

Consultation on exemption request for lead and cadmium used in ion selective electrodes including glass of pH electrodes under RoHS Regulations

November 2022

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# Introduction

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (the 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.

Industry can apply for exemptions to allow the supply of products using one or more of the restricted substances above the threshold limits set down in the RoHS Regulations where specified criteria are met. Applications for exemptions are made to the Secretary of State under regulation 6 of the Hazardous Substances and Packaging (Legislative Functions and Amendment) (EU Exit) Regulations 2020 (the 2020 Regulations). Any exemption that is granted can be used across industry, not just the business that applied for the exemption. Exemptions are granted where it is determined that the necessary criteria have been met following a detailed evaluation conducted in accordance with regulation 5 of the 2020 Regulations.

Following the UK’s withdrawal from the EU, the function of granting, renewing and revoking exemptions were, in relation to Great Britain, transferred to the Secretary of State by the 2020 Regulations using powers in section 8 of the European Union (Withdrawal) Act 2018 (the Withdrawal Act).

Part of the evaluation process is a 6-week consultation to collect contributions from stakeholders.

A request for renewal for an exemption was submitted for lead and cadmium to be used in ion selective electrodes including glass of pH electrodes. These ion selective electrodes are used in many diagnostic and analytical applications, such as within blood gas analysers. Many of the devices these electrodes are used to help in the diagnosis of several medical conditions, including respiratory conditions, diabetes, and infections. The lead and cadmium specified in the exemption request is for use in the thick film pastes in the ion selective electrodes that are required for the sensors to function.

The requested duration of the exemption is until August 2026 and according to the application it would be expected to lead to the introduction of 4.3g of cadmium and 9.9g of lead to the UK market annually. The applicant states that no suitable substitutes have been verified to meet the technical performance required.

The exemption covers in vitro applications under category 8 (medical devices) of Electrical and electronic equipment (EEE), as covered in the 2012 RoHS regulations. The applicant proposed the following change in the wording of the current exemption entry: Lead and cadmium in thick film pastes, in ion selective electrodes used for blood gas systems. The original wording is lead and cadmium used in ion selective electrodes including glass of pH electrodes.

# Purpose of this consultation

The purpose of this consultation is to seek views on the request for the renewal of an exemption to the substance restrictions in the RoHS Regulations, to collect additional data and information and to inform stakeholders about the application.

# Geographical extent

We are consulting on proposals applicable to England, Wales and Scotland only. The Secretary of State’s transferred function only applies in relation to England, Scotland and Wales.

1. <https://www.legislation.gov.uk/eudr/2011/65>

Northern Ireland is out of scope of this consultation. This is because the EU RoHS Directive is listed in the Northern Ireland Protocol of the Trade and Cooperation Agreement with the EU. As such, the EU RoHS Directive continues to apply in Northern Ireland and Northern Ireland continues to be bound by exemption decisions made by the EU.

The Government introduced legislation in June to remedy issues with operationalising parts of the Northern Ireland Protocol. This action is also taken with the aim of restoring power sharing, ensuring the delicate balance of the Belfast (Good Friday) Agreement is protected. The Northern Ireland Protocol Bill will allow the Government to address the practical problems the Protocol has created in Northern Ireland in four key areas: burdensome customs processes, inflexible regulation, tax and spend discrepancies and democratic governance issues. Given that the exemption would not apply in Northern Ireland, and are only consulting on matters applicable to England, Scotland, and Wales, our proposals are unlikely to impact Northern Ireland industry at present.

**Audience**

This is a public consultation, and we welcome all views, particularly views from the electrical and electronic equipment manufacturing and supply industry for medical devices and relevant trade bodies, medical organisations who use the equipment in question, research institutions and universities, NGOs, public administrations.

# 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

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

Please note, any responses sent by post must arrive at the above address by the closing date of the consultation of Wednesday 14th December 2022) 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.

Further exchange with stakeholders will be held after the consultation has ended for those issues where further need for information and / or need for (technical) discussion has been identified

# Duration

This consultation will be open for 6 weeks from Wednesday 2nd November 2022 until Wednesday 14th December 2022.

# After the consultation

A summary of the non-confidential responses to this consultation and the government response will be published and placed on government websites at [www.gov.uk/defra](http://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, for example 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](https://www.gov.uk/government/organisations/department-for-environment-food-rural-affairs/about/personal-information-charter), which gives details of your rights in respect of the handling of your personal data.

This consultation is being conducted in line with the [Consultation Principles](https://www.gov.uk/government/publications/consultation-principles-guidance) set out in the Better Regulation Executive guidance.

If you have any comments or complaints about the consultation process, please address them to: By email: 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 the supply of electrical equipment. The questions below are intended to put your responses in perspective with those of other respondents.

