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CLP Regulation and nanomaterial classification – a preliminary review of GHS and possible problem identification:

Nordic Stakeholder Survey on Nanomaterial Hazard Classification and Labelling.

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Finnish Institute of Occupational Health

CLP Regulation and nanomaterial classification – a preliminary review of GHS and possible problem identification:

Nordic Stakeholder Survey on Nanomaterial Hazard Classification and Labelling

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for the Nordic Chemical Group (Project number 2070)

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1 Abstract

Nanomaterials are chemical substances or materials with any external dimension on the nanometre scale. Due to their unique nature, nanomaterials, either natural, incidental or manufactured, might pose hazards that are different from those of their bulk form counterparts.

The CLP Regulation (1272/2008/EC) lays down the rules for classification, labelling and packaging of chemical substances and mixtures in the EU (1). CLP implements the UN Globally Harmonised System of Classification and Labelling (GHS) into the EU chemicals legislation. Regarding hazard assessment and hazard communication, it is generally concluded that the CLP Regulation also provides the framework for the classification and labelling of nanomaterials. However, nanomaterials are not specifically referred to in the CLP legal text, nor does this give specific instructions on how to classify e.g. mixtures containing nanomaterial(s).

At the UN level, the GHS subcommittee has included "Nanomaterials" in its programme of work for the biennium 2013–2014 (2). The mandate of the work is "to review the applicability of the GHS to manufactured nanomaterials, taking into account the progress of international scientific work, if necessary**".**

In order to provide input to the UN GHS work on nanomaterials, a survey was carried out to gain information from Nordic stakeholders on the current status and possible practical experience of nanomaterial classification and labelling. The survey was based on a questionnaire which was distributed to over 3,500 recipients in Denmark, Finland, Norway and Sweden. In total, 199 responses were received, most of them from Sweden (53%) and Finland (28%). 9% of the responses were from Norway, 5% from Denmark and 5% from other countries. The total response rate was relatively low (5.7%), which can partly be explained by the fact that the majority of recipients were picked from national product registries, representing any sector, and thus in the majority of cases were not involved with nanomaterials. The respondents were mainly from industry (79%), whereas the authorities were represented by 7% and others by 15%. As the vast majority of the respondents were from industry, the results naturally mainly reflect the opinions of that group. However, when examining the results on the basis of the responses of the three response groups (authority, industry, others), the major trends of the results were quite the same. Due to the fact that the number of respondents representing the authorities was very low (n= 13), it was not relevant to make any statistical analyses on the opinions of industry versus the authorities.

The respondents' knowledge of CLP and GHS was according to their own evaluation fairly good, but they were less familiar with nanomaterials and nanosafety issues. Only 28% thought their level of knowledge on nanomaterials was good or fairly good, whereas about a third of the respondents had "limited knowledge". The fact that the majority of the respondents were not familiar with nanomaterials was reflected in the answers given in the survey by frequent selection of the option "no opinion". In connection with most of the questions, the respondents were given the opportunity to give additional comments as free text. The number of comments received was surprisingly large. Selected comments representing different views are included in this report.

As a main summary of the findings of the study, it can be concluded that there is a request to include specific issues on nanomaterials into GHS/CLP and also to communicate nanospecific information on labels and on safety data sheets. In order to be able to set frames for the requirements related to classification and labelling, a definition of nanomaterials was considered to be necessary. The requirements related to classification and labelling of nanomaterials are preferably to be defined by amending GHS/CLP and to be communicated through updated guidance documents. The general impression obtained from the responses was that the respondents identified needs for specifying characterization criteria, for giving different classifications for different forms of nanomaterial, and perhaps also for a re-evaluation of the classification criteria with respect to nanomaterials. However, the respondents did not have a share view on how these actions should be done and what criteria they should be based on. In their final conclusions, 68% of the respondents considered it in some way necessary to specifically focus on nanomaterials within the GHS/CLP, while 16% had the impression that the current system covers nanomaterials and that there is no need for specific consideration.

The study was supported financially by the Nordic Council of Ministers.

2 Introduction

Nanomaterials are chemical substances or materials with any external dimension on the nanometre scale. Due to their unique nature, nanomaterials, either natural, incidental or manufactured, might pose hazards that are different from their bulk form counterparts. The physico-chemical properties of nanomaterials such as size, crystalline structure, surface area, reactivity, morphology and shape, might introduce new risks and also dictate their behaviour in the human body as well as in the environment.

The CLP Regulation (1272/2008/EC) lays down the rules for classification, labelling and packaging of chemical substances and mixtures in the European Union (EU)(1). CLP implements the UN Globally Harmonised System of Classification and Labelling (GHS; http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html) in the EU chemicals legislation. Regarding hazard assessment and hazard communication, it is generally concluded that the CLP Regulation also provides the framework for the classification and labelling of nanomaterials. However, nanomaterials are not specifically referred to in the CLP legal text, and nor does this give detailed instructions on how to classify e.g. mixtures containing nanomaterial(s).

At the UN level, the GHS subcommittee has included "Nanomaterials" in its programme of work for the biennium 2013-2014 (2). The mandate of the work is "to review the applicability of the GHS to manufactured nanomaterials, taking into account the progress of international scientific work, if necessary". As nanomaterials might possess intrinsic (hazard) properties that are different from "conventional" chemicals, a review of GHS is necessary to evaluate whether there are issues that should be revised in order to classify nanomaterials. In addition, the information on nanomaterials in safety data sheets and the requirements for information have to be reviewed.

The Nordic Classification Group[a], under the auspices of the Nordic Chemical Group/Nordic Council of Ministers launched a project (project number 2070) focusing on the collection of the views of Nordic stakeholders on issues related to nanomaterials and CLP/GHS. The purpose of the survey was to gain information from Nordic stakeholders on the current status and possible practical experience of nanomaterial classification and labelling. The results of the project may provide input and suggestions for the work of the GHS Sub-Committee.

The results of the project "Nordic survey on nanomaterial hazard classification and labelling" are presented in this report. The study was carried out by experts from the Finnish Institute of Occupational Health (FIOH), and it consisted of preparing a survey for Nordic stakeholders, distributing it, and collecting and analysing the results. The structure and specific questions of the survey were built up in co-operation between experts from FIOH and the Nordic Classification Group. The survey was conducted in May 2014 using the web-based tool Webropol (www.webropol.com).

This report presents the outcome of the survey, including brief analyses of the main outcomes of the responses to the questions asked.

[a] The Nordic Classification Group is a network of government officials/civil servants representing the Competent Authorities on CLP Regulation in Finland, Sweden, Norway, Iceland and Denmark.

