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and Food of Denmark**
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Registration of nanoproducts in different registers

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Sources must be acknowledged.

Preface

This study is part of the Danish Environmental Protection Agency's program for mapping chemistry in consumer products.

The purpose of the study is to get updated information on reporting in other countries' national nanoregisters. A further purpose of the study is to survey whether there are products notified to other countries' nanoregisters which could also be eligible for notification to the Danish nanoproduct register if available on the Danish market.

The project was carried out from June to December 2019 by Frans Christensen, COWI and followed by Nadine Heidi Brueckmann and Elisabeth Paludan from the Danish Environmental Protection Agency.

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Dansk Sammenfatning

Tilgængelige oplysninger fra de nationale nanoregistre i Sverige, Belgien og Frankrig er blevet analyseret for information, med henblik på at identificere forbrugerprodukter indeholdende nanomaterialer, som vil være indberetningspligtige til det danske nanoproduktregister, hvis forbrugerprodukterne er tilgængelige på det danske marked.

En første gennemgang af tilgængelig information viste, at information om nanomaterialer i forbrugerprodukter fra det svenske nanoregister stadig er meget begrænset, da indberetningspligten først trådte i kraft i 2019. Desuden har de tilgængelige oplysninger fra det belgiske nanoregister været for generelle til at være af værdi for projektets formål. Der er til gengæld relativt detaljerede ikke-fortrolige oplysninger tilgængelige fra det franske nanoregister, og de franske myndigheder har venligst stillet relevante specifikke udtræk til rådighed for nærværende projekt.

Det skal bemærkes, at indberetningsforpligtigelsen i hhv. det franske og det danske nanoregister adskiller sig ganske markant.

Indberetningspligten til det danske nanoproduktregister vedrører forbrugerprodukter, der indeholder nanomaterialer, og hvor nanomaterialet kan frigives under normal eller med rimelighed forventet brug.

Bestemmelserne om indberetning til det franske nanoregister indeholder ikke specifikke eller detaljerede oplysninger om, hvorvidt et nanomateriale bruges i et forbrugerprodukt. Indberetningspligten gælder for alle led i varekæden indtil den sidste aktør i den professionelle forsyningskæde. Den sidste registrerede anvendelse kan således enten være for en erhvervsmæssig anvendelse eller indberettet af en distributør / detailhandler, der sælger til forbrugermarkedet. Kun i sidstnævnte tilfælde kan der være et overlap mellem indberetning til hhv. det danske og det franske register.

Desuden er en række produkter såsom kosmetik, medicin, fødevarer, foder og pesticider / plantebeskyttelsesmidler fritaget fra indberetningspligten til det danske register via bestemmelserne i §3 i bekendtgørelsen for det danske nanoproduktregister. Indberetningspligten til det franske nanoregister indeholder ikke sådanne generelle undtagelser.

Ved indberetning til det franske nanoregister skal der for registreringen angives en såkaldt produktkategori (Eng. Product category - PC), og hvor relevant en artikelkategori (Eng. Article category - AC). Disse angiver, i hvilken type produkt / artikel nanomaterialet forekommer.

En første analyse af disse oplysninger viser, at følgende produkt- og artikelkategorier kan indeholde nanomaterialer, der findes i forbrugerprodukter, som ville være indberetningspligtige til det danske nanoproduktregister¹:

¹ Disse tabeller er ikke oversat til dansk, da de engelske versioner er specifikt godkendt til publicering af de franske myndigheder

| Product Category (PC) | Chemical Product Category wording |
|------------------------------|--|
| PC9a | Coatings and paints, thinners, paint removers |
| PC0 | Other |
| PC1 | Adhesives, sealants |
| PC18 | Ink and toners |
| PC9b | Non-pigment entries in PC9a Coatings and paints, thinners, paint removers |
| PC13 | Fuels |
| PC24 | Lubricants, greases, release products |
| PC8 | Biocidal products (e.g. Disinfectants, pest control) |
| PC20 | Products such as pH-regulators, flocculants, precipitants, neutralization agents |
| PC35 | Washing and cleaning products |
| PC26 | Paper and board dye, finishing and impregnation products; including bleaches and other processing aids |
| PC34 | Textile dyes, finishing and impregnating products; including bleaches and other processing aids |
| PC28 | Perfumes, fragrances |
| PC12 | Fertilizers |
| PC15 | Non-metal-surface treatment products |
| PC3 | Air care products |
| PC31 | Polishes and wax blends |
| PC37 | Water treatment chemicals |
| PC23 | Leather tanning, dye, finishing, impregnation and care products |
| PC30 | Photo-chemicals |

| Article Category (PC) | Article Category wording |
|------------------------------|--|
| AC0 | Other |
| AC4 | Stone, plaster, cement, glass and ceramic articles |
| AC8 | Paper articles |
| AC30 | Other articles with intended release of substances |
| AC5 | Fabrics, textiles and apparel |

En mere detaljeret analyse af de underliggende oplysninger afslører, at af de mere end 11.000 indberetninger tildelt en produktkategori (PC) i det franske nanoregister, kunne maksimalt 1.239 indberetninger potentielt vedrøre produkter, som vil være indberetningspligtige til nano-produktregistret, hvis de findes på det danske marked. Da det må antages at mange af disse produkter ikke sælges til forbrugere, vil det reelle antal være betydeligt lavere. Dette kan dog ikke bestemmes nærmere ud fra de foreliggende oplysninger.

For ovennævnte 1.239 indberetninger viser følgende tabel det nanomateriale, som udløser indberetningspligten²:

² Tabellen er ikke oversat til dansk, da den engelske version er specifikt godkendt til publicering af de franske myndigheder

| Nanomaterial | No. notifications |
|--|-------------------|
| Silicon dioxide | 642 * |
| Pigments | 249 * |
| Cerium and iron oxide isostearate | 114 * |
| Aluminium, lithium and magnesium salts of silicic acid | 41 * |
| Calcium carbonate | 29 * |
| Ethene, homopolymer, oxidized | 5 * |
| Tungsten disulphide | 4 * |
| Other (confidential) | 155 |
| Total | 1.239 |

* Number refers to minimum number of notifications for the (type of) nanomaterials, as they are also to some extent present in the 'Other (confidential) category'.

Som det fremgår, udløses indberetningspligten for 1.005 (642 + 249 + 114) af de 1.239 indberetninger (ca. 81%) af indhold af siliciumdioxid, af et velkendt brændstofadditiv (cerium- og jernoxid isostearat) og af pigmenter.

De resterende 234 indberetninger henviser til ca. 20 nanomaterialer, hvoraf ca. 15 er fortrolige. Identiteten af disse er kendt af forfatteren, men kan ikke vises i ovenstående tabel på grund af fortrolighed.

Generelt vurderes det af forfatteren af denne rapport, at næsten alle kombinationer af produktkategorier og indeholdte nanomaterialer ligner dem, der er identificeret i en række projekter, der blev udført under det danske "Bedre styr på nanomaterialer" initiativ. Dette gælder ikke mindst en kortlægning af markedsførte pigmenter og et projekt, der vurderede tilstedeværelse og risici forbundet med nanomaterialer i danske forbrugerprodukter. Resultaterne af disse aktiviteter har blandt andet været anvendt til at udarbejde vejledning og FAQ, som kan tilgås på hjemmesiden for det danske nanoproduktregister³.

