



24 September 2021

(21-7133)

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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

1. Notifying Member: <u>UNITED KINGDOM</u> If applicable, name of local government involved (Article 3.2 and 7.2): N/A
2. Agency responsible: UK TBT Enquiry Point Trade Policy Group Department for International Trade Old Admiralty Building London SW1A 2DY TBTEnquiriesUK@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 CCN 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.

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>.

Delegated Directive (EU) 2015/863:

[Delegated Directive \(EU\) 2015/863 "RoHS III"](#)

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>.

Delegated Directive (EU) 2015/863

[Delegated Directive \(EU\) 2015/863 "RoHS III"](#)

Relevant Documentation: Exemption for lead and hexavalent chromium compounds in electric and electronic initiators of explosives for civil (professional) use

Documentation 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](#)

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 systems

Scientific 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 Point
 Trade Policy Group
 Department for International Trade
 Old Admiralty Building
 London
 SW1A 2DY

TBTEnquiriesUK@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