United Nations ST/SG/AC.10/C.4/2012/30

Secretariat

Distr.: General
23 October 2012
English
Original: English and French

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

Twenty-fourth session
Geneva, 12 – 14 December 2012
Item 7 of the provisional agenda
Programme of work for the biennium 2013–2014

How appropriate guidance in the GHS should ensure harmonised hazard communication of nanomaterials

Transmitted by the expert from France[1]

1. By this document, the expert from France would like to give an update of informal document INF.22 (submitted at the 16th session) and document ST/SG/AC.10/C.4/2009/3 with the aim to:

(a) Give an overview of the worldwide expertise and risk management developments since 2008; and

(b) Continue the previous discussion on how hazard communication of nanomaterials should be addressed in the GHS.

Introduction

2. Chemical substances at a nanoscale are an actual breakthrough in chemistry. Such substances may have new properties in comparison with the same chemical substance at another scale (substance in its conventional form or among different nanoforms of the same substance).

3. Current scientific literature raises some concerns about some properties of nanomaterials, in particular those related to health and environmental issues. Therefore,

[1] In accordance with the programme of work of the Sub-Committee for 2011-2012 approved by the Committee at its fifth session (refer to ST/SG/AC.10/38, para. 16 and ST/SG/AC.10/C.4/40, Annex II).

many countries are considering their risk assessment capabilities with regard to these new properties, and more particularly with regard to the new surface chemical reactivity they present because of their particle size and granulometric distribution.

4. In the regulatory risk assessment paradigm, the hazard properties should be first identified, mainly by through a classification and information system. But the GHS does not provide any guidance on what specific nanomaterial information is relevant and when the communication of this information could be appropriate.

A. National activities

5. France has decided to set up a mandatory declaration of these substances and their uses, in addition to financing many research activities on the safety of nanomaterials and on studying the domestic market of substances at the nanoparticle state. The modalities of application of article 185 of the "Grenelle II" law[2] were defined by Decree No. 2012-232 of 17 February 2012, and the information to be reported is specified by the decree of 6 August 2012. This declaration comes into force on 1 January 2013 and will cover the substances at nanoparticle state placed on the market in 2012. The elements to be reported for each company introducing these substances on the market, including importers, concern: the identification of the substance, its quantity, uses and downstream users.

6. France, together with other Member States of the European Union such as Belgium or the Netherlands also wanted to support the development, at European level, of a harmonized regulatory framework addressing risk management of nanomaterials[3].

B. European activities

7. The European policy on nanomaterials was developed on the basis of a Strategy and Action Plan. In this framework, the Commission also adopted a code of conduct for responsible nanosciences and nanotechnologies research.

The definition of "nanomaterials"

8. On 18 October 2011 the Commission adopted a recommendation on the definition of nanomaterial[4]. According to this recommendation a "Nanomaterial" means:

"A natural, incidental or manufactured material containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50 % or more of the particles in the number size distribution, one or more external dimensions is in the size range 1 nm - 100 nm.

In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %.".

[2] Law N° 2010-788 of 12 July 2010 (available at: http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000022470434).

[3] Refer to the report "Working with nanomaterials: A seminar on policy, practice and the role of public authorities in dealing with uncertain risks") available at: http://www.travailler-mieux.gouv.fr/IMG/pdf/Working_with_nanomaterials_report_full.pdf

[4] Commission Recommendation of 18 October 2011 on the definition of nanomaterial, Official Journal of the European Union L 275 of 20 October 2011, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:275:0038:0040:EN:PDF

This definition is the basis for the amendments to existing legislation and the development of new pieces of legislation in the European Union.

Technical improvements in the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation) and the Regulation concerning the making available on the market and use of biocidal products

REACH Regulation[5]

9. An ad-hoc group "nanomaterials and REACH" started in July 2008 and a first document entitled "Nanomaterials in REACH" was endorsed by the Competent Authorities on 16 December 2008 and published on the European Commission's website[6].

