



13 October 2017

(17-5517)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2. Agency responsible: European Commission Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above: European Commission EU-TBT Enquiry Point Fax: +(32) 2 299 80 43 E-mail: grow-eu-tbt@ec.europa.eu Website: http://ec.europa.eu/growth/tools-databases/tbt/en/
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Chemical substances in nanoform/nanomaterials
5. Title, number of pages and language(s) of the notified document: Draft Commission Regulation 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 (and its accompanying annex) (6 + 26 pages, in English)
6. Description of content: Nanoforms are chemical substances that fulfil the Commission Recommendation 2011/696/EU on the definition of nanomaterial. The purpose of this draft Regulation is to clarify registration duties and obligations for nanoforms of substances under REACH by amending its technical Annexes: Annex I, with general provisions for assessing substances and preparing chemical safety reports; Annex III and Annexes VI to XI, with the standard information requirements for substances to be registered in different quantities placed on the market in the EU, requirements on substance identification and general rules for adaptation of standard testing regime; and Annex XII, containing provisions for downstream users to assess substances and prepare chemical safety reports.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health and the environment, ensuring the proper functioning of the EU internal market. The REACH Regulation 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. Nanoforms of substances may have specific toxicological profiles and exposure patterns, and may require specific risk assessment and adequate sets of risk management

	measures. Clarifications to requirements for the registration of nanoforms of substances and related downstream user obligations should be included in the Annexes I, III and VI-XII to the REACH Regulation to ensure that the risk assessments conducted are appropriate.
8.	Relevant documents: 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 (OJ L 353, 31.12.2008, p. 1.) http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02006R1907-20170102 Commission Recommendation 2011/696/EU of 18 October 2011 on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38–40) http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1486928403347&uri=CELEX:32011H0696
9.	Proposed date of adoption: End of March 2018 Proposed date of entry into force: 20 days from publication in the Official Journal of the EU (about a month after adoption). Mandatory application: 1 January 2020.
10.	Final date for comments: 60 days from notification
11.	Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body: European Commission, EU-TBT Enquiry Point, Fax: + (32) 2 299 80 43 E-mail: grow-eu-tbt@ec.europa.eu The text is available on the EU-TBT Website: http://ec.europa.eu/growth/tools-databases/tbt/en/ https://members.wto.org/crnattachments/2017/TBT/EEC/17_4642_00_e.pdf https://members.wto.org/crnattachments/2017/TBT/EEC/17_4642_01_e.pdf