



16 March 2022

(22-2327)

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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

<b>1. Notifying Member:</b> <u>UNITED KINGDOM</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> Department for Environment, Food and Rural Affairs (Defra) <b>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:</b>  UK TBT Enquiry Point Trade Policy Group Department for International Trade Old Admiralty Building London SW1A 2DY <a href="mailto:TBTEnquiriesUK@trade.gov.uk">TBTEnquiriesUK@trade.gov.uk</a>
<b>3. Notified under Article 2.9.2 [ ], 2.10.1 [X], 5.6.2 [ ], 5.7.1 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> 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) ( <a href="https://www.legislation.gov.uk/ukxi/2012/3032/made">https://www.legislation.gov.uk/ukxi/2012/3032/made</a> ). HS code 9018 for medical devices. Electronic Components in general (ICS 31.020); Electronic components in general (ICS 31.020)
<b>5. Title, number of pages and language(s) of the notified document:</b> Draft statutory instrument on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations 2022 (2 page(s), in English)
<b>6. Description of content:</b> 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 will grant new specific and temporary exemptions which will be added as entries 97 to 99 of Table 1 in Schedule A2 of the RoHS Regulations. The exemptions apply to:  (1) Bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids. This exemption will expire on 21 July 2028.  (2) Bis(2-ethylhexyl) phthalate (DEHP) in plastic components in MRI detector coils. This exemption will expire on 1 January 2024.  (3) Bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP) in spare parts recovered from and used for the

<p>repair or refurbishment of medical devices, including <i>in vitro</i> diagnostic medical devices, and their accessories, provided that the reuse takes place in auditable closed-loop business-to-business return systems and that each reuse of parts is notified to the customer. This exemption will expire on 21 July 2028.</p> <p>These regulations will also make minor incidental amendments to Schedule A2 of the RoHS Regulations to clarify the descriptions of the tables containing the exemptions.</p>
<p><b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> 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. A shorter entry into force period for the Amendment is necessary to avoid potential negative impacts on the supply of medical devices/spare parts. A longer delay may have a consequential impact on human health because of potential delays in diagnoses and treatment.; Protection of human health or safety; Protection of the environment</p>
<p><b>8. Relevant documents:</b></p> <p><u>Relevant UK documentation</u>  The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (The RoHS Regulations)  <a href="https://www.legislation.gov.uk/uksi/2012/3032/made">https://www.legislation.gov.uk/uksi/2012/3032/made</a></p> <p>The Hazardous Substances and Packaging (Legislative Functions and Amendment) (EU Exit) Regulations 2020 (SI 2020 No 1647) provides powers to amend, by regulation, the list of exemptions (Table 1 of Schedule A2)  <a href="https://www.legislation.gov.uk/uksi/2020/1647/contents/made">https://www.legislation.gov.uk/uksi/2020/1647/contents/made</a></p> <p>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)</p> <p>The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (Amendment) No 2 Regulations 2021, which introduces restriction on the use of phthalates in medical devices and monitoring and control instruments from 1 July 2022. See notification G/TBT/N/GBR/43.  <a href="https://www.legislation.gov.uk/uksi/2021/1395/made">https://www.legislation.gov.uk/uksi/2021/1395/made</a></p> <p>Technical and scientific analysis reports of the exemptions (see attachments).</p>
<p><b>9. Proposed date of adoption:</b> June 2022</p> <p><b>Proposed date of entry into force:</b> The relevant provisions in the draft instrument will come into force on 1 July 2022</p>
<p><b>10. Final date for comments:</b> 60 days from notification</p>

**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](mailto:TBTEnquiriesUK@trade.gov.uk)

Draft statutory instrument on the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (Amendment) Regulations 2022 (see attachment).

[https://members.wto.org/crnattachments/2022/TBT/GBR/22\\_2264\\_00\\_e.pdf](https://members.wto.org/crnattachments/2022/TBT/GBR/22_2264_00_e.pdf)

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