EXPLANATORY MEMORANDUM FOR EUROPEAN UNION LEGISLATION WITHIN THE SCOPE OF THE UK/EU WITHDRAWAL AGREEMENT AND NORTHERN IRELAND PROTOCOL

C(2021)5866 + ANNEX
C(2021)5867 + ANNEX
C(2021)5868 + ANNEX

COMMISSION DELEGATED DIRECTIVE (EU) .../… OF 11.8.2021 AMENDING, FOR THE PURPOSES OF ADAPTING TO SCIENTIFIC AND TECHNICAL PROGRESS, ANNEX IV TO DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS AN EXEMPTION FOR THE USE OF 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 REPAIR OR REFURBISHMENT OF MEDICAL DEVICES

COMMISSION DELEGATED DIRECTIVE (EU) .../… OF 11.8.2021 AMENDING, FOR THE PURPOSES OF ADAPTING TO SCIENTIFIC AND TECHNICAL PROGRESS, ANNEX IV TO DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS AN EXEMPTION FOR THE USE OF BIS(2-ETHYLHEXYL) PHTHALATE (DEHP) IN PLASTIC COMPONENTS IN MAGNETIC RESONANCE IMAGING (MRI) DETECTOR COILS

COMMISSION DELEGATED DIRECTIVE (EU) .../… OF 11.8.2021 AMENDING, FOR THE PURPOSES OF ADAPTING TO SCIENTIFIC AND TECHNICAL PROGRESS, ANNEX IV TO DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS AN EXEMPTION FOR THE USE OF BIS(2-ETHYLHEXYL) PHTHALATE (DEHP) IN ION-SELECTIVE ELECTRODES FOR ANALYSING HUMAN BODY FLUIDS AND/OR DIALYSATE FLUIDS

Submitted by the Department for Environment, Food and Rural Affairs

07 September 2021

SUBJECT MATTER

1. The Restriction of Hazardous Substances (RoHS) Directive (2011/65/EU) ("the RoHS Directive") restricts the use of certain hazardous substances in electrical and electronic equipment. The RoHS Directive sets out a process in which businesses can apply to the European Commission for exemptions to the threshold limits for the use of these substances in specific products. This is a recognition that in some limited circumstances components may need to use one or more of the restricted substances above the threshold limits in order to work properly or safely and where

it is proven technically that no alternative substance has yet been developed as a safe and effective alternative. Exemption applications are reviewed by the Commission and are published as part of a consultation process with business and Member States. If an application is successful, the RoHS Directive will be amended to add the exemption by means of a delegated directive. Exemptions are time-limited in their duration, typically to 5 years and 7 years in the case of medical devices and control and instrumentation equipment.

2. These delegated directives grant specific exemptions using the Commission's powers described above as follows:

a. C(2021)5866 + Add 1 - COMMISSION DELEGATED DIRECTIVE (EU) .../… of 11.8.2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of 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 repair or refurbishment of medical devices.

   Following an application for this exemption in 2018, the EU launched a technical and scientific study which included a consultation. The assessment concluded that manufacturing new parts not containing the substances (phthalates) rather than reusing existing spare parts, produces carbon dioxide emissions, introduces heavy metals in the market and leads to the generation of hazardous and non-hazardous waste. Overall their assessment concluded that the total negative environmental health and consumer safety impacts of substituting the four phthalates were likely to outweigh the benefits.

b. C(2021)5867 + Add 1 - COMMISSION DELEGATED DIRECTIVE (EU) .../… of 11.8.2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in plastic components in magnetic resonance imaging (MRI) detector coils.

