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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	D056122/02
Subject:	COMMISSION REGULATION (EU) …/… of XXX amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances

Delegations will find attached document D056122/02.

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EUROPEAN
COMMISSION

Brussels, XXX
D056122/02
[…](2018) XXX draft

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances

(Text with EEA relevance)

COMMISSION REGULATION (EU) …/…

of XXX

amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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[1], and in particular Article 131 thereof,

Whereas:

(1) Regulation (EC) No 1907/2006 lays down specific registration duties and obligations on manufacturers, importers and downstream users to generate data on substances they manufacture, import or use to assess the risks related to these substances and to develop and recommend appropriate risk management measures.

(2) The Commission Communication on the Second Regulatory Review on Nanomaterials[2] concluded that Regulation (EC) No 1907/2006 sets the best possible framework for the risk management of nanomaterials when they occur as forms of substances or mixtures but more specific requirements within the framework are necessary.

(3) The Commission performed an impact assessment[3] and further concluded that it is necessary to clarify the registration duties and obligations for nanomaterials. The term nanoform should be defined for the purposes of Regulation (EC) No 1907/2006 on the basis of Commission Recommendation of 18 October 2011 on the definition of nanomaterial.

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1 OJ L 396, 30.12.2006, p. 1.

2 COM(2012) 572 final.

3 Impact assessment on Possible amendments of Annexes to REACH for registration of nanomaterials [SWD REFERENCE TO BE ADDED LATER]

(4) Nanoforms may have specific toxicological profiles and exposure patterns and may therefore require specific risk assessment and adequate sets of risk management measures.

(5) Without the minimum standard information in the technical dossier and the chemical safety report specifically addressing nanoforms, it is not possible to ascertain whether the potential risks have been adequately assessed. Clarifications to requirements for the registration of substances with nanoforms and related downstream user obligations should be included in the Annexes I, III and VI to XII to Regulation (EC) No 1907/2006. This should ensure a clear and effective implementation with proportionate costs, guaranteeing a high level of protection of human health and the environment without adversely affecting innovation and competitiveness. The adopted changes for nanoforms should be without prejudice to the performance and documentation of risk assessment of other forms of the registered substance, unless it has implicitly included nanoforms in the assessment.

(6) Manufacturers and importers should assess and where relevant, generate the necessary information and document in the chemical safety report that the risks, arising from the identified uses of the substance with nanoforms they manufacture or import, are adequately controlled. To ensure clarity, the chemical safety report should describe whether and which different nanoforms are covered by the assessment and how the information is compiled in the report. A use may modify the nanoforms of the substance, potentially changing one nanoform into another form or generating a new nanoform. Downstream users should provide this information up the supply chain to ensure that the use is adequately covered by the registration dossier of the manufacturer or importer, or alternatively cover the specific use in their own chemical safety report.

(7) As the majority of nanomaterials are expected to be nanoforms of phase-in substances, the conditions for the requirements for generation of new toxicological and ecotoxicological information on phase-in low volume substances should be elaborated to ensure that the assessment criteria are based also on the predicted properties of nanoforms. The existing qualitative or quantitative structure-activity relationship (QSAR) and other tools do not yet enable prioritisation; therefore, the insolubility information should be applied as a surrogate for potential toxicological and ecotoxicological aspects for the nanoforms of a substance.

(8) For nanoforms, specific minimum characterisation information should be provided as part of the composition information under the substance identification. Particle size, shape and surface properties of a nanoform may influence its toxicological or ecotoxicological profile, exposure as well as behaviour in the environment.

(9) For reasons of workability and proportionality, it should be possible to group nanoforms with similar characteristics in sets of similar nanoforms. The characterisers of the different nanoforms within sets of similar nanoforms should be provided in ranges of values that clearly define the boundaries of the set of similar nanoforms. When set of similar nanoform is defined, a justification should be provided that a variation within these boundaries does not affect the hazard assessment, exposure assessment and risk assessment of the individual nanoforms within the set of similar nanoforms.

(10) All different nanoforms covered by the registration should be considered by the registrant in the demonstration of safety. Similarly, the information on manufacture, uses of and exposure to the different nanoforms should be provided separately to demonstrate their safe use. Where defined, a set of similar nanoforms may be used to document this information jointly for the nanoforms within the set.

(11) Nanoforms or sets of nanoforms, where defined, should be identified in the joint submission using the same nanoform characterisation principles and should provide the link between the nanoforms identified in the individual registrations and the relevant information in the joint submission.

