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Assessment of the administrative burdens on businesses with a reporting obligation to the Danish Nanoproductregister

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Assessment of the administrative burdens on businesses with a reporting obligation to the Danish Nanoproductregister

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Preface

The present project was undertaken to assess the administrative burdens of reporting to the Danish Nanoproductregister, cf. "the Danish statutory 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" [Bekendtgørelse om register over blandinger og varer, der indeholder nanomaterialer samt producenter og importørers indberetningspligt til registered], (Order no. 644/2014).

Another purpose of the project was to carry out and present the measurement of the administrative burdens so that the results can feed into the EU Impact Assessment of a possible EU nanomaterial registry. As the method used for measurements in this report is compatible with the method recommended by the Impact Assessment Guidelines of the European Commission. With this translation of the Danish report, the results are available to EU stakeholders.

The work has been followed by a steering group consisting of:

- Carsten Ellegaard, COWI A/S (project manager)
- Katrine Bom, Danish Environmental Protection Agency, Chemicals
- Louise Baad Rasmussen, Danish Environmental Protection Agency, Chemicals
- Flemming Ingerslev, Danish Environmental Protection Agency, Chemicals
- Frans Christensen, COWI A/S.

Preliminary results, including key assumptions for the project, were presented to and commented on by a reference group at a meeting held on 6 October 2015. The following trade associations participated:

- The Danish Association for Communication, Design & Media (Grakom)
- Association of Manufacturers and Importers of Domestic Electrical Appliances (FEHA)
- Danish Coatings and Adhesives Association (DFL)
- Danish Chamber of Commerce
- SPT Association (detergent and cleaning products, cosmetics and personal care products).

The steering group as well as representatives of a major retail chain also participated in the meeting.

Other trade associations listed in Appendix 1 were prevented from taking part in the meeting but participated in interviews or had written communication with COWI A/S.

The project was carried out by COWI A/S from July to November 2015.

Summary and conclusion

The project set out to estimate the administrative burdens arising from businesses' obligation to report to the Nanoproductregister, see "the Danish statutory 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" [Bekendtgørelse om register over blandinger og varer, der indeholder nanomaterialer samt producenter og importørers indberetningspligt til registered], (Order no. 644/2014). The project made use of the SCM[1] guidelines to estimate the size of the administrative burdens.

To do so, COWI extracted data from Statistics Denmark on producers or importers of products classified under a number of relevant commodity codes (CN codes) which in all likelihood contain nanomaterials. In addition to using statistical data, we conducted an interview survey. We interviewed five businesses that reported to the Nanoproductregister in 2015 (five of eight reporting businesses which agreed to an interview within the timeframe of the project). In addition, we interviewed six businesses that had checked whether they had a reporting obligation, but concluded this not to be the case, and 11 relevant trade associations[2].

The interviews provided information for the measurement of the administrative burdens and the *'evaluation'* of the barriers experienced by businesses reporting for the first time to the Nanoproductregister, including availability of auxiliary tools, etc. Finally, the interviews also contributed to extracting experience and learning that can help improve the Register and other models for mapping and generating knowledge about nanomaterials in products. Due to the project timetable and the limited number of reporting businesses, it was not possible to interview more stakeholders. Yet, we do not believe that additional interviews would have substantially improved the reliability of the estimates of the administrative burdens of reporting to the register.

The project introduces four scenarios to capture different situations and methodological challenges. The project provides more or less accurate estimates for the following scenarios:

1. Scenario 1 – The actual administrative burdens of businesses that reported to the Nanoproductregister in 2015
2. Scenario 2 – Recurring costs, i.e. excluding one-off costs from year 1 for businesses that reported to the register
3. Scenario 3 – Scenario 3 – Administrative burdens on all businesses that are assessed to have an obligation to check whether they must report to the register
4. Scenario 4 – The administrative burdens of businesses assessed to have an obligation to report at "full compliance".

For many complex reasons, this proved not to be straightforward. We elaborate on the considerable uncertainties associated with the survey in section 2.4, but list a number of them in the table below. For scenarios 3 and 4, we chose to provide a high and a low estimate to highlight some of the considerable uncertainties.

[1] Standard Cost Model (SCM)

[2] See Appendix 1 for a list of interviewees

TABLE 1
UNCERTAINTIES ASSOCIATED WITH SCENARIO ESTIMATES

Uncertainty	Scenario 1 – Burdens in 2015	Scenario 2 – Recurring costs, excluding one-off costs in year 1	Scenario 3 – Businesses which should check	Scenario 4 – Businesses which should report
Bias towards large/knowledgeable businesses during interviews	x	x	x	x
Insufficient data available (based on interviews with five out of eight businesses that reported to the Register)	x	x	x	x
Estimate of time consumption for businesses that check whether they have a reporting obligation, but do not report, is very uncertain			x	
Estimate of one-off costs is uncertain since data rely on *expected* costs in a year 2 based on few interviews		x	x	x
Personnel costs in scenarios 3 and 4 rely on an extrapolation of data from the businesses that reported to the Register in 2015			x	x
Estimate for a normally efficient business			x	x
Population (number of businesses affected by the order) depends on interpretations, including the criteria "release" and "intentionally produced"			x	x
Uncertainty in estimating the number of producers (mainly based on estimates from trade associations)			x	x
Uncertainties in estimating the number of importers (based on data on importers extracted from Statistics Denmark)			x	x
Estimate of assumed reporters to the Register, among those who should check whether they have a reporting obligation (1% and 5% for articles and 10% and 30% for mixtures)				x

For the above reasons, the uncertainties of the SCM estimate are overall deemed to be significantly higher than in 'normal' SCM measurements of other areas of law.
We have attempted to address the uncertainties and the complexity by making SCM measurements of all of the above-mentioned scenarios.

The central estimates[3] of the administrative burdens are summarised in the table below.

TABLE 2
SUMMARY OF CENTRAL ESTIMATES OF THE 4 SCENARIOS

Scenario	Population	Time consumption	Hourly rate	Low central estimate of administrative burdens in million DKK	High central estimate of administrative burdens in million DKK	Average central estimate of administrative burdens million DKK
1	8	772[1]	464	-	-	0.4
2	8	282[1]	399	-	-	0.1[3]
3	3,339	20-45[2]	464	21.8	48.9	35.43
4	193-641	20-45[2]	464	1.8	13.4	6.33[3]

NOTES:
1: TIME CONSUMPTION IS INDICATED AS A TOTAL FIGURE FOR ALL EIGHT BUSINESSES THAT HAVE REPORTED TO THE REGISTER.
2: NORMALLY EFFICIENT BUSINESS, I.E. THE 'STANDARD' BUSINESS ASSUMED TO SPEND EITHER 20 OR 45 HOURS. SCENARIOS 1 AND 2 ARE BASED DIRECTLY ON INTERVIEW DATA AND ARE NOT ASSOCIATED WITH THE SAME UNCERTAINTIES AS SCENARIOS 3 AND 4.
3: AVERAGE

It should be noted that the three rightmost columns represent *central estimates*. For scenarios 3 and 4, the high and low scenarios represent sub-scenarios that address some of the uncertainties associated with the estimates. Apart from the spread of figures indicated in the table, additional uncertainties are associated with not least the estimate of the population in scenarios 3 and 4, as indicated in the table of uncertainties above. It has not been possible to quantify these uncertainties, but they are considered substantial.

With these uncertainties in mind, we conclude as follows:

- Scenario 1 – the actual burdens on businesses that reported to the Register in 2015. Based on a very low number of reporters (eight businesses), we estimate the total administrative burdens in scenario 1 to be approximately DKK 350,000. This estimate is assessed to have a high accuracy.

- Scenario 2 – Based on the reporters in 2015 and their expectations to the administrative burdens in a year 2, we estimate that the administrative burdens decline by two-thirds (estimated 63%) for the reporting businesses that we interviewed. The accuracy of this estimate is assessed to be medium to high.

- Scenario 3 – Based on a number of assumptions about the time consumption in a normally efficient business, the number of importers and producers, we estimate the administrative burdens on businesses, which checked whether they had a reporting obligation, to be between DKK 21.7 and 48.9 million. The accuracy of this range is however assessed to be low.

- Scenario 4 – Based on a number of assumptions about the time consumption in the normally efficient business and a low and high estimate of importers and producers

[3] By central estimates are understood estimates for 'population' of businesses included, 'time consumption' in a normally efficient business and average 'hourly rate' for personnel doing the reporting to the Register.

at full compliance, we estimate the administrative burdens on businesses to be between DKK 1.8 and 13.4 million. The accuracy of this range is, however, very low.

- It should be noted that the figures in scenarios 3 and 4 include one-off costs incurred by the businesses in adapting to the requirements of the order. The costs of these scenarios in a year 2 are assessed to be significantly lower; approximately 60-80% lower for scenario 3 and 30-50% lower for scenario 4.

For comparison, the latest SCM measurement made by the Danish Ministry of the Environment in 2010 found that the overall administrative burdens within the remit of the Ministry was DKK 710 million[4].

The project should also consider a scenario that estimated the administrative burdens of abolishing the following four product-specific exemptions (Article3[1], items 11-14 of the Statutory Order). These include:

- 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.

- Textiles where nanomaterials are used as ink or for dyeing of textiles.

- Paint, wood preservative, glue and filler containing pigment on the nanoscale where the pigment is added solely for the purpose of colouring the mixture.

- Articles of rubber or rubber parts of articles that contain the nanomaterials carbon black (EINECS No 215-609-9) or silicon dioxide (EINECS numbers 231-545-4, 262-373-8, 238-455-4, 238-878-4 and 239-487-1 or CAS numbers 13778-37-5, 13778-38-6, and 17679-64-0).

It was found that assessing the administrative burdens of abolishing these exemptions would be subject to a number of uncertainties apart from those mentioned above – not least uncertainties of an interpretative character, such as whether newspapers that are sold should be reported whereas free newspapers should not (the wording of the order is *"sale to the general public"*). For this reason, and in consultation with the reference group, it was decided that it would not make sense to quantify the administrative burdens abolishing the product-specific exemptions. Qualitative assessments indicate that there could be very significant administrative burdens of abolishing the above exemptions. Especially the three first-mentioned exemptions where the pigment content is generally known to be nanomaterials as per the EU definition could result in a very high number of reportable articles and in some cases businesses having to hire new personnel. Generally, attention was drawn to the fact that the Danish Environmental Protection Agency has already mapped pigments and it was questioned whether additional reporting in this area would add any value.

Finally, we used the interviews to assess the barriers perceived by businesses in reporting for the first time to the Register. We identified several factors that could act as barriers to the businesses. According to the businesses, the most important barriers are:

- Special Danish legislation is inappropriate, partly because it is not considered important by suppliers outside Denmark, partly because Danish businesses are put at a competitive disadvantage

[4] https://erhvervsstyrelsen.dk/sites/default/files/amvab-opdatering-af-miljministeriet-endelig-version-09-10.pdf(in Danish)

- Knowledge about nanomaterials is restricted. More knowledge is required to simplify reporting to the Register. Today, there is too much ambiguity, open-ended matters of interpretation and lack of proper definitions of substances, etc.

- Communication with suppliers is difficult and time consuming. Communicating complex issues in a foreign language (such as Asian languages) and supplier mistrust/confidentiality about own products make reporting difficult.

These barriers may be part of the explanation why many businesses do not report to the register.

It is noted that many businesses and industries have been satisfied with the process surrounding the making of the order and the auxiliary tools (guidelines, helpdesk, etc.) provided by the Danish Ministry of the Environment. Still, the efforts made were not enough to overcome the barriers.

The businesses and trade associations interviewed have pointed to a number of initiatives and possibilities that could improve reporting.

An EU solution. Harmonisation across the EU is required to reach broad consensus throughout supply chains, i.e. between businesses in Europe and suppliers in Asia. Experience from REACH shows that if implemented at EU level, suppliers will gradually adapt to the order and put in place the necessary logistics for documentation.

More effective ways of mapping nanomaterials. The Register has not so far proved to be an effective way of mapping the nanomaterial use by businesses. Instead, it is recommended to make targeted analyses of supply chains in industries through strategic cooperation with selected industries and/or businesses. It is recommended selecting industries based on risk, focusing on significant exposure and/or usage of particularly hazardous nanomaterials to avoid a situation that may create a general mistrust in nanoproducts/nanotechnologies.

