Nanotechnology Industries Association

24 March 2017

NIA Comments on the Swedish Chemical Agency consultation on reporting requirements for nanomaterials in products aimed for the Swedish market: Reference Number H16-07940

NIA comments on the Swedish proposal

NIA welcomes the opportunity to provide comments to the consultation. We apologise that our reply is in English, but we are certain that this will not be any problem. Should there be any questions for clarifications, please contact david.carlander@nanotechia.org.

The following provides the NIA comments to the Swedish Proposal. The Swedish proposal, as presented to NIA Members is found in the Annex as an informal translation to English.

1. Limited value of the proposal

NIA is of the view that the information requirements and administrative burden of the proposal is not proportional to the objective to provide an overview of nanomaterials in products on the Swedish market. The claimed objective to provide a basis for future regulatory proposals and to use the gathered information as a basis for monitoring of industries can be achieved with information provided on a higher level, e.g. via the ECHA Observatory on Nanomaterials which is under construction. There is no need to require additional burdens for industries applying nanomaterials compared to conventional use of chemical substances in products. The proposal hamper innovation, competitiveness, requires heavy administrative burden and is of limited value as it lacks proportionality.

It is the view of NIA that the proposal should be withdrawn, and Sweden should focus its resources to support the ECHA Observatory for Nanomaterials.

2. Specific comments on the proposal

Paragraph 4 (*Undantag för vissa anmälningsskyldiga)*

Exemption for turnover below 5 million SKR is appropriate, but the amount should be considerably higher. A turnover of 5 million will roughly correspond to an industry with 5-10 employees, and the human and financial resources required to comply with the specificities can not be expected to be found in-house in small enterprises. The values should be at least 50 million SKR.

Further, the requirement to only report if the product contains nanomaterial or not, according to their knowledge ('för det fall de har vetskap om det, enbart ange om produkten innehåller nanomaterial eller inte') is very vague thus the information gathered will be of very limited, of any value. Thus, for the sake of proportionality, this should be removed.

Paragraph 11 (*Undantag gällande produkter som innehåller nanomaterial)*

This paragraph requires that the reporter, for nanomaterials that are pigments, and if the reporter has knowledge about it, to report only if the product contain nanomaterials or not. This paragraph also requires powders of pure metals to be reported if the products contain nanomaterials.

Both of these requirements are unclear and the current wording gives rise to uncertainty on what to report, as well as the value of the reporting.

Paragraph 16 (*Uppgifter som ska lämnas om produkten innehåller nanomaterial)*
Point 1 (classification following the CLP regulation) may not always be applicable. This needs to be reflected in the wording of this point.
Point 3 lacks clarity what is meant by all dimensions between 1-100 nm (Informationen anges för samtliga dimensioner som är mellan 1 och 100 nm). It may not be possible for certain size distributions to provide this level of detail.
Point 4, creates practical difficulties on what constitutes a nanomaterial with regard to agglomerates and aggregates. Would pencil lead be a nanomaterial as it could be considered to be an aggregate of graphene?
Point 9d refers to a test method 'zeta-metri'. It is not clear what this method is.

The Nanotechnology Industries Association

Formed in 2005 by a group of companies from a variety of industry sectors including healthcare, chemicals, automotive and consumer products, the Nanotechnology Industries Association (NIA) creates a clear single voice to represent the diverse industries in the multi-stakeholder debate on nanotechnologies. NIA provides a purely industry-led perspective, derived from the views of the collective membership and forms an interface with government, acting as a source for consultation on regulation and standards, communicating the benefits of nanotechnologies and interacting with the media to ensure an on-going advancement and commercialization of nanotechnologies.

For further information visit http://www.nanotechia.org or contact us on enquiries@nanotechia.org.

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Annex: The Proposal as Presented to NIA Members during the NIA consultation

Introduction to the Swedish proposal

The Swedish proposal is published as a consultation (remiss) in Swedish at the following link:
http://www.kemi.se/om-kemikalieinspektionen/verksamhet/remisser-och-remissvar

The consultation in Swedish is '**Remiss om förslag till två nya grundföreskrifter och en ändringsföreskrift som ska ersätta KIFS 2008:2**'

The proposal applicable for nanomaterials in Swedish is '**KIFS 2017:X om kemiska produkter och biotekniska organismer (förslag till nya grundföreskrifter)**'.
The Swedish version is found here:
http://www.kemi.se/global/om-kemikalieinspektionen/remisser/h16-07940/kemikalieinspektionens-foreskrifter-kifs-2017-x.pdf

The nano provisions are found in 'Chapter 3 Reporting to the Products Register' (**3 kap. Anmälan till produktregistret).**

Introduction to the Swedish regulatory proposal[1]

The text below is a non-official translation of the Swedish text aimed to give NIA Members a detailed understanding of the content of the requirements related to nanomaterials and how they should be reported in the Swedish products register ('Produktregistret').

