



Nordic Survey on Nanomaterial Hazard Classification and Labelling

Background information

1. In which country is your organization/company based?

- Denmark
 Finland
 Iceland
 Norway
 Sweden
 Other, please specify

2. What sector does your organization/company represent?

- Authority, please specify your role below
 Industry, please specify your sector (e.g. chemicals, biocides, cosmetics) and role (e.g. importer, manufacturer, downstream user) below
 Other (e.g. consultant, stakeholder), please specify sector and role below

Please specify your sector and role:

3. How well do you know the legislation for classification and labelling of chemicals- GHS and/or CLP?

GHS = United Nations' Globally Harmonized System of Classification and Labelling of Chemicals
CLP = EU regulation on Classification, Labelling and Packaging of substances and mixtures

- Good knowledge
 Fairly good knowledge
 Limited knowledge
 Poor knowledge
 Not familiar with the subject

Please specify your answer and give examples of your activities related to GHS/CLP:

4. How well do you know nanomaterials and issues related to nanosafety?

- Good knowledge
 Fairly good knowledge
 Limited knowledge
 Poor knowledge
 Not familiar with the subject

Please specify your answer:

Nanomaterials and GHS/CLP

There are several definitions established or under development for nanomaterials in order to determine whether a material should be considered as a 'nanomaterial' for legislative and policy purposes. Nanosized substances or materials may possess different properties and behave differently compared to the bulk form of the chemical. At the moment there is no specific definition used for classification and labelling of nanomaterials.

5. In your opinion, should there be a definition for nanomaterial in classification and labelling?

- Yes
 No
 No opinion

6. On what should the definition be based?

- [EU Commission recommendation for nanomaterial definition](#)
 ISO/CEN standard (e.g. [ISO/TS 27687:2008](#))
 A new specific definition for GHS
 Other, please specify
 No definition needed
 No opinion

Please specify your answer:

7. What would be the best way to handle nanomaterials in relation to classification and labelling?

- Amend GHS/CLP
 Amend GHS/CLP and update guidance documents
 Update guidance documents to cover nanomaterials
 Other, please specify
 No actions needed
 No opinion

Please specify:

Test results and classification criteria

8. 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.

Yes, please specify:

No, please specify

No opinion

9. 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.

Definitions according to ISO 26824:2013:

- Primary particle = original source particle of agglomerates or aggregates or mixtures of the two
- Aggregate = particle comprising strongly bonded or fused particles where the resulting external surface area is significantly smaller than the sum of surface areas of the individual components
- Agglomerate = collection of weakly or medium strongly bound particles where the resulting external surface area is similar to the sum of the surface areas of the individual components

- Yes, based on primary particle size
- Yes, based on shape
- Yes, based on surface properties
- Yes, based on solubility
- Yes, based on primary/agglomeration/aggregation state
- Yes, based on dissolution rate of ions
- Yes, based on dispersion stability
- Yes, based on other characteristics, please specify
- No
- No opinion

Please explain your answer:

10. How should coated nanomaterials, in your opinion, be considered under GHS/CLP?

- As a substance
- Same as core substance
- Same as coating material
- As a mixture
- Depending on solubility either same as coating material or as a mixture
- As an article
- Other, please specify
- No opinion

Please specify your answer:

11. In your opinion, is there a need to re-evaluate classification criteria (substances/mixtures) for nanomaterials concerning certain endpoints? Please explain your answers and give examples in the comment fields.

	Yes	No	No opinion	
Physical hazards				
Explosives	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Flammable gases (including chemically unstable gases)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Aerosols	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Oxidizing gases	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Gases under pressure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Flammable liquids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Flammable solids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Self-reactive substances and mixtures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Pyrophoric liquids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Pyrophoric solids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Self-heating substances and mixtures	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Substances and mixtures which, in contact with water, emit flammable gases	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Oxidizing liquids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Oxidizing solids	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Organic peroxides	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Corrosive to metals	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Health hazards				
Acute toxicity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Skin corrosion/irritation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Serious eye damage/eye irritation	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Respiratory or skin sensitization	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Germ cell mutagenicity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

Carcinogenicity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Reproductive toxicity	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Specific target organ toxicity - Single exposure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Specific target organ toxicity - Repeated exposure	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Aspiration hazard	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
Environmental hazards				<input type="text"/>
Hazardous to the aquatic environment	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	
Hazardous to the ozone layer	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
				<input type="text"/>

12. 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.

In the read-across technique, endpoint information for one chemical is used to predict the same endpoint for another chemical, which is considered to be similar in some way (usually on the basis of structural similarity). In principle, read-across can be applied to characterise physico-chemical properties, environmental fate, human health effects and ecotoxicity. (REACH Guidance on Information Requirements and Chemical Safety Assessment: [QSARs and grouping of chemicals \(Chapter R.6\)](#))

	Yes	No	No opinion	
From bulk material to nanomaterial	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
From another nanomaterial	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
From the same nanomaterial in a different size	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
From the same nanomaterial in a different shape	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>
From the same nanomaterial with a different coating	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="text"/>

13. 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.

Mass

Particle number

Surface area

Other, please specify

14. 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.

	Yes	No	No opinion	
Chemical mixture containing bulk material(s) and nanomaterial(s)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input style="width: 290px; height: 40px;" type="text"/>
Mixture of two or more nanomaterials (only nanos)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input style="width: 290px; height: 40px;" type="text"/>

15. 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?

- Yes
- No
- No opinion

Please explain your answer and give examples:

Labelling and Safety Data Sheets

Safety data sheets (SDS) provide a standardized format for the hazard communication. In GHS/CLP, SDS content and format are specified.

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

- Always (independent on the concentration of nanomaterial)
- Concentration of nanomaterial above certain limit
- Never
- Other, please specify
- No opinion

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

	Size	Shape	Surface area	Coating composition	Dissolution rate of ions	Dispersion stability	Other, please specify below	No additional data needs	No opinion
Pure nanomaterials (substances)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chemical mixtures containing nanomaterial(s)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Mixtures of two or more nanomaterials (only nanos)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Coated nanomaterials	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Please specify your answer:

18. In your opinion, how should you communicate information concerning nanomaterials?

	Always, independent of hazard	Conc. above an agreed limit	Based on hazard	Other, please specify below	No need for labelling	No opinion
In label	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Only in SDS	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Only as information to national product registry	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Other, please specify where	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please explain your answer:

Special questions to industry

19. There are a few additional questions, which we would like industry representatives to answer. Please select the category you belong to.

- Industry
 Other

Please note that the replies are handled anonymously.

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

- Pure nanomaterials, please specify below
 Coated nanomaterials, please specify below
 Mixtures containing one or more nanomaterials, please specify below
 Articles containing nanomaterial(s), please specify below
 Other, please specify below
 No nanoproducts
 I don't know

Please specify your answer:

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

- Specific nanomaterial data
 Bulk material classification
 other, please specify
 No classification experience on pure nanomaterials
 Not my responsibility

Please clarify why the specific approach(es) was selected:

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

- Mixture classification criteria
- Coating material classification
- Core material classification
- Other, please specify
- No classification experience on coated nanomaterials
- Not my responsibility

Please clarify why the specific approach(es) was selected:

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

- In connection with a REACH registration
- Joint notification to Classification and Labelling Inventory
- Single notification to Classification and Labelling Inventory
- Other, please specify
- Not my responsibility

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

25. If you have any other comments or remarks on nanomaterial classification, please add them below. Thank you for your participation!

Break

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