NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** European Union  **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](mailto: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; Products of the chemical industry (ICS 71.100) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Commission Regulation amending Annex XIV to Regulation (EU) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (5 page(s), in English; 4 page(s), in English) |
| **6.** | **Description of content:** This draft Commission Regulation aims at amending Annex XIV of the REACH Regulation. Annex XIV lists the substances which are subject to the authorisation requirement laid down in Title VII of the Regulation. The draft proposes to include additional properties to some existing entries in that Annex, namely:  − entry 4 (DEHP): to add endocrine disrupting (ED) properties for the environment;  − entries 4 to 7 (DEHP, BBP, DBP and DIBP): to add ED properties for human health.  Once the Regulation is adopted and enters into force, the placing on the market and the use of those substances in the EU will only be possible, after the date specified for each substance ("sunset date"), for those operators who have been granted an authorisation in accordance with Articles 60-64 of REACH, and for those who have submitted an application for authorisation before a given date ("latest application date") but a decision has not yet been adopted. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The objective of this draft Regulation is to include the endocrine disrupting properties to the existing Reprotoxic ones in Annex XIV for these substances. According to Article 55 of REACH, the aim of the authorisation provisions is *"to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable."*In accordance with Article 56 of REACH, a manufacturer, importer or downstream user shall not place on the market and/or use a substance listed in Annex XIV of REACH after a given date ("sunset date") unless that use has been authorised or an application has been submitted before the latest application date (and a decision has not yet been taken), or the use is exempted. With the inclusion of intrinsic properties relating to hazards for the environment in the entry for DEHP in Annex XIV, the exemptions from the authorisation requirement of uses of that substance in medical devices regulated by Directives 90/385/EEC, 93/42/EEC and 98/79/EC and in food contact materials within the scope of Regulation (EC) No 1935/2004 will no longer apply. In addition, due to the inclusion of ED properties in the entries of DEHP, BBP, DBP and DIBP, the concentration limit applicable to the presence of these substances in mixtures for the purposes of the exemption set out in Article 56(6) will become 0,1% weight by weight. Finally, the exemptions from the authorisation requirement for the use of the four substances in immediate packaging will no longer apply.  Protection of human health or safety; Other |
| **8.** | **Relevant documents:**   * Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 396, 30.12.2006, p. 1)   <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32006R1907&qid=1606121951237>   * Regulation as last amended by Commission Regulation (EU) 2020/1149 of 3 August 2020 amending Annex XVII to Regulation (EC) No 1907/2006 as regards diisocyanates (OJ L 252, 4.8.2020, p.24)   <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32020R1149&qid=1606122051349>   * Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).   <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31990L0385&qid=1606122296839>   * Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).   <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31993L0042&qid=1606122367928>   * Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).   <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31998L0079&qid=1606122402458>   * Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, (OJ L 338, 13.11.2004, p. 4).   <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32004R1935&qid=1606122440374> |
| **9.** | **Proposed date of adoption:** February 2021  **Proposed date of entry into force:** 20 days after publication in the Official Journal of the European Union |
| **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](mailto: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/2020/TBT/EEC/20_7250_00_e.pdf>  <https://members.wto.org/crnattachments/2020/TBT/EEC/20_7250_01_e.pdf> |