3 Background of the respondents

3.1 Country and sector

Question: In which country is your organization/company based?

Question: What sector does your organization/company represent?

The questionnaire was sent to over 3,500 recipients in four countries: 51 in Denmark, 1027 in Finland, 421 in Norway and 2,024 in Sweden. The recipients were selected by the members of the Nordic Classification Group. The Finnish, Norwegian and Swedish recipients were partly selected based on information available in the national product registers, which explains the high numbers of recipients in these countries compared to Denmark. The Danish recipients mainly represented enterprises for whom nanomaterials or products containing nanomaterials has known or expected relevance, and the authorities.

In total, 199 responses were received, most of them from Sweden (53%) and Finland (28%). Nine percent of the responses were from Norway, 5% from Denmark and 5% from other countries (the UK, Germany, France, Switzerland, Belgium; Table 1). The overall response rate was 5.7%. In Denmark the response rate was 20%, in Finland 5%, in Norway 4% and in Sweden 5%. The respondents (n=198) were mainly from industry (79%), whereas the authorities were represented by 7% and others by 15%.

The responses were anonymous and it was therefore not possible to identify the respondents.

Table 1. In which country is your organization/company based and what sector do you represent? (n=199)

Country	Industry	Authorities	Others (consultants etc.)	Unknown	Total No.	% of total responses
Denmark	5	1	4		10	5
Finland	40	4	12		56	28
Norway	14	0	4		18	9
Sweden	88	8	8	1	105	53
Other	9		1		10	5

3.2 Knowledge of GHS/CLP and nanomaterials

Question: How well do you know GHS and/or CLP?

Question: How well do you know nanomaterials and issues related to nanosafety?

To ascertain the level of knowledge, the respondents were first asked how well they knew the legislation for the classification and labelling of chemicals (GHS and/or CLP) or issues related to nanomaterials. Seventy percent had at least a fairly good knowledge of GHS and/or CLP, about 20% thought they had a “limited knowledge” of the subject and 10% responded that they had “poor knowledge” or were “not familiar with the subject”.

The respondents were less familiar with nanomaterials and issues related to nanosafety. Only 28% thought they had a “good” or “fairly good knowledge”, whereas about a third of them had a “limited knowledge”. About 40% of the respondents commented that their knowledge level was low (“poor knowledge”) or were “not familiar with the subject”.

4 Nanomaterials and GHS/CLP

4.1 Definition of nanomaterial

Question: In your opinion, should there be a definition for nanomaterial in classification and labelling?
Question: On what should the definition be based?

Respondents were asked to give their opinion on whether there should be a definition for "nanomaterial" in classification and labelling. Most of the respondents (59%, including the majorities of all three respondent groups) thought that a definition was needed, while one third were not able to give an opinion, and only 9% (seven persons from industry and one from the category "others") answered that there was no need for a definition (n=198).

When asked about the definition and what it should be based on, the most popular option chosen was "EU Commission recommendation for nanomaterial definition" (23%), but "ISO/CEN standards" as well as "a new specific definition for GHS" were also supported by 11% and 10% of the respondents, respectively (Fig. 1). Almost half of the respondents were not able to give an opinion.

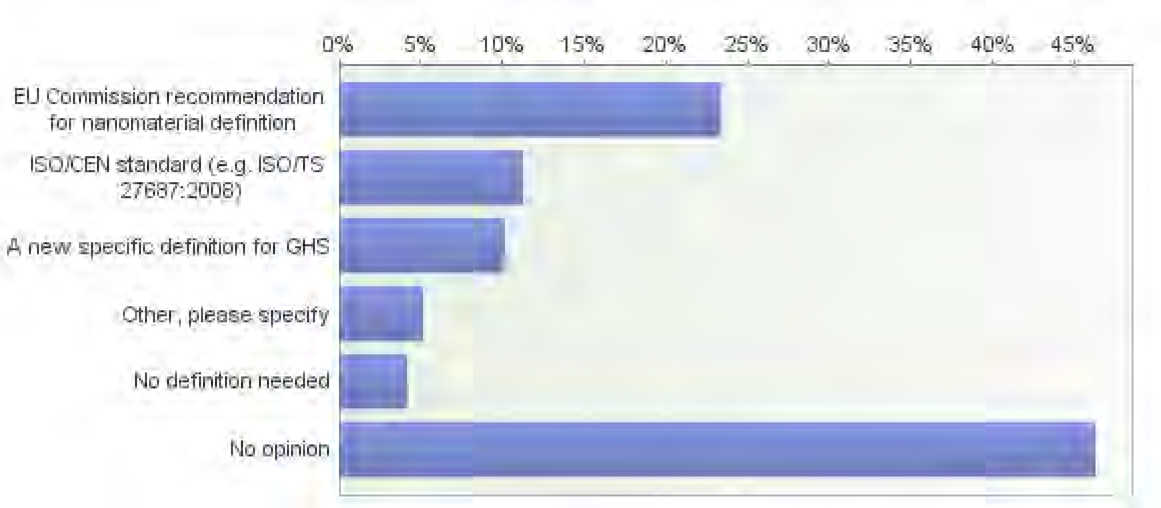

Figure 1. What should the definition be based on? (n=197)

The support for using the EU Commission recommendation (3) was mainly justified by a need to have only one definition for nanomaterials in all the different EU legislations. However, the EU Commission recommendation was also criticized as being too wide, also covering materials which are not by intention produced as nanomaterials. A general view was that a common understanding of the definition would be needed.

Basing the definition on an ISO standard was, for example, supported because it is used globally and is clear to everyone. By applying a global approach, a confusion caused by regional definitions could be avoided.

Those supporting a new definition for GHS commented that nanos and classification is a discipline on its own and needs a global definition, and that this could be based on EU/ISO definition.

General comments given by a few respondents also emphasized that regulatory issues are already very bureaucratic, time-consuming and expensive for (small) companies, and that including a definition for nanomaterials would not improve safety.

4.2 Handling of nanomaterials in classification and labelling

Question: What would be the best way to handle nanomaterials in relation to classification and labelling?

The best way to handle nanomaterials in relation to classification and labelling was thought to be by amending GHS/CLP and updating guidance documents (37%). Also, updating guidance documents to cover nanomaterials was supported by 18% of the respondents. Only 4% considered that no actions are needed. One third had no opinion on the matter (Fig. 2). The support for the most popular option ("Amend GHS/CLP and update guidance documents") was explained in comments concluding that these actions will be needed in order to ensure that these substances are evaluated for their hazards and mentioned in safety data sheets and labels, and that all classification should originate from the same instrument (CLP). Respondents who thought that no actions are needed concluded e.g. that GHS/CLP already cover nanomaterials and can be used as such without any amendments / specifications for nanomaterials.

