

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

September 2021

We are the Department for Environment, Food and Rural Affairs. We’re responsible for improving and protecting the environment, growing the green economy, sustaining thriving rural communities and supporting our world-class food, farming and fishing industries.

We work closely with our 33 agencies and arm’s length bodies on our ambition to make our air purer, our water cleaner, our land greener and our food more sustainable. Our mission is to restore and enhance the environment for the next generation, and to leave the environment in a better state than we found it.

Open Government Licence logo

© Crown copyright 2021

This information is licensed under the Open Government Licence v3.0. To view this licence, visit [www.nationalarchives.gov.uk/doc/open-government-licence/](http://www.nationalarchives.gov.uk/doc/open-government-licence/)

This publication is available at [www.gov.uk/government/publications](http://www.gov.uk/government/publications)

Any enquiries regarding this publication should be sent to us at

[rohs@defra.gov.uk](mailto:rohs@defra.gov.uk)

[www.gov.uk/defra](http://www.gov.uk/defra)

Contents

[Introduction 4](#_Toc81386052)

[Purpose of this consultation 4](#_Toc81386053)

[Geographical extent 5](#_Toc81386054)

[Audience 5](#_Toc81386055)

[Responding to this consultation 5](#_Toc81386056)

[Duration 6](#_Toc81386057)

[After the consultation 6](#_Toc81386058)

[Compliance with consultation principles 7](#_Toc81386059)

[About You 7](#_Toc81386060)

[Background 9](#_Toc81386061)

[The Proposal 12](#_Toc81386062)

[Questions: 12](#_Toc81386063)

# Introduction

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (RoHS Regulations) restricts 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. We propose to introduce a restriction on the use of four phthalates, in the manufacture of various medical devices and monitoring and control instrumentation equipment. This would start in July 2022, and is in the interests of public health and environmental protection, as these substances have long been of concern. When they are used in electrical and electronic equipment they can have a negative impact on effective recycling, human health and the environment during waste operations. The restriction of these phthalates has already been granted in the EU, meaning businesses and producers have already adapted to use alternatives, and a domestic restriction would prevent GB becoming a ‘dumping ground’ for certain phthalate-containing medical devices and monitoring and control instrumentation.

We intend to do this using the Hazardous Substances and Packaging (Legislative Functions and Amendment) (EU Exit) Regulations 2020 (‘the EU Exit Regulations’). This legislation provides the Secretary of State with powers to amend, by regulations, the list of restricted substances and maximum permitted concentration thresholds for each of those substances set out in the RoHS Regulations

# Purpose of this consultation

The restricted substances set out in the RoHS Regulations to which maximum concentration limits currently apply (in brackets) include four phthalates:

Bis(2-ethylhexyl) phthalate (DEHP) (0.1%),

Butyl benzyl phthalate (BBP) (0.1%),

Dibutyl phthalate (DBP) (0.1%) and

Diisobutyl phthalate (DIBP) (0.1%)

We commissioned an independent review from Anthesis which is published alongside this report (see page 11 for more detail) which recommends including the restriction of phthalates in medical devices and monitoring and control instruments including industrial monitoring and control instruments in GB.

The purpose of this consultation, therefore, is to ask for your views on this recommendation.

# Geographical extent

We are consulting on amendments applicable to England, Wales and Scotland only. Directive 2011/65/EU on the Restriction of the Use of Certain Hazardous substances in electrical and electronic equipment (‘ROHS Directive’) is in scope of the Northern Ireland Protocol (part of the Trade and Cooperation Agreement with the EU), and so at present, the EU ROHS Directive continues to apply in Northern Ireland. Thus, Northern Ireland is out of scope of this consultation.

The government is seeking a new, consensual approach to implementing the Northern Ireland Protocol, that ensures it operates in an enduring way. As outlined in the Command Paper – ‘The Northern Ireland Protocol (NIP): the way forward’ published on 21 July 2021, the government proposes to remove unnecessary burdens on trade in goods within the UK, while respecting the EU’s Single Market. We recognise that the NIP includes ambitious proposals that require significant changes to the existing Protocol.  As discussions progress, there may be an impact on how the Northern Ireland Protocol is applied in relation to this matter. However, given that we are not seeking to change how the RoHS Directive is applied in Northern Ireland, and instead consulting on amendments applicable to England, Scotland, and Wales only, this is unlikely to impact Northern Ireland industry at present.