   Following an application for this exemption the EU launched an in-depth study which included a consultation. The assessment concluded that the development of alternatives and substitutes would need more time. Given the lack of sufficient appropriate alternatives not granting an exemption would likely result in shortage of supply for health services. This would cause health impacts for many patients linked to the lack of relevant diagnosis and treatment facilities.

c. C(2021)5868 + Add 1 - COMMISSION DELEGATED DIRECTIVE (EU) .../… of 11.8.2021 amending, for the purposes of adapting to scientific and technical progress, Annex IV to Directive 2011/65/EU of the European Parliament and of the

Council as regards an exemption for the use of bis(2-ethylhexyl) phthalate (DEHP) in ion-selective electrodes for analysing human body fluids and/or dialysate fluids.

Following an application for this exemption, the EU launched a technical and scientific assessment which included a consultation. The assessment concluded that current alternatives were not performing well and may have adverse socio-economic impacts. Not granting the exemption would result in early obsolescence of around 500 tonnes of equipment. Not to grant the exemption could place high financial and organisational burdens on healthcare facilities as a result of replacing the equipment. This could delay or prevent analyses and health services may have to finance unplanned new equipment resulting in unintended and indirect health impacts. Overall, the total negative environmental and health impacts are likely to outweigh the benefits if the exemption was not granted.

PARLIAMENTARY SCRUTINY

3. The Parliamentary scrutiny history relevant to this Explanatory Memorandum is contained in the attached Annex A.

MINISTERIAL RESPONSIBILITY

4. Responsibility lies with the Secretary of State for Environment, Food and Rural Affairs. The Secretary of State for Business, Energy and Industrial Strategy also has an interest as the minister responsible for policy related to ecodesign for energy-related products. The Secretary of State for Health has an interest in these particular exemptions since they relate to the continued supply of medical equipment. The Minister for the Cabinet Office and Secretary of State for Northern Ireland have an interest due to the application of the Delegated Acts in Northern Ireland.

INTEREST OF THE DEVOLVED ADMINISTRATIONS

5. This RoHS Directive and these Delegated Acts fall into an area of reserved policy since they relate to the application of technical standards. But the Scottish and Welsh Governments and the Northern Ireland Executive have an interest in the Acts brought forward by the Commission, due to the environmental considerations. In particular, the RoHS Directive envisages that review and amendment of the list of restricted substances and the exemptions is to be coherent with other legislation related to chemicals, in particular with Annexes 14 and 15 of the REACH Regulation. Given their functions in relation to REACH Scottish and Welsh Governments have a related interest in RoHS. The Scottish and Welsh Governments are committed to maintaining or enhancing environmental standard and to seeking to keep pace with EU Directives and Regulations as far as possible. The DAs have been consulted in the preparation of this Explanatory Memorandum.

LEGAL AND PROCEDURAL ISSUES

6.

i. Legal basis

The European Commission's power to make these Delegated Acts is in Article 5(1)(a) of the RoHS Directive, following the procedure set out in Article 20 and subject to the conditions laid down in Articles 21 and 22 of that Directive. The RoHS Directive is listed in Annex 2 to the Northern Ireland Protocol. The effect of that listing is that the provisions of the RoHS Directive and any EU legislation (such as these Delegated Acts) that amends or replaced that Directive apply to the United Kingdom in respect of Northern Ireland.

ii. **Voting procedure**

The Delegated Acts shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

iii. Timetable for adoption and implementation

These Delegated Acts will enter into force on the 20th day following publication in the Official Journal. Member States must apply those provisions five months after the entry into force date.

POLICY IMPLICATIONS

7. In relation to Northern Ireland, the Delegated Acts will be transposed by means of an ambulatory reference in regulation 3(4) of the Restriction of Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 ("the RoHS Regulations). No further amending legislation is therefore required to comply with this Delegated Act and no new burdens arise for businesses based in Northern Ireland.

8. In relation to GB, the power of the European Commission to grant or renew exemptions to restrictions in the RoHS Directive were repatriated to the Secretary of State by the Hazardous Substances and Packaging (Legislative Functions and Amendment) (EU Exit) Regulations 2020 ("The 2020 Regulations"). The Secretary of State exercises those powers through regulations.