Det anslås af forfatteren, at oplysningerne i det franske nanoregister indikerer mindre end fem nye nanomaterialer (fortrolige i dette projekt), som kunne være til stede i danske forbrugerprodukter, der ville være indberetningspligtige til det danske nanoproduktregister, og som ikke allerede er kendt af de danske myndigheder. En nærmere konkretisering af dette ville indebære interview med relevante myndighedspersoner og gennemgang af rapporter og andet materiale fra "Bedre styr på nano" indsatsen. En sådan konkretisering har været uden for rammerne af nærværende projekt.

En detaljeret analyse af information om artikelkategorier (AC) i det franske nanoregister afslørede ingen nye oplysninger sammenlignet med den detaljerede analyse af information om produktkategorier (PC).

³ <https://mst.dk/kemi/kemikalier/fokus-paa-saerlige-stoffer/nano/nanoproduktregistret/>

Summary

Available information from the national nanoregisters in Sweden, Belgium and France was analysed for information with the purpose of identifying content of nanomaterials in consumer products, which would be eligible for notifications to the Danish nanoprodut register (Danish NPR) if available as consumer products on the Danish market.

An initial analysis revealed that information about nanomaterials in consumer products from the Swedish nanoregister is still limited as the notifications duties only entered into force in 2019 and the available information in the Belgian nanoregister is too generic to be of value for the current analysis. However, relatively detailed non-confidential information is available from the French nanoregister and the French authorities kindly provided extracts specifically relevant for the current project.

Notification duties differ quite significantly between the French nanoregister and the Danish NPR.

The notification requirements for the Danish NPR pertain to products containing nanomaterials sold to consumers. Further, notification is only triggered if release of the nanomaterial can be foreseen under normal and reasonably foreseeable use. In practice this mainly relates to articles, as mixtures are generally considered to lead to release.

The provisions for notification to the French nanoregister do not provide for specific or detailed information about whether a nanomaterial is used in a consumer product. Notification applies up until the last actor in the professional supply chain. The last actor might be either a professional/industrial user or a distributor/retailer selling to the consumer market. In the latter cases, there might be an overlap between notification duties in the Danish and French nanoregisters.

There are a range of products such as cosmetics, medicines, food, feed and pesticides/plant protection products which are exempt from the notification duty via the provisions in §3 of the Statutory Order for the Danish NPR. There are no such general exemptions from notification to the French nanoregister.

When notifying to the French nanoregister, Product Categories (PC), and where relevant, Article Categories (AC) must be assigned to notifications to indicate in which type of product/article the nanomaterial is present.

An initial analysis of this category information reveals that the following Product and Article Categories might contain nanomaterials present in consumer products, which would be eligible for notification to the Danish NPR:

| Product Category (PC) | Chemical Product Category wording |
|-----------------------|--|
| PC9a | Coatings and paints, thinners, paint removers |
| PC0 | Other |
| PC1 | Adhesives, sealants |
| PC18 | Ink and toners |
| PC9b | Non-pigment entries in PC9a Coatings and paints, thinners, paint removers |
| PC13 | Fuels |
| PC24 | Lubricants, greases, release products |
| PC8 | Biocidal products (e.g. Disinfectants, pest control) |
| PC20 | Products such as pH-regulators, flocculants, precipitants, neutralization agents |
| PC35 | Washing and cleaning products |
| PC26 | Paper and board dye, finishing and impregnation products; including bleaches and other processing aids |
| PC34 | Textile dyes, finishing and impregnating products; including bleaches and other processing aids |
| PC28 | Perfumes, fragrances |
| PC12 | Fertilizers |
| PC15 | Non-metal-surface treatment products |
| PC3 | Air care products |
| PC31 | Polishes and wax blends |
| PC37 | Water treatment chemicals |
| PC23 | Leather tanning, dye, finishing, impregnation and care products |
| PC30 | Photo-chemicals |

| Article Category (PC) | Article Category wording |
|-----------------------|--|
| AC0 | Other |
| AC4 | Stone, plaster, cement, glass and ceramic articles |
| AC8 | Paper articles |
| AC30 | Other articles with intended release of substances |
| AC5 | Fabrics, textiles and apparel |

Further detailed analysis of the underlying information reveals that of more than 11,000 notifications in the French nanoregister for which a product category (PC) had been assigned, a maximum of 1.239 notifications could potentially pertain to products, which *if* available on the Danish market and *if* sold to consumers could be eligible for notification to the Danish NPR. Thus, the actual number would be considerably lower, but the available information does not allow a further quantitative assessment of this.

For these 1.239 notifications, the nanomaterials triggering the notification to the French nanoregister are shown in the following table:

| Nanomaterial | No. notifications |
|--|-------------------|
| Silicon dioxide | 642 * |
| Pigments | 249 * |
| Cerium and iron oxide isostearate | 114 * |
| Aluminium, lithium and magnesium salts of silicic acid | 41 * |
| Calcium carbonate | 29 * |
| Ethene, homopolymer, oxidized | 5 * |
| Tungsten disulphide | 4 * |
| Other (confidential) | 155 |
| Total | 1.239 |

* Number refers to minimum number of notifications for the (type of) nanomaterials, as they are also to some extent present in the 'Other (confidential) category'.

As can be seen, 1.005 (642 + 249 + 114) or about 81% of the notifications refer to silicon dioxide, to a well-known fuel additive (cerium and iron oxide isostearate) and to pigments.

The remaining 234 notifications refer to about 20 nanomaterials of which 15 are confidential. The identity of these are known to the author but cannot be shown in the above table due to confidentiality.

Overall, it is assessed by the author of this report that almost all combinations of product categories and contained nanomaterials are similar to those identified in a range of projects carried out under the Danish EPA "Better Control of Nanomaterials" initiative. In particular, in a thorough survey of pigments on the market and in a project assessing presence and risks associated with nanomaterials in Danish consumer products. The results of these activities are also addressed in the guidance and FAQ on the Danish NPR website.

It is estimated by the author that the information in the French nanoregister indicates less than five new nanomaterials (confidential in this project), which could be present in Danish consumer products eligible for notification to the Danish NPR and which are not already known to the Danish authorities. To be more specific on this matter, relevant employees at the Danish authorities would need to be interviewed and reports from the "Better Control of Nanomaterials" initiative would need to be reviewed in detail. This was not a part of the present report.

A further detailed analysis of the article category (AC) information in the French nanoregister did not reveal any new information compared with the detailed analysis of the product category information.

1. Introduction

1.1 Background and objective

Due to the relatively limited number of notifications to the Danish nanoproduct register (from now on Danish NPR), the Danish EPA wishes to investigate whether information in national nanoregisters in other countries might provide evidence about types of products, which could be on the Danish market and eligible for notification to the Danish NPR.

The objective of this study is therefore:

- To investigate which information can be retrieved from other countries' nanoregisters
- To assess the relevance of such information vis-à-vis the scope of the Danish NPR and to which extent the information could indicate product types on the Danish market, which could be eligible for notification to the Danish NPR.

As will be evident in the following, there are quite some confidentiality restrictions associated with data in various nanoregisters. It will therefore not be possible to identify specific products based on available information. The aim of the report has been to try to identify *types* of products potentially eligible for notification to the Danish NPR as a basis for discussion with stakeholders about the future implementation of the Danish NPR provisions.

