

EXPLANATORY MEMORANDUM TO
THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN
ELECTRICAL AND ELECTRONIC EQUIPMENT (AMENDMENT)
REGULATIONS 2021

2021 No. 1395

1. Introduction

- 1.1 This explanatory memorandum has been prepared by the Department for the Environment, Food and Rural Affairs and is laid before Parliament by Command of Her Majesty

2. Purpose of the instrument

- 2.1 This instrument amends Schedules A1 and A2 to the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (S.I. 2012/2032) ('The RoHS Regulations') as they apply in England, Wales and Scotland. The RoHS Regulations ensure that electrical and electronic equipment ("EEE") placed on the market does not contain certain hazardous substances or does not contain those substances in concentrations exceeding specified maxima. Schedule A1 lists those restricted substances and maximum concentration values. Schedule A2 lists exemptions to those restrictions.

3. Matters of special interest to the Joint Committee on Statutory Instruments

- 3.1 None.

4. Extent and Territorial Application

- 4.1 The territorial extent of this instrument is England and Wales and Scotland
4.2 The territorial application of this instrument is England and Wales and Scotland

5. European Convention on Human Rights

- 5.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

6. Legislative Context

- 6.1 This instrument is made in exercise of powers conferred on the Secretary of State, in relation to England and Wales and Scotland, by regulations 3 and 5 of the Hazardous Substances and Packaging (Legislative Functions and Amendment) (EU Exit) Regulations 2020 ("the 2020 Regulations"). -
- 6.2 Regulation 3 of the 2020 Regulations allows the Secretary of State to amend the list of restricted substances in Schedule A1 to the RoHS Regulations and regulation 5 allows the Secretary of State to grant, extend or revoke exemptions listed in Schedule A2 to the RoHS Regulations.
- 6.3 In accordance with regulation 8 of the 2020 Regulations, the Secretary of State has consulted on the amendment to Schedule A1, which adds four phthalates: (Bis (2-

ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) to the list of restricted substances.

- 6.4 The amendments to Schedule A2 trigger transitional provisions set out in regulations 9 and 10 of the 2020 Regulations.
- 6.5 Regulation 9 applies in relation to the new exemption listed in Schedule A2 for the use of lead and hexavalent chromium in the use of electronic and electric initiators in civil explosives used in mining and quarrying and which has substantially the same effect as an EU exemption granted in relation to an application made to the European Commission before IP completion day (see EU Delegated Directive 2021/647).
- 6.6 Regulation 10 applies in relation to the renewal of the exemption listed in Schedule A2 for mercury to be used in electrical rotating connectors used in ultrasound imaging systems and for which the European Commission has published a decision to renew the corresponding EU exemption (see also EU Delegated Directive 2021/884).

7. Policy background

What is being done and why?

- 7.1 The RoHS Regulations restrict the use of 10 hazardous substances in electrical and electronic equipment (EEE) with a view to contributing to the protection of human health and the environment, including the sound recovery and disposal of waste.
- 7.2 This instrument uses powers transferred from the European Commission under the RoHS Directive to the Secretary of State in relation to England and Wales and Scotland to amend the list of restricted substances and maximum concentration values in Schedule A1, and the list of exemptions in Schedule A2, to the RoHS Regulations.
- 7.3 Specifically, this instrument will amend the list of exemptions in Schedule A2 so that lead and hexavalent chromium are permitted in the manufacture of electric initiators in civil explosives which are used in mining and quarrying and mercury is permitted in the manufacture of rotating connectors used in ultrasound imaging systems. As indicated above the EU has granted similar exemptions. Failure to do so in GB could jeopardise the supply of intravascular ultrasound imaging systems since there are no scientifically or technically viable substitutes to mercury. In the case of electric and electronic initiators used in civil explosives, the exemption will ensure products continue to meet several criteria including having a high initiating strength and being safe to manufacture.
- 7.4 This instrument will also extend the restriction on the use of the four phthalates listed above to medical devices and control and instrumentation equipment that is placed on the GB market.
- 7.5 Before leaving the EU, the UK supported Delegated Directive (EU) 2015/863, to add the four phthalates: (Bis (2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) to the list of restricted substances. This was because they have long been substances of concern because of the risk of environmental releases and the health risk that they present to those in the waste management sector. For most categories of equipment these new restrictions applied from July 2019. But for medical devices and monitoring & control equipment the entry into force date was July 2021 It is therefore necessary to use the transferred powers to apply the restriction in GB.

