This text is to be regarded as an unofficial translation based on the latest official [Statutory Order no. 644 of 13 June 2014](http://mst.dk/media/mst/9424487/Bekendtg%C3%B8relse%20Final%20order%20after%20notification%20uoff%20translation%20to%20English.docx). Only the Danish document has legal validity.

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[[1]](#footnote-1))

The following is laid down pursuant to § 42(1), (2), and (4), § 45 (1), § 47, § 55(1) and (2), § 58 (4), and § 59(4) of the Chemicals Act - see Consolidation Act No 878 of 26 June 2010 as amended by Act No 294 of 11 April 2011, Act No 1273 of 21 December 2011, Act No 161 of 28 February 2012, Act No 277 of 13 March 2013, and Act No 489 of 21 May 2013:

Chapter 1

*Purpose and scope*

**§ 1.** The purpose of this Order is to establish a register of mixtures and articles that contain nanomaterials (the nano product register) and which are intended for sale to the general public, as well as require producers and importers of these mixtures and articles to report to the nano product register information on said mixtures and articles and the nano materials they contain.

**§ 2.** The reporting requirement to the nano product register includes mixtures and articles that are intended for sale to the general public and which contain nanomaterials, where the nanomaterial itself is released under normal or reasonably foreseeable use of the mixture or article or where the nanomaterial itself is not released but substances in soluble form that are classified as CMRs or environmentally dangerous substances are released from the nanomaterial; except as provided for in § 3.

**§ 3.** The required reporting to the nano product register does not include:

1. Foodstuffs and food contact materials.
2. Feed.
3. Medicinal products.
4. Medical devices.
5. Cosmetic products.
6. Pesticides.
7. Waste.
8. Mixtures and articles in which the nanomaterial is the nanoscale of substances listed in Annex IV or V to Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH).
9. Mixtures and articles for which the nanomaterial is not intentionally produced at the nanoscale.
10. Articles in which the nanomaterial is part of a fixed matrix, unless wear and tear, washing, breaking, and similar normal use of the article leads to the release of free nanomaterials; see § 2.
11. 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.
12. Textiles where nanomaterial is used as ink or for dyeing of textiles.
13. Paint, wood preservative, glue and filler containing pigment on the nanoscale where the pigment is added solely for the purpose of colouring the mixture.
14. 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).

*(2)* Mixtures and articles produced or imported by individuals for their own, non-commercial use are not covered by this Order.

Chapter 2

*Definitions*

**§ 4.** In this Order, the following terms shall have the following meanings:

1. Nanomaterials: A natural, incidental, or manufactured material that contains particles in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm-100 nm (nanometres). The definition follows Commission Recommendation 2011/696/EU on the definition of nanomaterial.
2. Particle, cf. no. 1): a minute piece of matter with defined physical boundaries.
3. Agglomerate, cf. no. 1): a collection of weakly bound particles or aggregates where the resulting external surface area is similar to the sum of the surface areas of the individual components.
4. Aggregate, cf. no. 1): a particle comprising of strongly bound or fused particles.
5. Substances that are classified as CMRs or environmentally dangerous substances: Substances that are to be classified as carcinogenic, mutagenic or toxic for reproduction in category 1A or 1B or those that are to be classified as environmentally dangerous in acute category 1 or chronic category 1-4 under Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures.

Chapter 3

*The obligation for producers and importers to report to the nano product register*

**§ 5.** Companies that manufacture or import mixtures and articles covered by § 2 must report information on the mixtures and articles, as set out in Annex 1, to the nano product register, except as provided for in paragraphs (3)-(6) below.

*(2)* Companies covered by paragraph 1 may in addition voluntarily report to the nano product register the information on mixtures and articles found in Annex 2.

*(3)* If a mixture has already been notified to the common register of the Ministry of Employment and the Ministry of the Environment for substances, materials, and products (the product register), reporting to the nano product register under paragraph 1 may be narrowed down to information on the mixture's registration number in the product register, CAS numbers of the substances of which the nanomaterial is on the nanoscale as well as information on the nanomaterial in the mixture and production volume of the mixture as required under Annex 1 which is not stated in the notification to the product register.