# Audience

This is a public consultation and we welcome all views, including views from the medical equipment and control and instrumentation equipment industry, and trade bodies.

# Responding to this consultation

Please respond to this consultation in one of the following ways:

Online using the Citizen Space consultation hub at Defra <https://consult.defra.gov.uk/>

For ease of analysis, responses via the Citizen Space platform would be preferred, but alternative options are provided below if required: By email to: [rohs@defra.gov.uk](mailto:rohs@defra.gov.uk)

In writing to:

Consultation Coordinator, Defra

2nd Floor, Foss House, Kings Pool,

1-2 Peasholme Green, York, YO1 7PX

Or email: [consultation.coordinator@defra.gov.uk](mailto:consultation.coordinator@defra.gov.uk)

Please note, any responses sent by post must arrive at the above address by the closing date of the consultation (12th October) to be counted. Unfortunately, any responses received after this date will not be analysed. To ensure your response is included in the analysis, please consider responding online via Citizen Space.

# Duration

This consultation open for four weeks and will close on 12 October 2021

# After the consultation

A summary of the responses to this consultation and the Government response will be published and placed on Government websites at www.gov.uk/defra,

The summary will include a list of respondents and organisations that responded but not personal names, addresses or other contact details. However, information provided in response to this consultation document, including personal information, will be shared with the Devolved Administrations and may be subject to publication or release to other parties or to disclosure in accordance with the access to information regimes e.g. Freedom of Information Act 2000 (FOIA) and the Data Protection Act 2018.

If you want information, including personal data that you provide to be treated as confidential, please say so clearly in writing when you submit your response to the consultation and explain why you need these details to be kept confidential.

If we receive a request for disclosure under the FOIA, we will take full account of your explanation, but due to the law we cannot provide an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as a confidentiality request.

Defra is the data controller in respect of any personal data that you provide, and Defra’s Personal Information Charter, which gives details of your rights in respect of the handling of your personal data, can be found at: <https://www.gov.uk/government/organisations/department-for-environment-foodrural-affairs/about/personal-information-charter>

# Defra has contracted the Office of Public Management Ltd, trading as Traverse, to support the analysis of responses to this consultation. Traverse will treat personal data they receive and analyse as confidential and will only have access to the response data for the period of the analysis, following which the data will be permanently removed from their system and supplied to Defra. Please find further information in the accompanying Privacy Notice for this consultation.

This consultation is being conducted in line with the Consultation Principles set out in the Better Regulation Executive guidance which can be found at:

Consultation principles: guidance - GOV.UK (www.gov.uk)

If you have any comments or complaints about the consultation process, please address them to: By e-mail: [consultation.coordinator@defra.gov.uk](mailto:consultation.coordinator@defra.gov.uk)

Or in writing to:

Consultation Co-ordinator,

Department for Environment, Food and Rural Affairs,

1C, Nobel House, 17 Smith Square, London

SW1P 3JR

# About You

A wide range of businesses, organisations and individuals are involved with or take an interest in electricals and managing waste electricals. The questions below are intended to grasp this diversity and put your responses in perspective with those of other respondents.

**Q1. Your name?**

**Q2. Your email address?**

This is optional, but if you enter your email address you will be able to return to edit your consultation response in Citizen Space at any time until you submit it. You will also receive an acknowledgement email when you submit a completed response.

**Q3. Which best describes you?**

Please provide the name of the organisation/ business you represent and an approximate size/number of staff (where applicable). (Please tick one option. If multiple categories apply, please choose the one which best describes the organisation you are representing in your response.)