1.2 Approach

The responsible authorities for the national nanoregisters in Sweden, Belgium and France have been contacted. These authorities were enquired to extract knowledge from their registers – beyond what is already available on their web-sites - that could potentially provide information about nanomaterials used in consumer products.

The information collected was initially reviewed. The results of this initial review is summarised in Chapter 2. As will be evident, it was assessed that it could be beneficial to further analyse information from the French nanoregister. The results of that detailed review can be found in Chapter 3.

It shall be mentioned, that also the website of the European Union Nanomaterials Observatory (EUON) was reviewed to investigate if it contains information of relevance for the current project. This however revealed that current information is too general for the purpose of the current project.

2. Preliminary findings

2.1 The Swedish nanoregister

The Swedish nanoregister provides for notification of the following products (Cited from Christensen, 2017):

'The same scope as for the general product register (RED: The general Swedish Product Register) will apply, i.e. nanomaterials used occupationally or in consumer products, either on their own or in mixtures.

The same tonnage threshold of 100 kg per year per product applies. It should be noted that this threshold refers to the product being registered and not to the amount of contained nanomaterial.

During an evaluation period of three years, nanomaterials in pigments and nano-sized metal powders will be exempted from registration. Companies with an annual turnover less than 5 million SEK will also be exempted from the registration requirements during this period'.

Correspondence with the Swedish nanoregister revealed (by autumn 2019) that since the start of the register in January 2019, there have been three (3) notifications of consumer products containing nanomaterials. Given this low number, no information about the type or identity of these notifications can be shared with the author of this project. Thus, no further investigation of information in the Swedish nanoregister has been undertaken.

2.2 Belgian nanoregister

The Belgian nanoregister provides for notification of the following products (Cited from Christensen, 2017):

'Currently, deadlines have been set for registration of substances and mixtures containing one or more nanomaterials. The legal basis does not exclude registration of articles containing nanomaterials, but there is currently no deadline specified for registration of articles with nanomaterials.

The professional part of the supply chain (importers, manufacturers, B2B distributors) has to register. Registrants down the supply chain can refer back to information in registrations from previous actors in relation to the physicochemical characterisation of the nanomaterials.

There is no registration duty for the consumer or for the retailer (B2C).'

The Belgian authorities publish every year a report with aggregated information from the nano notifications received. At the time of carrying out the initial analysis (autumn 2019), the latest available report could be found here: <https://www.health.belgium.be/nl/nanoregistry-rapport-2017>.

The information provided in this yearly reporting is assessed to be too generic for the purpose of the current study. Upon enquiry to the Belgian authorities, we have been informed that due to strict confidentiality provisions, no further or more detailed information can be obtained.

In consultation with the Danish EPA, it was therefore decided not to analyse information from the Belgian nanoregister in further detail in the current project.

2.3 The French nanoregister

The French nanoregister provides for notification of the following products (Cited from Christensen, 2017):

'Nanomaterials on their own, in mixtures and in materials (incl. articles) from which nanomaterials are "intended to be released by a material in normal or reasonably foreseeable conditions of use" are within scope of registration. Thus, articles without intentional release are outside scope.

The register requires registrations for the same nanomaterial through the entire professional supply chain: importers, producers, distributors up until the 'last professional user'. As part of this, each actor in the supply shall identify clients "to whom ownership of the nanoparticle substance has been transferred". This means that the same product (and the same contained nanomaterial) can be registered several times (e.g. by a producer and by a B2B-distributor). In these cases, actors with registration duties down the supply chain can refer to registrations made by previous actors regarding detailed information about the nanomaterial.

The scope of the register is to cover all nanomaterials substances, mixtures and articles (with intentional release) regardless of the ultimate use of these substances and mixtures (i.e. also products used by consumers are within scope).¹

The French authorities publish a yearly report with non-confidential information which can be downloaded here: https://www.ecologique-solidaire.gouv.fr/sites/default/files/Rapport_R-nano_2017.pdf

The report contains rather detailed information about nanomaterials names, amounts (in ranges), as well as a number of identifiers: Sector Use (SU), Product Category (PC), Articles Category (AC), Environmental Release Category (ERC) and Process Category (PROC). Based on an initial assessment of this information, it was decided to analyse the French data in further detail. This analysis is presented in Chapter 3.

3. Further analysis of information in the French nanoregister

The French authorities inform that there is strict confidentiality around the information in the nanoregister and therefore no further detail than what is published in public can be shared.

However, the French authorities have kindly shared some extracts where the information in the public report has been recompiled in a way more applicable for this project. These extracts can be referred with some restrictions as will be visible in the following sections.

It shall be noted that notification duties differ quite significantly between the French nanoregister and the Danish NPR.

The notification requirements for the Danish NPR pertain to products containing nanomaterials sold to consumers. Further, notification is only triggered if release of the nanomaterial can be foreseen under normal and reasonably foreseeable use (in practice this mainly relates to articles, as mixtures are generally considered to lead to release). Finally, a range of products are exempt from the notification duty via the provisions in §3 of the Statutory Order⁴.

The provisions for notification to the French nanoregister do not provide for specific or detailed information about whether a nanomaterial is used in a consumer product. As set out in Section 2.3 above, notification applies up until the last actor in the supply chain. The last actor might be either a professional/industrial user or a distributor/retailer selling to the consumer market.

In the following analysis, it will in some instances be possible to *exclude* that a given French notification pertains to a consumer product which would be within the scope of the Danish NPR. This for example relates to notification of cosmetics which are exempted from the Danish NPR or to products clearly only sold to professional users.

Notifications in Product and Article Categories (PCs and ACs), which are not upfront excluded will be assessed in more detail based on the specific extract provided by the French authorities in relation to whether they could be eligible for notification to the Danish NPR.

It shall be noted that a notification in the French nanoregister might pertain to a product which is not available on the Danish market and thus naturally not eligible for notification to the Danish NPR. This cannot be assessed in this report as no specific product ID information is available for this analysis.

Therefore, the following can only identify *types of products* and contained nanomaterials which *might* be eligible for notification to the Danish NPR.

⁴ Bekendtgørelse (644/2014) om register over blandinger og varer, der indeholder nanomaterialer samt producenter og importørers indberetningspligt til registeret (Order on a register of mixtures and articles that contain nanomaterials as well as the requirement for producers and importers to report to the register)

3.1 Top-down view on notification information based on Product Categories (PC)

Table 1 provides an overview of the more than 11,000 notifications to the French nanoregister divided according to Product Categories (PC) in the notifications.

The right column in the table assesses whether the notifications cover products, which potentially could be within the scope of the Danish NPR.