(12) To allow for adequate assessment of the relevance of any physicochemical, toxicological and ecotoxicological information for the different nanoforms, the test material should be appropriately characterised. For the same reasons, test conditions documented and a scientific justification for the relevance and adequacy of the utilised test material as well as documentation for the relevance and adequacy of the information obtained from means other than testing for the different nanoforms should be provided.

(13) The rate of dissolution in water as well as in relevant biological and environmental media should always be considered for nanoforms as it represents an important complementary information to water solubility as a basic physico-chemical property of nanoforms that may determine the approach to their risk assessment and testing.

(14) The partition coefficient in octanol-water is generally used as a proxy for adsorption or accumulation but may often not be applicable to nanoforms. In those cases, the study of dispersion stability in the different relevant test media that significantly influences these endpoints as well as any estimations of exposure to nanoforms, should be considered instead.

(15) Certain physico-chemical properties such as water solubility or partition coefficient in octanol-water serve as input to well established QSARs and other predictive models that can be used for adaptations of some of the information requirements. As the underlying assumptions may not always apply to nanomaterials, such adaptations should be used for nanoforms only with scientific justification. In specific cases, the dissolution rate in the relevant test media may be used instead.

(16) To allow efficient assessment of the potential exposure for inhalable nanoforms, in particular in workplaces, information on dustiness should be provided for the different nanoforms.

(17) The specific properties of the nanoform may sometimes prevent their uptake through the cell wall of bacteria, rendering the **i**n vitro gene mutation study in bacteria (the AMES test B.13-14, OECD TG 471) inappropriate. To ensure that the tiered strategy for mutagenicity can still be implemented also in such cases, one or more other in vitro mutagenicity study(ies) in mammalian cells or other internationally recognised in vitro methods should be provided in such cases also for low-volume substances.

(18) Although acute toxicity testing for the lowest tonnage is required via the oral route, for nanoforms, inhalation is considered as more appropriate route of exposure and should be required instead, unless the exposure to humans is unlikely.

(19) For the generation of information on short term repeated dose and sub-chronic toxicity via inhalation route, testing of a nanoform should always include histopathological determination of brain, lung tissues as well as examination of bronchoalveolar lavage (BAL) fluid, kinetics and an appropriate recovery period, in line with the OECD technical guidance. .

(20) Unless the nanoform dissolves fast once entering the organism, the distribution of a nanoform in the body may affect the toxicological profile when compared to other forms of the same substance. Therefore, an assessment of the toxicokinetic behaviour should be available for the chemicals safety assessment of a nanoform, when such assessment is required. This should allow the development of effective testing strategy or its adaptation for the substance with nanoforms with the aim of minimizing animal testing. Where relevant, a study complementing the compilation of existing toxicokinetic information should be proposed by the registrant or may be requested by the European Chemicals Agency (the Agency) in accordance with Article 40 or 41 of the Regulation (EC) No 1907/2006.

(21) A number of specific physico-chemical properties in addition to those used to identify the different nanoforms may be considered relevant for scientific understanding of the hazard and exposure of a nanomaterial, with the necessary parameters depending on the individual case. For reasons of workability and proportionality, only registrants for substances (including any nanoforms) that are placed on the market in higher volumes than 10 tonnes/year should be required to explicitly consider such further information in case other particle properties significantly influence hazard or exposure to those nanoforms.

(22) The adaptation of the standard testing requirements in Annexes VII to X to Regulation (EC) No 1907/2006 applying general rules for adaptation under Section 1 of Annex XI should address different nanoforms separately. For grouping of different nanoforms, the molecular structural similarity alone cannot serve as justification for the application of read-across or grouping.

(23) The Agency, in cooperation with Member States and stakeholders, should further develop guidance documents for the application of the test methods and waiving possibilities for the standard information requirements provided by this Regulation for the purposes of Regulation (EC) No 1907/2006.

(24) Annexes I, III and VI to XII to Regulation (EC) No 1907/2006 should therefore be amended accordingly.

(25) Compliance with the provisions of this Regulation should not be required immediately in order to allow all registrants and downstream users adequate time to adapt to the more specific requirements for substances with nanoforms. However, it should be possible for registrants to comply with those provisions already before the date of application.

(26) The measures provided for in this Regulation are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I, III and VI to XII to Regulation (EC) No 1907/2006 are amended in accordance with the Annex to this Regulation.

Article 2

By way of derogation from the second paragraph of Article 3, manufacturers and importers registering substances with nanoforms either as non-phase-in or phase-in substances pursuant to Article 5 of Regulation (EC) No 1907/2006 as well as downstream users generating chemical safety reports may comply with this Regulation before 1 January 2020.

Article 3

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 January 2020.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
[…]