Mapping of nanomaterials though producers. One way of mapping the spread of nanoproducts would be to start at the producers of nanomaterials and then follow the products down the value chain. Combining the producer and importer value chains may be an appropriate way of mapping nanomaterials, but one that requires international cooperation since nanomaterials are not manufactured commercially in Denmark.

E-trading products are not covered by the reporting obligation. E-trading of products constitutes an increasing share of markets, but international e-trade is not covered, which distorts competition.

1. Introduction

It is the stated aim of the Danish government to create the best possible framework conditions for the Danish business sector, which also involves reducing unnecessary administrative burdens. One of the tools that can help meet the aim of the government is the standard cost model called the SCM[5]. In June 2015, the Danish Environmental Protection Agency commissioned COWI A/S to measure the administrative burdens from 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"[6] [Bekendtgørelse om register over blandinger og varer, der indeholder nanomaterialer samt producenter og importørers indberetningspligt til registered]. Potentially, a large number of businesses and industries are required to report to the Danish Nanoproductregister (hereafter the Register). As far as possible, the analysis has mapped the administrative impact on typical businesses and industries assessed to have a reporting obligation. In addition, the report is an '*evaluation'* of the burdens and barriers, as perceived by businesses, to the first reporting to the Register. Finally, the report highlights experiences and learning that can serve to improve reporting and ways to map and procure knowledge about nanomaterials in products in the future.

1.1 Background

The 'Better Control of Nanomaterials agreement led to the establishment of a Nanoproductregister pursuant 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" [Bekendtgørelse om register over blandinger og varer, der indeholder nanomaterialer samt producenter og importørers indberetningspligt til registered].

The order requires Danish producers and importers of products intended for sale to the general public and which contain nanomaterials, where the nanomaterial itself is released under normal or reasonably foreseeable use to report to the Register. The first deadline for reporting was 30 August 2015 covering the period 20 June 2014 to 20 June 2015.

The purpose of the Register is to collect new knowledge about the occurrence of nanomaterials in products sold in Denmark. Today, this knowledge is neither available from authorities, consumers, researchers nor from businesses. The purpose of the Register is to gradually build knowledge, experience and data in the nanoproduct area based on information from businesses.

The order provides for a number of exemptions (Statutory Order, Section 3). The exemptions reflect a political desire to avoid placing unnecessary burdens on businesses. Exemptions include products sold to the public containing nanomaterials that are covered by other EU regulation requiring authorisation, registration or the similar of nanomaterials. These exemptions are not addressed in the project. Likewise, the project does not consider general exemptions relating to intentionally produced nanomaterials and nanomaterials that are part of a fixed matrix (Statutory Order, Article 3(1)).

[5] The model is used for Measurement of Businesses' Administrative Burdens

[6] Can be downloaded from: http://mst.dk/virksomhed-myndighed/kemikalier/miljoestyrelsens-nanoindsats/nanoproduktregistret/

The project estimates the administrative burdens of a number of scenarios and addresses the implications of abolishing four existing product-specific exemptions from the reporting obligation, resulting from the political negotiations about the order (Statutory Order, Article 3(1), nos. 11-14). These exemptions are described in more detail in section 3.4. The decision to exempt these products is partly based on the Danish Environmental Project 1451 *"Use of nanoproducts on the Danish market [Anvendelse af nanoprodukter på det danske marked]"* from 2012 and on an assessment of the expected burdens dating back to the autumn of 2013 (Danish Environmental Project 1462 – *"Possibilities of reducing the administrative burdens of businesses of reporting to the Nanoproductregister – Muligheder for reduction af virksomhedernes administrative byrder ved indberetning til det danske Nanoproduktregister)"*. Since the two reports were drafted before the order was adopted, they do not address the final wording and, likewise, estimates are not based on reporting of actual data to the Register. This means that the findings of these reports cannot compared with the findings in the current report.

This project updates the assessment of burdens relative to the present scope of the Register and the actual burdens by businesses. In addition, the project assesses, in qualitative terms, the burdens of abolishing the four product-specific exemptions. The assessment of the administrative burdens follows the guidelines of the SCM manual published by the Danish Business Authority in 2012.[7]

1.2 Objective

The overall objective of the project is to provide solid and comprehensive information about the Register from which practical learning and experience from the first period of reporting in 2015 can be extracted to feed into the general reporting of the Danish effort in the field of nanomaterials from 2012 to 2015. This objective is to be met by means of three sub-targets:

TEXT BOX 1
SCOPE OF THE PROJECT

1 **Measurement of administrative burdens.** The report estimates the administrative burdens of the following scenarios:

- 1.1 Scenario 1 – The actual administrative burdens of businesses reporting to the Register in 2015
- 1.2 Scenario 2 – Recurring costs, excluding one-off costs in year 1 for businesses reporting to the Register
- 1.3 Scenario 3 – Administrative burdens on all businesses that are assessed to have an obligation to check whether they must report to the Register
- 1.4 Scenario 4 – The administrative burdens on businesses that are assessed to have a reporting obligation at "full compliance" (subset of 1.3).

2 **Assessment of the administrative burdens on businesses of abolishing the four existing product-specific exemptions.** This assessment is based on qualitative criteria.

3 **Assessment of barriers encountered by businesses** during their first reporting to the Register. The assessment considers access to information, dialogue with suppliers, registration at virk.dk, information material and helpdesk. The evaluation extracts learning, experience and proposals for improvement and simplification.

[7] https://erhvervsstyrelsen.dk/sites/default/files/media/amvab-manual.pdf (in Danish)

1.3 Reporting to the Nanoproductregister in 2015

For various reasons discussed later in the report, only eight businesses reported to the Register in the first reporting period. The limited number gives rise to a number of confidentiality issues as information about product types/industries is considered confidential if less than three businesses have registered the same product type in the Register.

Likewise, the identity of a reporter is confidential and cannot be disclosed in a public report.

Due to the distribution of reports in the Register, we can only disclose that more than three businesses in the paint and adhesives industry reported to the Register. For the same reason, we cannot publish data to indicate the extent of the administrative burdens of reporters distributed on type of business. Consequently, we have chosen to use average figures based on more detailed underlying figures. Chapter 2 describes the methodology applied in more detail, while chapters 3 and 4 describe how we addressed the overall objective of the project.

2. Method

The measurement has been carried out in accordance with the framework and methodology set out in the SCM manual published by the Danish Business Authority. The elaborations we present in this chapter are thus based on the manual. An SCM measurement can be used to quantify the actual administrative burdens (ex post measurement) arising from businesses' obligation to report to the Nanoproductregister.

TEXT BOX 2
WHAT IS AN SCM MEASUREMENT? (THE VERY SHORT STORY)

The SCM model measures the actual administrative burdens of businesses in a specific area of law. First, the textual parts of the order are broken down into administrative activities that businesses are required to perform (information obligations), then a value is assigned to the administrative activities arising from the information obligation. This is measured by recording the time consumption in a normally efficient business through interviews. The time consumption is then extrapolated to national level to make an overall assessment of burdens.

An SCM measurement can:

1 assess the administrative costs of businesses at a given time, including determining the share of administrative costs that is an administrative burdens.[8].

2 assess the administrative impact on businesses by introducing new regulation in an area of law.

3 provide input to help simplify regulation and propose measures to help reduce the administrative burdens.

2.1 Measuring the administrative burdens

The administrative burdens is always established using the formula:

$$\text{Administrative burdens} = P \times C \times F$$

where P is the number of businesses (population) affected, *C* is the cost for the normal efficient business taken to meet the obligation; and *F* is the frequency that the activity must be completed each year.

The administrative burdens are always stated as an annual cost to society. The administrative cost for the individual business (C in the formula) is stated for the normally efficient business, which means that the SCM measurement excludes businesses that for various reasons are more effective or less effective than the average business.

[8] are defined as activities businesses simply sustain because it is a requirement of regulation. Financial accounting and day-to-day administrative activities are not considered administrative burdens, since businesses would perform these activities even if the regulation was abolished.

According to the manual, an SCM measurement must be based on a situation of full compliance. From this, it follows that the administrative burdens are the burdens imposed on businesses if they follow the order to the letter (i.e. full compliance with order).

2.1.1 Costs parameters and one-off costs in an SCM context

An SCM measurement distinguishes between one-off costs and recurring costs imposed by order. One-off costs are costs that are only sustained once in connection with the business adapting to the new order. In contrast, recurring administrative burdens are the costs that businesses constantly have in meeting the information obligation under the order. When businesses report to the Register for the first time, it is therefore relevant to distinguish between one-off costs and recurring costs.

The most important cost parameters of an SCM measurement are:

- The time spent on the individual administrative activities
- Hourly pay of personnel carrying out the activities
- An overhead of 25% on internal wage costs
- Acquisitions, if any, to meet the information obligation, including hiring of external consultants.

We have linked wage costs to the time spent carrying out the administrative activities. The wage costs are based on standard hourly rates for selected staff listed in Appendix 2 "personnel groups with associated hourly rates" of the SCM manual. The hourly rates used are shown in Appendix 2 of this report. We have written up hourly rates to reflect wage developments up to 2015 (cf. Statistics Denmark's wage index for the private sector, which is always computed and published in the second quarter of the year). Data on the wage development up to 2015 are included in Appendix 2 to this report.

2.2 Methodological challenges encountered

A number of issues made it difficult to follow the SCM method strictly. This section describes the challenges we encountered:

- **Many businesses are unfamiliar with the order or do not know that they are or could be covered by it.** The main challenge and also the most critical one is that many businesses are apparently unaware of the order and/or do not know whether they have nanomaterials in their product portfolio which may be reportable. This is because knowledge and understanding of nanomaterials and nanoproducts are restricted to very few businesses. Paradoxically, this makes some businesses spend many resources on checking various issues while others give up understanding the order and ignore it.
- **Broad scope.** Potentially, the order affects a wide range of industries, products and businesses, each acting in its own context and with challenges of its own. As will be seen, the present report builds on the inspiration list of potentially reportable[9] consumer products, which was published by the Danish Environmental Protection

[9] Downloadable under "FAQ" at http://mst.dk/virksomhed-myndighed/kemikalier/miljoestyrelsens-nanoindsats/nanoproduktregistret/ (in Danish)

Agency. This list gives examples of industries and products that may be covered by the order. As will emerge from the discussion in section 3.4, a number of exemptions of specific products that contain pigments have significantly narrowed down the scope of products for which there is a reporting obligation. However, the scope is still broad, and a wide range of businesses from many different sectors finds it difficult to assess whether they have a reporting obligation. Furthermore, the approach to reporting in the businesses varies and the scope and timeframe of the project did not allow us to go into detailed specific work flows/processes. As a result of the very limited number of businesses reporting to the Register, the empirical basis for measuring the administrative burdens also becomes limited. Knowing that it is unlikely that all businesses in a certain industry are covered by the order, we were also prevented from using the statistics normally applied when using the SCM model.

- **Much uncertainty about the number of businesses covered by the order.** For the above-mentioned reasons, a key challenge turned out to be estimating the type and number of businesses covered by the order if it was followed to the letter. Paradoxically, it was problematic to identify and quantify business types that could be associated with nanoproducts – an overview which the Register itself was meant to give.

- **Ambiguous order.** Due to interpretive issues, there is ambiguity whether a number of products are covered by the reporting obligation. Two examples of this are understanding and interpreting concepts such as *"release"* and *"intentionally produced"*. Difficulties of interpretation are also encountered in assessing the impact of abolishing the product-specific exemptions. The latter will be elaborated on in section 3.4.

Due to the above factors, we estimate that it would be too uncertain to apply a traditional SCM approach, in particular when it comes to estimating quantities for the normally efficient (average) businesses and the population of businesses.

2.3 Methodological adaptations

The considerable challenges described above forced us to make a number of methodological adjustments to the traditional SCM measurement. This also involved distinguishing between what it is meaningful to measure or - rather - estimate in view of the challenges described above.