TABLE 1: List of notifications where a Product Category (PC) has been indicated in notifications to the French nanoregister in 2019. Notifications are retrospective and pertain to the marked situation in the previous year; i.e. 2018. The table has cordially been provided by the French Ministry for an Ecological and Solidary Transition. The right column has been added by the author of this report.

| Product Category (PC) | Product Category wording | Occurrence | Percentage | Number of notifications in 2019 | Potentially within scope of DK NPR * |
|-----------------------|--|------------|------------|---------------------------------|--|
| pc27 | Plant protection products | 7.053 | 63,5 | 7.053 | No (ex. §3.6) |
| pc39 | Cosmetics, personal care products | 1.113 | 10,0 | 1.113 | No (ex. §3.5) |
| pc9a | Coatings and paints, thinners, paint removers | 1.043 | 9,4 | 1.033 | Yes, although those with pigments are ex. via §3.13 |
| pc32 | Polymer preparations and compounds | 333 | 3,0 | 333 | No – i) these must be assumed mainly to be raw materials; ii) If (consumer) products release is not likely |
| pc0 | Other | 263 | 2,3 | 263 | Yes |
| pc29 | Pharmaceuticals | 246 | 2,2 | 246 | No (ex. §3.3) |
| pc1 | Adhesives, sealants | 165 | 1,5 | 165 | Yes, although those with pigments are ex. via §3.13 |
| pc18 | Ink and toners | 159 | 1,4 | 159 | Yes |
| pc9b | Fillers, putties, plasters, modelling clay | 136 | 1,2 | 127 | Yes |
| pc13 | Fuels | 108 | 0,97 | 108 | Yes |
| pc19 | Intermediate | 64 | 0,6 | 64 | No (not consumer product) |
| pc21 | Laboratory chemicals | 61 | 0,5 | 61 | No (not consumer product) |
| pc24 | Lubricants, greases, release products | 52 | 0,5 | 52 | Yes |
| pc8 | Biocidal products (e.g. Disinfectants, pest control) | 51 | 0,5 | 51 | Yes |
| pc20 | Products such as pH-regulators, flocculants, precipitants, neutralization agents | 50 | 0,5 | 50 | Yes, but most of these types of products are largely used industrially/professionally and not by consumers |

| Product Category (PC) | Product Category wording | Occurrence | Percentage | Number of notifications in 2019 | Potentially within scope of DK NPR * |
|-----------------------|--|------------|------------|---------------------------------|--|
| pc35 | Washing and cleaning products (including solvent based products) | 42 | 0,4 | 42 | Yes |
| pc14 | Metal surface treatment products, including galvanic and electroplating products | 38 | 0,3 | 38 | No (not likely to be consumer products) |
| pc33 | Semiconductors | 26 | 0,2 | 26 | No (Can be in consumer products, but if so, no release is foreseen) |
| pc26 | Paper and board dye, finishing and impregnation products: including bleaches and other processing aids | 25 | 0,2 | 25 | Yes |
| pc34 | Textile dyes, finishing and impregnating products; including bleaches and other processing aids | 14 | 0,1 | 14 | Yes |
| pc2 | Adsorbents | 10 | 0,09 | 9 | No – 1) many are likely not part of consumers products; 2) if part of consumer products, release is unlikely |
| pc28 | Perfumes, fragrances | 10 | 0,09 | 10 | Yes, if used in non-cosmetic products |
| pc12 | Fertilizers | 8 | 0,07 | 8 | Yes, but most of these types of products are largely used industrially/professionally and not by consumers |
| pc15 | Non-metal-surface treatment products | 8 | 0,07 | 8 | Yes, but most of these types of products are largely used industrially/professionally and not by consumers |
| pc7 | Base metals and alloys | 7 | 0,06 | 7 | No – release from consumer products unlikely |
| pc3 | Air care products | 5 | 0,05 | 5 | Yes |
| pc31 | Polishes and wax blends | 5 | 0,05 | 5 | Yes |
| pc37 | Water treatment chemicals | 5 | 0,05 | 5 | Yes, but most of these types of products are largely used industrially/professionally and not by consumers |
| pc25 | Metal working fluids | 3 | 0,03 | 3 | No – not sold to consumers |

| Product Category (PC) | Product Category wording | Occurrence | Percentage | Number of notifications in 2019 | Potentially within scope of DK NPR * |
|-----------------------|---|------------|------------|---------------------------------|--|
| pc38 | Welding and soldering products (with flux coatings or flux cores.), flux products | 3 | 0,03 | 3 | No – not consumer products |
| pc23 | Leather tanning, dye, finishing, impregnation and care products | 2 | 0,02 | 2 | Yes, but most of these types of products are largely used industrially/professionally and not by consumers |
| pc11 | Explosives | 1 | 0,01 | 1 | No - Not consumer product |
| pc16 | Heat transfer fluids | 1 | 0,01 | 1 | No – not consumer product |
| pc17 | Hydraulic fluids | 1 | 0,01 | 1 | No – not consumer product |
| pc30 | Photo-chemicals | 1 | 0,01 | 1 | Yes, but most of these types of products are largely used industrially/professionally and not by consumers |

* *ex. §3.X' refers to exemptions in the Statutory Order for the Danish NPR.

For 8.959 of the notifications (about 81%), it is upfront assessed that the products cannot potentially be within the scope of the Danish NPR.

The remaining notifications are analysed in further detail in the next section.

3.2 Detailed analysis of Product Category (PC) information

In order to assess in further detail the product category information for not-excluded products, the French authorities have provided an extract where the number of notifications for the same PC and the same nanomaterial (name and CAS no) are listed. To retain a high level of confidentiality, it has been agreed with the French authorities not to list CAS numbers and to only list the nanomaterial name if there are more than 3 entries for that nanomaterial in a given PC.

The same PC order as shown in Table 1 will be followed.

3.2.1 Coatings and paints, thinners, paint removers (PC9a)

Of the 1.033 notifications in this Product Category, 708 are pigments, which must be considered outside the scope of the Danish Product register, see legal reference in Table 1.

Table 2 provides an overview of the remaining 325 notifications for non-pigment nanomaterials in this category.

TABLE 2: Non-pigment entries in PC9a: Coatings and paints, thinners, paint removers

| Nanomaterial | Function * | No. notifications |
|---|--|-------------------|
| Silicon dioxide | E.g. Flattening agent | 273 |
| Silicic acid, aluminium sodium salt | E.g. anticaking/rheology control agent | 19 |
| Silicic acid, lithium magnesium sodium salt | E.g. anticaking/rheology control agent, | 11 |
| Calcium carbonate | Binder/filler | 9 |
| Ethene, homopolymer, oxidized | E.g. Anti-settling agent | 5 |
| Confidential (4 nanomaterial substances) | Binders/fillers and anticaking/rheology control agents | 8 |
| | Total | 325 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

It can be seen that 273 of these notifications are for silicon dioxide and the remaining are for well-known additives in paints. There are a few confidential entries (8 notifications covering 4 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

3.2.2 Other (PC0)

For 263 notifications, the notifier has chosen PC0 – 'Other'. However, in this case the notifier can add a free-text describing the product. These free text descriptions, which per definition are not standardised, have been analysed. Based in these freetext descriptions, 123 can be excluded upfront as they refer to various applications exempted from notifications to the Danish NPR. These largely cover applications in food, feed, medicines, cosmetics, in articles where release cannot be foreseen under normal or reasonably foreseeable use, or they refer to uses which are not consumer uses.

Due to the unique nature of the free text descriptions, these generally cover less than four entries. The descriptions are therefore considered confidential for the purpose of this report. However, Table 3 provides an overview over the nanomaterials notified in PC0.