Explanations

What did any law do before the changes to be made by this instrument?

- 7.6 Without this instrument there would be no restriction on the use of the four phthalates listed above, the use of mercury in rotating connectors in ultrasound imaging systems and the use of lead and hexavalent chromium in electronic initiators used in civil explosives would be subject to the restrictions set out in the RoHS Regs Why is it being changed?
- 7.7 This instrument will mean domestic law will restrict the amount of four phthalates in medical devices and monitoring and control instruments as well as allowing exemptions from the restrictions on mercury used in ultrasound imaging systems and lead and hexavalent chromium in electronic initiators used in civil explosives.

What will it now do?

- 7.8 This instrument specifically adds four new substances to restrictions that currently apply to medical and control & instrumentation equipment. It will also allow electric rotating connectors used in ultrasound imaging systems containing levels of mercury above the thresholds laid down in the RoHS Regulation to continue to be placed on the GB market. It will allow electric initiators used in civil explosives used in mining and quarrying containing levels lead and hexavalent chromium above the thresholds laid down in the ROHS Regulations to continue to be placed on the GB market.

8. European Union Withdrawal and Future Relationship

- 8.1 This instrument does not relate to withdrawal from the European Union / trigger the statement requirements under the European Union (Withdrawal) Act

9. Consolidation

- 9.1 Not considered necessary as it is not considered that enough amendments have been made that consolidation is required at this point in time.

10. Consultation outcome

- 10.1 Regulation 8 of The Hazardous Substances and Packaging (Legislative Functions and Amendment (EU Exit) Regulations 2020 require the Secretary of State to consult before making any Regulations under Part 2.
- 10.2 A public consultation on amendments to the RoHS Regulations relating to the obligations set out in Regulation 2(2) was published on gov.uk. Industry bodies that represent the medical devices and monitoring and control and instruments sectors were targeted. Eight responses were received and all supported the proposal to amend the list of restricted substances so that the use of four types of phthalates is restricted in medical devices and monitoring and control instruments. All respondents agreed with our analysis that the impacts on businesses would be low.

11. Guidance

- 11.1 BEIS and the Office for Product Safety and Standards are responsible for publishing guidance which will be updated accordingly: <https://www.gov.uk/guidance/rohs-compliance-and-guidance>

12. Impact

- 12.1 There is no significant, impacts on business, charities or voluntary bodies.
- 12.2 There is no, or no significant, impact on the public sector.
- 12.3 A full Impact Assessment has not been prepared for this instrument because the impact on businesses are judged to be well below the threshold for which an impact assessment is required. The only cost on businesses is the one they may incur to familiarise themselves with the Regulations. These familiarisation costs amount to £0.3m.

13. Regulating small business

- 13.1 There are not disproportionate impacts on small businesses. This is because they must already comply with the requirements placed on producers and importers set out in the ROHS Regulations and must have necessary systems in place to ensure compliance.
- 13.2 No specific action is proposed to minimise regulatory burdens on small businesses.

14. Monitoring & review

- 14.1 The compliance monitoring of this legislation is undertaken by the Office of Product Safety and Standards (OPSS).
- 14.2 A statutory review clause is included in the RoHS Regulations which states that the Secretary of State must from time to time carry out a review of these Regulations. The review must set out the objectives intended to be achieved by these Regulations and assess to what extent they are achieved. The reviews must take place every five years

15. Contact

- 15.1 Liz Moorman at Defra, email: liz.moorman@defra.gov.uk can be contacted with any queries regarding the instrument.
- 15.2 Chris Preston, Deputy Director for Resources and Waste, at Defra can confirm that this Explanatory Memorandum meets the required standard.
- 15.3 Minister Churchill at Defra can confirm that this Explanatory Memorandum meets the required standard.