- The adaptations have been made to provide the best possible estimate of the administrative burdens of reporting to the Register

- We have classified the administrative burdens measured in this project relative to the accuracy/uncertainty:

    - **Scenario 1** - the actual burdens in 2015 – businesses that reported to the Register in 2015 (relatively high accuracy)
    - **Scenario 2** – Difference between year 1 and year 2 (i.e. without one-off costs) based on the businesses that reported to the Register in 2015 (medium to high accuracy).
    - **Scenario 3 –** The administrative burdens for all businesses assessed to have an obligation to check whether they should report to the Register (low accuracy).

- **Scenario 4** – The administrative burdens for all businesses assessed to have a reporting obligation at full compliance (subset of scenario 3) (very low accuracy).
- Administrative burdens from abolishing the four product-specific exemptions (no accuracy).

The figure below illustrates our methodological approach and the process:

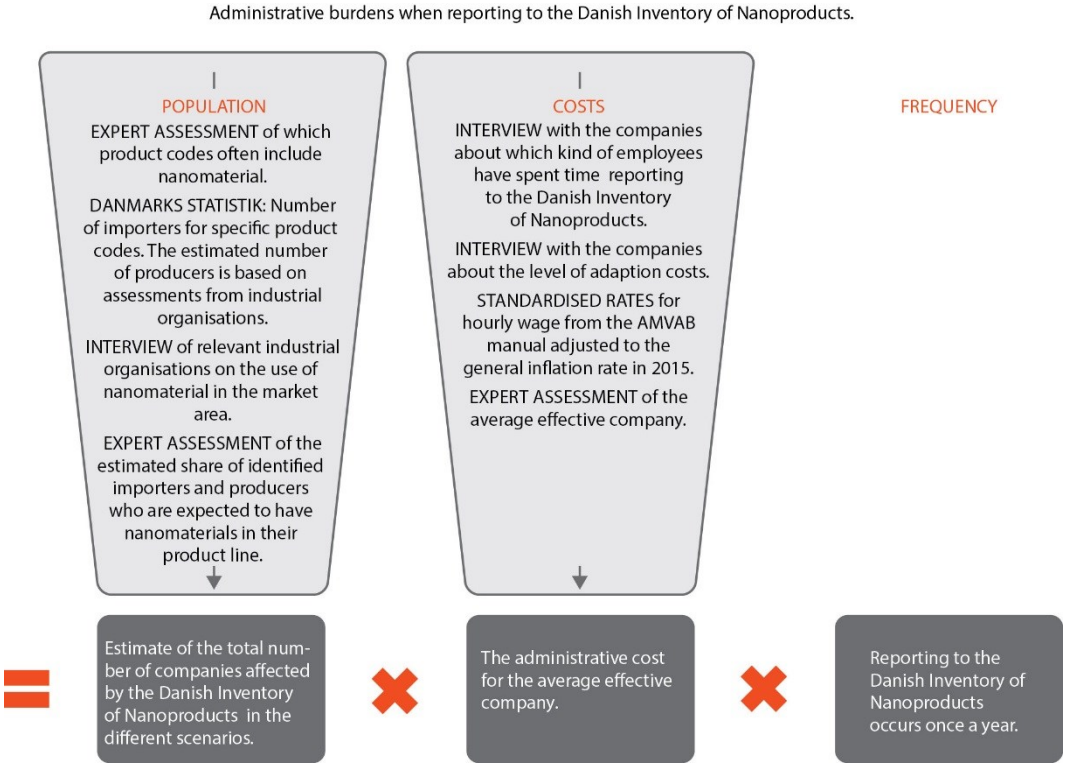


FIGURE 1
ILLUSTRATION OF DATA COLLECTION AND METHODIOLOGICAL APPROACH

2.3.1.1 Estimates of population

As shown in the figure, we used the funnel method to qualify the population relevant to the project. We:

- selected 36 commodity codes (CN codes) from Statistics Denmark and ordered a data sample of the total number of businesses registered within each of the commodity codes (duplicates removed)[10]. We selected the 36 commodity codes from the Danish Environmental Protection Agency's inspiration list of consumer products that may be reportable[11].

- interviewed/were in dialogue with a wide number of industries[12] on the use and spread of nanoproducts in the different industries (qualification of expert estimates in scenario 3).

[10] See Appendix 4 in which the product categories (CN codes) are listed. Note that the product categories (CN codes) do not show businesses with a turnover of less than DKK 6 million annually.

[11] Downloadable under "FAQ" at http://mst.dk/virksomhed-myndighed/kemikalier/miljoestyrelsens-nanoindsats/nanoproduktregistret/ (in Danish)

[12] See list of trade associations participating in the survey in Appendix 1

- made expert estimates of the population covered by the order in a given scenario
  - Scenarios 1 and 2: the population is set to the number of reporters in 2015 (= eight)
  - Scenario 3: the population is set to the total number of importers and producers assessed to have an obligation to check whether they should report to the Register. The number of importers are determined by the number of businesses registered under the 36 commodity codes (duplicates have been removed in the cases where businesses trade in products that belong to more than commodity code). The number of Danish producers are determined by information from the trade associations/expert estimates
  - Scenario 4: the number of businesses are the sum of importers and producers (subset of scenario 3) assessed to have a reporting obligation. The number of importers are determined by a low and high estimate for each of the 36 commodity codes. The number of producers are also determined using a low and a high estimate respectively. In consultation with the project reference group, we chose to assess sub-scenarios using 1% (low) and 5% (high) for articles and 10% (low) and 30% (high) for mixtures respectively.

Based on the above considerations, we provide the best possible estimate of the number of businesses (importers + producers) for each of the scenarios.

From the available data, we could not estimate the number of articles with a reporting obligation.

2.3.1.2 Estimate of costs incurred by businesses

We have interviewed five businesses that reported to the Register in 2015 (five out of a total of eight reporters which agreed to an interview within the timeframe of the project). In addition, we have interviewed six businesses that checked whether they had a reporting obligation, but did not report and 11 trade associations[13]. The interviews provided information about the costs incurred by the individual businesses distributed on:

- different administrative activities/work flows in the businesses

- time taken to carry out the administrative activities (estimated by the individual activities) and aggregated for activities in the business
  - Scenario 1: Estimate of *time spent on reporting in 2015*. We can estimate this fairly accurately as we have estimates from five out of eight businesses. It is relatively simple to estimate the total time spent by the eight reporting businesses (sum of five interviewed reporting businesses * 8/5).
  - Scenario 2: Based on the interviews with the five businesses that reported to the Register, we present the average estimate of the difference between year 1 and year 2.
  - Scenarios 3 and 4: Estimate of a normally efficient business. From the interviews with the businesses, mainly large businesses spending a large amount of time, we have estimated the *time consumption* of a *normally efficient business*. We use a high and a low estimate to illustrate some of the uncertainty of the estimate.

[13] See list of trade associations participating in the survey in Appendix 1.

- Personnel groups in charge of the administrative activities in the individual businesses and determination of hourly pay according to the SCM manual.

- One-off costs – assessment of differences in cost levels for the businesses between year 1 and year 2 relative to scenarios 3 and 4.

Based on the above information, we present expert estimates of the time spent and administrative costs in a normally efficient business.

The normally efficient business in scenarios 3 and 4 is assessed by an upper and lower estimate respectively.

2.4 Uncertainties

As indicated above, the SCM estimates are subject to much uncertainty. In the following, we discuss some of the most significant uncertainties.

The preliminary estimates of the above have been validated/quantified and fine-tuned by the reference group, which is composed representatives of a number of trade associations and businesses. However, the measurements of the administrative burdens from reporting to the Register are in general subject to much ambiguity and a range of uncertain assumptions. We have strived to be transparent about the shortcomings of the method and the assumptions and estimates on which the measurements are based. Especially, scenarios 3 and 4 have inherent uncertainties. We use upper and lower estimates to illustrate some but not all of the uncertainty. We summarise the most important uncertainties below:

- Overall, our interview survey is biased towards large businesses and businesses that have a relatively good knowledge of the Register. It turned out to be extremely difficult to identify/clarify how the very small businesses and/or businesses without prior knowledge of the Register go about the reporting. We approached a number of small businesses, however, no one was interested in giving an interview, not even when confidentiality was guaranteed.

Uncertainties about population estimates

- The choice of commodity codes (CN codes) used to estimate **the population of producers** is ambiguous, since, on the one hand, it is impossible to identify all product categories with nanomaterials, and on the other hand, population data for each commodity code purchased from Statistics Denmark do not contain information about businesses with a turnover below DKK 6 million. This is particularly a challenge in scenarios 3 and 4.

- **Estimates of the population of producers** have mainly been provided by trade associations. Some of the trade associations were unable to estimate the number of producers of nanomaterials. We have not been in contact with/obtained data from all relevant trade associations. See Appendix 1 for a list of trade associations that have been consulted.

- The data basis and particularly the small number of businesses (eight) that reported to the Register only give very limited knowledge of the number and type of businesses.

- Implicitly, the population also depends on how criteria such as 'release' and 'intentionally produced' are interpreted (or ought to be interpreted). A very strict interpretation of 'release' would for example (reporting obligation if the tiniest fraction of nanomaterial is released) mean that a very high number of businesses have a reporting obligation.

- In scenario 4, we assume that the share of businesses with a reporting obligation at full compliance accounts for 1% and 5% of articles and 10% and 30% for mixtures. These figures are uncertain and partly based on arbitrary expert estimates.

Uncertainties associated with the estimate of costs

- **The estimate of the normally efficient business** and the generalised view on businesses applied in scenarios 3 and 4 are difficult to make and inherently uncertain. This is because it covers very different businesses measured against a wide number of parameters (the limited empirical data available in the project made it impossible to distinguish):

    - Differences between producers and importers
    - Differences between large and small businesses
    - Differences between industries due to differing conditions, etc.
    - Differences in number of products (the time consumption depends, to some degree, on the number of products). Due to the limited data available, we could not estimate how many products a business needs to check.

- To calculate the personnel costs, we use an estimate of the average wage consumption per hour. The estimate is based on the different occupation groups in the businesses involved in the reporting in 2015. In scenarios 3 and 4, we assume that this distribution is the same for all businesses. However, this approach can be challenged as the personnel groups in the businesses reporting in 2015 are not necessarily representative of all businesses.

- In scenario 3, we estimate the time businesses spend on checking if they have a reporting obligation. The estimate assumes that businesses reach the middle of phase 3 of the reporting activity. This estimate is based on what businesses are required to do in the individual phases of the reporting and what the reporters in 2015 actually did. This introduces an uncertainty since we do not know how far the individual business proceeds on average before it stops in case reporting is not required.

- Assessments of population and how much time businesses spend on checking whether their products contain nanomaterials depend on how thorough the business is and how much time it can legitimately be expected that businesses spend on the uses. The experience from interviews is that some businesses spend more time than others on this - and thus also have found that they actually have products that must be reported.

- One-off costs are difficult to assess, since data rely on the *expected* costs in a year 2 based on only five interviews with businesses.

Table 3 below sums up, compares and illustrates the above uncertainties for each of the scenarios.

TABLE 3 UNCERTAINTIES ASSOCIATED WITH THE SCENARIO ESTIMATES

Uncertainty	Scenario 1 – Burdens in 2015	Scenario 2 – Recurring costs, excluding one-off costs in year 1	Scenario 3 – Businesses which should check	Scenario 4 – Businesses which should report
Bias towards large/knowledgeable businesses during interviews	x	x	x	x
Insufficient data available (based on interviews with five out of eight businesses that reported to the Register)	x	x	x	x
Estimate of time consumption for businesses that check whether they have a reporting obligation, but do not report, is very uncertain			x	
Estimate of one-off costs is uncertain since data rely on *expected* costs in a year 2 based on few interviews		x	x	x
Personnel costs in scenarios 3 and 4 rely on an extrapolation of data from the businesses that reported to the Register in 2015			x	x
Estimate for a normally efficient business			x	x
Population (number of businesses affected by the order) depends on interpretations, including the criteria "release" and "intentionally produced"			x	x
Uncertainty in estimating the number of producers (mainly based on estimates from trade associations)			x	x
Uncertainties in estimating the number of importers (based on data on importers extracted from Statistics Denmark)			x	x
Estimate of assumed reporters to the Register, among those who should check whether they have a reporting obligation (1% and 5% for articles and 10% and 30% for mixtures)				x

For the above reasons, the uncertainties associated with this SCM measurement are overall assessed to be higher than for 'standard' SCM measurements in other areas of law.