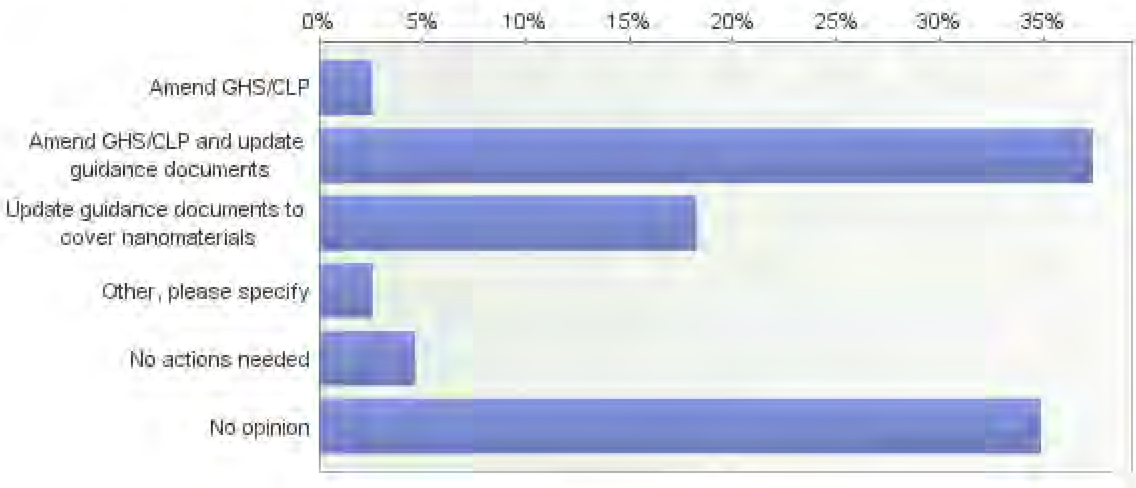

Figure 2. What would be the best way to handle nanomaterials in relation to classification and labelling? (n=198)

5 Test results and classification criteria

5.1 Characterization and identification details on nanomaterials

Question: Is there a need to include more details on the characterization and identification (e.g. form, fiber flexibility, surface charge) of nanomaterials in relation to classification? Please specify your answer in the comment field.

When asked about the need to include more details on the characterization and identification (e.g. form, fiber flexibility, surface charge) of nanomaterials in relation to classification, almost a third of the respondents (31%) considered it necessary, whereas only 5% considered that there is no need for such details. Most of the respondents (64%) were not, however, able to give an opinion.

Some of the respondents, supporting the inclusion of detailed information on the characteristics of the nanomaterial, specified their opinion by stating that this would be needed in particular if particles of different size/shape are known to cause different types of hazardous effects. Specific data on those properties which are responsible for a hazardous behaviour should be included in sufficient detail. There are enormous numbers of different nanomaterials, and thus one property alone cannot be used to define and identify them. It was also emphasized that it is not just the size that characterizes a nanomaterial; specific properties often arise e.g. from the surface chemistry of such particles. Other examples given on such properties were active surface area, fiber properties, form, and surface charge.

Among those who did not regard the inclusion of detailed characterization data as important for classification, one stated that the form is already considered today and that the surface charge is a product-related issue and not a substance-related one. It was also suggested that detailed information should be required only for (new) engineered nanomaterials but not for well-known nanomaterials such as carbon black, amorphous silica, titanium and calcium carbonate.

5.2 Different forms of nanomaterials

Question: In some situations, nanomaterials may cause different hazardous effects depending on their physico-chemical properties. Would it in such cases be necessary to give different classifications for the different forms of the same nanomaterial? Please select one or more options.

In some situations, different forms of a nanomaterial may cause different hazardous effects depending on their physico-chemical properties. The respondents were asked whether in such cases it would, in their opinion, be necessary to give different classifications for the different forms of the same nanomaterial. Most popular options were “Yes, based on primary particle size” (23%) and “Yes, based on surface properties” (20%). Almost as important properties were “shape”, “solubility” and “primary/agglomeration/aggregation state” (16 to 18%). “Dissolution rate”, “dispersion stability” and “other characteristics” were selected by about 11% of the respondents. By other characteristics, respondents mostly meant other properties found relevant in the risk assessment of specific nanomaterial. On the basis of the responses, many respondents had a clear view that different classifications might be needed, but there was no consensus on what the critical parameters would be.

In their comments, a number of respondents stressed the need to identify the most critical properties which might be different depending on the nanomaterial type, and to analyse the need for different classifications based on those parameters. It was also noticed that, even now for example, SiO_2 has different classifications according to its structural properties (crystalline or amorphous) and in line with that, a man-made nanoform of SiO_2 might be classified in another way. It was also suggested that the smallest available (not theoretical primary) particle and solubility should drive the classification. However, assigning different classifications depending on the form of the nanomaterial was also said to be too complicated, and the classifications should hence be based on the properties of the primary particles.

