NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

|  |  |
| --- | --- |
| **1.** | **Notifying Member:** United Kingdom **If applicable, name of local government involved (Article 3.2 and 7.2):** N/A |
| **2.** | **Agency responsible:** UK TBT Enquiry PointTrade Policy GroupDepartment for International TradeOld Admiralty BuildingLondonSW1A 2DYTBTEnquiriesUK@trade.gov.uk**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:**  |
| **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 (EEE). More detail on product coverage can be found in Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (SI 2012/3032) and corresponding EU legislation. HS code 9018 for medical devices, and HS code 36 for civil explosives.; EXPLOSIVES; PYROTECHNIC PRODUCTS; MATCHES; PYROPHORIC ALLOYS; CERTAIN COMBUSTIBLE PREPARATIONS (HS 36); Instruments and appliances used in medical, surgical, dental or veterinary sciences, incl. scintigraphic apparatus, other electro-medical apparatus and sight-testing instruments, n.e.s (HS 9018) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Draft Statutory Instrument: The Restriction of The Use of Certain Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations 2021 (2 page(s), in English) |
| **6.** | **Description of content:** These measures will amend the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 ("the RoHS Regulations") as they apply in England and Wales and Scotland. Regulation 2(2) will amend the list of restricted substances in Schedule A1 to extend the restriction on the use of four restricted substances (Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Disobutyl phthalate (DIBP)) to medical devices and monitoring and control instruments.Regulation 2(3) will renew the exemption for mercury to be used in electric rotating connectors used in ultrasound imaging systems in entry No. 93 of Table 1 in Schedule A2 to the RoHS Regulations for a period of 5 years.  Regulation 2(3)(b) will grant a new exemption from the list of restricted substances in Schedule A1 to the RoHS Regulations by adding certain lead compounds and one hexavalent form of chromium (barium) to be used in the supply of electric and electronic initiators of explosives for civil explosives to the list in Table 1 in Schedule A2 of applications exempted from the restriction in regulation 3(1) of the RoHS Regulations. The exemption will be granted for a period ending on 20th April 2026. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Adaptation of existing legislation to scientific and technical progress; phase-out of substances of very high concern (SVHC) in electrical equipment in order to facilitate recycling and reduce possible negative impacts on human health and the environment, while granting economic operators adequate transition time for compliance. ; Protection of human health or safety; Protection of the environment |
| **8.** | **Relevant documents:** These measures were pre-notified to the WTO by the European Commission at a time when the UK was a member of the EU.  The relevant notifications are:[G/TBT/N/EU/256](https://www.epingalert.org/en?notification-type-radio=false#/browse-notifications/details/13201)[G/TBT/N/EU/725](https://www.epingalert.org/en?notification-type-radio=false#/browse-notifications/details/81241)[G/TBT/N/EU/726](https://www.epingalert.org/en?notification-type-radio=false#/browse-notifications/details/81242)Relevant UK documentationThe Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (The RoHS Regulations) <https://www.legislation.gov.uk/uksi/2012/3032/made>The Hazardous Substances and Packaging (Legislative Functions and Amendment) (EU Exit) Regulations2020 (SI 2020 No 1647) provides powers to amend, by regulation, the list of restricted substances (Schedule A1) and exemptions (Table 1 of schedule A2)<https://www.legislation.gov.uk/uksi/2020/1647/contents/made>Review of the inclusion of phthalates in the RoHS Regulations in medical devices and monitoring and control instruments.  (Annex B)Consultation on amendments to the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations. The inclusion of restrictions on phthalates in medical devices and monitoring and control instruments.[Restriction of phthalates medical devices, monitoring and control instruments - GOV.UK (www.gov.uk)](https://www.gov.uk/government/consultations/restriction-of-phthalates-medical-devices-monitoring-and-control-instruments)Relevant Documentation: Extension of the 4 phthalates to medical devices and control and instrumentation equipment: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 (recast). <https://www.legislation.gov.uk/eudr/2011/65>Direct links to substance evaluation and recommendations:Study for the review of the list of restricted substances under RoHS2 <https://op.europa.eu/en/publication-detail/-/publication/39eb0f95-27a8-4ae6-8ec3-627c7336ae65>.24th Meeting of the Committee for Risk Assessment 2013 <https://echa.europa.eu/documents/10162/21961120/rac_24_dnel_dehp_comments_en.pdf/e0506f6b-35f7-433e-99da-35464a26e2df#:~:text=Derivation%20of%20reference%20DNELs%20for%20DEHP&text=As%20the%20DNELs%20are%20based,most%20sensitive%20endpoint%20for%20DEHP..