The provisions are proposed to enter into force on 1 January 2018, and the first reporting from industry will be required by 28 February 2019.

Chapter 3 Reporting to the Products Register (3 kap. Anmälan till produktregistret)

Paragraph 1 of Chapter 3 states that the provisions in the Chapter complements the provisions provided for reporting to the Product Register, paragraphs 3-6 in the Swedish Regulation 2008:245 Chemical Products and Biotechnical Organisms Ordinance[2].

[1] It should be noted, that this is a non-official in-house translation of the Swedish text, and liability for its correctness can not be provided by NIA. It is aimed to be accurate according to our knowledge.

[2] **Excerpt from Swedish Regulation '2008:245 Chemical Products and Biotechnical Organisms Ordinance'**
Paragraph 3 provides that chemical products or biotechnical organisms which are manufactured in or imported into Sweden in the course of business must be notified to the Kemikalieinspektionen (Swedish Chemical Agency, KEMI) for registration in the product register which that body is required to hold if such products or organisms relate to a product listed in the annex to that ordinance.
Under Paragraph 4 of the ordinance, it is the person who, in the course of business, manufactures a chemical product or a biotechnical organism in or imports it into Sweden who must make that notification.
Paragraph 5 provides for an exception from the notification requirement which covers persons who import less than 100 kilogrammes of a product per annum.

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Definition of nanomaterial in the proposal

Paragraph 2 gives the nanomaterial definition. It is basically a translation of the European Commission 2011 recommendation for a nanomaterial definition. For the purpose of the reporting, a nanomaterial is 'an intentionally produced material containing particles in an unbound state, or in the form of aggregates or agglomerates where at least 50 % of the particles in the particle size distribution have one of more outer dimensions in the size interval of 1 - 100 nm. Fullerenes, graphene flakes and nanotubes are regarded as nanomaterials if they have one or more outer dimensions smaller than 1 nm.

The definition also defines particle, aggregate and agglomerate as well as pigment. A pigment is 'a dry, insoluble chemical substance whose principal function is to provide colour to the product'.

Who should report [to the products register]

Paragraph 3 outlines who should report to the product register. The basis is provided in the Swedish Regulation 2008:245 paragraphs 3-4. These paragraphs states that the one who professionally manufacturers or brings into Sweden chemical products should report these products for registration to the products register managed by the Swedish Chemical Agency. The requirement to register is also applicable to anyone who in its own name packages, repackages or changes name to a chemical product without having manufactured it or is importing that product to Sweden. The requirements are also applicable for import for one's own uses.

However, paragraph 4 outlines instances that are exempt from registering. If the annual turnover is less than 5 million Swedish crowns (SKR), the entity responsible for reporting are exempt from registering the physical and chemical parameters of the nanomaterial the product contains. In this case, the entity responsible for reporting should only report if the product contains nanomaterial or not, according to their knowledge.

What should be reported

Paragraph 5 states what should be reported. The obligation to report applies both importing to Sweden from EU countries as well as from countries outside the EU.

Paragraph 6 states that the reporting shall be done latest when the activity is about to commence.

Paragraph 7 states that if more than 100 kg of product is managed, the information provided should be complemented with additional information as stated in paragraph 13, points 3-16 (see below). This information should be reported to the Swedish Chemical Agency no later than 28 February the year after the activity starts. The amount to be reported shall following paragraph 21.

Exemptions

Paragraph 8 states that reporting is not required for products covered by the pharmaceutical regulation (2015:315), food legislation (2006:804), Animal feed (2006:805) and the regulation on tattoo pigments (2012:503). Reporting is also not required for cosmetic products or chemical products considered as waste.

Products containing nanomaterials in quantities less than 1000 kg for use by a restricted number of users for product or process research are also exempted from reporting, as stated in paragraph 9.
Products that are only transported via Sweden to another country are also exempt (paragraph 10).

Paragraph 11 states that for nanomaterials that are pigments, the reporting only needs to state if the products contain nanomaterials or not, according to the knowledge of the reporter. This paragraph also states that powders of pure metals should be reported if the products contain nanomaterial.

Information to be reported

Paragraph 12 states that a product required to be reported is defined by its trade name, goods name or goods designation, its composition and the level of each constituent.