## Q1. What is your name?

**Q2. What is 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 electrical and electronic equipment
* Business end-user of electrical or electronic equipment
* Public end-user of electrical or electronic equipment (e.g., NHS, educational institution)
* 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 (for example 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

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

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

# Background

The EU RoHS Directive limits the use of specified hazardous substances in the manufacture of certain electrical and electronic products. The UK played a key role in developing the original European legislation, and the RoHS Regulations transposed the EU RoHS Directive into UK law. The RoHS Regulations limits the use of 10 substances and maximum concentration values tolerated by weight in homogeneous materials as follows:

Lead (0.1%)

Mercury (0.1%)

Cadmium (0.01%)

Hexavalent chromium (0.1%) Polybrominated biphenyls (PBB) (0.1%)

Polybrominated diphenyl ethers (PBDE) (0.1%)

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

Butyl benzyl phthalate (BBP) (0.1%)

Dibutyl phthalate (DBP) (0.1%)

Diisobutyl phthalate (DIBP) (0.1 %)

The scope of the RoHS Regulations is wide ranging, covering most types of electrical and electronic equipment intended for household or commercial use. A limited list of products is exempt such as large-scale fixed installations, large-scale industrial tools, military equipment, items designed specifically for R&D, most forms of transport and active implant devices.

As explained above, businesses can apply for exemptions that allow the manufacture and supply of products that exceed these threshold limits where it can be proven that alternative less hazardous substances are not available or not reliable or the total environmental, health and safety impacts of the substitution would outweigh the benefits thereof. Following the UK withdrawal from the EU, the Secretary of State now has the power to determine applications for exemptions for products supplied to or in Great Britain. Businesses can apply to the Secretary of State for new exemptions and renewal of existing exemptions. A list of existing exemptions can be found in Table 1, Schedule A2, of the 2020 Regulations..

Under Regulation 5 of the 2020 Regulations, an exemption may only be granted where the following conditions are satisfied:

1. The exemption does not weaken the environmental or health protection afforded by UK REACH; and
2. The elimination or substitution of the material or component, via design changes or use of materials or components which do not include any restricted substances, is scientifically or technically impracticable.
3. The reliability of substitute materials or components is not ensured; or
4. The total negative environmental, health and consumer safety impacts caused by substitution of another material or component is likely to outweigh the total environmental, health and consumer safety benefits of that substitution.

# The Exemption Request

Entry 65 in Table 1, Schedule A2 of the 2020 Regulations is for lead and cadmium to be used in ion selective electrodes including glass of pH electrodes. The exemption for category 8 (medical devices) applications is due to expire by 21st July 2023; the applicant, COCIR (the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries, representing one main manufacturer of blood gas system producers) has requested a renewal until August 2026.

Granting the renewal of this exemption would lead to the continued introduction of 4.3g of cadmium and 9.9g of lead to the GB market annually. The applicant states that no suitable substitutes that have been verified to meet the technical performance required have been identified.

## Proposed Change to Exemption Wording

The applicant proposed the following change in the wording of the exemption entry: lead and cadmium in thick film pastes, in ion selective electrodes used for blood gas systems. This wording is more specific to the applicant’s exemption requirements but may narrow the potential applications for which the exemption can be used. Therefore, it is important to understand whether there are other exemption uses that may not be covered within the specific application that the applicant proposes to use.

**Details on the Narrowed Exemption Application**

Blood gas analysis systems use ion selective electrodes in their sensors, to detect blood gases such as pO2 and pCO2 and biomarkers in patients’ blood. Blood gas systems are used to accurately diagnose various conditions such as asthma, chronic obstructive pulmonary disease (COPD), kidney failure, uncontrolled diabetes and severe infections, as well as treat patients in respiratory and/or metabolic distress. Lead and cadmium are constituents of thick film screen printable paste used in the sensors. These constituents are used to promote reaction bonding and for ensuring strong adhesion of the paste base metal (typically gold or palladium) to the ceramic substrate material on firing. A planar sensor array can contain up to 10 sensors, with performance integral to the reliability, sensitivity and quick response time of the system. The sensors themselves rely on the integrity of the connections formed by the thick film paste. For good connections to be made the paste must have a precise viscosity to allow for the printing of fine features and low resistivity (≤ 4.5mΩ @ 10μm) which is determined by the percent solids, the ability to form a dense film with minimal defects and good adhesion to the substrate.

**Alternatives & Substitutes Testing**

According to the exemption applicant, testing is still ongoing for alternative RoHS compliant thick film pastes, with a focus on alternatives developed by the same manufacturer to minimise the changes to the technical characteristics of the paste, and thus reduce the timeframes for substitute development and approval. Alternative technologies which avoid the use of thick film pastes are possible but would require additional time to qualify alternatives due to more significant product design and production process changes. In addition to these changes, the many decades of experience and reliability of data gathered while using thick film pastes would also have to be overcome, resulting in considerably longer timeframes for substitute development and approval.