2.5 The SCM method compared with the EU Impact Assessment

The SCM method is compatible with the method used for measuring the administrative burdens presented in the Impact Assessment Guidelines of the European Commission and the available EU impact assessment[14]. Basically, the SCM and EU Impact Assessment guidelines recommend measuring the administrative costs and burdens by means of the Standard Cost Model. Since the measurement method of SCM is essentially the same as the method used for EU impact assessments, the calculations made in this project are applicable in an EU context. The Danish report has therefore been translated into this English version to make results available to EU stakeholders.

[14] BIPRO/RPA report from 2014: *"Study to Assess the Impact of Possible Legislation to Increase Transparency on Nanomaterials on the Market"*

3. Results of the SCM measurements

In this chapter, we present the results of the SCM measurement. First, we introduce the process adopted by a typical business to report to the Register. This includes a review of the typical activities conducted and the time spent. Then, we present the results of the SCM measurements for each of the four scenarios:

1. **Scenario 1** – actual burdens in 2015 – businesses that reported to the Register in 2015 (relatively high accuracy).

2. **Scenario 2** – difference between year 1 and year 2 (i.e. less one-off costs) based on the costs incurred by businesses reporting in 2015 (medium to high accuracy)

3. **Scenario 3** – administrative burdens for all businesses assessed to have an obligation to check whether they should report to the Register (low accuracy).

4. **Scenario 4** – Administrative burdens of businesses assessed to have a reporting obligation at 'full compliance'(subset of scenario 3) (very low accuracy)

5. Administrative burdens of abolishing the four product-specific exemptions (no accuracy). Exemptions are assessed qualitatively.

3.1 Work flow in a business

The interview survey provided input to identifying work processes and flows in the businesses that check whether they have a reporting obligation and possibly report to the Register.

The process followed by a business to investigate this is illustrated in the figure below.

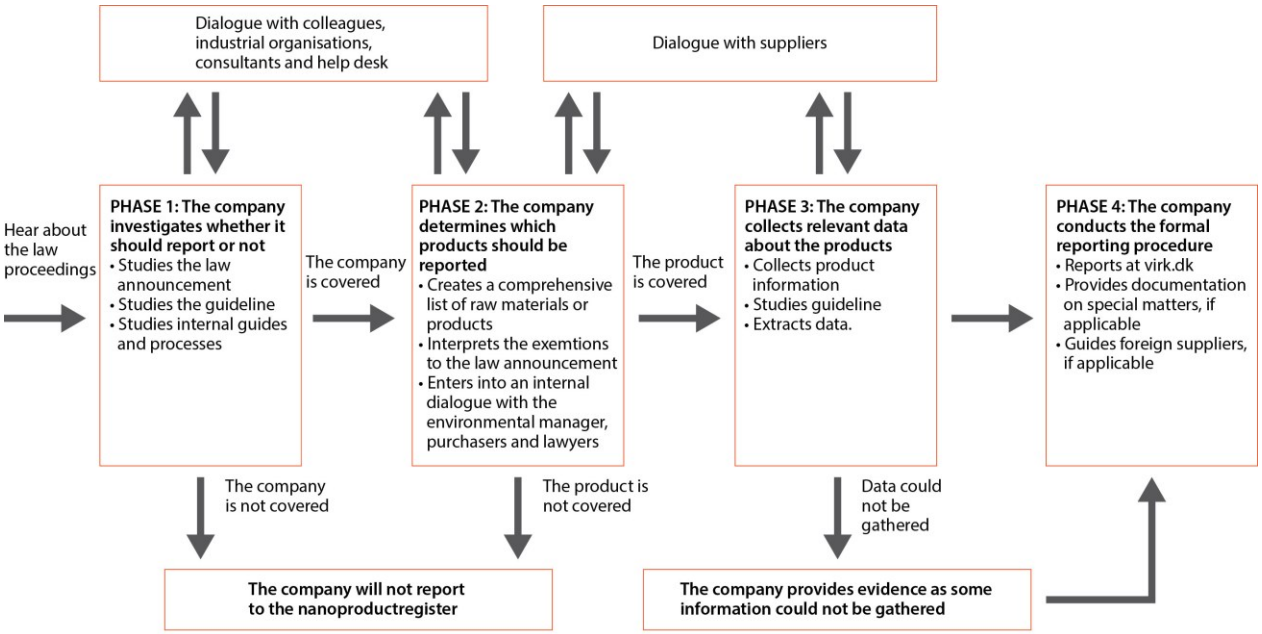
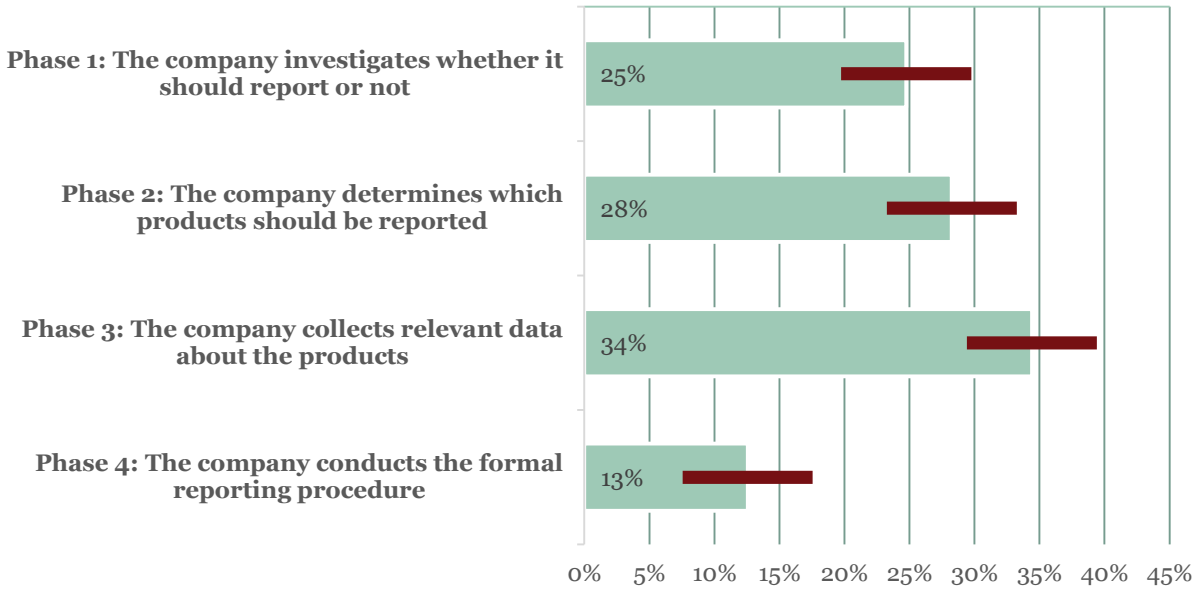


FIGURE 2 ILLUSTRATION OF THE PROCESS IN A BUSINESS REPORTING TO THE INVENTORY

The figure is divided into four phases, but the workflow is very iterative in the sense that businesses often have to go back one step to for example check the exact wording of the guideline or to add or delete a product based on new information from suppliers.

Figure 3 below gives an idea of the total time consumption distributed on the four phases. The figure shows the average percentage of the total time spent on reporting distributed on the phases. The measurement is based on estimates from five of the eight businesses that reported to the Register. To reflect the uncertainty resulting from the limited database, we have indicated a margin of error of 5% on both sides of the average (this could be even larger). For example, it is assessed that a business uses 20-30% of the total time to complete phase 1 (in year 1, i.e. including one-off costs).



NOTE: The margin of uncertainty is marked with red showing an interval of ± 5%.

FIGURE 3 AVERAGE DISTRIBUTION OF USED TIME BETWEEN THE FOUR PHASES.

Below, we highlight processes and experiences of businesses in reporting to the Register:

- **By formulators of mixtures, the process typically starts** by an assessment of the reporting obligation based on the list of the raw materials used in the mixtures. This list is then reduced to a limited number of raw materials, which are examined in more detail by contacting suppliers and scrutinising supplier data, etc. From the list of raw materials, it is easy to identify mixtures containing this raw material. By formulators, the environmental/QA manager is typically in charge of this.

- **The large importers** with a large portfolio to be examined (e.g. retail industry) often have to pay substantial one-off costs to establish internal work flows and procedures to collect the necessary data from purchasers responsible for certain countries and product areas, who must interact with suppliers to collect data. At the importers, the QA managers are typically responsible for developing and establishing internal work flows, and ultimately for reporting. It is difficult for the purchasers to implement the rules, legislation and the internal work flows to obtain the required information from the suppliers.

- **Short-lived consumer articles/industries where articles and suppliers change frequently** are most affected by administrative burdens (e.g. textiles and certain non-food articles sold by food retailers) since the product portfolio changes quickly. This requires frequent contact to suppliers to obtain data for a large number of articles. A textile company may put up to four clothing collections on the market every year.

- **Phases 2 and 3 – communicating with and obtaining data from suppliers - are the most resource-demanding phases**. Phase 3 and partly phase 2 require communication with suppliers, and suppliers do not always understand why it is important to furnish the data. For reasons of confidentiality, suppliers may be less inclined to cooperate or unable to procure the data. Phases 1, 2 and 3 are very iterative and hard to separate.

- **The time consumption in phases 1 and 2 –** checking whether the business is covered by the order – is typically higher for importers than for producers, since importers have less knowledge and data about products and raw materials.

- **Phase 4 – the reporting and entering of data in Virk.dk** is the least resource demanding part. Compared with the data procurement requirement in the other phases, completing phase 4 is relatively easy under the current scope of the order.

3.2 SCM results

This section presents the results of the SCM measurements. We explain how we obtained intermediate results and indicate when we use expert estimates for lack of data.

3.2.1 Measurement of the actual burdens in 2015 – Businesses reporting to the Register in 2015

This scenario only concerns businesses that reported to the Register in 2015. Only eight businesses reported to the Register; this is a very modest number, both in absolute numbers but also in terms of the number of businesses assessed to have a reporting obligation in a situation of "full compliance". One of the reasons for the limited number of reporting businesses is probably the barriers encountered. Section 4.1 gives a detailed account of barriers. During interviews, we found that an unknown, but possibly large number of businesses have spent time and resources checking whether they had a reporting obligation, but ended up not reporting to the Register. This resource consumption is not included in the table below, instead it is addressed in scenario 3.

TABLE 4 CENTRAL ESTIMATE[15] OF ACTUAL TOTAL BURDENS ON REPORTING BUSINESSES IN 2015

Producers	Importers	Time consumption	Man years	Hourly rate	Administrative cost in DKK
8		772	0.4	464	3-400,000

NOTE: TIME CONSUMPTION AND HOURLY RATE ARE BASED ON DATA PROVIDED BY THE REPORTING BUSINESSES. MAN YEARS CORRESPOND TO 1,924 HOURS. THE RESULTS ARE GENERATED BY MULTIPLYING THE SUM TOTAL OF THE FIVE REPORTING BUSINESSES,772 HOURS BY DKK 464, WHICH IS THE HOURLY RATE FOR THE PERSONNEL GROUP, BY 8/5 BUSINESSES.

[15] By a central estimate is understood estimates of 'population' of businesses covered, 'time consumption' of normally efficient businesses and average 'hourly rate' of personnel doing the reporting to the Inventory.

We have calculated the hourly rate from information about the personnel groups doing the reporting in the businesses. The wage including overhead is based on Appendix 2 of the SCM manual and extrapolated to reflect wage developments, cf. Statistics Denmark (see also Appendix 2). The fixing of the hourly rate to DKK 464 is subject to some uncertainty as it is an average of the time consumption reported by businesses distributed on the different personnel groups available from Statistics Denmark. The business' assessment of the time consumption is an estimate of the time spent on all four phases of activities by key personnel in the business. While the estimates are fairly accurate for the individual businesses, they may not be representative of the entire population of potential reporters. However, in the scenarios presented later in the report, we assume that the distribution of time on personnel groups can be scaled up from the businesses interviewed to the remaining population. Naturally, as pointed out in Chapter 2, this introduces an uncertainty since 'our' businesses are not representative of the entire population and because the small businesses were reluctant to participate. The same hourly rate is applied in scenario 3 and 4 as it represents our best estimate from the data available.