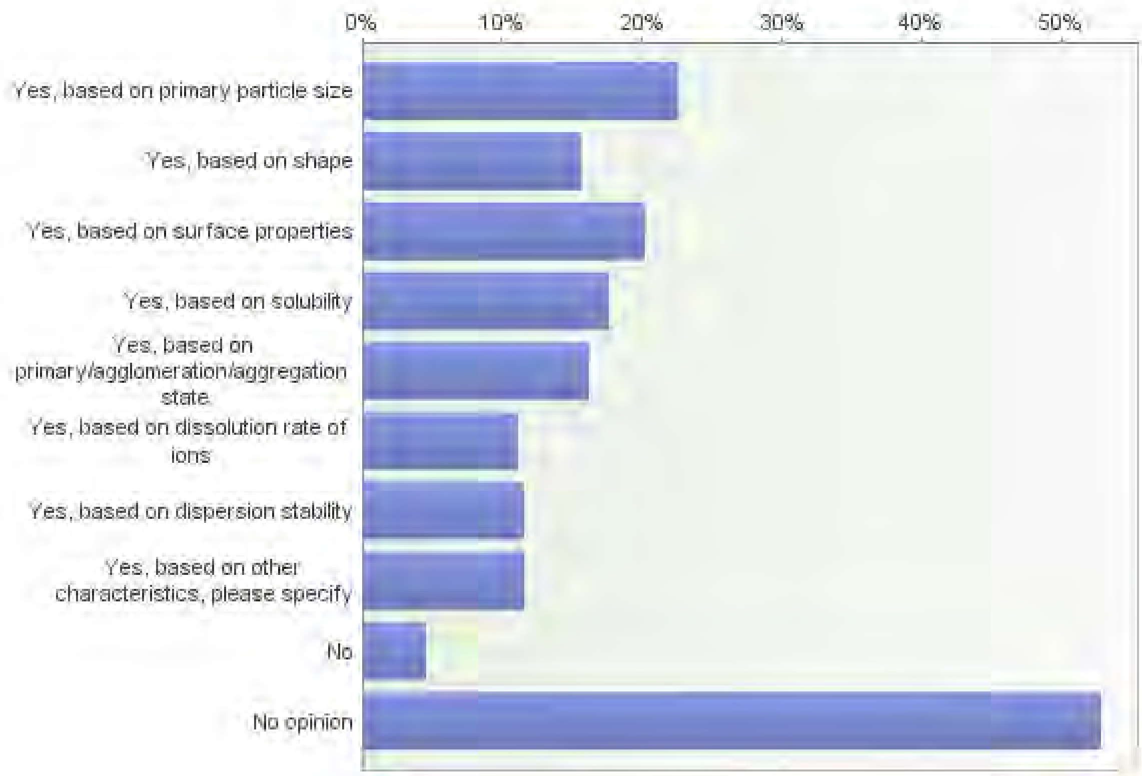

Figure 3. In some situations, nanomaterials may cause different hazardous effects depending on their physico-chemical properties. Would it in such cases be necessary to give different classifications for the different forms of the same nanomaterial? One or more options are possible. (n=199)

5.3 Coated nanomaterials under GHS/CLP

Question: How should coated nanomaterials, in your opinion, be considered in GHS/CLP?

The next question was about coated nanomaterials and how the respondents thought that those should be considered under GHS/CLP. The main opinion of the respondents was that the best way would be to consider those either as equivalent to the coating material or as a mixture, depending on solubility. This option was selected by 16% of the respondents. “As a substance” and “as a mixture” were also supported by 9% and 8% of the respondents, respectively. More than half of the respondents were not able to give an answer (Fig. 4).

The support for considering coated nanomaterials as substances was for example justified by statements that these types of materials may have (hazard) properties not reflecting those either of the core or the surface material. Therefore, it would be justified to regard these as substances and primarily base the classification on data related to the material *per se*. However, based on the same arguments, it was also concluded that this would imply that coated nanomaterials should be considered as articles. Furthermore it was also said that, as long as there is no data on the lifespan behaviour of the coating material, the coated nanomaterials should be regarded as substances.

It was also pointed out that, if the classification is based on the coating material, the possibilities of leakage from the core should be investigated. One suggestion was to consider such materials on a case-by-case basis, depending on solubility, either as an article (according to the definition in the REACH Regulation; 4), coating material or mixture. When the coating material is soluble, the classification should be triggered by the properties of the core material, but when the coating material is not soluble, classification should be based on coating.

One of the respondents assumed that the coating is not covalently attached to the nanomaterial, and hence it would be justified to decide that the coated nanomaterial is a mixture.

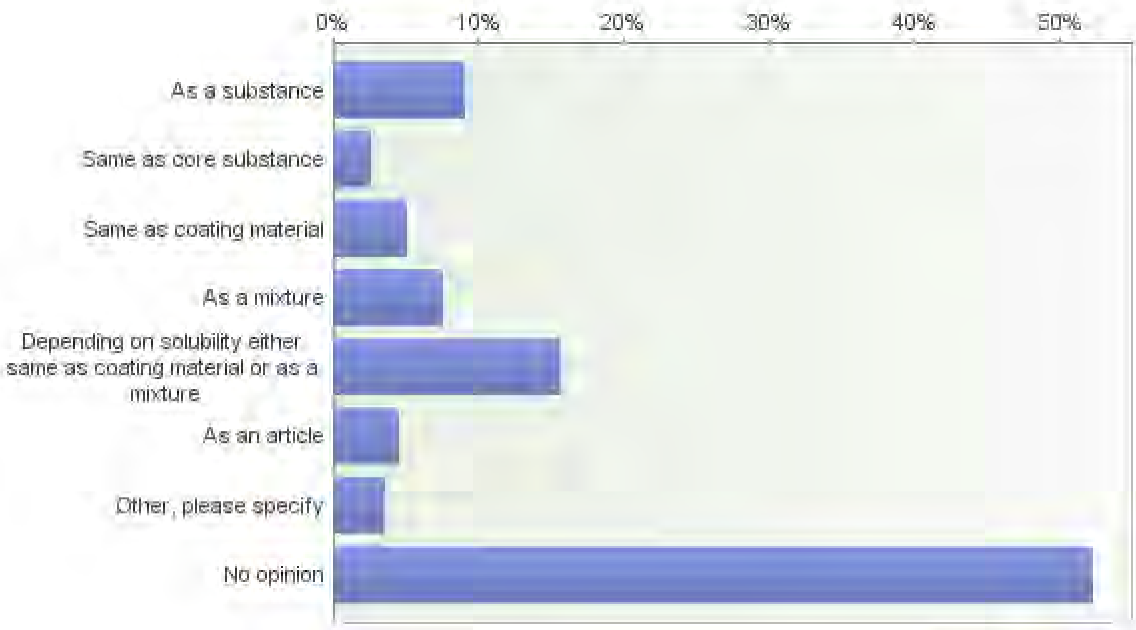

Figure 4. How should coated nanomaterials, in your opinion, be considered under GHS/CLP? (n=199)

5.4 Classification criteria for nanomaterials – physical, health and environmental hazards

*Question: In your opinion, is there a need to re-evaluate classification criteria for nanomaterials concerning certain endpoints**?** Please explain your answers and give examples in the comment fields.*

The question about the need to re-evaluate classification criteria (substances/mixtures) for nanomaterials concerning certain endpoints (physical hazards, health hazards and environmental hazards) was clearly difficult for the respondents. Fifty-nine to 79% (depending on the endpoint) could not decide between “yes” and “no” and selected “no opinion”. Respondents were clearly unsure about the criteria concerning physical hazards. More opinions were expressed concerning health and environmental hazards.