TABLE 3: Entries in PC0: Other

| Nanomaterial | Function * | No. notifications |
|--|---|-------------------|
| Silicon dioxide | E.g. Flattening agent | 79 |
| Pigments (covering 36 nanomaterial substances) | Pigment | 45 |
| Cerium and iron oxide isostearate | Fuel (diesel) additive / detergent | 6 |
| Confidential (8 nanomaterial substances) | Mainly fillers, binders and anticaking agents | 10 |
| | Total | 140 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

It can be seen that 79 of these notifications are for silicon dioxide, 45 for pigments and 6 are for cerium/iron oxide isostearate used as a fuel additive/detergent, see also Section 3.2.6 on fuels. There are some confidential entries (10 notifications covering 8 nanomaterials). These nanomaterials are based on the author's knowledge rather normal ingredients, which are also found in other product categories addressed in this chapter.

3.2.3 Adhesives, sealants (PC1)

Of the 165 notifications in this category, 58 covers pigments and would be exempted from the Danish NPR if part of adhesives and sealants (see legal reference in Table 1). Table 4 gives an overview of the remaining 107 notifications in this category.

TABLE 4: Non-pigment entries in PC1: Adhesives, sealants

| Nanomaterial | Function * | No. notifications |
|--|---|-------------------|
| Silicon dioxide | E.g. Flatting agent | 74 |
| Calcium carbonate | Binder/filler | 14 |
| Silicic acid, magnesium salt | E.g. anticaking/rheology control agent | 11 |
| Confidential (4 nanomaterial substances) | Binders/fillers, curing agents, and anti-caking/rheology control agents | 8 |
| | Total | 107 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

It can be seen that 74 of these notifications are for silicon dioxide and the remaining are for well know additives in adhesives and sealants. There are a few confidential entries (8 notifications covering 4 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

3.2.4 Ink and toners (PC18)

An overview of the 159 notifications in this category is provided in Table 5.

TABLE 5: Nanomaterials in PC18: Ink and toners

| Nanomaterial | Function * | No. notifications |
|--|--|-------------------|
| Pigments (56 nanomaterial substances).** | Pigment | 122 |
| Silicon dioxide | E.g. Flatting agent | 30 |
| Confidential (4 nanomaterial substances) | Binders/fillers and anticaking/rheology control agents | 7 |
| | Total | 159 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

** The following non-confidential: Carbon Black, Pigment Blue 15, Pigment Orange 34, Pigment Violet 19, Pigment Violet 23, Pigment Yellow 83.

It can be seen that 122 notifications are for pigments and 30 are for silicon dioxide. There are in addition a few confidential entries (7 notifications covering 4 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

It shall be noted that §3.11 in the Statutory order for the Danish NPR exempts "*Articles on which the nanomaterial is used as ink directly on the article or on labels on the article, including newspapers, periodicals, magazines, packaging that is not coloured in the mass or dyed, etc.*".

Thus, if the nanomaterials notified to the French nanoregister in this PC end up on such products, those products would be exempt from the Danish NPR.

3.2.5 Fillers, putties, plasters, modelling clay (PC9b)

Pigments in this category are assumed to be largely exempt from the Danish NPR via §3.13 "Paint, wood preservative, glue and filler containing pigment on the nanoscale where the pigment is added solely for the purpose of colouring the mixture".

However, this product category also includes products for which this exemption does not apply; e.g. modelling clays. Thus, no pigments entries can be excluded upfront and all notifications are summarised in Table 6.

TABLE 6: Entries in PC9b: Fillers, putties, plasters, modelling clay

| Nanomaterial | Function * | No. notifications |
|--|---|-------------------|
| Silicon dioxide | E.g. Flattening agent | 69 |
| Pigments (8 nanomaterial substances).** | Pigment | 50 |
| Calcium carbonate | Binder/filler | 6 |
| Confidential (2 nanomaterial substances) | Binder/filler and anticaking/rheology control agent | 2 |
| | Total | 127 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

** The following non-confidential: Carbon Black, iron hydroxide oxide, diiron trioxide

It can be seen that 69 notifications are for silicon dioxide, 50 are for pigments (where those pertaining to fillers and putties would be exempt) and 6 are for calcium carbonate. There are in addition a few confidential entries (2 notifications covering 2 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

3.2.6 Fuels (PC13)

As can be seen from Table 7, all notifications in this category relate to cerium/iron oxide stearate used as a fuel additive. If this type of fuel is sold to consumers, exposure cannot be excluded, and such fuels would therefore be eligible for notification to the Danish NPR.

TABLE 7: Entries in PC13: Fuels

| Nanomaterial | Function * | No. notifications |
|-----------------------------------|------------------------------------|-------------------|
| Cerium and iron oxide isostearate | Fuel (diesel) additive / detergent | 108 |
| | Total | 108 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

3.2.7 Lubricants, greases, release products (PC24)

Table 8 provides an overview of notifications for this category.

TABLE 8: Entries in PC24: Lubricants, greases, release products

| Nanomaterial | Function * | No. notifications |
|--|---|-------------------|
| Silicon dioxide | E.g. Flatting agent | 41 |
| Tungsten disulphide | Lubricant | 4 |
| Confidential (5 nanomaterial substances) | Pigments, anti-settling agents, lubricants and anticaking/rheology control agents | 7 |
| | Total | 52 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

It can be seen that 41 notifications are for silicon dioxide and 4 are for Tungsten disulphide, which are well-known ingredients in these types of products. There are in addition a few confidential entries (7 notifications covering 5 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

3.2.8 Biocidal products (e.g. Disinfectants, pest control) (PC8)

Table 9 provides an overview of the nanomaterials registered in this category.

TABLE 9: Entries in PC8: Biocidal products (e.g. Disinfectants, pest control)

| Nanomaterial | Function * | No. notifications |
|--|----------------------|-------------------|
| Silicon dioxide | E.g. Flatting agent | 46 |
| Confidential (3 nanomaterial substances) | Pigments and fillers | 5 |
| | Total | 51 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

As can be seen, 46 of these entries relate to silicon dioxide. There are in addition a few confidential entries (5 notifications covering 3 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

3.2.9 Products such as pH-regulators, flocculants, precipitants, neutralization agents (PC20)

Many of the products in this category must be assumed to be for professional/industrial use and would thus be outside the scope of the Danish NPR. However, this is not possible to judge based on the information from the French nanoregister and therefore all entries are summarised in Table 10.

TABLE 10: Entries in PC20: Products such as pH-regulators, flocculants, precipitants, neutralization agents

| Nanomaterial | Function * | No. notifications |
|--|---|-------------------|
| Silicon dioxide | E.g. Flatting agent | 47 |
| Confidential (3 nanomaterial substances) | Pigments and anticaking/rheology control agents | 3 |
| | Total | 50 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

As can be seen, 47 of these entries relate to silicon dioxide. There are in addition a few confidential entries (3 notifications covering 3 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

3.2.10 Washing and cleaning products (including solvent based products) (PC35)

Table 11 provides an overview of the nanomaterials registered in this category.

TABLE 11: Entries in PC35: Washing and cleaning products (including solvent based products)

| Nanomaterial | Function * | No. notifications |
|--|--|-------------------|
| Silicon dioxide | E.g. Flattening agent | 19 |
| Oxirane, 2-[[3-(triethoxysilyl)propoxy)methyl]-, hydrolysis products with silica | Pigment | 4 |
| Confidential (12 nanomaterial substances) | Pigments, anti-settling agents and anti-caking/rheology control agents | 19 |
| | Total | 42 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

As can be seen, 19 of these entries relate to silicon dioxide and four to a specific pigment. There are in addition 19 confidential entries (covering 12 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

3.2.11 Paper and board dye, finishing and impregnation products: including bleaches and other processing aids (PC26)

An overview of notifications in this category is provided in Table 12.

