Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals

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Item 2 (g) of the provisional agenda
Work on the Globally Harmonized System of Classification
and Labelling of Chemicals: Nanomaterials

Latest developments in the European Union on nanomaterials

Transmitted by the European Union

Background

- 1. At its twenty-sixth session in 2013, the GHS Sub-Committee agreed on the creation of an informal correspondence group (ICG) on reviewing the applicability of GHS to nanomaterials¹.
- 2. The terms of reference of this ICG have been:
 - (a) To establish whether there is a need to amend the GHS to make clear that nanoforms of a substance are within scope of the GHS;
 - (b) To review the classification and labelling criteria in the GHS to establish whether they are appropriate for nano-, as well as bulk-forms of a substance;
 - (c) To review the content of safety data sheets set out in the GHS in terms of their applicability to nano-forms of a substance;
 - (d) To report back to the Sub-Committee on the outcomes of (a) to (c) and to propose further work, as appropriate.
- 3. During the following sessions, the GHS Sub-Committee has been informed of the advancement of the work until the thirty-eight session². At that time, the expert from leading country reported that they were no longer able to continue leading this work without the help of other delegations. There was a call for expressions of interest from other delegations to lead the work on nanomaterials, but no delegation has been able to take the role. Nonetheless, the GHS Sub-Committee has kept the agenda item in its programme of work for the following biennia.
- 4. This document presents the latest developments on the matter, at the European Union level.

European Commission's recommendation on the definition of nanomaterial

5. On 10 June 2022, the European Commission adopted a new recommendation on the definition of nanomaterial³ that updates the previously existing definition from 2011.

¹ See Annex II of document ST/SG/AC.10/C.4/52 https://unece.org/reports-33

² See summary table in Annex I.

European Commission, 2022. Commission Recommendation of 10 June 2022 on the definition of nanomaterial 2022/C 229/01 https://europa.eu/!BtcQxH

- 6. "Nanomaterial" means a natural, incidental or manufactured material consisting of solid particles⁴ that are present, either on their own or as identifiable constituent particles in aggregates⁵ or agglomerates⁶, and where 50 % or more of these particles in the number-based size distribution fulfil at least one of the following conditions:
 - (a) One or more external dimensions of the particle are in the size range 1 nm to 100 nm;
 - (b) The particle has an elongated shape, such as a rod, fibre or tube, where two external dimensions are smaller than 1 nm and the other dimension is larger than 100 nm;
 - (c) The particle has a plate-like shape, where one external dimension is smaller than 1 nm and the other dimensions are larger than 100 nm.
- 7. In the determination of the particle number-based size distribution, particles with at least two orthogonal external dimensions larger than 100 μ m need not be considered. However, a material with a specific surface area by volume of $< 6 \text{ m}^2/\text{cm}^3$ shall not be considered a nanomaterial.
- 8. It is recommended to use such definition when addressing materials or issues concerning products of nanotechnologies:
 - (a) by the European Commission, when preparing legislation, policy programmes or research programmes and when implementing such legislation or programmes also with other Union institutions and agencies;
 - (b) by Member States of the European Union, when preparing legislation, policy programmes or research programmes and when implementing such legislation or programmes;
 - (c) by economic operators, when preparing and conducting their own policies and research.
- 9. From a legislative perspective, the definition is used in different European regulations to harmonise how nanomaterials are defined in different European regulations where such status may trigger specific/additional provisions. Under REACH⁷, forms of a substance fulfilling the definition of nanomaterial⁸ are called nanoforms. In particular, nanoforms of a substance fall under the existing REACH and CLP⁹ definition of a substance, and provisions set by both regulations apply.
- 10. As of 1 January 2020 (and changes to the requirements regarding new Safety Data Sheets since 1 January 2021 and for existing datasheets since 31 December 2022), explicit legal requirements under REACH apply for companies that manufacture or import nanoforms as well as for the downstream users. These reporting obligations address specific information requirements, outlined in revised annexes to the REACH regulation:
 - (a) Characterisation of nanoforms or sets of nanoforms covered by the registration (Annex VI);
 - (b) Chemical safety assessment (Annex I);

^{4 &}quot;Particle" means a minute piece of matter with defined physical boundaries; single molecules are not considered 'particles'.

⁵ "Aggregate" means a particle comprising of strongly bound or fused particles.

^{6 &}quot;agglomerate" means 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.

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) https://europa.eu/!dD9Mhw

Included in Annex VI as a copy of the definition in the 2011 Recommendation. Revision to update with the new Recommendation is in progress.

⁹ 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 https://europa.eu/!9NpmrK

- (c) Requirements for the compilation of Safety Data Sheets (Annex II)
- (d) Registration information requirements (Annexes III and VII-XI); and
- (e) Downstream user obligations (Annex XII).
- 11. The amendments apply to all new and existing registrations covering nanoforms.

Guidance on the implementation of the Commission Recommendation

- 12. Following the adoption of the 2022 Recommendation by the European Commission; the Joint Research Centre of the European Commission (JRC) published a new, revised guidance on the implementation of the Commission Recommendation 2022/C 229/01 on the definition of nanomaterial ¹⁰;
- 13. The guidance builds upon the two JRC Science for Policy Reports: "<u>An overview of concepts and terms used in the European Commission's definition of nanomaterial</u>" and "<u>Identification of nanomaterials through measurements</u>" from 2019.
- 14. It gives an overview of the key terminology and concepts, provides a decision tree to identify nanomaterials and addresses identification of nanomaterials through measurements for the Recommendation on the definition of nanomaterial (2022/C 229/01).
- 15. Furthermore, an annex was added that lists documentary standards relevant for a harmonised and coherent regulatory implementation of the definition of nanomaterial at European Union and national level.