In the physical hazards group, a need for re-evaluation of the classification criteria for nanomaterials was identified for aerosols, requested by more than a quarter of the respondents. Other needs for re-evaluation were related to “explosives”, “flammable solids”, “self-reactive substances and mixtures”, “pyrophoric solids”, “self-heating substances and mixtures”, “substances and mixtures which, in contact with water, emit flammable gases” and “oxidizing solids”. Concerning the classification of “flammable gases”, “oxidizing gases”, and “gases under pressure”, some respondents pointed out that nanoparticles are solid substances and not gases, and that solid particles are not present in gases.

The need for re-evaluation of the criteria for health hazard endpoints was more obvious: 25 to 31% of the respondents (depending on the endpoint) expressed this need. A requirement for re-evaluation of all health hazard classes was indicated, particularly for “carcinogenicity”, “respiratory or skin sensitization”, “acute toxicity” and “germ cell mutagenicity, but no further conclusions can be made based on the responses.

It was said that, if a nanomaterial is proved to have additional hazardous consequences or to accelerate hazardous properties (compared to the bulk material), a re-evaluated classification should be considered. It was also stressed that the permeability may differ, and therefore the classification criteria should perhaps be different for nanomaterials. Furthermore, some people commented that the behaviour might be different depending on the physicochemical characteristics of the material compared to bulk material, and that very little is known about those physicochemical characteristics that might be harmful to life. It was also recognized that spread in the body and function in the cells (surface properties of the particles) is not necessarily known yet.

Regarding environmental hazards, a classification criteria re-evaluation was requested especially for aquatic environment hazards (29%). As an example, one of the respondents asked us to think about polyethylene nanoparticles from toothpaste or plastic bag material, when discharged into rivers and the ocean. Regarding the effects on the ozone layer, it was pointed out that nanoparticles cannot exist in the stratosphere.

5.5 Read-across

Question: If data is not available for a certain nanomaterial, is data from similar substances (read-across) usable for classification purposes in the following cases? Please explain your answers and give examples in the comment fields.

For the question on usability of read-across for classification purposes, a large part of the respondents (65 to 71%) had no opinion. Of those who expressed their opinion, 20% would not use data from bulk material to nanomaterial whereas 14% thought that read-across between bulk and nanosized material would be useful. Concerning the options “from another nanomaterial” or “from the same nanomaterial with a different coating”, answers were quite evenly divided between yes and no. Respondents thought that the most useful read-across data would be “from the same nanomaterial in a different size” (22% yes, 10% no). Information “from the same nanomaterial in a different shape” was also considered usable by 19% of the respondents.

Read-across from the bulk form to the nanoform of the same substance was supported as the chemical structure/composition is the same. However, comments also stated that possibilities to use read-across from bulk material data depends on the physicochemical characteristics that might be different between bulk and nanomaterial. Also, the hazardous properties of a nanomaterial can differ very much from those of the bulk material. It was pointed out that read-across always needs scientific proof. In cases where it can be shown that size, shape, coating, etc. does not affect the outcome of a specific test read-across can be accepted. Also, for example, solubility properties are important to take into consideration, and if major differences are seen, read-across may not be appropriate.

Read-across from the same nanomaterial but with a different size was in theory considered possible within a certain size range. Expert judgment was identified as important for those cases.

According to some of the respondents, considering data from the same nanomaterial with a different coating might be possible, depending on the coating properties. However, many people pointed out that the coatings may dramatically change the properties of a nanomaterial, and therefore read-across would not be applicable.

5.6 Metrics in classification

Question: At the moment, concentration limits and cut-off values for particles are expressed as weight/weight % in classification. In some cases other parameters than mass may be more informative. In your opinion, which are the most suitable metrics to be used for nanomaterials? Please select one or more options and explain your answers in the comment fields.

The respondents were asked to select the most suitable metrics to be used for nanomaterial classifications (n = 134). Surface area had the highest support (49%), followed by mass and particle number, 40% and 34%, respectively. Twenty percent of the respondents selected the option “other”, mostly because they had no opinion.

Some explanations were given in the comments field, but it remained unclear on which basis the surface area option was supported. Mass was supported as it is the easiest unit to measure and is already in use in GHS/CLP. Also, the expression of mass always was considered important in addition to other metrics. One person stressed that particle number and/or surface area (which are often related) are more relevant parameters than mass for describing nanomaterials, and should be included in the identity description of the material, but that mass-based cut-off values could still be used.

Measuring particle number was said to be difficult, but there was a clear support for using this metric. It was further commented that the number of particles per cm^3 should be given, as the particles are so small, and that this information should be included when relevant, in addition to the weight/weight %. Also, it was suggested that the surface area be included when relevant. In one of the comments it was stated that it is the presence rather than the weight of the materials that decides the effect, and therefore it would be more relevant to have a cut-off value based on either particle number or specific surface area.

In their comments, some of the respondents emphasized that different metrics might be required for different types of materials. It was also suggested that one focus on the number of molecules in clusters of material.

5.7 Concentration limits for mixtures

Question: A mixture containing a classified substance must be classified if the concentration of that specific substance is above concentration limits specified in GHS/CLP. Are the present concentration limits suitable for classification of mixtures containing nanomaterial? Please explain your answers and give examples in the comment fields.

GHS/CLP concentration limits for the classification of a chemical mixture containing bulk material(s) and nanomaterial(s) were considered unsuitable by 15% of the respondents; whereas almost the same number (14%) thought that the current limits can be used. The current concentration limits were concluded to be unsuitable for mixtures of bulk and nanosized materials as the hazards of a nanomaterial might differ from what can be estimated based on its concentration in the mixture. In the case of mixtures of two or more nanomaterials (only nanos), there was greater support for using the GHS/CLP concentration limits (17%), than against it (10%). Again, the great majority had no opinion.

Support for the current concentration limits was expressed, as there were worries that the result may otherwise be a more stringent classification of nanomaterials than of bulk material. One proposal was to classify according to activity instead of concentration. It was also highlighted that, although the quantity of nanomaterial may remain undeterminably low, it may still influence the properties of a mixture. As the weight%-based limits do not consider the amount of active surface of the substance, at least the concentration values for classification were proposed to be smaller for nanoparticles than for other substances.

5.8 Additivity approach

Question: If test data for acute toxicity, irritation, corrosivity or aquatic toxicity for the whole mixture is not available, the additivity formula may be used (1272/2008/EC). Basically this means that each ingredient contributes to the hazard in proportion to its potency and concentration. In your opinion, is the additivity approach applicable for nanomaterials?