From the above scenario 1 – the actual burdens of the Register in 2015 – we estimate the overall burdens to be DKK 358,000 r 0.4 man years for the eight businesses that reported. This estimate is assessed to be relatively accurate (+/- 50%).

3.2.2 Difference between year 1 and year 2 (i.e. without one-off costs) based on the businesses reporting in 2015

Table 5 shows that the time consumption for all reporters in 2015 will drop from 772 hours to approximately 282 hours in year 2 corresponding to a two thirds reduction in time spent on administrative activities.

TABLE 5
CENTRAL ESTIMATE OF THE DIFFERENCE BETWEEN YEAR 1 AND YEAR 2 (I.E. LESS ONE-OFF COSTS) FOR REPORTERS – BASED ON EXPECTED TIME CONSUMPTION IN YEAR 2 INDICATED BY REPORTERS

	Time consumption	Expected average hourly rate
Expected time consumption, year 2	282	399
Difference between year 1 and year 2	-63%	-14%

Table 5 thus illustrates the level of recurring costs, and thus how much lower these costs are expected to be in year 2, when the one-off costs have been defrayed. This calculation is based on information from the interviews with five of the eight reporting businesses. This gives a bias towards large businesses that spent relatively much time on setting up internal processes and work flows in year 1 and businesses which devoted many resources to participating in the legislative work at national and international level. Considering this, we assess that, overall, the general reduction in adaptation costs from year 1 to year 2 will be less than the 63% observed for the businesses reporting in 2015, which we interviewed. In addition, the estimated hourly rate in year 2 will be lower as the activities, including the actual reporting, involve fewer managers than in year 1, where processes and work flows needed to be developed.

Another plausible cause of the observed reduction in the administrative burdens is better knowledge of the order and overview of products containing nanomaterials. Moreover, in year 2 the businesses have reported all relevant products in their current portfolio to the Register and established contact to the suppliers of the nanoproducts.

The accuracy of the estimate for scenario 2 is assessed to be medium to high.

3.2.3 Administrative burdens for all businesses assessed to have an obligation to check whether they should report to the Register

Non-reporters that checked whether they had a reporting obligation have incurred substantial burdens in doing so. It can be questioned whether this category of businesses is part of a traditional SCM measurement, but it is definitely important in this study to give a more true and fair view of the actual burdens from the order. Interviews with reporters and non-reporters indicate that the order generates significant administrative costs for businesses that are assessed to have an obligation to check whether they have a reporting obligation to the Register for some of their products. The population in scenario 3 thus covers all businesses that use resources to check whether they have a reporting obligation, including businesses that realise that they have to report.

As previously mentioned, it turned out to be impossible to estimate the actual number of businesses that actually checked whether they had a reporting obligation in 2015. Instead, this scenario seeks to assess how many businesses need to check whether they have a reporting obligation in a situation of "full compliance".

Also, as we have explained, the interviews are biased towards large and/or businesses active in the area of nanomaterials. Thus, we expect the time consumption of the normally efficient business across producers to be lower than in the five businesses interviewed. It may also be so in some industries that trade associations inform businesses about products that do not usually contain nanomaterials. For these businesses, the time consumption will be very low. The time consumption reported by the businesses indicates some variation. We estimate that the normally efficient business devotes 20-45 hours to administrative activities related to reporting to the Register. This estimate primarily builds on extrapolation of data from interviews but also on the fact that the typical business is small or medium sized in contrast to the businesses interviewed. The span between 20 and 45 hours illustrates the significant uncertainty of the assessment, and the span may be even larger. In the following analyses, we have calculated the administrative burdens using 20 hours and 45 hours respectively to reflect the uncertainty of the time used by the normally efficient business. See also chapter 2 for a more comprehensive list of uncertainties associated with the project.

Table 6 shows an estimate of the time consumption for the businesses which need to check whether they have a reporting obligation. We assume that the average business will reach the middle of phase 3. This illustrates our point that some businesses will go all the way and end up reporting while others will stop after phase 1, phase 2 or phase 3. Many businesses probably have to contact their suppliers to check whether their articles contain nanomaterials. Based on our interviews with business that reported in 2015, a fair estimate of the time consumed by these companies is approximately 70% of the time spent by a normally efficient business on full reporting.

An extract from Statistics Denmark of 36 commodity codes (CN codes), which could contain nanomaterials indicates that at least 2,724 importers are assessed to have an obligation to check whether they have a reporting obligation. The estimate is based on the description of the CN codes. In addition, we have used interviews and assessments of different trade associations to estimate the number of producers that need to check whether they have a reporting obligation.

Table 6 uses the number of relevant producers and importers, the hourly rate and the normally efficient business to perform the SCM measurement.

TABLE 6
CENTRAL ESTIMATES OF ADMINISTRATIVE BURDENS FOR ALL BUSINESSES THAT NEED TO CHECK WHETHER THEY SHOULD REPORT TO THE REGISTER. THE ESTIMATES INDICATE COSTS IN THE FIRST YEAR, INCL. ONE-OFF COSTS.

	Producers	Importers	Time consumption	Man years**	Hours rate***	Administrative cost in million. DKK ****
Administrative burdens. *Low time consumption*	615	2,24	14*	24	464	21.8
Administrative burdens. *Medium time consumption*	615	2,724	23*	40	464	35.3
Administrative burdens. *High time consumption*	615	2,724	32*	55	464	48.9

NOTES:
* TIME CONSUMPTION IS BASED ON TWO INTERVAL VALUES FOR THE NORMALLY EFFICIENT BUSINESS. LOW TIME CONSUMPTION = 20 HOURS. MEDIUM TIME CONSUMPTION = 33 HOURS, HIGH TIME CONSUMPTION = 45 HOURS. WE HAVE THAT THE BUSINESSES WILL REACH THE MIDDLE OF PHASE 3 ON AVERAGE, CORRESPONDING TO APPROX. 70% OF THE FULL WORKING HOURS USED BY THE NORMALLY EFFICIENT COMPANY ON THE ENTIRE REPORTING PROCESS.
** ONE MAN YEAR CORRESPONDS TO 1,924 HOURS.
*** THE HOURLY RATE IS CALCULATED BASED ON THE INFORMATION PROVIDED BY THE BUSINESSES INTERVIEWED IN 2015 PRICES.
**** ADMINISTRATIVE COSTS ARE CALCULATED IN ACCORDANCE WITH THE SCM METHOD.

Man years are included in the measurement to illustrate the magnitude of the estimated annual costs of personnel conducting activities of no immediate value to the business. The calculation provides estimates of the administrative burdens of businesses in a situation of full compliance in the order of 24 to 55 man years.

The table thus highlights the fact that reporting to the Register amounts to DKK 22 to 49 million of administrative costs in a situation of full compliance.

However, the range is estimated to be much wider since the figures do not reflect all the uncertainty associated with the time estimate and the considerable uncertainty associated with the population estimate.

We have made high and low central estimates for the administrative burdens in scenario 3. Overall, we assess accuracy of the estimates for scenario 3 to be **low.**

It should be noted that this is a measurement of the situation in 'year 1', which includes one-off costs. Many of the businesses that conclude that they do not have a reporting obligation do probably not have to consider the order in year 2 – unless they include (entirely) new products in their portfolio. The one-off costs for scenario 3 are thus assessed to be considerable – 60-80%. **Overall, the costs in year 2 will thus be significantly lower than in year 1.**

3.2.4 Scenario 4 – Administrative burdens of businesses assessed to have a reporting obligation at 'full compliance'

This scenario measures the burdens on the businesses assessed to have a reporting obligation to the Register (in a situation of full compliance).

Scenario 3 operates with three variables. Apart from the high/low estimate for the normally efficient business already shown, we include

- Importers – high/low estimate of the share of businesses assessed to have a reporting obligation within each of the relevant 36 commodity codes (CN codes) extracted from Statistics Denmark[16] – 1% and 5% for articles and 10% and 30% for mixtures.

- High/low estimate of the share of producers assessed to have a reporting obligation – based on estimates of 1% and 5% for articles and 10% and 30% for mixtures[17] respectively.

The three variables can be combined to form eight different models indicating a spread in the central estimates of the administrative burdens in scenario 4 between DKK 1.8 and 13.4 million. Table 7 below presents three of the combinations: the lowest estimate, the highest estimate and the mean value of the variation across the three parameters. Appendix 5 presents the full SCM measurement.

TABLE 7
CENTRAL ESTIMATES OF ADMINISTRATIVE BURDENS FOR ALL BUSINESSSES THAT SHOULD REPORT TO THE REGISTER (FULL COMPLIANCE). ESTIMATES ILLUSTRATE COSTS IN THE FIRST YEAR, INCL. ONE-OFF COSTS

	Producers *	Impor-ters*	Time consump tion**	Man years ***	Hourly rate****	Administrative cost in million DKK
Administrative burdens of businesses at *full compliance – Lowest estimate*	9	184	20	2	464	1.8
Administrative burdens of businesses at *full compliance – Average*	19	398	33	7	464	6.3
Administrative burdens of businesses at *full compliance – Highest estimate*	29	613	45	15	464	13.4

NOTES:
*THE CALCULATION OF THE NUMBER OF PRODUCERS AND IMPORTERS IS SUBJECT TO MUCH UNCERTAINTY. THE SCENARIO IS CALCULATED FOR EIGHT DIFFERENT MODELS, OF WHICH ONLY THE LOWEST, THE AVERAGE AND THE HIGHEST ESTIMATE ARE SHOWN. SEE APPENDIX 5 FOR A PRESENTATION OF ALL RESULTS OF THE MODELLING.
** TIME CONSUMPTION ARE BASED ON THE NORMALLY EFFICIENT BUSINESS.
*** ONE MAIN YEAR CORRESPONDS TO 1,924 HOURS.
****THE HOURLY RATE IS CALCULATED BASED ON THE INFORMATION PROVIDED BY THE BUSINESSES INTERVIEWED. ADMINISTRATIVE COSTS ARE CALCULATED IN ACCORDANCE WITH THE SCM METHOD.

The result of the SCM measurement is shown in Table 7. It can be seen that for businesses with a reporting obligation (full compliance – all businesses with a reporting obligation report to the

[16] See Appendix 4 for details

[17] See Appendix 7 for details

Register), the overall administrative costs are estimated to be between DKK 1.8 and 23.4 million. The mean value of the lowest and highest estimates is DKK 6.3 corresponding to seven full-time staff in the first year.

It should be noted that there are a number of uncertainties which are not reflected in the variation of the three parameters.

Scenarios 1 and 2 show that businesses reporting to the Register can look forward to a substantially lower cost in the years following the first reporting. It seems safe to assume that businesses with a reporting obligation at full compliance will also reduce their administrative burdens, cf. results of scenario 2. Given that there are more small businesses in scenario 4 than in scenarios 1 and 2, we assess that the drop in one-off costs will reduce the administrative burdens of businesses with 30 to 50% in year 2 (compared with two thirds in scenario 2).

In scenario 4, the mean value estimate of the administrative burdens is DKK 6.3 million, albeit with a very large spread of uncertainty. As mentioned previously, it can be argued that the variation is bigger than the quantified interval as the figures do not reflect all uncertainties of the measurement. The accuracy of the measurement in scenario 4 is assessed to be **very low.**

3.3 Summary of the SCM measurement of reporting to the Register

The above measurements estimate the resources spent on reporting by a business in a number of scenarios. As mentioned above, it is important to note that the measurement of scenario 4 is a subset of the measurement of scenario 3, which covered all businesses which are assessed to have an obligation to check whether they have a reporting obligation. Since the order in question can be ambiguous, we found it relevant to distinguish between businesses which should check whether they have a reporting obligation and businesses that should report to the Register.

In the methodology and results sections, we highlighted the many uncertainties. Table 8 below summarises the central estimates for the four scenarios, including the spread in scenarios 3 and 4, where we varied some of the parameters.

As mentioned, there are additional uncertainties, not least in estimating the population (number of businesses) covered by the order; uncertainties which proved impossible to quantify.