Paragraph 13 lists 16 points that should be provided.
Point 1 states that the reporter needs to provide its name and social security number, or company name and corresponding VAT number or organisation number.
Point 2. The address, telephone number and e-mail address should also be provided.
Point 3. The name of the product and if available its common denomination.
Point 4. The product's statistical denomination following the combined nomenclature (KN) following Council Regulation (EEG) No 2658/87.
Point 5. If the product is manufactured in Sweden or imported from EU from a third country.
Point 6. If the product has been given a new trade name, goods name or goods designation.
Point 7. If the reporter is an agent that has the authorisation from the Swedish Chemical Agency to act as an agent.
Point 8. If the product is aimed to be used by consumers.
Point 9. For products with custom code 28 or 29 under regulation 2008:245, that are used as raw material for manufacturing, a percentage estimate of the use of the product in various sectors. For other products, the main use should be reported. In addition, if the reporter is exporting the product, the estimated amount exported in percent.
Point 10. The function.
Point 11. Information on the classification of the product regarding hazard according to Regulation (EC) No 1272/2008 (CLP).
Point 12. Information on substance name and level for all constituent parts classified according to Regulation (EC) No 1272/2008 (CLP) as cancerous category 1A or 1B, mutagenic category 1A or 1B, toxic to reproduction category 1A or 1B or skin or airway sensitisers category 1. The presence of other substances hazardous to health or the environment in a level requiring reporting in a safety data sheet following Annex II, section 3 of Regulation (EC) No 1907/2006 (REACH).
Point 13. This points refers to goods falling under customs code 22, 28 and 29 of Regulation 2008:245.
Point 14. This point is applicable for certain paints and lacquers as defined in Directive 2004/42/EC.
Point 15. Information on what substances in the product are regarded as conservatives, and their level.
Point 16. If the function of the product is as biocide or as a fragrance, information on the active substance/substances.

Names of substances shall be reported with their preferred name following CAS or IUPAC nomenclature, ISO names or trivial names. CAS number or EC number can also be used.

Paragraph 14 states that the reported concentrations, from point 12 or 15 in paragraph 13 should be reported as accurately as possible in the interval 0-1 %, and can be rounded of in higher concentrations.

Paragraph 15 outlines specific measures of cadmium in fertilizers.

Information to be provided if the product contains nanomaterials

Paragraph 16 details the information to be provided in addition to paragraph 13 if the product contains nanomaterials.

Point 1. The classification following Regulation (EC) No 1278/2008 (CLP).
Point 2. The function of the nanomaterial in the product.
Point 3. The primary particle size, average size, standard deviation, the distribution curve. Information should be provided for all dimensions between 1 and 100 nm. The test method used should be provided.
Point 4. For nanomaterials present in the product as agglomerates or aggregates, the average size should be provided as weight, number or z-average size. If a polymodal distribution is present, several average sizes can be provided. Standard deviation and test method used should be provided.
Point 5. The shape of the nanomaterial as

a) Number of dimensions between 1 and 100 nm
b) Qualitative description of the shape as:
   - Spherical
   - Pseudo spherical
   - Rods
   - Star shape
   - Fibre
   - Hollow fibre
   - Film
   - Capsule
   - Other (specify)
c) Test method

Point 6. The crystalline structure, if this can be assessed by x-ray diffraction.

a) Trivial name of Bravais lattice
b) Concentration of each phase (including amorphous phase)

Point 7. Specific surface area

a) Specific surface area in m^2/g
b) Test method

Point 8. Surface treatment

a) Chemical identification of the surface
b) Hydrophilic or hydrophobic surface
c) Test method

Point 9. Surface charge

a) Zeta potential
b) pH at measurement
c) Medium used at measurement
d) Distribution curve (if available). The 'Zeta-metri' test method should be used.

Paragraph 17 stats that if the reporter does not have available the required information following paragraph 16, this should be mentioned and a justification provided. The Swedish Chemical Agency will decide if the required information should be provided.

Paragraph 18 stipulates that certain products, as mentioned in Annex 1 can be reported under a common denomination.

Paragraph 19 stipulates that the information for the reporting should be provide in a form provided by the Swedish Chemical Agency or electronically.

Paragraph 20 stipulates that Swedish Chemical Agency will designate a reporting number to the registered products.

Annual reporting

Paragraph 21 states that if a product has been reported following paragraph 7, annual information should be provided to the Swedish Chemical Agency about:

1. Product name, reporting number or the common designation
2. Manufactured or imported amounts referring to the previous year and
3. Any changes to previous reported information

The reporting should be provided to Swedish Chemical Agency no later than 28 February.

Paragraph 22 states that the amounts reported can be rounded off to

1. nearest tenth of a ton in the interval 0.1-9.9 tonnes,
2. to nearest ton in the interval 10-999 tonnes and
3. to nearest 10 tonnes about 1000 tonnes.

The last paragraphs (23-27) in Chapter 3 are related to changed contact details and if the reporter is acting as an agent.

The NIA, Nanotechnology Industries Association, is the sector-independent, responsible voice for the industrial nanotechnologies supply chains; it proactively supports the ongoing innovation and commercialisation of nanotechnologies and promotes their safe and reliable advancement.

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