EXPLANATORY MEMORANDUM TO

THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT (AMENDMENT) REGULATIONS 2022

2022 No. 622

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department for Environment, Food and Rural Affairs ("Defra") and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument amends Schedule A2 to the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (S.I. 2012/2032) ("RoHS Regulation") 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 A2 lists exemptions to those restrictions. This instrument also makes minor amendments to correct errors made in the Hazardous Substances and Packaging (Legislative Functions and Amendment) (EU Exit) Regulations 2020 (S.I. 2020/1647) ("the 2020 Regulations").

3. Matters of special interest to Parliament

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 this 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 5 and 11 of the 2020 Regulations. The power in regulation 5 derives from European Commission legislative functions in the RoHS Directive that were transferred to the Secretary of State in relation to Great Britain by the 2020 Regulations.

6.2 Regulation 5 of the 2020 Regulations allows the Secretary of State to grant, extend or revoke exemptions listed in Schedule A2 to the RoHS Regulations. Regulation 11

provides for consequential, incidental or supplementary provision to be included in regulations made under Part 2 of the 2020 Regulations.

6.3 The RoHS Regulations set out restrictions on the use of particular substances in EEE, including the use of Bis(2-ethylhexyl) phthalate (DEHP), butyl benzyl phthalate (BBP), and diisobutyl phthalate (DIBP) ("the phthalates"). From 1 July 2022, following amendments made by the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment (Amendment) (No.2) Regulations 2022 ("S.I. 2021/1395"), these restrictions will include the use of the phthalates in medical devices.

6.4 This instrument will amend Schedule A2 of the RoHS Regulations to introduce exemptions from the restrictions for the following uses of the phthalates in relation to certain medical devices and spare parts: DEHP in ion selective electrodes applied in point of care analysis of ionic substances present in human body fluids and/or in dialysate fluids; DEHP in plastic components in magnetic resonance imaging detector coils; and DEHP, BBP and DIBP in spare parts recovered from and used for the repair of 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.

6.5 These exemptions have substantially the same effect as EU exemptions granted in relation to applications made to the European Commission before IP completion day (see Commission Delegated Directives (EU) 2021/1978, 2021/1979 and 2021/1980). The amendments to Schedule A2 therefore trigger the transitional provisions set out in regulation 9 of the 2020 Regulations, which provides that the Secretary of State can treat certain requirements of the 2020 Regulations as satisfied without having to consider or determine them.

6.6 This instrument also makes minor, correcting amendments to paragraphs 1 and 2 of Schedule A2 to ensure that the descriptions of Tables 1 and 2 match the contents of those tables. Accordingly, the free issue procedure applies.

7. Policy background

What is being done and why?

7.1 The RoHS Regulations implemented the requirements of EU Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment ("the RoHS Directive"). They restrict the use of 10 hazardous substances in EEE with a view to contributing to the protection of human health and the environment, including the sound recovery and disposal of waste. They provide that EEE placed on the market must not contain those ten substances (which are listed in Schedule A1 to the RoHS Regulations) in quantities greater than the specified maximum concentration values.

7.2 Before leaving the EU, the UK supported Delegated Directive (EU) 2015/863, which added the phthalates to the list of restricted substances in Schedule A1 to the RoHS Directive. This delegated directive came into effect in relation to medical devices after the end of the implementation period. As a result, S.I. 2021/1395 was made using powers in the 2020 Regulations to implement these restrictions in Great Britain from 1 July 2022.

7.3 In August 2021, the European Commission adopted three exemptions (see paragraph 6.8 above) that allow specified types of medical equipment and spare parts to be

placed on the EU market where they contain levels of the phthalates that exceed the maximum concentration values specified in the RoHS Directive. These decisions on exemptions apply in Northern Ireland as a consequence of the Northern Ireland Protocol.

7.4 This instrument amends the list of exemptions in Schedule A2 to the RoHS Regulations to introduce substantially similar exemptions to those granted by the EU in relation to Great Britain.

Explanations

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

7.5 As a result of amendments to the RoHS Regulations being made by S.I. 2021/1395, from 1 July 2022 medical devices cannot be placed on the market in Great Britain unless they comply with the restrictions on the maximum concentration values of the phthalates set out in Schedule A1 to the RoHS Regulations.

Why is it being changed?

7.6 This instrument will introduce exemptions from the restrictions on the use of the phthalates in medical devices for the types of medical devices and spare parts described in paragraph 6.8 above. For these uses, there are either no viable substitutes for phthalates, or the potential substitutions would pose a greater risk to human health and the environment than the use of phthalates. Without these exemptions, the supply of essential hospital equipment could be disrupted, resulting in delay in diagnoses and treatment of patients. There could also be premature generation of waste, resulting in negative environmental impacts.

What will it now do?

7.7 This instrument will allow the types of medical devices and spare parts described in paragraph 6.8 above to continue to be placed on the market in England, Wales and Scotland where they contain levels of the phthalates that are above the maximum concentration values laid down in Schedule A1 to the RoHS Regulations.

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 No consultation is necessary ahead of the introduction of this Statutory Instrument.

11. Guidance

11.1 It is not proposed to publish guidance on this instrument.

12. Impact

12.1 There is no, or no significant, impact on charities or voluntary bodies.

12.2 There is no, or no significant, impact on the public sector

12.3 An Impact Assessment has not been prepared for this instrument because there will be no impacts on business as a result of introducing these three new exemptions because it allows the relevant products to continue to be placed on the market in England, Wales, and Scotland with no new regulatory requirements.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses.

13.2 No specific action is proposed to minimise the impact of the requirements on small businesses (employing up to 50 people), since no such impact is anticipated.

14. Monitoring & review

14.1 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 those Regulations. The review must set out the objectives intended to be achieved by those Regulations and assess to what extent they are achieved. The reviews must take place every five years.

15. Contact

15.1 Graeme Vickery at the Department for Environment, Food and Rural Affairs - Email address: Graeme.vickery@defra.gov.uk Telephone number: 020 8225 7406 - can be contacted with any queries regarding the instrument.

15.2 Chris Preston for the Resources and Waste Division, at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.

15.3 Minister Jo Churchill at the Department for Environment, Food and Rural Affairs can confirm that this Explanatory Memorandum meets the required standard.