* Business representative organisation/trade body
* Producer of control and instrumentation equipment
* Producer of medical devices
* Distributor (including Online Marketplaces)
* Local government
* Community group
* Non-governmental organisation
* Charity or social enterprise
* Consultancy
* Academic or research
* Individual
* Other
* If you answered ‘Other’, please provide details:

**Confidentiality and data protection information**

A summary of responses to this consultation will be published on the Government website at: [www.gov.uk/defra](http://www.gov.uk/defra). An annex to the consultation summary will list all organisations that responded but will not include personal names, addresses or other contact details. Defra may publish the content of your response to this consultation to make it available to the public without your personal name and private contact details (e.g. home address, email address, etc).

If you click on ‘Yes’ in response to the question asking if you would like anything in your response to be kept confidential, you are asked to state clearly what information you would like to be kept as confidential and explain your reasons for confidentiality. The reason for this is that information in responses to this consultation may be subject to release to the public or other parties in accordance with the access to information law (these are primarily the Environmental Information Regulations 2004 (EIRs), the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 2018 (DPA)). We have obligations, mainly under the EIRs, FOIA and DPA, to disclose information to particular recipients or to the public in certain circumstances. In view of this, your explanation of your reasons for requesting confidentiality for all or part of your response would help us balance these obligations for disclosure against any obligation of confidentiality. If we receive a request for the information that you have provided in your response to this consultation, we will take full account of your reasons for requesting confidentiality of your response, but we cannot guarantee that confidentiality can be maintained in all circumstances.

If you click on ‘No’ in response to the question asking if you would like anything in your response to be kept confidential, we will be able to release the content of your response to the public, but we won’t make your personal name and private contact details publicly available.

There may be occasions when Defra will share the information you provide in response to the consultation, including any personal data with external analysts. This is for the purposes of consultation response analysis and provision of a report of the summary of responses only. This consultation is being conducted in line with the Cabinet Office “Consultation Principles” and be found at: <https://www.gov.uk/government/publications/consultation-principles-guidance>.

Please find our latest privacy notice uploaded as a related document alongside our consultation document.

 If you have any comments or complaints about the consultation process, please address them to:

* Consultation on amendments to the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations
* Consultation Coordinator, Defra
* 2nd Floor, Foss House, Kings Pool,
* 1-2 Peasholme Green, York, YO1 7PX
* Or email: [consultation.coordinator@defra.gov.uk](mailto:consultation.coordinator@defra.gov.uk)

**Q4. Would you like your response to be confidential?**

Yes / No If you answered ‘Yes’, please provide your reason.

# Background

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment is a piece of European legislation that limits the amount of ten hazardous substances that can be used in certain products. The UK played a key role in developing the original European legislation, and the ROHS Regulations 2012 transposed the Directive into UK law.

Powers conferred on the European Commission under the RoHS Directive to amend the list of restricted substances and associated concentration limits in that Directive and to consider applications from business for exemptions from the restrictions for specific products have been repatriated to the Secretary of State by Regulations made using powers from the European Union (Withdrawal) Act 2018 (EU Exit Regulations). These repatriated powers enable the Secretary of State to amend the list of restricted substances and maximum permitted concentration thresholds for each of those substances inserted into the RoHS Regulations by EU Exit Regulations, as they apply in GB. The RoHS Regulations, as they apply in relation to NI, continue to be automatically updated to take account of amendments to the list of restricted substances, concentration limits and exemptions in the Directive.

The European Union adopted legislation (Commission Delegated Directive (2015/863)) in 2015, which amended the RoHS Directive to add the following four phthalates to the list of restricted substances and maximum concentration values in Annex II to that Directive (the maximum concentration values are in brackets):

Bis(2-ethylhexyl) phthalate (DEHP) (0.1%)

Butyl benzyl phthalate (BBP) (0.1%),

Dibutyl phthalate (DBP) (0.1%) and

Diisobutyl phthalate (DIBP) (0.1%)

These phthalates have long been considered substances of very high concern (SVHC). When they are used in electrical and electronic equipment they can have a negative impact on effective recycling, human health and the environment during waste operations. Areas of concern include environmental releases during WEEE treatment, the potential for secondary poisoning and risks to workers, particularly, waste workers of effects on respiratory tracts because of inhalation. Substitutes for these phthalates have fewer negative impacts.