10. In February 2012, the Commission assessed how nanomaterials have been addressed in REACH registrations and notifications in accordance with the Classification, Labelling and Packaging Regulation (CLP)[7]: 7 substance REACH registrations and 18 CLP notifications were identified as "nanomaterial". A further assessment has identified additional substances with potential nanoforms; in fact it was found that many registrations for substances known to have nanomaterial forms do not mention clearly which forms are covered or how current information relates to the nanoform of the substance.

11. These findings were partly explained by the absence of detailed guidance addressed to those who have to register the nanomaterials and a too general wording of the annexes to the REACH regulation.

12. The results of the "REACH implementation project substance identification of nanomaterials (RIP-oN1)"[8] suggest that flexibility is needed, but for the Commission the key issue is whether the registration provides clear information on the safe use for all nanoforms of the substance.

13. The European Chemicals Agency (ECHA) has updated technical guidance to take into account the final RIP-oN reports, and ECHA set up a Group assessing already registered nanomaterials (GAARN), to identify best practices for assessment and reporting of nanomaterials in REACH registrations, and to develop recommendations on how to fill potential data gaps. In addition, ECHA has set up a Nanomaterials Working Group to give scientific and technical advice on issues in relation to nanomaterials under REACH.

Biocidal product Regulation[9]

14. The new Biocidal Product Regulation N°528/2012 sets that nano forms of biocidal active substances should be considered independently from the bulk form. A mandatory labelling scheme of treated articles containing nano forms of a biocidal active substance is introduced as well.

[5] 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) available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20120601:EN:PDF

[6] Available at: http://ec.europa.eu/enterprise/sectors/chemicals/reach/nanomaterials/index_en.htm.

[7] Regulation (EC) No.1272/2008 of the European Parliament and of the Council on classification labelling and packaging of chemicals, which includes the corresponding elements from the GHS.

[8] Available at : http://ec.europa.eu/environment/chemicals/nanotech/pdf/report_ripon1.pdf.

[9] Regulation (EU) No.528/2012 of the European Parliament and of the Council of 22 may 2012 concerning the making available on the market and use of biocidal products, available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:EN:PDF

The second regulatory review on nanomaterials

15. The Commission has conducted two regulatory reviews for nanomaterials (the last one was adopted on 3 October 2012).

16. The main conclusions were that:

> "*In the light of current knowledge and opinions of the EU Scientific and Advisory Committees and independent risk assessors, nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not. Possible risks are related to specific nanomaterials and specific uses. Therefore, nanomaterials require a risk assessment, which should be performed on a case-by-case basis, using pertinent information. Current risk assessment methods are applicable, even if work on particular aspects of risk assessment is still required*."

> "*Overall the Commission remains convinced that REACH sets the best possible framework for the risk management of nanomaterials when they occur as substances or mixtures but more specific requirements for nanomaterials within the framework have proven necessary.* […] *The Commission will carefully follow developments, and report back to the Parliament, the Council and the European Economic and Social Committee within 3 years*."

17. So, if the current legislation seems to cover in principle the potential health, safety and environmental risks in relation to nanomaterials, knowledge on essential technical questions such as their characterisation, hazards, exposure, and risk evaluation and assessment, should be improved.

18. For that purpose:

(a) The definition of nanomaterial will be reviewed in 2014 to ensure the consistency of the approach for all sectors;

(b) A study has been launched in 2011, on occupational risks and environmental fate of nanomaterials, to provide more insight for further legislative guidance;

(c) A Nano subgroup has been set up to elaborate a draft opinion on risk assessment and management of nanomaterials at the workplace. This opinion should be subsequently endorsed by the Advisory Committee on Safety and Health at Work.

(d) Amendments of the REACH regulation annexes are envisaged to ensure clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers. The Commission encourages ECHA to further develop guidance for registrations after 2013.

Additional information is available at:

ttp://ec.europa.eu/nanotechnology/policies_en.html

C. International activities

The WHO "Guidelines on Nanomaterials and Worker's Health"

19. The WHO Global Network of Collaborating Centres in Occupational Health has selected manufactured nanoparticles as one of its key activities. This project of guidelines on "Protecting Workers from Potential Risks of Manufactured Nanomaterials" (WHO/NANOH) is part of the activities under the Global Plan of Action on Workers Health, adopted in 2007.

