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):** Electrical and electronic equipment |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Commission Delegated Directive amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for lead as a thermal stabiliser in polyvinyl chloride used in certain in-vitro diagnostic medical devices for the analysis of blood and other body fluids and body gases (7 pages + Annex 2 pages, in English) |
| **6.** | **Description of content:** This draft Commission Delegated Directive concerns an application specific and temporary exemption from the RoHS 2 (Directive 2011/65/EU) substance restrictions. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Adaptation of existing legislation to scientific and technical progress, granting manufacturers adequate transition time for compliance |
| **8.** | **Relevant documents:**   * Scientific background studies justifying the specific exemption are available ([<https://publications.europa.eu/en/publication-detail/-/publication/33a336f0-e0ef-11e8-b690-01aa75ed71a1/language-en/format-PDF/source-84895526>](https://publications.europa.eu/en/publication-detail/-/publication/33a336f0-e0ef-11e8-b690-01aa75ed71a1/language-en/format-PDF/source-84895526)). * 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>](http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1438768100804&uri=CELEX:32011L0065) |
| **9.** | **Proposed date of adoption:** November 2019  **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/2019/TBT/EEC/19_4880_00_e.pdf> <https://members.wto.org/crnattachments/2019/TBT/EEC/19_4880_01_e.pdf> |