Over 60% of the respondents did not have an opinion on the applicability of the additivity approach in cases where the test data for acute toxicity, irritation, corrosivity or aquatic toxicity for the whole mixture containing nanomaterial(s) is not available. About a quarter of the respondents thought that applying the additivity approach for classification purposes could be justified; however, it was also acknowledged that it could only be used in case the hazard profile is the same for the bulk and nanoform. Arguments in favour of the additivity approach were that the approach has already been used without any problems in cases including nanomaterials (e.g. silica). It was commented that the approach can be applied in case the toxicity is based on the individual nanomaterials and not based on the toxicity of the bulk material. The applicability might also depend on how the ingredient is present in the material, e.g. is it inside the nanomaterial or on the surface.

Twelve per cent of the respondents considered the additivity approach unsuitable for nanomaterials. The resulting classification was considered to be too severe when applying the additivity approach in cases where the particle is very stable and the hazardous substance is in the core. On the other hand, if the hazardous material is in the coating, the classification might be too mild. It was also concluded that mass-based concentrations may not be suitable for nanomaterials, as particle size, solubility, and form may be more important. Also, the nanoform introduces the possibility of new modes of action for chemical substances and, therefore, additive effects may not be relevant.

6 Labelling and Safety Data Sheets

6.1 Nanospecific information - When?

Question: In case of nanomaterials or chemical mixtures containing nanomaterial(s), when should SDS contain nanospecific information (e.g. particle size)?

Safety data sheets (SDS) was clearly a more familiar issue among the respondents than for example the classification-related issues. A total of 77% of the respondents had an opinion on when the SDS should contain nanospecific information. Thirty-seven percent would like always to have the information included in the SDS, whereas 29% thought that information should be presented in the SDS when the concentration of nanomaterial is above a certain limit (Fig. 5). The option "always" was selected by 62% of the respondents representing the authorities, by 32% of industry representatives and by 52% of those belonging to the category "others". The highest support for the option "concentration of nanomaterial above a certain limit" came from industry (32% of industry respondents). Only less than 3% would never include nanospecific information in the SDS. All the respondents selecting this option were from industry.

A number of additional suggestions were also given. Some people proposed that the information should be required only if the presence of nanomaterial results in a specific hazard. Specific information could be important in cases where it was relevant for exposure assessment; e.g. when added as an ingredient in a mixture of powder. It was also stressed that including this kind of data is important in order to be able to select the correct personal protective equipment.

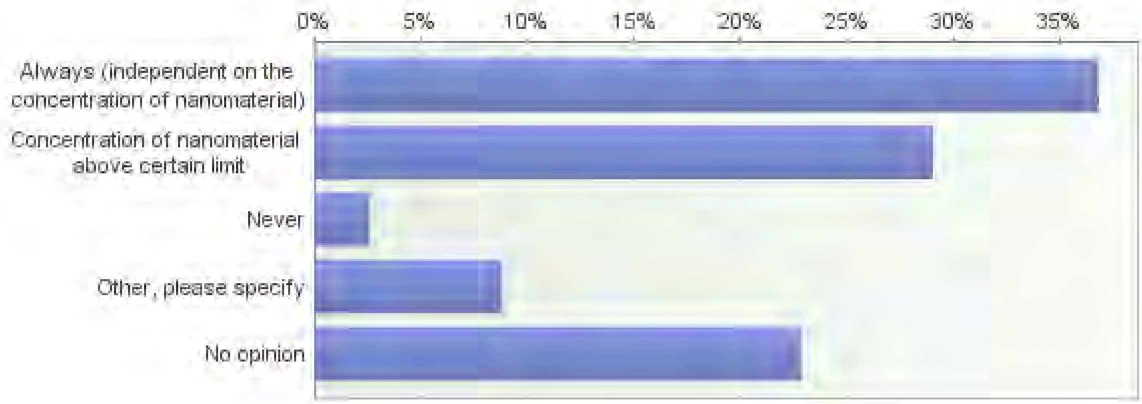

Figure5. In case of nanomaterials or chemical mixtures containing nanomaterial(s), when should SDS contain nanospecific information (e.g. particle size)? (n=193)

6.2 Nanospecific information – What?

Question: In your opinion, which of the following nanospecific properties should be mentioned in the SDS? Please select one or more options.

The most important nanospecific properties that should be mentioned in the SDS were size, surface area and shape, with size being the most important property, according to the respondents. For coated nanomaterials, the composition of the coating should be required as well. Dissolution rate of ions, dispersion stability or other properties were requested by fewer people (<10%). Only 2% to 4% of the respondents considered that there are no additional data needs for nanomaterials (Table 2).

Some of the respondents commented that there should not be any obligatory fields, but important information should be included on a case by case basis. Technical data, which is relevant for human health and risk to the environment, should be mentioned in the SDS. Also, a few people said that, in the SDS, hazard data is more important than technical data. There were also opposite views, requesting that as much relevant information as possible should be included in the SDS.

Table 2. In your opinion, which of the following nanospecific properties should be mentioned in the SDS? One or more options are possible (total n = 338-378). (n=189)

	Size (%)	Shape (%)	Surface area (%)	Coating composition (%)	Dissolution rate of ions (%)	Dispersion stability (%)	Other (%)	No additional data needs (%)	No opinion (%)	Total n
Pure nanomaterials (substances)	**19**	**12**	**14**	9	7	8	3	2	25	378
Chemical mixtures containing nanomaterial(s)	**17**	**12**	**12**	8	7	9	4	4	29	338
Mixtures of two or more nanomaterials (only nanos)	**18**	**12**	**13**	8	7	9	3	2	28	358
Coated nanomaterials	**17**	**10**	**12**	15	6	7	3	3	28	351

6.3 Communicating nanospecific information

Question: In your opinion, how should you communicate information concerning nanomaterials?

The question of communicating nanospecific information was complex and perhaps difficult to understand. However, almost everyone answered the question. On the basis of the responses to this question, there is a request for communicating nanospecific information, both in labels and safety data sheets. This view was supported by respondents from all categories (authority, industry, others).

More than one third would communicate nanospecific information to the downstream users by labelling nanomaterial-containing products based on their hazard. The support for hazard-based labelling was greatest among respondents from industry. Twenty-two percent of the respondents always prefer labelling, independent of hazard.

The support for always labelling was greatest among authority representatives (4 out of 11 responses), but also 27 of the respondents from industry (19%) expressed a need for labelling in any case. Only 3% (all representing industry) considered that there is no need for labelling. When looking only at the responses of respondents coming from industry, the division of the options selected were about the same as for the total survey. This is logical, because the majority of respondents (78% for this question) were from industry. The authority group was so small (n=11 for this question) that no real conclusions can be made, but it can be mentioned that the options “always” and “based on hazard” were most popular in that group as well.