This consultation aims to collect opinions on the current state of play regarding alternatives and substitutes, at a substance and a device level, and to further understand the alternatives and any limitations that the alternatives currently available might have for end users.

## Socio-economic Impacts

This consultation is also looking to further understand how the granting or revocation of this exemption request may impact on business, from manufacturing through to end user applications, as well as wider society and social impacts (e.g., human health impacts). We welcome opinions and supporting evidence for any viewpoints associated with the socio-economic impacts of this exemption.

1. Table 1, Schedule A2 of the 2012 RoHS Regulations <https://www.legislation.gov.uk/uksi/2012/3032/schedule/A2>

**Consultation Specific Questions:**

## Do you agree or disagree that the exemption for lead and cadmium used in ion selective electrodes including glass of pH electrodes to the Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations should be renewed?

Agree

Disagree

Don’t know

## *Please provide evidence to support your answer, explaining why you either support the applicant’s request or object to it. To support your views, please provide detailed technical argumentation / evidence in line with the criteria in regulation 5 of the 2020 Regulations. to support your statement.*

1. **Do agree or disagree with the proposed end date (i.e. August 2026) of the exemption renewal?**

Agree

Disagree

Don’t know

## *Please provide evidence to support your answer, explaining why you either support the applicant’s request or object to it. To support your views, please provide detailed technical argumentation / evidence in line with the criteria in regulation 5 of the 2020 Regulations. to support your statement.*

1. **Do you agree or disagree that the wording of the exemption should be changed noting that if the wording is changed, the scope of the exemption would be much narrower*?***

***Existing wording: lead and cadmium to be used in ion selective electrodes including glass of pH electrodes***

 ***Proposed wording: lead and cadmium in thick film pastes, in ion selective electrodes used for blood gas systems.***

Agree

Disagree

Don’t know

*Please provide evidence to support your answer. Please suggest an alternative wording and explain your proposal if you do not agree with the proposed exemption wording.*

## Do you know of alternative substances to lead and cadmium that can be used in the production of the ion selective electrodes used in these blood gas systems? For example, lead-free thick film pastes.

Yes, I do know of alternative materials which do not rely on RoHS-restricted substances,

No, I do not know of alternative materials which do not rely on RoHS-restricted substances

*Please provide evidence to support your answer and if possible, links to supporting information on alternative materials and any limitations of those alternatives.*

1. **Do you know of alternative devices (with comparable features and performance), which do not rely on RoHS-restricted substances. For example, blood gas systems which do not use replaceable cartridges using the lead-containing electrodes.**

Yes, I do know of alternative devices with comparable features

Yes, I do know of alternative devices, but these do not have comparable features

No, I do not know of alternative devices

*Please provide an explanation to support your answer and if possible, links to supporting information. Please provide any thoughts on why the alternatives are or are not suitable for use by your organisation.*

1. **Are you aware of any research initiatives (past, present or planned) which are looking into possible alternatives for some or all of the application range of lead and cadmium in thick film pastes, in ion selective electrodes used for blood gas systems.**

Yes, I do know of research initiatives which will help in the eventual production of RoHS compliant devices

No, I do not know of research initiatives which will help in the eventual production of RoHS compliant devices

*Please provide evidence to support your answer and if possible, links to supporting information. If you answered yes, please provide an estimate of the time required until the technology will be available for use in the market.*

1. **Can you estimate how many lead-containing cartridges, or other equipment covered by this exemption your organisation produces or purchases per year (if applicable)?**

*Please provide quantitative data to support your view.*

1. **As part of the evaluation, environmental impacts will be assessed. Please estimate possible amounts of waste to be generated through a forced substitution should the exemption not be granted. For example, can you estimate the number of devices that would no longer be useable without replacements, and therefore would become waste (if applicable)?**

*Please provide quantitative data to support your view.*

1. **As part of the** **evaluation, socio-economic impacts shall also be assessed. Please estimate possible impacts on employment in total, in GB and outside GB, should the exemption not be granted. Please tick to indicate the main sectors in which possible impacts are expected:**
* Manufacturers
* Importers/Distributors/ Professional sellers
* End users
* Other (please state)

*Please provide any quantitative data available to support your view.*

## Please estimate additional costs associated with a forced substitution should the exemption not be granted, and how this is divided between various sectors:

* Manufacturers
* Supply chain (e.g., distribution)
* Distributors/ Retailers (selling devices)
* End users
* Other (please state)

*Please provide any quantitative data available to support your view.*

1. **Please summarise your view on the potential impacts on human health, if this exemption was not granted?**

*Please provide quantitative data to support your view.*

## Please provide any further information and/or data that you think is of importance to substantiate your views.