*(4)* A mixture or an article may be subject to the reporting obligation under paragraph 1 when the mixture or article contains another mixture or article for which reporting is required or when the mixture or article is a further processing of another mixture or article for which reporting is required. In these cases, reporting to the nano product register under paragraph 1 may be narrowed down to the reporting number in the nano product register (see § 7) for the other reported mixture or article if the other mixture or article has indeed been reported and no further nanomaterials have been added.

*(5)*Reporting of certain pieces of information in categories C and D of Annex 1 (see paragraph 1) may be omitted from reporting if, in conjunction with the reporting, it is also concomitantly documented that it is not possible or excessive costs would be incurred to obtain the information.

*(6*) An importer may agree with his foreign manufacturer, whether it is a manufacturer from an EU country or a third country, that the manufacturer himself or the manufacturer’s only representative in the EU report specific information stated in Annexes 1 and 2 on behalf of the importer. The importer will then be released from the part of the reporting obligation which the manufacturer fulfils. The importer can make the same agreement with other foreign actors in the importer's supply chain. The importer must then in his report state the reporting numbers of the reports that were made ​​on behalf of the importer, and inform what information these reports replace.

**§ 6.** Reporting under § 5 shall be once annually. The reporting is to cover mixtures and articles manufactured or imported in the period from 20 June the previous year to 20 June of the year being reported. The reporting must be made by 30 August at the latest.

*(2)* Reporting is to be made digitally via virk.dk in Danish or in English.

**§ 7.** Reported mixtures and articles are assigned a report number that is communicated digitally to the reporting party.

Chapter 4

*Access to information in the nano product register*

**§ 8.** When reporting to the nano product register (see § 5), the reporting party may indicate that selected information is to be regarded as a trade secret, including information on chemical information, substance identification, composition or purity. The reporting party must justify why the information is to be regarded as a trade secret.

*(2)* The following information shall normally be regarded as confidential without this being specified separately by the reporting party:
1) Details of the full composition of a mixture.

2) The precise use, function or application of a substance or mixture, including information about its precise use as an intermediate.

3) The precise tonnage of the substance or mixture manufactured or placed on the market.

4) Links between a manufacturer or importer and his distributors or downstream users.

*(3)* Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, the information referred to in paragraph (1) and (2) of this article may be disclosed.

**§ 9.** The Danish Environmental Protection Agency shall draw up internal security rules for the nano product register as well as security rules for persons who have direct access to the register (see § 10) to ensure that direct access to the nano product register by unauthorised persons is prevented. The rules are not available to the public.

*(2)* The internal security rules for the nano product register shall include organisational conditions and physical security, including administration of access control mechanisms and guidelines for monitoring compliance with the security measures laid down for the nano product register.

**§ 10.** The nano product register is not publicly accessible. The Danish Environmental Protection Agency and the Danish Working Environment Authority shall have exclusive direct access to the nano product register in accordance with the security rules; see § 9.

*(2)* Only those employees of the Environmental Protection Agency who work with the nano product register, and are assigned to do so by the director of the Environmental Protection Agency, may have direct access to the register.

*(3)* The director of the Working Environment Authority designates those employees in the Working Environment Authority that are to have direct access to the nano product register and then notifies the Environmental Protection Agency thereof. Only persons whose work tasks necessitate direct access to the nano product register may be designated.

*(4)* Employees of other authorities can obtain information from the nano product register upon request and in accordance with the Public Administration Act rules on disclosure.

*(5)* Researchers and persons who perform duties under environmental and working environmental legislation or under contract with the Environmental Protection Agency or the Working Environment Authority and who obtain information from the nano product register may be placed under a duty of confidentiality in accordance with the Public Administration Act’s rules on confidentiality.

*(6)* All employees who have direct access to the nano product register (see paragraphs 2 and 3) as well as employees and persons who obtain information from the register (see paragraphs 4 and 5) are to be made familiar with the security rules laid down under § 9. Persons covered by paragraph 5 must also sign a statement of confidentiality.