Communication through SDS was always considered important (independent of hazard) by 33% of the respondents. About a fifth would provide information about nanomaterials in the SDS only if justifiable, based on hazard.

According to 24% of the respondents, information on nanomaterials should always be sent to a national product registry, whereas 16% and 13%, respectively, think it should be done based on hazard or when the concentration exceeds an agreed limit.

It was stressed that, since nanomaterial does not mean “hazardous”, stigmatizing nanomaterials must be avoided, and any classification and labelling must be hazard-based. If uncertainties on the hazards related to nanomaterials as such still remain despite new studies and research, it might be justified to indicate on the label that the product contains nanomaterial. It was also said that this kind of information in the SDS is needed for workplaces and communication in the supply chain, but information on the labels of consumer products would only be necessary in cases where the reason to inform really is justified (due to harmful effects). Also, a registry of nanomaterials should be at an EU, instead of a national, level. The information need should be carefully defined considering competition laws and aspects.

7 Specific questions to industry

One hundred and thirty-two persons (68%) responded to the special section of the questionnaire targeted at industry representatives.

7.1 Type of nanoproducts placed on the market

Question: What kind of nanoproducts does your company place on the market? Please select one or more options and specify your answers.

The first question in this part of the survey was about nanoproducts that companies have placed on the market. A fifth of the respondents (28 responses) came from companies having some kind of nanoproducts. Most of the products (18 responses) were mixtures containing one or more nanomaterials. Pure nanomaterials, coated nanomaterials or articles containing nanomaterials were more uncommon (3 to 6 responses) (Fig. 6).

The products mentioned included, e.g. paints, metal powders, lubricants, liquid products containing carbon black and amorphous silica, paper, and thin film coated products.

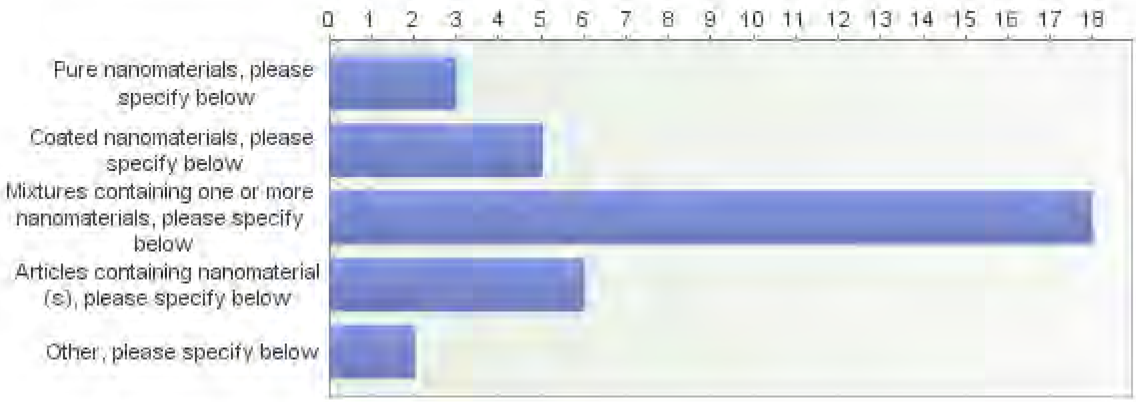

Figure 6. What kind of nanoproducts does your company place on the market? One or more options are possible. (n=28)

7.2 Nanomaterial classification

Question: If you have classified pure nanomaterials / coated nanomaterials, on what basis did you make the classification? Please select one or more options.

Seven (out of 99) respondents stated that their company has classified pure nanomaterials. Four of the respondents based the classification on specific nanomaterial data, one on specific nanomaterial data as well as on bulk material classification, and two on some other data.

Only five respondents (out of 98) had experience in classifying coated nanomaterials. Three of them based their classification on mixture classification criteria, one on coating material classification (more precisely on coating method), and one on core material classification.

7.3 Notification to ECHA

Question: If you have classified your nanomaterials, how was ECHA notified? Please select one or more options.

The respondents had notified ECHA about the classified nanomaterials mainly "in connection with a REACH registration". This option was selected by four of the respondents who had experience in classifying pure and/or coated nanomaterials (total n=77). Of those four respondents, one had also made a "joint notification to the Classification and Labelling Inventory". A large amount of respondent (n=55) selected the option "not my responsibility".

7.4 Respondents' conclusions on the need to address nanomaterials in GHS/CLP

Question: GHS/CLP in its current form does not specifically address nanomaterials. As your final conclusion, at a general level, is there in your opinion a need to consider those separately in GHS/CLP?

In the final part of the survey, the respondents were asked to make overall conclusions about the need to specifically address nanomaterials in GHS/CLP. Most of the respondents (68%, 79 out of 117) considered it in some way necessary to specifically focus on nanomaterials within the GHS/CLP, while 16% of the respondents had the impression that the current system covers nanomaterials and there is no need for specific consideration.

A large number of comments were received, emphasizing, for example, the following issues:

- There is a need to know which nanomaterials are dangerous and classify according to that. Many nanomaterials are (most likely) not dangerous, and other are encapsulated and do not affect the consumer. Any material should be classified accordingly to its hazards, not its size.
- More guidance is requested on how to classify nanomaterials. Much research is obviously needed to understand the variations in hazard profile.
- There is no need to separately consider nanomaterials for testing and classification, but users/industry should be informed when nanomaterials are present in order to be able to select the correct personal protective equipment.
- In many cases, any tested chemicals in powder form may contain nano-fractions due to abrasions through mechanical handling. To single out nano-materials and to give different guidelines for those will probably create as many problems, if not more, as it solves.
- The size distribution and other physico-chemical properties of a material should be taken into consideration in determining the classification, especially if there is data indicating that the intrinsic hazard properties are dependent on these. Further guidance and examples would be useful. In addition, if there are still severe uncertainties of the hazards related to nanoscale as such, it might be justified from a precautionary perspective to indicate on the label that the chemical is defined as a nanomaterial.
- The starting point for instructions related to nanomaterials should be GHS, cascading down in national/regional legislation. Classification rules should similarly be agreed and interpreted globally. It is important to consider that a lot of nanomaterials are produced outside the EU, and global harmonization including China and India is important.
- A number of comments stated that there is no need to consider nanomaterials separately, and that there are already mechanisms to introduce different classifications for the same substance if needed.
- A nanomaterial should be treated as any other chemical substance. Attempts to try to simplify as much as possible would be important in order not to turn this into a too bureaucratic and tough a task for industry.