TABLE 8 SUMMARY OF CENTRAL ESTIMATES OF THE FOUR SCENARIOS

Scenario	Population	Time consumption	Hourly rate	Minimum administrative burdens in DKK	Maximum administrative burdens in DKK	Mean in million. DKK
1	8	772[1]	464	-	-	0.4
2	8	282[1]	399	-	-	0.1
3	3,339	20-45[2]	464	21.8	48,9	35.4[3]
4	193-641	20-45[2]	464	1.8	13.4	6.3[3]

NOTES:
1: THE TIME CONSUMPTION IS PROVIDED AS A TOTAL FOR ALL EIGHT REPORTING BUSINESSES
2: NORMALLY EFFICIENT BUSINESS, I.E. A STANDARD BUSINESS IS ASSUMED TO SPEND EITHER 20 OR 45 HOURS. SCENARIOS 1 AND 2 ARE BASED DIRECTLY ON INTERVIEW DATA AND ARE LESS SUBJECT TO UNCERTAINTY THAN SCENARIOS 3 AND 4.
3: AVERAGE. SCENARIO 4 HAS A STANDARD DEVIATION OF 4,514 AND A STANDARD ERROR OF 1,596.

3.4 Assessment of the consequences of removing four article-specific exemptions specific to certain articles

When the Statutory Order on the Register of Nanoproducts came into effect, a number of exemptions were introduced (Article 3 of the order) to ease the businesses' administrative burdens.

Several consultation responses in connection with the Statutory Order, including views from researchers and NGOs, have quoted that the exemptions are too extensive/wide-ranging and that it is not possible to obtain a comprehensive picture of nanomaterials in articles.

One of the purposes of this project was to estimate the administrative burdens related to a possible abolishment of the following four article-specific exemptions (Article 3(1), items 11-15):

- 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.
- Textiles where nanomaterial is used as ink or for dyeing of textiles.
- Paint, wood preservative, glue and filler containing pigment on the nanoscale where the pigment is added solely for the purpose of colouring the mixture.
- Articles of rubber or rubber parts of articles that contain the nanomaterials carbon black (EINECS No 215-609-9) or silicon dioxide (EINECS numbers 231-545-4, 262-373-8, 238-455-4, 238-878-4 and 239-487-1 or CAS numbers 13778-37-5, 13778-38-6, and 17679-64-0).

3.4.1 Preliminary observations

Most of the interviews conducted as part of the project addressed the consequences of abolishing these four exemptions, as the abolishment of the exemptions, to a greater or lesser extent, could affect the concerned businesses and industries.

It should be noted that the content of pigments, which is generally deemed to fulfil the recommended EU definition of nanomaterial[18], is a key element in exemptions 1 to 3.

These interviews revealed a number of issues to be clarified, if the exemptions are abolished:

- Are materials wrapped around consumer articles (i.e. packaging) and labels applied to consumer articles to be perceived as independent articles or as an integrated part of the articles? The latter may ultimately result in an obligation to report almost all consumer articles due to their content of pigments in the printing ink.
- The general practice is to report articles with unique CN codes. Does this mean that reporting is obligatory for all editions of newspapers, periodicals, magazines etc.?
- Is reporting obligatory for free newspapers, advertisements, brochures etc.? (The Statutory Order specifies "*sale to the general public*", but it can be difficult to understand why there is an obligation to report newspapers that are being sold, while newspapers, which are distributed freely, are exempt from reporting).
- Based on the present guidelines, the industry does not accept an obligation to report plastic articles, as they are of the opinion that plastic articles do not release free

[18] Sørensen, M.A., Ingerslev, F., Bom, K., Lassen, C., Christensen, F., Warming, M. (2015). Survey of products with nanosized pigments. Environmental project no 1638. *Danish Environmental Protection Agency.*

nanoparticles. If this interpretation is accepted, the abolishment of exemption 4 will not affect the administrative burdens, while another interpretation would lead to an obligation to report a very high number of plastic products.

- The interpretation of the release criterion is also an important factor when assessing the consequences of abolishing exemptions 1 and 2.

Given the uncertainties, which should be added to those already described in section **Fejl! Henvisningskilde ikke fundet.**, it was decided in dialogue with the reference group and the Danish Environmental Protection Agency that in view of the present findings, it would make no sense trying to quantify the burdens related to the abolishment of the exemptions.

In the following, we will therefore discuss the qualitative consequences of abolishing the exemptions.

3.4.2 The consequences of abolishing exemption 1. Articles with a nanomaterial in the printing ink on the surface of the article or on the label on the article, including newspapers, periodicals, magazines, packaging material

As already indicated, the abolishment of this exemption could imply that articles, which are marketed in packaging and/or with a label, i.e. basically all consumer articles, will be subject to reporting. This will affect thousands of businesses.

Dependent on the interpretation, the abolishment could result in an obligation to report a large number of newspapers, periodicals, brochures, advertisements, etc.

Reference is also made to section 3.4.5 on general observations on exemptions 1 to 3.

3.4.3 The consequences of abolishing exemption 2. Textile articles, if the nanomaterial is used as a printing ink or to dye the textile

Abolishment of this exemption would potentially imply that basically all consumer textiles would be subject to reporting due to their use of colouring agents containing pigments. Add to this that the textile industry is influenced by fashion with frequent change of collection and suppliers. Players in the industry find it difficult to estimate how much effort would be needed to meet an obligation to report like this. Several big players however mention that it may demand a full-time employee to administer the necessary information flow in complicated product chains. A number of players also mention that there would definitely be importers, who would not be able to meet such a demand and/or who would "skip" it, which may lead to unfair competition.

Reference is also made to section 3.4.5 on general observations on exemptions 1 to 3.

3.4.4 The consequences of abolishing exemption 3. Paint, wood preservatives, adhesives and fillers containing nanoscale pigment, where the pigment has solely been added to dye the mixture

Generally, all paint, adhesives etc. contain pigments, and the abolishment of this exemption may thus imply that basically all paints and adhesives would be subject to reporting.

Players in the industry find it difficult to estimate how much time they would have to spend on reporting. Many businesses are fully in control of what kind of pigments are used, but on the other hand, they would have to report a very large number of articles. Some businesses mention that pigment pastes are often not classified and that it would therefore demand intensive supplier contact to obtain the necessary information.

From interviews with a number of paint/adhesive businesses, which have based their reporting on the content of other nanomaterials than pigments, a conservative estimate is that the abolishment of this exemption would more than a double the time consumed compared to the present scope in the order.

Reference is also made to section 3.4.5 on general observations on exemptions 1 to 3.

3.4.5 General observations on exemptions 1 to 3

As mentioned above, the exemptions 1 to 3 concern the content of pigments in a number of article types. The players in the relevant industries have questioned whether it would give any "added value" to report an extremely large number of articles containing pigments, referring to the general mapping of the use of pigments made by the Danish Environmental Protection Agency, which already gives an overview of their use. According to the industry, the best way to address a further need for information on pigments could be in the form of follow-up surveys.

3.4.6 The consequences of abolishing exemption 4. Rubber articles or articles with the rubber subcomponents carbon black (EINECS number 215-609-9) or silicon dioxide (EINECS numbers 231-545-4, 262-373-8, 238-455-4, 238-878-4 and 239-487-1 or CAS numbers 13778-37-5, 13778-38-6 and 17679-64-0)

As already indicated in the beginning of this section, the consequences of abolishing this exemption may vary from no consequences (i.e. nanomaterials are not released from the plastic article) to far-reaching consequences (if the plastic article are considered to release nanomaterials). Thus, it is difficult to come up with further reflections on the consequences of abolishing this exemption.

4. Reporting barriers experien by businesses in connection the reporting

This chapter evaluates and analyses the businesses' experience – good or bad – with their first reporting to the Nanoproductregister.

In the following, we describe the businesses' experience with the guidelines, the reporting module at virk.dk, the help desk, etc. We have based the evaluations and analyses on interviews with businesses and trade associations. The aim of the section is to establish a good qualitative basis for promoting learning and suggesting improvements.

4.1 Barriers and frustrations experienced by the businesses

In general, the most important barriers experienced are the fact that the businesses do not have the required knowledge to determine whether their products are reportable, including the data demanded for reporting to the Register. According to the businesses, reporting requires information on matters, which they are not concerned with in the day-to-day running of the business, production processes or environmental procedures. The Danish Environmental Protection Agency is aware of these issues and has tried to mitigate them by proactively providing information, facilitating and placing auxiliary tools at the disposal of the businesses. The Danish Environmental Protection Agency has:

- developed guidelines
- developed a covering letter to the supplier in Danish and English for use by the businesses
- established a reference group, which has been involved on a regular basis
- toured with informative lectures and to urge dialogue
- made available a fully manned and competent help desk.

Interviews show that businesses and industrial organisations seem very satisfied with the above efforts. However, due to the complexity of the task, the subject field and the unclear definition of the target group, the businesses experience considerable barriers and frustrations despite the Agency's good work.

The interviewed businesses, which had all either performed the reporting or had checked whether they had a reporting obligation, mentioned that to the best of their belief, there are a great many businesses, which do not know the order, but which are supposed to know it, and/or which at an early stage "give up" understanding what the order is about (what is "nano"?).

We have summarized the most important barriers experienced below:

- **Danish special legislation is not appropriate**. According to Danish businesses, the suppliers will not prioritise spending time on special legislation made by Denmark. This causes problems during the implementation, because businesses are dependent on the suppliers' assistance in collecting valid data. In

addition, the businesses find it a competitive problem that Danish businesses are burdened with special charges, which our competitors are not subjected to.

- **The businesses find that the actual subject field (the Statutory Order on the Nanoproductregister) is very complex and difficult to understand**. In Denmark, there is a majority of small businesses – many of them are importers/business persons/non-technicians, who have very restricted knowledge of nanomaterials. This means that many businesses, which have a reporting obligation or had to check whether they were reportable, have not been aware of this or have not had any idea of how to address the reporting.
- **Communication with suppliers** – in English or for example Asian languages, etc. – on complex matters has been very time consuming for the businesses. The process has been characterised by many long and detailed iterations with follow-ups on inquiries, questions, replies, new questions, etc. The supply chains are often long with many ramifications, which sometimes makes it difficult to find the right entry point for obtaining the necessary information. In addition, suppliers may mistrust the importer or lack confidence when it comes to disclosing data. The businesses may also find it difficult to explain to the suppliers why they need to provide data according to specific Danish regulation. Overall, when and if the businesses eventually obtain data from the supplier, there are a number of circumstances, which make the businesses believe that there is a considerable risk of either losing relevant information due to the complexity of the subject field and/or the communication or a risk of obtaining wilfully distorted information.
- **Frustrations due to problems with virk.dk.** During a period up to deadline for performing the reporting to the Register, the reporting module (accessed via virk.dk) was not available due to IT failure. The businesses experienced this as an extra source of irritation. Several of the interviewed businesses estimate that this may have contributed to the relatively limited reporting for 2015.
- **The staff responsible for reporting to the Register do not have the digital signature NemID.** It has been a nuisance for the personnel of some businesses having to report via virk.dk (which requires that the employee obtains a company NemID), because the staff responsible for reporting to the Register have not obtained the NemID beforehand. With a company NemID, it is possible to change a large number of company reports (and not only the reporting to the Register). Typically, the company's digital signature lies with the finance department. Especially in large businesses with well-established quality management/risk management systems, this has caused problems when deciding which staff were to have access to a NemID signature and thus in principle be authorised signatories for the company.
- **Open-ended matters of interpretation and ambiguities cause irritation.** The order contains issues open to interpretation that the businesses do not know how to address. This is particularly the case when understanding the concepts *release* and *intentionally produced*. It provides an inadequate and unclear basis and contributes to the businesses' irritation. *The authors' comment: It needs to be said, however, that these criteria were introduced in the order to ease the burdens on businesses, i.e. they are only to report if the products contain nanomaterial that can be released and only if the nanomaterial has been intentionally manufactured. This is therefore a paradox.*

4.2 Improvements of the existing model

Many things have functioned well and should continue in the future, such as communication, assistance and the process between the Danish Environmental Protection Agency, the industry and the businesses. Generally, the businesses and the trade associations praise the process of creating the order, the current involvement and the set-up of back-up facilities. The Danish Environmental Protection Agency has facilitated good meetings and listened to input from the industry resulting among others in a number of exemptions to the order. The businesses welcome the fact that there has been a help desk assisting in all kinds of situations as well as a guideline to lean on.

