Annex II: Final version of Classification, labelling and packaging of nanomaterials in REACH and CLP

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Classification, labelling and packaging of nanomaterials in REACH and CLP

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This document reflects the current state of ongoing discussions within the REACH-CLP Competent Authorities and its subgroup on nanomaterials on how CLP and REACH applies to nanomaterials. Further updates of this document can be expected following continued discussions. Stakeholders are invited to take note of the content of this document and follow its further development.

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CLASSIFICATION, LABELLING AND PACKAGING OF NANOMATERIALS

1. INTRODUCTION

The aim of this paper is to describe some relevant aspects known at this stage related to the classification, labelling and packaging of nanomaterials in accordance with REACH and CLP[1] and how registrants should proceed with this issue in order to ensure a coherent approach. The terminology applied in this paper is in line with that of CA/59/2008[2]. The approach proposed below is in line with the guidance on Classification, Packaging and Labelling in the context of REACH and CLP which were finalised in summer 2009.

2. CLASSIFICATION AND LABELLING OF NANOMATERIALS

2.1. Regulatory process

The legislation on classification and labelling (67/548/EEC and 1999/45/EC),)[3] as well as the new Classification, Labelling and Packaging (CLP) Regulation[4] (1272/2008/EC) which came into force January 20, 2009, implementing the Globally Harmonised Systems (GHS), also provides the general framework for the classification and labelling of nanomaterials. According to the transitional arrangements, substances must be classified based on 67/548/EEC until 30 Nov 2010 and the information about the old classification has to be provided in the SDS until 1 June 2015. Mixtures[5] must be classified based on the old legislation until 31 May 2015. If preferred, companies can apply CLP earlier on a voluntary basis.

The purpose of the CLP regulation is to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and certain articles. Manufacturers, importers and downstream users are obliged to classify substances and mixtures (preparations) which are placed on the market. Suppliers are obliged to label and package substances and mixtures which are placed on the market. Substances that are placed on the market and either, meet the criteria for classification as

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1 CLP Regulation has now replaced the Title XI in REACH and other issues related to classification and labelling are further modified in CLP.

2 http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/nanomaterials_en.pdf; http://ec.europa.eu/environment/chemicals/reach/pdf/nanomaterials.pdf

3 In force.

4 Regulation of the European Parliament and of the Council 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, entered in force in January 2009. After a transitional period, the new regulation will replace the current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and mixtures (Directive 1999/45/EC). The rules on harmonised classification and notification to the inventory will apply from entry into force. The deadline for substance classification according to the new rules will be 1 December 2010 and for mixtures 1 June 2015.

5 The term 'mixture' in this document refers to 'preparation' under REACH.

hazardous or, are subject to registration in accordance with REACH, have to be notified to the European Chemicals Agency (ECHA), in general by 3 January 2011.

ECHA will establish a CLP Inventory, containing the information provided in accordance with Article 40(1) of CLP. This information, as far as it corresponds to the information specified in Article 119 (1) of REACH, will be made publicly available. The list of harmonised classifications of substances at Community level (CLP, Part 3 of Annex VI) will continue to be updated. The procedure for such harmonisation includes a dossier made by Member State CAs (revisions and new proposals) or manufacturers, importers or downstream users (new proposals) an opinion of the Risk Assessment Committee of ECHA and a decision of the Commission that shall be adopted by comitology procedure (regulatory procedure with scrutiny).

Information on classification and labelling must be included in the respective Safety Data Sheets (SDSs) of the substance and mixture when communicating throughout the supply chain and in the registration dossier, if appropriate.

2.2. Classification and labelling of nanomaterials

"*When evaluating the available information for the purpose of classification, the manufacturers, importers and downstream users shall consider the forms or physical states in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used*" (CLP Art. 9(5)). The hazard classification should be based on *available data* on the intrinsic properties that relate to the forms or physical state in which the substance or mixture is placed on the market and in which it can reasonably be expected to be used[6] (CLP Art.5(1), 6(1) and 8(6)). The group of companies[7] or individual companies are expected to make use of relevant available information created e.g. under REACH and conduct additional testing where required for physico-chemical properties (CLP Art.8(1-2)).

According to the guidance on classification[8], putative forms may comprise properties such as crystal structure, particle size, homogeneity (e.g., emulsion) and texture (e.g., viscosity, tablet form). Examples of physical state factors are agglomeration state, surface treatment, moisture content, residual solvent, activation or stabilisation. Any tested sample should be representative for the substance or mixture as it is placed on the market. Therefore if the form or physical state of a substance is changed, it has to be evaluated whether that affects the classification.