TABLE 12: Entries in PC26: Paper and board dye, finishing and impregnation products: including bleaches and other processing aids

| Nanomaterial | Function * | No. notifications |
|---|-----------------------|-------------------|
| Silicon dioxide | E.g. Flattening agent | 13 |
| Confidential (10 nanomaterial substances) | Pigments | 12 |
| | Total | 25 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

As can be seen 13 of these entries relate to silicon dioxide and the remaining 12 to pigments.

It shall be noted that §3.11 in the Statutory order for the Danish NPR exempts "Articles on which the nanomaterial is used as ink directly on the article or on labels on the article, including newspapers, periodicals, magazines, packaging that is not coloured in the mass or dyed, etc."

Thus, if the nanomaterials notified in this PC in the French nanoregister end up on such products, those products would be exempt from the Danish NPR.

3.2.12 Textile dyes, finishing and impregnating products; including bleaches and other processing aids (PC34)

An overview of notifications in this category is provided in Table 13.

TABLE 13: Entries for PC34: Textile dyes, finishing and impregnating products; including bleaches and other processing aids

| Nanomaterial | Function * | No. notifications |
|--|---------------------|-------------------|
| Carbon black | Pigment | 6 |
| Silicon dioxide | E.g. Flatting agent | 4 |
| Confidential (4 nanomaterial substances) | Pigments | 4 |
| | Total | 14 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

As can be seen, 6 of these entries relate to the pigment carbon black and 4 to silicon dioxide. There are in addition a few confidential entries (4 notifications covering 4 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

3.2.13 Perfumes, fragrances (PC28)

As can be seen in Table 14, all 10 entries in this category relate to silicon dioxide.

TABLE 14: Non-pigment entries in PC28: Perfumes, fragrances

| Nanomaterial | Function * | No. notifications |
|-----------------|---------------------|-------------------|
| Silicon dioxide | E.g. Flatting agent | 10 |
| | Total | 10 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

3.2.14 Fertilizers (PC12)

As can be seen in Table 15, all 8 entries in this category relate to silicon dioxide.

TABLE 15: Entries for PC12: Fertilizers

| Nanomaterial | Function * | No. notifications |
|-----------------|---------------------|-------------------|
| Silicon dioxide | E.g. Flatting agent | 8 |
| | Total | 8 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

3.2.15 Non-metal-surface treatment products (PC15)

Entries in this category are shown in Table 16.

Table 16: Entries in PC15: Non-metal-surface treatment products

| Nanomaterial | Function * | No. notifications |
|--|--|-------------------|
| Silicon dioxide | E.g. Flattening agent | 4 |
| Confidential (4 nanomaterial substances) | Pigments, detergents, polishing agents, anticaking/rheology control agents | 4 |
| | Total | 8 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

As can be seen, 4 of these entries relate to silicon dioxide. There are in addition a few confidential entries (4 notifications covering 4 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

3.2.16 Air care products (PC3)

Entries in this category are shown in Table 17.

TABLE 17: Entries in PC3: Air care products

| Nanomaterial | Function * | No. notifications |
|--|--|-------------------|
| Confidential (4 nanomaterial substances) | Pigments, detergents and flattening agents | 5 |
| | Total | 5 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

There are a few confidential entries (4 notifications covering 4 nanomaterials). These are based on the author's knowledge rather normal ingredients in these types of products.

3.2.17 Polishes and wax blends (PC31)

Entries in this category are shown in Table 18.

TABLE 18: Entries in PC31: Polishes and wax blends

| Nanomaterial | Function * | No. notifications |
|--|-------------------------------------|-------------------|
| Confidential (2 nanomaterial substances) | Anti-settling and flattening agents | 5 |
| | Total | 5 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

There are a few confidential entries (5 notifications covering 2 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

3.2.18 Water treatment chemicals (PC37)

As can be seen in Table 19, all 5 entries in this category relate to silicon dioxide.

TABLE 19: Entries for PC37: Water treatment chemicals

| Nanomaterial | Function * | No. notifications |
|-----------------|---------------------|-------------------|
| Silicon dioxide | E.g. Flatting agent | 5 |
| Total | | 5 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

3.2.19 Leather tanning, dye, finishing, impregnation and care products (PC23)

As can be seen in Table 20, both entries in this category relate to a confidential nanomaterial. This nanomaterial is based on the author's knowledge a rather normal ingredient in these types of products.

TABLE 20: Entries for PC23: Leather tanning, dye, finishing, impregnation and care products

| Nanomaterial | Function * | No. notifications |
|--|--------------|-------------------|
| Confidential (1 nanomaterial substances) | Confidential | 2 |
| Total | | 2 |

* The author's best guess. The function is not provided by the data from the French nanoregister

3.2.20 Photo-chemicals (PC30)

As can be seen in Table 21, the single entry in this category relates to a confidential nanomaterial. This nanomaterial is based on the author's knowledge a rather normal ingredient in these types of products.

TABLE 21: Entries for PC30: Photo-chemicals

| Nanomaterial | Function * | No. notifications |
|--|--------------|-------------------|
| Confidential (1 nanomaterial substances) | Confidential | 1 |
| Total | | 325 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

3.3 Discussion of Product Category Information

Comparing available Product Category information for notifications to the French nanoregister with the criteria for notification to the Danish NPR reveals that 1.239 French notifications could *potentially* relate to products which would be eligible for notifications to the Danish NPR. An overview of relevant product categories and number of notifications and nanomaterials for each category is shown in Table 22.

The Danish NPR only addresses nanomaterials in products sold to private use (to consumers), whereas the French register is much broader, see Section 2.3. This explains the wording *potentially* and the numbers discussed in this section are therefore upper limits of what could be within the scope of the Danish NPR. The actual numbers would be much lower. Further, there might be products on the French market which are not available on the Danish market. Table 22 gives a qualitative indication of the number of products within each category which could be consumer products.