Conclusion

16. The Sub-Committee is invited to take note and comment on the information provided.

Rauscher, H., Kestens, V., Rasmussen, K., Linsinger, T. and Stefaniak, E., <u>Guidance on the implementation of the Commission Recommendation 2022/C 229/01 on the definition of nanomaterial</u>, EUR 31452 EN, Publications Office of the European Union, Luxembourg, 2023, ISBN 978-92-68-01243-7, doi:10.2760/237496, JRC132102.

Annex I

Summary of Informal Correspondence Group' status of work

GHS Session	Summary of status of work	Reference
26 th	The Sub-Committee adopted the terms of reference for the work of the informal group on the basis of the proposal in INF.29, with a minor editorial change to subparagraphs (a), (b) and (c) (see Annex II of the Final Report)	ST/SG/AC.10/C.4/52
27 th	The Sub-Committee noted that the ICG had identified a small number of nanomaterials for which data were available and intended to assess the applicability of GHS criteria for their classification. The expert from France also informed the Sub-Committee that the informal group would continue the discussions on on-going work related to classification of these materials in other international, regional or national bodies.	ST/SG/AC.10/C.4/2014/9 and ST/SG/AC.10/C.4/54
28 th	The Sub-Committee noted that the ICG would focus its work on the classification of some selected nanomaterial substances. The informal group stressed the importance of exchanging information with OECD on available classification data.	ST/SG/AC.10/C.4/2014/25, UN/SCEGHS/28/INF.28 and ST/SG/AC.10/C.4/56
	The Sub-Committee agreed to keep this item in its programme of work for the next biennium. The terms of reference for the work of the group agreed by the Sub-Committee at its 26 th session remained unchanged (see annex III).	
29 th	France initiated a classification exercise of some selected manufactured nanomaterials at national level with a possible proposal of a harmonised classification at EU level for one of them.	ST/SG/AC.10/C.4/58
	The Sub-Committee also noted the update provided by Finland on the classification for environmental hazards made by the group.	
30 th	The informal group examined the results of a classification exercise for environmental hazards conducted by Finland using data on carbon nanotubes and titanium dioxide and had considered some issues identified by France relating to testing of nanomaterials for physical hazards, and evaluation of the carcinogenic properties of titanium dioxide.	UN/SCEGHS/30/INF.20, UN/SCEGHS/30/INF.30 – issue 14 and ST/SG/AC.10/C.4/60
	Based on the work undertaken so far, the group concluded that GHS criteria can be applied to some extent for classification of nanomaterials and that some technical aspects of the classification might need to be addressed to OECD.	
	Regarding the applicability of test methods for physical hazard characterization of nanomaterials, the expert from France indicated that some shortcomings had been identified, such as the need for a minimum particle size to perform some tests or the impossibility to apply the test conditions to nanomaterials.	
31 st	No discussion	ST/SG/AC.10/C.4/62
32 nd	The Sub-Committee noted the information on the progress made by the informal correspondence group (ICG) and agreed to the programme of work for the next biennium proposed in paragraph 9 of INF.27 (thirty-second); i.e.:	UN/SCEGHS/32/INF.27 and ST/SG/AC.10/C.4/64
	 a) monitoring work concerning classification related issues regarding nanoform materials by other bodies, including the OECD Working party on Manufactured Nanomaterials and other relevant research projects on nanomaterials (worldwide); 	
	b) discuss which findings are relevant from the viewpoint of classification;c) develop a plan how to continue this work after the coming biennium.	

GHS Session	Summary of status of work	Reference
	The ICG coordinator reiterated his invitation to interested experts to participate in the work of the informal correspondence group.	
33 rd	No discussion took place	ST/SG/AC.10/C.4/66
34 th	The Sub-Committee noted that the ICG was following the progress of the work on safety of nanomaterials undertaken by the OECD and ECHA and that it intended to build on these outcomes to consider the applicability of GHS to such substances.	ST/SG/AC.10/C.4/68
35 th	No discussion took place	ST/SG/AC.10/C.4/70
36 th	INF.35 (thirty-sixth session) informed the Sub-Committee about ongoing work on nanomaterials at OECD level and under the Nordic Chemical Group. The Sub-Committee noted the information and agreed to keep this item in the programme of work for the next biennium with the current terms of reference (see annex II).	UN/SCEGHS/36/INF.35 and ST/SG/AC.10/C.4/72
37 th	INF.11 (thirty-seventh session) informed the GHS Sub-Committee on the completion of the project by the Nordic Chemical Group on the applicability of GHS criteria to four selected manufactured nanomaterials (single-walled carbon nano tubes, nano silicon dioxide, nano silver and nano zinc oxide) for the hazard classes listed in paragraph 3. The expert from Sweden briefly presented the main conclusions of the study ¹¹ . The Sub-Committee thanked the Nordic classification group for the work done, which provides useful information on classification of nanomaterials.	UN/SCEGHS/37/INF.11 and ST/SG/AC.10/C.4/74
38 th	No progress due to leader country no longer in a position to continue leading	ST/SG/AC.10/C.4/76
39 th	The Sub-Committee decided to keep the item on nanomaterials on its programme of work for 2021-2022.	ST/SG/AC.10/C.4/78

Reports of the above-mentioned GHS Sub-Committee sessions are available at https://unece.org/reports-33

The full report of the project is available on the website of the Nordic Council of Minister http://norden.diva-portal.org/smash/record.jsf?pid=diva2%3A1315194&dswid=295