9. Regulations 9 and 10 of the 2020 Regulations make provision for transitional measures in respect of applications made to the EU before Implementation Period Completion Day for new exemptions and for the renewal of exemptions. Where the Commission did not publish its decision before the end of the Implementation Period, those provisions remove the need for businesses to make separate applications for a new exemption or the renewal of the relevant exemption in GB. Regulations 9 and 10 further provides for the Secretary of State to grant an exemption or renew an exemption, by way of regulation, following a decision by the European Commission.

10. As the applications for the exemptions set out in these delegated directives were made before the end of the Implementation Period, the transitional measures in regulation 9 therefore apply.

11. Defra is undertaking an appraisal of the Commission's decision to grant these new exemptions to inform the decision of the Secretary of State as to whether to grant similar exemptions in relation to GB or not. This will also consider whether there are any GB specific circumstances to take into account when deciding whether to grant a GB exemption. Any decision to grant these exemptions in GB be put into effect by means of an SI amending Schedule A1 of the RoHS Regulations. Schedule A1, as it stands, allows these products to be placed on the GB market as it currently allows for a wider exemption for phthalates in medical devices.

CONSULTATION

12. The European Commission has undertaken a formal consultation before reaching a determination on these particular applications for exemptions. The transitional measures set out in the 2020 Regulations do not require the Secretary of State to undertake a further consultation before reaching a decision on whether to apply these exemptions to GB.

FINANCIAL IMPLICATIONS

13. There are no new financial implications arising from this delegated act to renew an existing exemption in respect of Northern Ireland. There is a minimal cost to Defra in appraisal of the delegated acts to determine whether an extension should be applied to GB.

REBECCA POW MP
PARLIAMENTARY UNDER SECRETARY OF STATE
DEPARTMENT FOR ENVIRONMENT, FOOD AND RURAL AFFAIRS

ANNEX A

PARLIAMENTARY SCRUTINY HISTORY RELEVANT TO A:

COMMISSION DELEGATED DIRECTIVE (EU) .../… OF 11.8.2021 AMENDING, FOR THE PURPOSES OF ADAPTING TO SCIENTIFIC AND TECHNICAL PROGRESS, ANNEX IV TO DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS AN EXEMPTION FOR THE USE OF 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 REPAIR OR REFURBISHMENT OF MEDICAL DEVICES

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EM 6860/21+ADD 1:COMMISSION DELEGATED DIRECTIVE (EU) .../… OF 8.3.2021 AMENDING, FOR THE PURPOSES OF ADAPTING TO SCIENTIFIC AND TECHNICAL PROGRESS, ANNEX IV TO DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AS REGARDS THE VALIDITY PERIOD OF AN EXEMPTION FOR THE USE OF MERCURY IN ELECTRIC ROTATING CONNECTORS USED IN INTRAVASCULAR ULTRASOUND IMAGING SYSTEMS (AND ANNEX)

DATE EM SIGNED: 29/06/2021

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
SCRUTINY COMPLETED (OUTCOME AGENDA NO 5 07/07/2021)	NOT SIFTED FOR SCRUTINY (PROTOCOL ON IRELAND/NORTHERN IRELAND SUB-COMMITTEE) AT CHAIR'S SIFT 7 7/7/2021

EM 5708/17: PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING DIRECTIVE 2011/65/EU ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT (AND ADD 1-2)

DATE EM SIGNED: 15/2/2017

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
POLITICALLY IMPORTANT CLEARED (AGENDA FOR REPORT NO 3;29/11/2017) POLITICALLY IMPORTANT NOT CLEARED, FURTHER INFORMATION REQUESTED (REPORT 33,28/2/2017)	CLEARED BUT SENT FOR INFORMATION TO ENERGY AND ENVIRONMENT AT (CHAIRMAN'S SIFT 1649- 21/2/2017)