There is a major difference in the level of activity of the different industrial organisations. Some trade associations have been very active in taking specific initiatives, interpreting and making guidelines tailored to the businesses in the specific industry. These industries have had a significantly higher state of knowledge compared to others in the field of nanoproducts. In the future, it should therefore be considered making better use of the existing trade channels, as these are closely linked to their businesses.

Making use of the good dialogue, auxiliary tools and communication is, however, not sufficient to compensate for the fact that it is extremely difficult for businesses to understand and meet the requirements of the order.

The existing obligation to report is hard to meet even for businesses that do their utmost to perform the reporting. It is of critical importance that the reporting obligation *becomes more practical*. This may be in the form of a list of specific substances (names of nanomaterials) on which the businesses are obliged to provide information and data. This would make reporting much more feasible for those businesses, which possess neither knowledge nor opportunities to solve complicated technical matters. It is especially the open-ended matters of interpretation, which confuse and frustrate the businesses, in particular, the wordings *release* and *intentionally manufactured*. The businesses find it strange that this uncertainty is passed on to the businesses. The businesses are frustrated that experts, researchers or the Danish Environmental Protection Agency do not give a more precise definition of the concepts.

Another field where the businesses find room for improvement is to include more examples in the guidelines. They mention the use of examples as important for the understanding and the practical use. *The authors' comment: This is always a balancing of how long guidelines should be to explain matters in detail while, at the same time, other businesses may find the explanations long and irrelevant, if the examples do not match their situation. Furthermore, the businesses may perceive many examples as suitable for all relevant products. This should be balanced against the fact that the Register was established in order to determine, which products contain (and release) nanomaterials.*

Besides that it was not accessible via virk.dk for some time, the users have been satisfied with the reporting module. This is also illustrated by the fact that according to the results in chapter 3, it is not the actual reporting, which has proved to be time consuming. Nevertheless, several businesses have identified minor issues, which could be improved:

- The user should be able to report in one window in the browser instead of moving back and forth all the time

- It should be clearly stated how to report the volume of products (instead of letting the user decide, which unit to use, numbers/kg/litre). Thus, some businesses have spent time on unnecessary recalculations.

- One of the businesses interviewed had first tried to use the developed XML-based tool for group reporting, but found it too complicated. As an alternative, several businesses have found the "copy product" function in the ordinary reporting module very useful.

4.3 Proposals for other models

The basic reporting problem experienced by the businesses is that the knowledge required by the Register is inaccessible. As several businesses put it:

The knowledge asked for is not available in Denmark! This knowledge should be obtained from suppliers and producers abroad! This means that we (the businesses) have to collect information abroad and often far down the supplier chain.

In this way, the reporting to the Register becomes very much an exercise in good communication and in coaxing data from the suppliers to the businesses. This is very difficult for the businesses and in reality, often beyond their control. It is not so easy for suppliers in Asia to inform Danish businesses of "nano" substances in their products. As the businesses put it:

"They (the Asian suppliers) may have an interest in saying that there are no nanomaterials in their product, if they sense that the Danish businesses think that "nano" sounds dangerous."

The many links in the supplier chain make it very difficult to ensure that all suppliers give correct information and, subsequently, that the purchasers understand the information correctly. This information chain is very vulnerable and the businesses will definitely receive very uncertain data from the suppliers.

It is not clear whether the present model "Reporting to the Register of Nanoproducts" will provide a general view of the use of nanomaterials in products in Denmark. Businesses and industrial organisations are therefore critical of the Register and question its value, if any.

Danish special legislation is expensive and ineffective – harmonisation of the EU regulations. The businesses find it difficult to obtain information from the suppliers in the case of Danish special legislation. The suppliers do not attach enough importance to the matter when a single Danish company asks for "hard-to-get" data, which are not generally prevalent in the supply chain. In addition, Danish businesses cooperating with suppliers may see their competitiveness reduced compared to foreign competitors, which do not request answers on nanoproducts. There is a need for EU harmonisation - such as for example the REACH regulation, which requires provision of data about products with a content of substances of very high concern exceeding more than 0.1% - in order to form a consensus between the supplier chains, which are often composed of businesses in Europe and suppliers in Asia. Experience from REACH shows that when implemented at the EU level, the suppliers will gradually adapt to the order and establish the necessary logistics for providing documentation.

Mapping of nanomaterials through a focused analysis of industrial supplier chains. Another and, according to several sources, more efficient way of obtaining data is by mapping specific selected industries and supplier chains etc. The method applied could be in the form of a strategic cooperation with selected industries or businesses with the purpose of examining the supplier chains in detail and mapping the nanomaterials. A selection of relevant industries should be made, based on significant exposure and/or use of particularly hazardous nanomaterials. This risk consideration is important in order to focus on significant exposures/hazardous nanomaterials instead of directing a general suspicion towards nanoproducts/nanotechnology.

Mapping of nanomaterials through producers. A mapping of the dissemination of nanoproducts could start with the producers of nanomaterials which are then followed down the value chain. A combination of both producer and importer chains could be an appropriate way of mapping nanomaterials, but this will require international cooperation, as Denmark does not produce nanomaterials commercially on a large scale.

Today, e-trading articles are not covered by the order. E-trading of articles constitutes an increasing share of markets[19]. Especially the significant growth in foreign e-trading may constitute a problem to the present model. This is partly because e-trading articles are not covered by the order and partly because the very concept distorts trade and put Danish businesses at a competitive disadvantage.

[19] The total Danish e-trade (articles and services) amounted to DKK 80 billion in 2014. Of this, approx. DKK 20 billion were purchases from abroad, while DKK 60 billion were purchases from Danish webshops. E-trade grows at a rate of 15% annually. Source: Danish Chamber of Commerce

Appendix 1 List of interviewees

Trade associations
Danish Coatings and Adhesives Association (DFL)
The Danish Plastics Federation (PI)
Packaging industry
Danish Fashion and Textile
The Danish Association for Communication, Design & Media (Grakom)
Danish Chamber of Commerce
Association of Manufacturers and Importers of Domestic Electrical Appliances (FEHA)
The Retail Trade
Confederation of Danish Industry, DI CONSTRUCTION
SPT Association (detergent- and cleaning products, and cosmetics and personal care products)
Danish Toy Association
In addition, we have interviewed 11 businesses, of which five reported to the Register in 2015. As per agreement, the names of the businesses are confidential.

Appendix 2 Hourly rates

Job title	Hourly rate (2011-prices)	Hourly rate (2015-prices)	Overhead (25%)	Incl. over head	Consumption in year 1	Consumption in year 2
Environmental manager	378	400	100	500	74,375	24,875
Development manager	378	400	100	500	41,250	7,500
QA manager	378	400	100	500	73,125	7,500
IT supporter	339	358	90	448	896	448
Procurement officer	283	299	75	374	4,675	4,675
Trainee/office girl/boy	217	229	57	286	21,450	21,450
Chemist	372	393	98	491	6,138	3,683
Finance assistant	373	394	99	493	370	247
Lawyer	404	427	107	534	0	0
External consultants	889	940	0	940	0	0
Marketing manager	513	542	136	678	1,356	0
					357,815	112,603

Salary developments	2010	2011	2012	2013	2014	2015
	2.2%	1.8%	1.5%	1.3%	1.3%	1.5%

Calculated mean hourly rate		
YEAR 2	YEAR 1	
112,603	357,815	TOTAL COSTS
282	771.6	WORKING HOURS REPORTED BY INTERVIEWED BUSINESSES
399.3	463.7	HOURLY RATE

Appendix 3 Information about industries

Trade	Estimate
Coatings and Adhesives industry	90% of businesses have joined the trade association 30 members of the trade association
Plastics industry	Approx. 200 members of the trade association Approx. 250 businesses in the plastics industry
Packaging industry	Approx. 40 members of the Danish Confederation of Industry are from the packaging industry
Textile industry	300 businesses in the Danish fashion and textile industry Approx. 400-500 businesses in the sector overall
Printing industry	Approx. 400 businesses are members of the Danish Association for Communication, Design & Media (GRAKOM), of which approx. 200 are printing offices (the entire trade, however, no newspaper printing offices among these). Estimate of newspaper printing offices: 30
Retail industry	60% of non-food products are imported
IT industry	-
Electronics industry	50 businesses. Almost all import electronic products
Textile industry	Approx. 500 businesses in the trade
Retail industry	Approx. 15,000 businesses in the wholesale industry in DK Approx. 26,000 businesses in the retail industry in DK (no overlap between the figures)
Danish Chamber of Commerce	
Retail industry	Typically, one third of the retail industry manufactures private label products and two thirds of the industry import products from extra-EU countries
Construction industry	<5% of the businesses in the construction industry use nanoproducts (it is estimated that each of these businesses only uses a few product codes (CN codes))
Business size	75% of all businesses in DK employ less than 10 persons

Appendix 4 Statistics Denmark – Data for 36 relevant CN codes

CN Code	Description	Share who should to report to the Register	Simplified percen-tage	Low estimate	High estimate	No.	Value (DKK)	Imported by small businesses, value (DKK)	No., value of total imports (%)	No., relevant to the Danish Nanoproduc tregister
32089091	Paint, varnish and coatings, etc.	Many businesses (50-80%)	0.65	0.10	0.30	154	211,858,002	32,892,447	0.87	100
32139000	Artists colours, amusement colours and the like	Some businesses (20-50%)	0.35	0.10	0.30	68	16,324,241	3,269,231	0.83	24
32141010	Sealing compounds and fillings	Some businesses (20-50%)	0.35	0.10	0.30	205	226,007,947	40,958,242	0.85	72
34021190	Organic surface-active agents	All businesses (80-100%)	0.90	0.10	0.30	75	60,995,917	7,026,133	0.90	68
34022090	Washing preparations, etc.	Few businesses (0-20%)	0.10	0.10	0.30	356	624,221,007	24,577,619	0.96	36
34051000	Polishes, creams and similar preparations, for footwear or leather	Many businesses (50-80%)	0.65	0.10	0.30	90	13,223,019	10,842,073	0.55	59
34053000	Polishes and similar preparations for coachwork	Few businesses (0-20%)	0.10	0.10	0.30	86	20,589,241	11,151,381	0.65	9
34059090	Polishes and creams for	Few businesses	0.10	0.10	0.30	136	8,847,603	2,553,957	0.78	14

CN Code	Description	Share who should to report to the Register	Simplified percen-tage	Low estimate	High estimate	No.	Value (DKK)	Imported by small businesses, value (DKK)	No., value of total imports (%)	No., relevant to the Danish Nanoproduc tregister
	glass	(0-20%)								
34060000	Candles, tapers and the like	Few businesses (0-20%)	0.10	0.01	0.05	180	366,162,164	36,174,307	0.91	18
34070000	Modelling pastes, including those put up for children's amusement	Few businesses (0-20%)	0.10	0.01	0.05	62	26,308,341	4,058,210	0.87	6
38112100	Additives for lubricating oils containing petroleum oils or oils obtained from bituminous minerals	Many businesses (50-80%)	0.65	0.10	0.30	32	2,981,849	149,199	0.95	21
38119000	Anti-knock preparations, oxidation inhibitors, gum inhibitors, viscosity improvers, anti-corrosive preparations and other prepared additives, for mineral oils	Few businesses (0-20%)	0.10	0.10	0.30	75	158,194,909	4,468,545	0.97	8
61130090	Garments, made up of knitted or crocheted fabrics	Some businesses (20-50%)	0.35	0.01	0.05	123	46,724,922	1,705,758	0.96	43
61159699	Pantyhose, tights,	Few businesses	0.10	0.01	0.05	202	44,528,880	8,973,528	0.83	20