20. These Guidelines incorporate elements of risk assessment and risk management and sectorial contextual issues. They also provide recommendations to improve occupational safety and protect the health of workers using nanomaterials in all countries and especially in low and middle-income countries.

Additional information is available at:

http://www.who.int/occupational_health/topics/nanotechnologies/en/

The OECD Working Party on Manufactured Nanomaterials (WPMN)

21. The WPMN was established in September 2006 to promote international co-operation in human health and environmental safety aspects of manufactured nanomaterials. There are nine projects covered under "steering groups" on the following subjects:

(a) overview of ongoing and planned research;

(b) legislation and voluntary schemes;

(c) test data on substances;

(d) nanomaterials and OECD tests methods;

(e) alternative methods;

(f) risk assessment and exposure.

22. Two recent documents provide a good overview of:

(a) Regulation schemes from the OECD members[10]; and

(b) Current developments on hazard and risk assessments in a regulatory perspective[11] . This document also highlights that:

"[hazards properties] *are commonly identified in standardised acute and chronic (eco)toxicity tests. As concluded by SG4 in its Preliminary Review of OECD Test Guideline for their applicability to Manufactured Nanomaterials (OECD 2009a,), the OECD guidelines are in general considered applicable to manufactured nanomaterials, particularly with regard to investigating their health effects, with the important proviso that additional consideration needs to be given to the physicochemical characteristics of the material tested, including dosing. In some cases, there may be a need for further modification to the OECD guidelines*."

More information is available at:

http://www.oecd.org/env/chemicalsafetyandbiosafety/safetyofmanufacturednanomaterials/publicationsintheseriesonthesafetyofmanufacturednanomaterials.htm

GHS Sub-Committee's activities

23. Discussions on nanomaterials started in 2008 with:

(a) A proposal for inclusion of the issue in the programme of work for the biennium 2009-2010 (see INF.22 submitted at the 12th session of the Sub-Committee)[12];

[10] http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono%282012%2913&doclanguage=en)

[11] http://search.oecd.org/officialdocuments/displaydocumentpdf/?cote=env/jm/mono%282012%298&doclanguage=en

[12] http://www.unece.org/fileadmin/DAM/trans/doc/2008/ac10c4/UN-SCEGHS-16-inf22e.pdf

(b) An overview of worldwide activities (see document ST/SG/AC.10/C.4/2009/3)[13];

(c) Information provided by the expert from Australia about the relevant physicochemical properties to be addressed in the Safety Data Sheet (SDS) and the correspondent annex 4 in the GHS (see document ST/SG/AC.10/C.4/2010/19)[14];

(d) Information provided by the European Commission about the appropriate information in the SDS that should be included in annex 2 of the REACH Regulation and the related clarifications to be included on a guidance document (see INF.25 submitted at the 20th session of the Sub-Committee)[15].

24. However, no work has been undertaken yet to explain explicitly in the GHS how to produce appropriate information on nanomaterials for classification and labelling purposes (including hazard communication *via* the SDS).

Proposal

25. Because much work has been done worldwide, but it still missing an explicit and harmonized approach which should define the appropriate information in the SDS, the expert from France proposes to include the following new item in the program for the biennium 2013-2014:

"improve technical guidance on the classification and hazard communication of nanomaterials in the GHS"

26. If the Sub-Committee agrees to this proposal, the expert from France, with the possible contribution of an informal working group, would be able to prepare a formal document for the next session that will consider the main issues relating to nanomaterials in the GHS and the possible ways for further work on hazard communication of nanomaterials.

[13] http://www.unece.org/fileadmin/DAM/trans/doc/2009/ac10c4/ST-SG-AC10-C4-2009-03e.pdf

[14] http://www.unece.org/fileadmin/DAM/trans/doc/2010/ac10c4/ST-SG-AC10-C4-2010-19e.pdf

[15] http://www.unece.org/fileadmin/DAM/trans/doc/2010/ac10c4/UN-SCEGHS-20-INF25e.pdf