For example, a substance with different particle sizes or forms can have different classifications, as is the case for e.g. nickel and nickel powder (particle diameter < 1 mm). If substances are produced/imported both at nanoscale and as bulk, a separate classification and labelling may be required if the available data on the intrinsic

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6 In this context, reasonably expected use summarises all physical forms and states of a substance or mixture that may occur during intended or unintended use conditions.

7 For instance the respective Substance Information Exchange Forum (SIEF) of the substance.

8 http://guidance.echa.europa.eu/docs/guidance_document/clp_en.htm?time=1256044522

properties indicates a difference in hazard class between the nano form and ones the bulk form[9].

Due to the knowledge gaps on the properties of the rapidly emerging nanomaterials, it is not yet possible to identify any systematic rules for the toxicological characteristics of all nanomaterials (SCENIHR 2006 and 2007). The SCENIHR opinion (2009) recognised, with reference to the discussions in the OECD and ISO that a consensus is emerging on the physical-chemical properties of nanoparticles that need to be addressed in the risk assessment process of nanomaterials. The main physical parameters of interest with respect to nanoparticle characterisation are: the size, shape, specific surface area, aspect ratio, agglomeration/aggregation state, and size distribution, and surface morphology/topography, structure including crystallinity and defect structure and solubility. The main chemical parameters are: structural formula/molecular formula, composition of nanomaterials (including degree of purity, known impurities or additives), phase identity, surface chemistry, composition, charge tension, reactive sites, physical structure, photocatalytic properties, zeta potential and hydrophilicity/lipophilicity (SCENIHR, 2009).

Moreover, the SCENIHR stated that not all nanoparticle formulations have been found to induce a more pronounced hazard than the bulk formulations of the same substance. This suggests that the hazard characterisation of nanoparticle formulations should be carried out on a case-by-case basis. The potential influence of several physico-chemical parameters for the hazard profile of nanomaterials needs to be considered in the hazard assessment.

Another important question, which is scrutinised by the OECD Working Party on Manufactured Nanomaterials (WPMN), is the adequacy of current test guidelines to deliver results for hazard classification of nanomaterials. Important issues in relation to the adequacy of the test guidelines remain unanswered. So far it has been concluded in the preliminary ~~initial~~ review that "*Many of the OECD Test Guidelines are applicable, with conditions in some cases, while some are inadequate for testing MN as measuring, dosing, delivery and tracking nanomaterials are not reliably accomplished at this stage. Therefore, the review of OECD Test Guidelines reinforced the need for a guidance document(s) for sample preparation and dosimetry.*[10] A special guidance addressing the latter issue has been prepared with priority and is currently about to be presented for declassification.

France has raised several issues with UN GHS on the classification of nanomaterials (ST/SG/AC.10/C.4/2009/3). In case further work will be needed, such initiative should preferably be taken under the umbrella of the UN SCE GHS (UN Subcommittee of Experts on GHS) to enable a harmonised approach at the global level.

Due to above-mentioned reasons, the classification and labelling of nanomaterials has to be done on a case-by-case basis.

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9 REACH Article 10(a)

10 http://www.olis.oecd.org/olis/2009doc.nsf/LinkTo/NT000049AE/$FILE/JT03267900.PDF

3. CLASSIFICATION AND LABELLING OF NANOMATERIALS BY REGISTRANTS

The task of registrants is to facilitate data sharing for registration and agree on the classification and labelling of the substances concerned. The classification and labelling of nanomaterials should follow the rules set out in CLP, but the experience with nanomaterials is still very limited and the approach described below represent only some general elements. Taking into account the current knowledge on the properties of nanomaterials, a proper substance identification[11] is essential and it is advisable that registrants would consider the following approaches in the classification and labelling of nanomaterials:

1) The data sharing, should cover all relevant information including (but not limited to) sizes, forms and morphologies of the nanomaterial;

2) It is vital to evaluate whether changes in e.g. size, form or physical state influence considerably on the hazardous properties of the nanomaterial;

3) All available information of nanomaterials should be evaluated in the hazard assessment of the nanomaterial (REACH, Article 1(3));

4) Special attention needs to be devoted to the appropriateness of the sample preparation and dosimetry used in the testing of nanomaterials,

5) The classification of nanomaterials should be done on a case-by-case basis giving due consideration to relevant available data on e.g. the bulk form and read-across to other nanomaterials.

6) On the basis of the classification in accordance with CLP, the nanomaterial should also be labelled and packaged in accordance to CLP.

[11] As indicated in REACH Annex VI, item 2.