8 Discussion and summary of the main results

The Nordic Classification Group, under the auspices of the Nordic Chemical Group/Nordic Council of Ministers launched a project on the collection of Nordic stakeholders' views on issues related to nanomaterials in relation to GHS/CLP Regulation (1). The purpose of the survey was to provide input for the informal correspondence group on nanomaterials of the UN Sub-Committee of Experts on GHS so as to indicate possible challenges concerning classification of nanomaterials. The survey was conducted as a web-based questionnaire which was distributed to over 3,500 recipients in Denmark, Finland, Norway and Sweden in May 2014.

The total response rate was relatively low (199 respondents, 5.7%), which can for the most part be explained by the fact that the majority of recipients were selected from national product registries, representing any chemical sector, and thus in the majority of cases not specifically selecting nanomaterials. The respondents were mainly from industry (79%), whereas the authorities were represented by 7% and others by 15%. Twenty eight percent of the industry respondents represented companies placing some kind of nanoproducts on the market. Most of their products were mixtures containing one or more nanomaterials. Seven respondents informed that their company has classified pure nanomaterials and five respondents had experience of the classification of coated nanomaterials.

The respondents' knowledge of CLP and GHS was fairly good according to their own evaluation, but they were less familiar with issues related to nanomaterials and nanosafety. The fact that the majority of the respondents were not familiar with nanomaterials and related questions was reflected by a relatively high proportion of "no opinion" answers. Some of the questions required in-depth knowledge of classification and others were perhaps too ambiguous and possibly misunderstood, which was probably reflected in some of the answers. However, a selection of prevailing views was extracted from responses and from a substantial number of written comments. These comments were relevant with respect to ongoing discussions of the scientific and regulatory communities regarding nanomaterial identification, characterization, potential hazards, metrics, grouping and read-across. Taken together, the outcome and the conclusions of the survey can in the opinion of the Nordic Classification Group be considered as a preliminary mapping of the possible challenges in nanomaterial classification.

A summary of the main outcomes with relevance to the work of GHS on nanomaterials is presented below. The conclusions are based on the outcome of the survey and do not necessarily represent views of the Nordic authorities in chemical legislation or the Nordic Council of Ministers.

Conclusions:

Inclusion of a definition for "nanomaterials" in GHS/CLP

Inclusion of a definition was supported by the majority of the respondents, and it was mainly suggested that it be based on the EU commission recommendation for a definition. It should be noted that the respondents are situated in the European Economic Area (EEA).

Amendment of GHS/CLP and update of relevant guidance documents

The best way to handle nanomaterials in relation to classification and labelling was thought to be by amending GHS/CLP and updating relevant guidance documents

Inclusion of detailed information on the characterization and identification of the nanomaterial

There was clear support for the inclusion of detailed information on the characterization and identification of nanomaterial in relation to classification. Data on those properties responsible for hazardous behaviour should be included in sufficient detail. Some examples given of such properties were active surface area, fiber properties, form, surface chemistry, and surface charge.

Classification of different forms of nanomaterials

Many of the respondents saw the need to give different classifications to different forms of the same nanomaterial. They could not explicitly name the main driving physico-chemical parameter for hazardous effects, but agreed that primary particle size, shape, surface properties, solubility, aggregation/agglomeration state, and dispersion stability could be such parameters. Also, other properties relevant to specific material were suggested. It was also pointed out that the smallest available (and not theoretical primary) particle should drive the classification.

Classification of coated nanomaterials

The best way to handle coated nanomaterials under GHS/CLP would be to consider these, depending on solubility, either as equal to the coating material or as a mixture. Support was also given for a classification of coated nanomaterial as a substance. This was justified on the basis that it might present properties not reflecting either coating or core material.

Re-evaluation of classification criteria for substances and mixtures

The question about the need to re-evaluate classification criteria of both substances/mixtures for nanomaterials in each hazard class proved to be difficult. In physical hazards, the major need for re-evaluation was for the hazard class "aerosols". In health hazards, there was equal support for the re-evaluation of each endpoint; however, no details were suggested. In environmental hazards a classification criteria re-evaluation was requested especially for aquatic environment hazards.

Read-across possibilities in nanomaterial classification

When considering the usability of read-across data for classification purposes, the respondents thought that the most useful read-across data would be from the same nanomaterial in a different size or in a different shape. Read-across from bulk to the nanoform was also supported on the basis of the same chemical structure/composition; however, limitations such as different physico-chemical properties were acknowledged. Limitations were also seen in read-across between same nanomaterials with different coatings.

Suitable metrics for nanomaterials

The most suitable metrics to be used for nanomaterial classification were thought to be surface area, followed by mass and particle number. However, the expression of mass was always considered important in addition to other metrics.

Concentration limits in mixture classification

The current concentration limits were considered to be unsuitable for mixtures of bulk and nanosized materials, as the hazards of a nanomaterial might differ from what can be estimated based on its concentration in the mixture. However, there were opposite opinions supporting the current concentration limits, as there were concerns about a more stringent classification of nanos than bulk material.

Applicability of the additivity approach

The applicability of the additivity approach for nanomaterial classification purposes received more support than opposition; however, it was also acknowledged that it could only be used in case the hazard profile is the same for bulk and nanoform. Applying the approach to coated nanomaterials was considered especially problematical as well as the use of mass-based concentrations. Also, the nanoform introduces the possibility of new modes of action for chemical substances, and therefore additive effects may not be relevant.

Communication on nanomaterials

An obvious need for communicating nanospecific information was identified. The majority of respondents would like to have nanospecific information included in Safety data sheets (SDS), with somewhat higher support for including the information regardless of the concentration of nanomaterial. The most important properties that should be mentioned in the SDS were size, surface area and shape, size being the most important property. For coated nanomaterials, the coating composition should be required. The majority of the respondents would also communicate nanospecific information to the downstream users by labelling nanomaterial-containing products, with greater support for labelling of these products based on their hazards than for labelling just for being nanomaterial.

In their final conclusions, 68% of the respondents considered it in some way necessary to specifically focus on nanomaterials within the GHS/CLP, while 16% had the impression that the current system covers nanomaterials and there is no need for specific consideration.

9 References

1 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:L:2008:353:TOC

2 Report of the Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals on its twenty-fourth session, ST/SG/AC.10/C.4/48
http://www.unece.org/trans/main/dgdb/dgsubc4/c4rep.html

3 European Commission recommendation of 18 October 2011 on the definition of nanomaterial (2011/696/EU)
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF

4 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
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