



6 October 2016

(16-5339)

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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

<b>1. Notifying Member:</b> <u>EUROPEAN UNION</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> European Commission <b>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:</b>  European Commission EU-TBT Enquiry Point Fax: +(32) 2 299 80 43 E-mail: <a href="mailto:grow-eu-tbt@ec.europa.eu">grow-eu-tbt@ec.europa.eu</a> Website: <a href="http://ec.europa.eu/growth/tools-databases/tbt/">http://ec.europa.eu/growth/tools-databases/tbt/</a>
<b>3. Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [X], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances as a substance on its own and as a constituent of other substances, in mixtures, or in articles or any part thereof, in a concentration equal to or greater than 25ppb of PFOA or 1000 ppb of one or a combination of related substances.
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft Commission Regulation amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards perfluorooctanoic acid (PFOA), its salts and PFOA-related substances (4 pages + Annex 4 pages, in English).
<b>6. Description of content:</b> This draft Regulation relates to a new entry in Annex XVII to Regulation (EC) No 1907/2006.  It would restrict the manufacturing, the use and placing on the market of perfluorooctanoic acid (PFOA), its salts and PFOA-related substances as a substance on its own and as a constituent of other substances, in mixtures, or in articles or any part thereof, in a concentration equal to or greater than 25ppb of PFOA or 1000 ppb of one or a combination of related substances.  Exemptions are proposed for several applications as included in the Annex, paragraphs 4 to 7.  Application of the restriction is deferred for 36 months to allow industry sufficient time to adapt and achieve compliance. Specific deferred dates are provided for the exemptions listed in the Annex.

<b>7.</b>	<p><b>Objective and rationale, including the nature of urgent problems where applicable:</b> to address the risks to human health and the environment from the manufacture, placing on the market and use of PFOA, its salts and PFOA-related substances which may degrade to PFOA. The restriction proposal is based on the PBT (persistent, bioaccumulative and toxic substance) properties of PFOA. No relevant quantitative environmental risk assessment can as such be conducted for PBT substances (REACH Guidance R.11.1 page 10, version 2.0, 2014), so the overall intention is to minimise emissions. Any environmental exposure has the potential to give rise to risks (including indirect risks to the general public because of potential long-term effects on the food chain).</p> <p>Human biomonitoring data can to some extent be used as a proxy for emissions, as indirect exposure via food and drinking water is an important source of PFOA for humans (beside direct exposure via specific articles or uses).</p>
<b>8.</b>	<p><b>Relevant documents:</b></p> <ul style="list-style-type: none"> <li>• Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH Regulation): <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1423064258789&amp;uri=CELEX:32006R1907">http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1423064258789&amp;uri=CELEX:32006R1907</a></li> <li>• The opinions of the Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC): <a href="https://echa.europa.eu/documents/10162/2f0dfce0-3dcf-4398-8d6b-2e59c86446be">https://echa.europa.eu/documents/10162/2f0dfce0-3dcf-4398-8d6b-2e59c86446be</a></li> <li>• Further background information is available at: <a href="https://echa.europa.eu/documents/10162/61e81035-e0c5-44f5-94c5-2f53554255a8">https://echa.europa.eu/documents/10162/61e81035-e0c5-44f5-94c5-2f53554255a8</a></li> <li>• REACH Guidance: <a href="https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf">https://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf</a></li> </ul>
<b>9.</b>	<p><b>Proposed date of adoption:</b> First half of 2017</p> <p><b>Proposed date of entry into force:</b> 20 days from publication in the Official Journal of the EU</p>
<b>10.</b>	<p><b>Final date for comments:</b> 60 days from notification</p>
<b>11.</b>	<p><b>Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:</b></p> <p>European Commission EU-TBT Enquiry Point Fax: + (32) 2 299 80 43 E-mail: <a href="mailto:grow-eu-tbt@ec.europa.eu">grow-eu-tbt@ec.europa.eu</a></p> <p>The text is available on the Website: <a href="http://ec.europa.eu/growth/tools-databases/tbt/">http://ec.europa.eu/growth/tools-databases/tbt/</a> <a href="https://members.wto.org/cnattachments/2016/TBT/EEC/16_4205_01_e.pdf">https://members.wto.org/cnattachments/2016/TBT/EEC/16_4205_01_e.pdf</a> <a href="https://members.wto.org/cnattachments/2016/TBT/EEC/16_4205_00_e.pdf">https://members.wto.org/cnattachments/2016/TBT/EEC/16_4205_00_e.pdf</a></p>