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 [****], 3.2 [****], 7.2 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Electrical and electronic equipment (ICS – 31.020) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Commission Delegated Directive amending Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabilizer in polyvinyl chloride used as base material in sensors used in in-vitro diagnostic medical devices; (7 page(s), in English), (Annex - 2 page(s), in English) |
| **6.** | **Description of content:** This draft Commission Delegated Directive concerns applications for a specific and temporary exemption from the RoHS 2 (Directive 2011/65/EU) substance restrictions. The criteria for a new exemption are met and it is proposed to grant a time-limited exemption in Annex IV of that Directive. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Adaptation of the Annexes to scientific and technical progress in order to allow innovation without compromising the objectives in Article 1 of the Directive 2011/65/EU; Protection of human health or safety; Protection of the environment |
| **8.** | **Relevant documents:**  A scientific background study evaluating the specific exemption is available at <https://op.europa.eu/en/publication-detail/-/publication/49205318-3249-11ed-975d-01aa75ed71a1/language-en> .  **Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment:**  <http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1438768100804&uri=CELEX:32011L0065> |
| **9.** | **Proposed date of adoption:** March 2023  **Proposed date of entry into force:** 20 days from publication in the Official Journal of the EU (about three months after adoption approximately) |
| **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/2023/TBT/EEC/23_0440_01_e.pdf>  <https://members.wto.org/crnattachments/2023/TBT/EEC/23_0440_00_e.pdf> |