TABLE 22: Overview of French Product Category notifications for which the associated product could be within the requirements for notification to the Danish NPR if available on the Danish market

| Chemical Product Category (PC) | Chemical Product Category wording | Max number of notifications <i>potentially</i> relevant for DK register / max. number of nanomaterials | Most, Many, Some or Few entries likely to be relevant for Danish NPR | New knowledge ? |
|--------------------------------|---|--|---|---|
| PC9a | Coatings and paints, thinners, paint removers | 325 / 9 | Some to many | No 273 of the entries relate to silicon dioxide and the rest to well-known constituents in this type of products |
| PC0 | Other | 140 / 46 | Some to many | No 79 of the entries relate to silicon dioxide, 45 to pigments and the rest to well-known constituents in products |
| PC1 | Adhesives, sealants | 107 / 7 | Some to many | No 74 of the entries relate to silicon dioxide and the rest to well-known constituents in this type of products |
| PC18 | Ink and toners | 159 / 61 | Some Many of these products are only used professionally/industrially | No 122 of the entries relate to pigments and 30 to silicon dioxide. The rest relate to well-known constituents in this type of products |
| PC9b | Non-pigment entries in PC9a Coatings and paints, thinners, paint removers | 127 / 12 | Some to many | No 50 of the entries relate to pigments and 69 to silicon dioxide. The rest relate to well-known constituents in this type of products |
| PC13 | Fuels | 108 / 1 | Most It must be assumed that this fuel additive is also present in fuels sold to consumers | No Well-known fuel additive |
| PC24 | Lubricants, greases, release products | 52 / 7 | Some Many of these products are only used professionally/industrially | No 41 of the entries relate to silicon dioxide and the rest to well-known constituents in this type of products |
| PC8 | Biocidal products (e.g. Disinfectants, pest control) | 51 / 4 | Some to many | No 46 of the entries relate to silicon dioxide and the rest to well-known constituents in this type of products |

| | | | | |
|------|--|---------|---|---|
| PC20 | Products such as ph-regulators, flocculants, precipitants, neutralization agents | 50 / 4 | Few Most of these products are for professional/industrial use | No 46 of the entries relate to silicon dioxide and the rest to well-known constituents in this type of products |
| PC35 | Washing and cleaning products | 42 / 14 | Most | No 19 of the entries relate to silicon dioxide and ca. 10 to pigments. The rest relate to well-known constituents in this type of products |
| PC26 | Paper and board dye, finishing and impregnation products: including bleaches and other processing aids | 25 / 11 | Some Many of these products are only used professionally/industrially | No 13 of the entries relate to silicon dioxide and 12 to pigments. The rest relate to well-known constituents in this type of products |
| PC34 | Textile dyes, finishing and impregnating products; including bleaches and other processing aids | 14 / 6 | Some Many of these products are only used professionally/industrially | No 10 of the entries relate to pigments and 4 to silicon dioxide. |
| PC28 | Perfumes, fragrances | 5 / 1 | Most | No All entries relate to silicon dioxide |
| PC12 | Fertilizers | 8 / 1 | Some to many | No All entries relate to silicon dioxide |
| PC15 | Non-metal-surface treatment products | 8 / 5 | Few Most of these products are for professional/industrial use | No 4 of the entries relate to silicon dioxide. The rest relate to well-known constituents in this type of products |
| PC3 | Air care products | 5 / 4 | Some to many | No Well-known ingredients for this type of products. |
| PC31 | Polishes and wax blends | 5 / 2 | Many | No Well-known ingredients for this type of products. |
| PC37 | Water treatment chemicals | 5 / 1 | Few to some Most of these products are for professional/industrial use | No All entries relate to silicon dioxide |
| PC23 | Leather tanning, dye, finishing, impregnation and care products | 2 / 1 | Some Many of these products are only used professionally/industrially | No Well-known ingredients for this type of products. |
| PC30 | Photo-chemicals | 1 / 1 | Few | No Well-known ingredients for this type of products. |

Most of these products are for professional/industrial use

Total notifications
1.239

Of the 1.239 notifications, most are accounted for by a few nanomaterials, see Table 23.

TABLE 23: Specific nanomaterials included in French nanoregister notifications potentially within the scope of the Danish NPR

| Nanomaterial | No. of notifications |
|--|----------------------|
| Silicon dioxide | 642 * |
| Pigments | 249 * |
| Cerium and iron oxide isostearate | 114 * |
| Aluminium, lithium and magnesium salts of silicic acid | 41 * |
| Calcium carbonate | 29 * |
| Ethene, homopolymer, oxidized | 5 * |
| Tungsten disulphide | 4 * |
| Other (confidential) | 155 |
| Total | 1.239 |

* Number refers to minimum number of notifications, as the nanomaterial is also to some extent present in the 'Other (confidential) category'.

The group 'Other' (confidential) refers to nanomaterials which occur in a number less than 4 in the individual product categories which are therefore considered confidential for the purpose of this report. These 155 notifications cover approx. 20 different nanomaterials (including those specifically listed in Table 23). Most of these appear well-known to the author of this study. Overall, it is assessed that almost all combinations of product categories and contained nanomaterials are similar to those identified in a range of projects carried out under the Danish 'Better Control of Nanomaterials' initiative (see summary in Christensen et al., 2015a). The nanomaterials are in particular included in a thorough survey of pigments on the market (Sørensen et al., 2015) and in a project assessing presence and risks associated with nanomaterials in Danish consumer products (Christensen et al., 2015b). The results of these activities are also addressed in the guidance and FAQ on the Danish NPR website⁵.

It is estimated that the French nanoregister indicates less than five new nanomaterials (confidential in this project), which could be present in Danish consumer products eligible for notification to the Danish NPR and not already known to the Danish authorities via previous nano survey projects. In order to further clarify this, one would need to interview relevant authorities and thoroughly screen the reports and other material generated during the Danish 'Better Control of Nano-materials' initiative. This has been outside the scope of the current project.

3.4 Top-down view on notification information based on Article Categories (AC)

As noted above, all actors along the professional supply chain in which a nanomaterial occur have to report to the French nanoregister. This includes those handling articles with intended release. As can be seen in Table 3, an article category has been specified for 1.888 notifications.

⁵ <https://mst.dk/kemi/kemikalier/fokus-paa-saerlige-stoffer/nano/nanoproduktregistret>

It should be noted that the information from the French nanoregister does not provide an overview of which products have been assigned a product category (PC) as well as an article category (AC). There is therefore most likely a significant overlap between notifications discussed here and those discussed under Product Categories above.

TABLE 24: List of notifications where an Article Category (AC) has been indicated in notifications to the French nanoregister in 2019. Notifications are retrospective and pertain to the marked situation in the previous year; i.e. 2018. The table has cordially been provided by the French Ministry for an Ecological and Solidary Transition. The right column has been added by the author of this report.

| Article Category (AC) | Article Category wording | Occurrence | Percentage | Number of notifications in 2019 | Potentially within scope of Danish NPR |
|-----------------------|--|------------|------------|---------------------------------|--|
| Ac0 | Other | 581 | 31,2 | 581 | Yes |
| ac13 | Plastic articles | 351 | 18,5 | 351 | In general no release in the meaning of the Danish NPR |
| ac4 | Stone, plaster, cement, glass and ceramic articles | 286 | 15,2 | 286 | Yes |
| ac7 | Metal articles | 267 | 14,1 | 267 | In general no release in the meaning of the Danish NPR |
| ac1 | Vehicles | 133 | 7 | 131 | In general no release in the meaning of the Danish NPR |
| ac10 | Rubber articles | 125 | 6,6 | 123 | In general no release in the meaning of the Danish NPR |
| ac2 | Machinery, mechanical appliances, electrical/electronic articles | 52 | 2,7 | 52 | In general no release in the meaning of the Danish NPR |
| ac8 | Paper articles | 50 | 2,6 | 48 | Yes |
| ac3 | Electrical batteries and accumulators | 14 | 0,7 | 14 | In general no release in the meaning of the Danish NPR |
| ac30 | Other articles with intended release of substances, please specify | 13 | 0,7 | 13 | Yes |
| ac5 | Fabrics, textiles and apparel | 11 | 0,6 | 11 | Yes |

The right column in Table 3 is the author's assessment as to whether the various categories represent products which could be within the scope of the Danish NPR. As can be seen, it is assessed upfront that most of these categories do not represent products which would be assumed to be within the scope of the Danish NPR as no release under normal and reasonably

foreseeable use can be assumed. See also the guidance for the Danish NPR (Sørensen et al., 2014). It shall be noted that it cannot be excluded that single products in these categories could cause release, but this would require more information than what is available from the extracts received from the French nanoregister.

