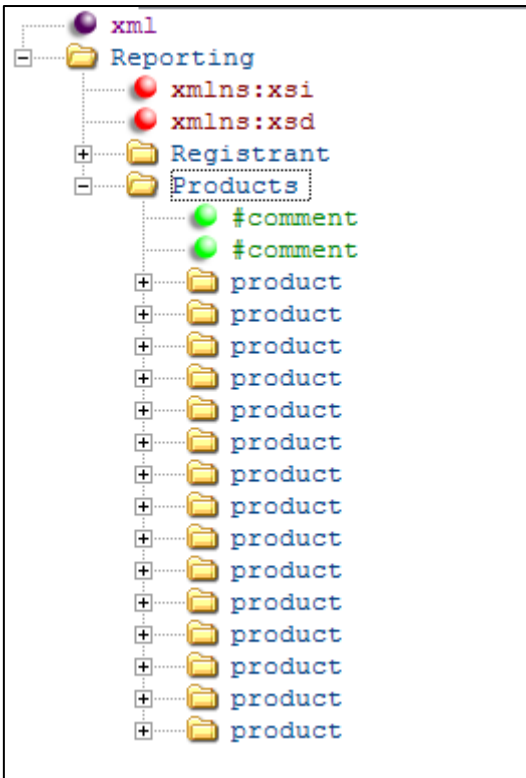
The tree structure of the XML file is illustrated in the figure below, which shows that the root ('reporting') is sub divided in two:

- "Registrant"
- "Products"

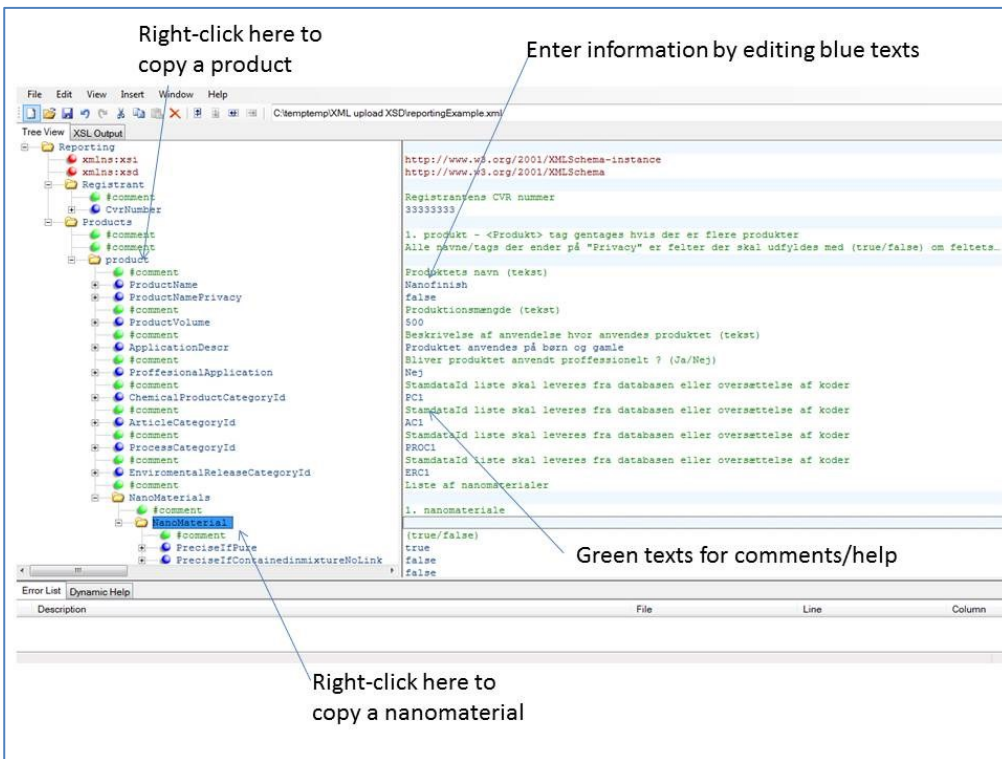


"Registrant" only contains the CVR no. (business registration no.; i.e. the same number registered when you log on to virk.dk, and which is required for you to be able to upload the data to the system).

"Products" can be sub divided corresponding to all the products that need to be reported (figure to the left), and under each product is the product information as well as another sub division on the nanomaterials in the products (figure to the right).



With Microsoft XML Notepad you can edit the data in the file or you can copy products or nanomaterials as illustrated in the figure below. (Note, that colour codes and right-click functions are unique to the XML editor chosen and may therefore differ if you use another XML editor).



Guideline for the Danish Inventory of Nanoproducts

The Guidance is an aid to companies who are responsible for reporting to the Danish register for nanoproducts according to “Statutory Order no. 644 of 13/06/2014 on a register of mixtures and articles that contain nanomaterials as well as the requirement for producers and importers to report to the register”.



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