EM 8050/16: REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL ON THE EXERCISE OF THE POWER TO ADOPT DELEGATED ACTS CONFERRED ON THE COMMISSION PURSUANT TO DIRECTIVE 2011/65/EU ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT

DATE EM SIGNED: 10/5/2016

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
NOT IMPORTANT CLEARED (REPORT 3; 25/5/16)	CLEARED (ENERGY AND ENVIRONMENT) AT CHAIRMAN'S SIFT 1621- 25/5/2016

EM 5403/07: PROPOSAL FOR A DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING DIRECTIVE 2002/95/EC ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT, AS REGARDS THE IMPLEMENTING POWERS CONFERRED TO THE COMMISSION

SUBMITTED BY THE DEPARTMENT OF TRADE AND INDUSTRY ON THE 6TH FEBRUARY 2007

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
THE COMMONS EUROPEAN SCRUTINY CTTE CONSIDERED IT POLITICALLY AND LEGALLY IMPORTANT AND CLEARED IT (REPORT NO. 15, SESSION 06/07).	THE LORDS SELECT CTTE ON THE EU CLEARED IT (PROGRESS OF SCRUTINY: 16TH MARCH 2007, SESSION 06/07).

EM 9932/05: PROPOSAL FOR A COUNCIL DECISION AMENDING FOR THE PURPOSES OF ADAPTING TO THE TECHNICAL PROGRESS THE ANNEX TO DIRECTIVE 2002/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT

SUBMITTED BY THE DEPARTMENT OF TRADE AND INDUSTRY ON THE 29TH JULY 2005

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
THE COMMONS EUROPEAN SCRUTINY CTTE CLEARED IT (REPORT NO. 6, ITEM NO. 26624, SESSION 05/06)	THE LORDS SELECT CTTE ON THE EU REFERRED IT TO SUB-CTTE G AND CLEARED IT AT THE MEETING OF THE 13TH OCTOBER 2005 (PROGRESS OF SCRUTINY: 24TH OCTOBER 2005, SESSION 05/06).

EM 12610/04: PROPOSAL FOR A COUNCIL DECISION AMENDING DIRECTIVE 2002/95/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL FOR PURPOSES OF ESTABLISHING THE MAXIMUM CONCENTRATION VALUES FOR CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT

SUBMITTED BY THE DEPARTMENT OF TRADE AND INDUSTRY ON THE 21ST OCTOBER 2004

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
THE COMMONS EUROPEAN SCRUTINY COMMITTEE CLEARED IT (REPORT NO. 35, SESSION 03/04)	THE LORDS SELECT COMMITTEE ON THE EU CLEARED IT (PROGRESS OF SCRUTINY: 1ST NOVEMBER 2004, SESSION 03/04).

EM 10731/02: COMMON POSITION ON A PROPOSAL FOR A EUROPEAN PARLIAMENT AND COUNCIL DIRECTIVE ON THE RESTRICTION OF THE USE OF CERTAIN HAZARDOUS SUBSTANCES IN ELECTRICAL AND ELECTRONIC EQUIPMENT (ROHS)

SUBMITTED BY THE DEPARTMENT OF TRADE AND INDUSTRY ON THE 15TH MARCH 2002.

SCRUTINY COMMITTEES' RECOMMENDATIONS:

COMMONS	LORDS
THE COMMONS EUROPEAN SCRUTINY COMMITTEE CONSIDERED IT POLITICALLY IMPORTANT AND IT WAS DEBATED ON 17TH JULY 2002 IN THE EUROPEAN STANDING CTTE C WHERE IT WAS CLEARED (REPORT NO. 32, ITEM NO. 23309, SESSION 01/02).	THE LORDS SELECT COMMITTEE ON THE EU REFERRED IT TO SUB-COMMITTEE D AND IT WAS CLEARED AT THE MEETING OF THE 8 MAY 2002 (PROGRESS OF SCRUTINY: 20TH MAY 2002, SESSION 01/02).