The new substance restrictions applied for most products with effect from 22 July 2019. However, the application of these new restrictions to medical devices and control & instrumentation equipment was deferred to 21 July 2021 in recognition of the longer innovation and product development cycles that are typical for these products.

The UK government supported these measures in 2015. However, the timing of EU Exit means it must use repatriated powers to apply the restrictions to medical devices and control & instrumentation equipment. Those powers require the Secretary of State to consult before making the necessary regulatory changes

**Review of the inclusion of Phthalates in the RoHS Regulations in medical devices and monitoring and control instruments**

Defra commissioned a technical report,’ Review of the inclusion of phthalates in the RoHS Regulations in medical devices and monitoring and control instruments’ on the inclusion medical devices and control & instrumentation equipment in the restrictions currently applied to the four of phthalates for other categories of equipment in the RoHS Regulations. This report is published alongside this consultation. The report, along with associated reports and studies[[1]](#footnote-2), published by the European Commission set out

* references and scientific evidence in support of the adoption of the proposed restrictions
* information on the use of the substances in equipment
* information on detrimental effects and exposure, in particular during waste management operations;
* information on possible substitutes and other alternatives, and on their availability and reliability
* justification for the proposed provision being the most appropriate measure
* information socio-economic impacts

**Assessment of Impacts on Business**

Engagement with relevant UK trade bodies during the production of the technical report accompanying this consultation suggests there is strong evidence that industry has already moved away from the use of phthalates in their equipment in order to comply with the EU requirements. This is illustrated further by the fact that only four exemption requests have been made to the EU for the use of phthalates above 0.1% in medical devices and monitoring and control instruments including industrial monitoring and control instruments The government will appraise applications for exemptions for specific products granted by the EU with a view to applying those exemptions to Great Britain.

Along with industry being invested to ensure compliance with the requirements, informal engagement indicates strong support for extension of the requirements in GB legislation. Indeed, UK businesses were instrumental in drafting the RoHS harmonised standard, EN IEC 63000:2018, which defines the tasks expected of a manufacturer to comply with the requirements.

Anecdotal evidence from informal engagement with key trade associations also suggests little or no extra costs would be imposed on businesses since they are already compliant with the EU requirements and had not anticipated any deviation from those requirements in the UK following the departure from the EU. Conversely industry has expressed concern that not extending the proposed measures to medical devices and control and instrumentation equipment in GB legislation could lead to GB becoming a dumping ground for components containing phthalates, potentially polluting the supply chain.

We are particularly interested to know whether you agree with this assessment and seeing any evidence that supports your view.

# The Proposal

The proposal on which we seek views and evidence in this consultation is to restrict the use of the following substances in the manufacture of medical devices and control and instrumentation equipment to be placed on the GB market. The maximum concentration limits proposed are indicated in brackets.:

Bis(2-ethylhexyl) phthalate (DEHP) (0.1%)

Butyl benzyl phthalate (BBP) (0.1%),

Dibutyl phthalate (DBP) (0.1%) and

Diisobutyl phthalate (DIBP) (0.1%)

It is proposed that the restriction would apply from 1 July 2022.

# Questions:

**5. Do you agree with the proposal to add four phthalates, Bis(2-ethylhexyl) phthalate (DEHP), Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP) and Diisobutyl phthalate (DIBP) to the restricted substances applied to in medical and monitoring & control instruments at a maximum concentration level of 0.1%**

**Yes**

**No**

**Don’t know**

**Please provide relevant evidence to support your answer**

**6. Do you agree with the findings of the independent technical evaluation in support of this proposal**

**Yes**

**No**

**Don’t know**

**Please provide relevant information or evidence in support of your answer**

**7. Do you agree with our assessment of business impacts**

**Yes**

**No**

**Don’t know**

**Please provide evidence available to quantify new costs on business arising from this proposal that could be used to strengthen our assessment.**

1. Referenced on page 16 of Review of the inclusion of phthalates in the RoHS Regulations in medical devices in monitoring and control instruments. [↑](#footnote-ref-2)