CN Code	Description	Share who should to report to the Register	Simplified percen-tage	Low estimate	High estimate	No.	Value (DKK)	Imported by small businesses, value (DKK)	No., value of total imports (%)	No., relevant to the Danish Nanoproduc tregister
	stockings, socks and other hosiery	(0-20%)								
62019300	Overcoats, cloaks, anoraks	Few businesses (0-20%)	0.10	0.01	0.05	375	780,378,109	28,064,288	0.97	38
62032210	Occupational clothing and protective clothing	Few businesses (0-20%)	0.10	0.01	0.05	21	919,535	2,890,396	0.24	2
63026000	Toilet linen and kitchen linen	Few businesses (0-20%)	0.10	0.01	0.05	368	252,626,602	12,377,002	0.95	37
63062200	Tents made of synthetic fibres	Few businesses (0-20 %)	0.10	0.01	0.05	120	155,584,951	8,295,040	0.95	12
64021900	Sports footwear with outer soles and uppers of rubber or plastics	Few businesses (0-20%)	0.10	0.01	0.05	113	102,421,537	13,164,517	0.89	11
64069050	Removable insoles, heel cushions and similar articles	Few businesses (0-20%)	0.10	0.01	0.05	120	35,919,364	17,338,032	0.67	12
66011000	Garden umbrellas and similar umbrellas	Few businesses (0-20%)	0.10	0.01	0.05	102	51,799,328	2,562,140	0.95	10
84182900	Refrigerators, household type	Few businesses (0-20%)	0.10			42	14,853,523	684,332	0.96	4

CN Code	Description	Share who should to report to the Register	Simplified percen-tage	Low estimate	High estimate	No.	Value (DKK)	Imported by small businesses, value (DKK)	No., value of total imports (%)	No., relevant to the Danish Nanoproduc tregister
84439990	Parts and accessories for printers	Few businesses (0-20%)	0.10	0.01	0.05	370	1,814,782,168	127,248,872	0.93	37
84716060	Keyboards for automatic data-processing machines and units thereof	Few businesses (0-20%)	0.10	0.01	0.05	331	173,882,697	15,953,018	0.92	33
85163100	Electrical hairdryers	Few businesses (0-20%)	0.10	0.01	0.05	75	28,286,066	3,552,474	0.89	8
94042110	Mattresses of cellular rubber	Few businesses (0-20%)	0.10	0.01	0.05	50	84,483,525	19,463,635	0.81	5
94042910	Mattresses fitted with springs	Few businesses (0-20%)	0.10	0.01	0.05	44	100,729,606	45,169,564	0.69	4
95030041	Toys in the shape of animals	Few businesses (0-20%)	0.10	0.01	0.05	235	156,191,325	8,473,277	0.95	24
96032100	Toothbrushes, including dental-plate brushes	Few businesses (0-20%)	0.10	0.01	0.05	119	89,493,818	7,805,236	0.92	12
96082000	Felt-tipped and other porous-tipped pens and markers	Few businesses (0-20%)	0.10	0.10	0.30	234	45,223,411	9,925,299	0.82	23
96099010	Pastels and drawing charcoals	Many businesses (50-80%)	0.65	0.10	0.30	29	1,654,789	72,474	0.96	19

Appendix 5 SCM calculations

Scenario		Producers	Importers	Time consumption	Man years	Hourly rate	Administrative costs in DKK	Accuracy
1	The actual burdens in 2015 – Businesses reporting to the Register in 2015 – 20 hours	8		772	0,4	464	357,815	High
2	Difference between year 1 and 2 (one-off costs) based on businesses that reported in 2015, in %	8		-63%	-63%	-14%	-69%	Medium to high accuracy
3.A	Administrative burdens for all businesses that checked but did not report. 20 hours	615	2,724	14	24	464	21,747,769	Medium accuracy
3.B	Administrative burdens for all businesses that checked but did not report. 33 hours	615	2,724	23	40	464	35,340,125	
3.C	Administrative burdens for all businesses that checked but did not report. 45 hours	615	2,724	32	55	464	48,932,481	

Scenario		Producers	Importers	Time consumption	Man years	Hourly rate	Administrative costs in DKK	Accuracy
4.A	Administrative burdens for all businesses with a reporting obligation (full compliance).	29	613	45	15	464	13,381,536	Low accuracy
4.B	Administrative burdens for all businesses with a reporting obligation (full compliance).	9	184	45	5	464	4,020,200	
4.C	Administrative burdens for all businesses with a reporting obligation (full compliance).	9	613	45	15	464	12,960,005	
4.D	Administrative burdens for all businesses with a reporting obligation (full compliance).	29	184	45	5	464	4,441,731	
4.E	Administrative burdens for all businesses with a reporting obligation (full compliance).	29	613	20	7	464	5,947,349	
4.F	Administrative burdens for all businesses with a reporting obligation (full compliance).	29	184	20	2	464	1,974,103	
4.G	Administrative burdens for all businesses with a reporting obligation (full compliance).	9	184	20	2	464	1,786,755	
4.H	Administrative burdens for all businesses with a reporting obligation (full compliance).	9	613	20	6	464	5,760,002	
4.Gns.	Average of the different scenario 4 models	19	398	33	7	464	6,283,960	

Appendix 6 Distribution of time on phases

% of consumption, reporters							
Overall time consumption [hours in year 1]	**Business 1**	**Business 2**	**Business 3**	**Business 4**	**Business 5**	**Mean**	**Variance**
Phase 1: The business checks whether it has a reporting obligation	17%	26%	29%	48%	5%	25%	0.02
Phase 2: The business identifies reportable products	21%	20%	6%	19%	75%	28%	0.06
Phase 3 The business collets relevant product data	54%	51%	33%	25%	10%	34%	0.03
Phase 4: The business reports	9%	3%	33%	8%	10%	13%	0.01
Total	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**	

Hourly share for the business in the middle of Phase 3 of the reporting	0.702266938

% of consumption, non-reporters			
Overall time consumption [hours in year 1]	**Business 1**	**Business 2**	**Average**
Phase 1: The business checks whether it has a reporting obligation	69%	50%	60%
Phase 2: The business identifies reportable products	7%	32%	20%
Phase 3 The business collects relevant product data	23%	0%	12%
Phase 4: The business reports	0%	0%	0%
Total	**100%**	**82%**	**91%**

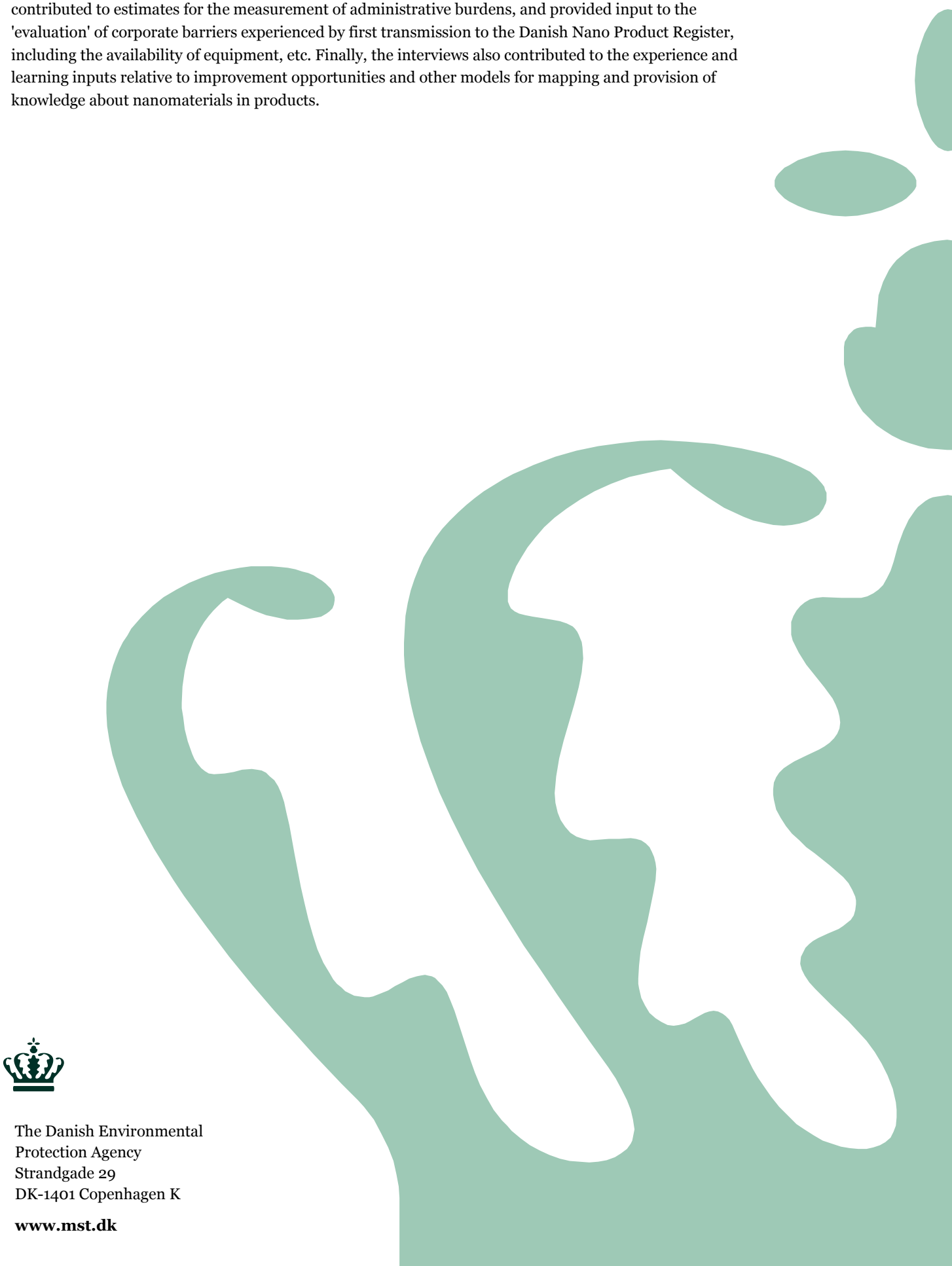
Appendix 7 Producers' estimates

Industry	Number of businesses	Importer/producer	Manu-facturers' estimates- of no. of businesses that need to check	Producers' estimate of no. of businesses with a reporting obligation (full compliance). Low percentage 1% articles and 10% mixtures	Producers' estimates of no. businesses with a reporting obligation (full compliance). High percentage 5% articles and 30% mixtures
Paint and adhesives	Approx. 35 in the trade organisation	Producers (some also import paint for resale to consumers)	20	2	6
Plastics	Approx. 250 in the industry	Producers (mainly)	150	0	0
Packaging	37 members in the trade organisation	Producers (and a high number of importers)	40	0	0
Printing	Approx. 200 printing offices in the industry Approx. 30 newspaper printing offices in the industry	Producers	200	0	0
Electronics (domestic appliances, incl. kitchen appliances)	Approx. 50 businesses in the industry	Importers (and a few producers)	5	0.05	0.25
Textiles	Approx. 500 businesses in the industry	:	100	1	5

Industry	Number of businesses	Importer/producer	Manu-facturers' estimates- of no. of businesses that need to check	Producers' estimate of no. of businesses with a reporting obligation (full compliance). Low percentage 1% articles and 10% mixtures	Producers' estimates of no. businesses with a reporting obligation (full compliance). High percentage 5% articles and 30% mixtures
Retail (commerce)	Approx. 15,000 businesses in the wholesale industry Approx. 26,000 businesses in the retail industry	Importers (we have no knowledge of the number of importers of articles and purchasers of Danish articles only)	Many	0	0
Construction	-	-	50	0.5	2.5
Detergent and cleaning products	-	-	30	3	9
Toys, etc.	-	-	20	2	6
IT (television, PC, telephone)	NA		0	0	0
Total			**615**	**9**	**29**

Assessment of the administrative burdens on businesses with a reporting obligation to the Danish Nanoproductregister

The project estimates the administrative burden of businesses reporting to the Danish Nano Product Register using the standard cost method. Interviews with companies and industry associations have contributed to estimates for the measurement of administrative burdens, and provided input to the 'evaluation' of corporate barriers experienced by first transmission to the Danish Nano Product Register, including the availability of equipment, etc. Finally, the interviews also contributed to the experience and learning inputs relative to improvement opportunities and other models for mapping and provision of knowledge about nanomaterials in products.



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