#>Adopted opinions and previous consultations on applications for exemptions <https://echa.europa.eu/applications-for-authorisation-previous-consultations?diss=true&search_criteria_ecnumber=204-211-0&search_criteria_casnumber=117-81-7&search_criteria_name=Bis%282-ethylhexyl%29+phthalate>.Analysis of alternatives non-confidential report -DEHP Use 3 <https://echa.europa.eu/home?p_p_state=maximized&p_p_mode=view&saveLastPath=false&_com_liferay_login_web_portlet_LoginPortlet_mvcRenderCommandName=%2Flogin%2Flogin&p_p_id=com_liferay_login_web_portlet_LoginPortlet&p_p_lifecycle=0&_com_liferay_login_web_portlet_LoginPortlet_redirect=%2Fdocuments%2F10162%2Fa85d2e25-5cef-41be-9089-cd83cc3d6718>.REACH Authorisation for DEHP in Medical Devices Factsheet <https://www.osservatoriobiomedicaleveneto.it/wp-content/uploads/2020/09/200921_MTE_DEHP-factsheet_FINAL-DRAFT.pdf>Study to assess three (3) exemption requests relating to Annex IV to Directive 2011/65/EU: request for amendment of existing exemption 31a; request for a new exemption for bis- (ethylhexyl) phthalate (DEHP) in ion selective electrodes for point of care an. May 2020.<https://op.europa.eu/en/publication-detail/-/publication/df0ab036-8b52-11ea-812f-01aa75ed71a1/language-en/format-PDF/source-146143357>Study to assess one (1) request for a new exemption to Annex IV of Directive 2011/65/EU for bis-(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils (Pack 20) – Draft final Report. June 2020.<https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_20/RoHS_Pack-20_final_30062020.pdf>ECHA. Recommendation of the European Chemicals Agency of 10 July 2019 to amend the Annex XIV entries to REACH of DEHP, BBP, DBP and DIBP. [Online] 10 July 2019. <https://echa.europa.eu/documents/10162/13640/axiv_amend_recommendation_phthalates_july2019_en.pdf/1889866a-bec3-fe16-6322-67c16a13b09d>ECHA. SCIP<https://echa.europa.eu/scip>Study for the Review of the list of Restricted Substances under RoHS2: <https://op.europa.eu/en/publication-detail/-/publication/39eb0f95-27a8-4ae6-8ec3-627c7336ae65>.**DelegatedDirective(EU) 2015/863:**[Delegated Directive (EU) 2015/863 "RoHS III"](https://www.qualcomm.com/media/documents/files/delegated-directive-eu-2015-863-rohs-iii.pdf#:~:text=On%204%20June%202015%2C%20Delegated%20Directive%20%28EU%29%202015%2F863,restricted%20substances%3A%20Bis%282-Ethylhexyl%29%20phthalate%20%28DEHP%29%3A%20max%200.1%20wt%25)Study for the Review of the list of Restricted Substances under RoHS2. <https://op.europa.eu/en/publication-detail/-/publication/39eb0f95-27a8-4ae6-8ec3-627c7336ae65>.**DelegatedDirective(EU) 2015/863**[Delegated Directive (EU) 2015/863 "RoHS III"](https://www.qualcomm.com/media/documents/files/delegated-directive-eu-2015-863-rohs-iii.pdf#:~:text=On%204%20June%202015%2C%20Delegated%20Directive%20%28EU%29%202015%2F863,restricted%20substances%3A%20Bis%282-Ethylhexyl%29%20phthalate%20%28DEHP%29%3A%20max%200.1%20wt%25)Relevant Documentation: Exemption for lead and hexavalent chromium compounds in electric and electronic initiators of explosives for civil (professional) useDocumentation Scientific background studies <https://op.europa.eu/en/publication-detail/-/publication/7e6bf135-f0b9-11e9-a32c-01aa75ed71a1/language-en/format-PDF/source-120742148>Commission Delegated Directive (EU) 2021/647 [EUR-Lex – 32021L0647 – EN – EUR-Lex](https://eur-lex.europa.eu/legal-content/EN/TXT/?elqTrack=true&elqTrackId=AAFE484BA94F2843F969300A0607A430&uri=CELEX:32021L0647#:~:text=Commission%20Delegated%20Directive%20%28EU%29%202021%2F647%20of%2015%20January,for%20civil%20%28professional%29%20use%20%28Text%20with%20EEA%20relevance%29) Relevant Documentation: Extension of the validity period for the exemption for for the use of mercury in electric rotating connectors used in intravascular ultrasound imaging systemsScientific background studies <https://op.europa.eu/en/publication-detail/-/publication/7e6bf135-f0b9-11e9-a32c-01aa75ed71a1/language-en/format-PDF/source-120742148>Delegated Directive EU 21/884 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021L0884#:~:text=Commission%20Delegated%20Directive%20%28EU%29%202021%2F884%20of%208%20March,intravascular%20ultrasound%20imaging%20systems%20%28Text%20with%20EEA%20relevance%29> |
| **9.** | **Proposed date of adoption:** December 2021 **Proposed date of entry into force:** 1 July 2022 |
| **10.** | **Final date for comments:** 23 November 2021 |
| **11.** | **Texts available from: National enquiry point [****X]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:** UK TBT Enquiry PointTrade Policy GroupDepartment for International TradeOld Admiralty BuildingLondonSW1A 2DYTBTEnquiriesUK@trade.gov.uk<https://members.wto.org/crnattachments/2021/TBT/GBR/21_6085_00_e.pdf><https://members.wto.org/crnattachments/2021/TBT/GBR/21_6085_01_e.pdf> |