3.5 Detailed analysis of Article Category (PC) information

For those categories not excluded upfront, a more detailed analysis of the extracts provided by the French authorities is given in the following.

3.5.1 Article category 'Other' (AC0)

For 581 notifications, the notifier has chosen AC0 – 'Other'. However, in this case the notifier can add a free-text describing the product. These free text descriptions, which per definition are not standardised, have been analysed. Based in these free text descriptions, 451 notifications can be excluded upfront as they refer to various applications exempted from notifications to the Danish NPR. These largely cover applications in food, feed, medicines, cosmetics, in articles where release cannot be foreseen under normal or reasonably foreseeable use or in uses which are not consumer uses. It also covers products where the pigment is indicated to be part of paints.

Due to the unique nature of the free text descriptions, these generally cover less than four entries. The descriptions are therefore considered confidential for the purpose of this report. However, Table 25 provides an overview of the nanomaterials notified.

TABLE 25: Entries in AC0: 'Other'

| Nanomaterial | Function * | No. notifications |
|---|---|-------------------|
| Pigments (33 different nanomaterial substances) | Pigment | 77 |
| Silicon dioxide | E.g. Flattening agent | 48 |
| Confidential (3 nanomaterial substances) | Binders/fillers, anticaking/rheology control agents | 5 |
| | Total | 130 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

As can be seen, 77 notifications relate to pigments and 48 to silicon dioxide. There are in addition a few confidential entries (5 notifications covering 3 nanomaterials). These are based on the author's knowledge also rather normal ingredients.

3.5.2 Stone, plaster, cement, glass and ceramic articles (AC4)

Nanomaterials notified in this Article Category are shown in Table 26.

TABLE 26: Entries in AC4: Stone, plaster, cement, glass and ceramic articles

| Nanomaterial | Function * | No. notifications |
|---|---|-------------------|
| Silicon dioxide | E.g. Flattening agent | 218 |
| Iron hydroxide oxide | Pigment | 13 |
| Titanium dioxide | Pigment | 12 |
| Silicic acid, magnesium salt | E.g. anticaking/rheology control agent | 9 |
| Carbon Black | Pigment | 8 |
| Diiron trioxide | Pigment | 7 |
| Confidential (18 nanomaterial substances) | Pigments, binders/fillers, anticaking/rheology control agents | 19 |
| | Total | 286 |

* The author's best guess. The function is not provided by the data from the French nanoregister

As can be seen, 218 notifications relate to silicon dioxide, 40 to pigments and 9 to silicic acid, magnesium salt. There are in addition some confidential entries (19 notifications covering 18 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

3.5.3 Paper articles (AC8)

Nanomaterials notified in this Article Category are shown in Table 27.

TABLE 27: Entries in AC8: Paper articles

| Nanomaterial | Function * | No. notifications |
|--|---|-------------------|
| Silicon dioxide | E.g. Flattening agent | 23 |
| Titanium dioxide | Pigment | 12 |
| Confidential (7 nanomaterial substances) | Pigments, binders/fillers, anticaking/rheology control agents | 13 |
| | Total | 48 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

As can be seen, 23 notifications relate to silicon dioxide and 12 to titanium dioxide. There are in addition some confidential entries (13 notifications covering 7 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

3.5.4 Other articles with intended release of substances (AC30)

Nanomaterials notified in this Article Category are shown in Table 28.

TABLE 28: Entries in AC30: Other articles with intended release of substances

| Nanomaterial | Function * | No. notifications |
|--|---|-------------------|
| Silicon dioxide | E.g. Flattening agent | 8 |
| Confidential (4 nanomaterial substances) | Pigments, binders/fillers, anticaking/rheology control agents | 5 |
| | Total | 13 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

As can be seen, 8 notifications relate to silicon dioxide. There are in addition a few confidential entries (5 notifications covering 4 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

3.5.5 Fabrics, textiles and apparel (AC5)

Nanomaterials notified in this Article Category are shown in Table 29.

TABLE 29: Entries in AC5: Fabrics, textiles and apparel

| Nanomaterial | Function * | No. notifications |
|--|---------------------------|-------------------|
| Silicon dioxide | E.g. Flattening agent | 8 |
| Confidential (3 nanomaterial substances) | Pigments, binders/fillers | 3 |
| Total | | 11 |

* The author's best guess. The function is not provided by the data from the French nanoregister.

As can be seen, 8 notifications relate to silicon dioxide. There are in addition a few confidential entries (3 notifications covering 3 nanomaterials). These are based on the author's knowledge also rather normal ingredients in these types of products.

3.6 Discussion of Article Category Information

Comparing available Article Category information for notifications to the French nanoregister with the criteria for notification to the Danish NPR reveals that 342 French notifications could potentially relate to products which could be eligible for notifications to the Danish NPR. An overview of relevant article categories and number of notifications and nanomaterials for each category is shown in Table 30.

As it appears from the table and the specific tables in Section 3.5, the same picture as for Product Categories is seen, namely that the vast majority of the notifications relate to pigments and silicon dioxide. Further, the analysis (also of the confidential information) did not reveal any surprises in terms of new nanomaterials.

Thus, overall, the same discussion as given in Section 3.3 applies here.

TABLE 30: Overview of French Article Category notifications for which the associated product could be within the requirements for notification in the Danish NPR if available on the Danish market

| Article Category (PC) | Article wording | Max number of notifications <i>potentially</i> relevant for DK register / max. number of nanomaterials | Most, Many, Some or Few entries likely to be relevant for Danish NPR | New knowledge ? |
|-----------------------|--|--|--|--|
| AC0 | Other | 130 / 37 | Some to many | No 77 of the entries relate to pigments and 48 to silicon dioxide. The rest refer to well-known constituents |
| AC4 | Stone, plaster, cement, glass and ceramic articles | 140 / 24 | Some to many | No 218 of the entries relate to silicon dioxide, 45 to pigments and the rest to well-known constituents in products |
| AC8 | Paper articles | 48 / 9 | Some to many | No 23 of the entries relate to silicon dioxide and 19 to pigments and the rest to well-known constituents in this type of products |
| AC30 | Other articles with intended release of substances | 13 / 5 | Some to many | No 8 of the entries relate to silicon dioxide and 4 to pigments. The rest relate to well-known constituents in this type of products |
| AC5 | Fabrics, textiles and apparel | 11 / 4 | Some to many | No 8 of the entries relate to silicon dioxide and 2 to silicon dioxide. The rest relate to well-known constituents in this type of products |
| | | Total notifications 342 | | |

4. References

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Registration of nanoproducts in different registers

This study is part of the Danish Environmental Protection Agency's program for mapping chemistry in consumer products.

The purpose of the study is to get updated information on reporting in other countries' national nanoregisters. A further purpose of the study is to survey whether there are products notified to other countries' nanoregisters which could also be eligible for notification to the Danish nanoproduct register if available on the Danish market.



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