**§ 11.**The Environmental Protection Agency publishes an annual report on the previous year's reporting to the register. The report will not contain information listed in § 8, paragraph 2, No. 1)-4), or information which the reporting party has indicated as confidential in accordance with the procedures in article 119, paragraph (2) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH).

Chapter 5

*Inspections and administrative provisions*

**§ 12.** The Environmental Protection Agency is responsible for creating the nano product register, managing it, and performing duties related to the register under the provisions of this Order.

**§ 13.** The Environmental Protection Agency shall carry out inspections and checks to ensure compliance with the rules in this Order; see provisions of the Act.

**§ 14.** Appeals against decisions of the Danish Environmental Protection Agency under this Order cannot be made to any other administrative authority.

Chapter 6

*Penalty clauses*

**§ 15.** Unless higher penalties are stipulated by other legislation, failure to report to the nano product register information on mixtures and articles under § 5(1) is penalised by fines.

*(2)* Criminal liability may be imposed on companies, etc. (legal persons) in accordance with the rules of Chapter 5 of the Penal Code.

Chapter 7

*Entry into force*

**§ 16.** This Order shall enter into force on 18. June 2014.

*(2)* The first reporting (see § 6) must be made by 30 August 2015 at the latest for the period of 20 June 2014 to 20 June 2015.

**Annex 1**

**Mandatory information to be reported on mixtures and articles that contain nanomaterials; see § 5(1).**

1. Registrant's identity
2. CBR No
3. Registrant's name (entity name)
4. Address
5. Registrant's contact person(s)/email(s)
6. Type of entity *(NACE-kode)*
7. Size of the entity
8. Product information
9. Product name
10. Is the mixture / article manufactured in Denmark / imported to Danmark?
11. Quantity (number of articles / volume/mass of the mixture) manufactured or imported with the intention of sale to the general public on the Danish market during the reporting period, see § 6(1). The information listed in § 8, paragraph (2), No. 1)-4), shall normally be regarded as confidential without this being specified separately by the reporting party.
12. Is the mixture / article used professionally as well (yes/no)? The information listed in § 8, paragraph (2), No. 1)-4), shall normally be regarded as confidential without this being specified separately by the reporting party.
13. Description of application (free text). The information listed in § 8, paragraph (2), No. 1)-4), shall normally be regarded as confidential without this being specified separately by the reporting party.
14. Information on the nanomaterial
15. Name of nanomaterial
16. The nanomaterial's manner of inclusion in the mixture / article[[2]](#footnote-2)
17. Is the nanomaterial, or substance with which the nanomaterial is made, registered in REACH? Yes/no
18. Is there information which ECHA has accepted as confidential after the procedure in article 119, paragraph 2, in Regulation (EC) No 1907/2006 of the European Parliament and of the Council (REACH)?
19. Chemical information on the nanomaterial
20. Name of the chemical compound (IUPAC)
21. CAS No
22. EU number (EINECS/ELINCS/INCI)
23. Formula

**Annex 2**

**Optional information to be reported on mixtures and articles that contain nanomaterials; see § 5(2).**

1. Category
2. Chemical product category/REACH (PC)
3. Process category/REACH (PROC)
4. Environmental release category/REACH (ERC)
5. Article category/REACH (AC)
6. Content of the nanomaterial in the article or mixture
7. Nano content/product (grams)
8. Nano content/product (%)
9. Physical information on the nanomaterial
10. Particle size
11. Numerical size distribution
12. Aggregation
13. Agglomeration
14. Form
15. Specific surface area
16. Crystalline state
17. Surface chemistry
18. Surface charge
1. This Order has been notified as a draft in accordance with Directive 98/34/EC of the European Parliament and of the Council (the Information Procedure Directive), as amended by Directive 98/48/EC. [↑](#footnote-ref-1)
2. For example, if it is in a solid form, dispersion, aerosol, etc. [↑](#footnote-ref-2)