

## Stakeholder consultation on one exemption request under Directive 2011/65/EU

### 1. Introduction

The RoHS Directive (2002/95/EC) (RoHS 1) has been recasted and has now become Directive 2011/65/EU that entered into force on 21 July 2011, repealing Directive 2002/95/EC on 3 January 2013. Directive 2011/65/EU is available here:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT>.

The European Commission has appointed the Oeko-Institut<sup>1</sup> to technically assist in reviewing the requests for exemptions from the substance restrictions of Directive 2011/65/EU (RoHS 2). Exemption requests have to be evaluated against the criteria for exemptions in Art. 5(1)(a).

This consultation is run by Oeko-Institut on behalf of the European Commission, with the purpose to collect stakeholder contributions, under

<https://rohs.exemptions.oeko.info/exemption-consultations/2022-consultation-1>.

Please note that the role of Oeko-Institut is only to collect and evaluate the information provided by stakeholders with a goal to provide the Commission with a recommendation on an exemption's justification. Any decision making, however, is the sole responsibility of EU institutions.

**Neither the fact that a stakeholder consultation is being launched, nor the results of this stakeholder consultation should be interpreted as a political or legal signal that the Commission intends to take a given action.**

### 2. Consultation scope

The scope of the current consultation concerns one new exemption request as shown in the table below.

The application for the exemption was submitted under the project "*Study to assess requests for one (-1-) exemption, for lead as a thermal stabiliser in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices, in Annex IV of Directive 2011/65/EU*".

Oeko-Institut – on behalf of the European Commission – has published the request as worded by the applicant, therefore the applicant is solely responsible for the wording and supporting evidence it has provided.

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<sup>1</sup> Contract is implemented through Framework Contract No. ENV.A.3/FRA/2019/0017 led by Ramboll Deutschland GmbH

**Table 2-1: RoHS exemption request covered by this stakeholder consultation**

No.	Wording according to the terms of reference	Applicant
<b>Requested new exemption</b>		
2022-1	<i>“Lead as a thermal stabilizer in polyvinyl chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors which are used in in-vitro diagnostic medical devices for the analysis of Creatinine and Blood Urea Nitrogen (BUN) in whole blood”</i>	Instrumentation Laboratory & Intertek Health, Environmental & Regulatory Services

### 3. How to submit a stakeholder contribution

The following general guidelines should be taken into account:

- Refer to the exemption request listed in Table 2-1 and have a clear reference as to the exemption number.
- Take the **questionnaires** on the exemption requests into account (questionnaires available under the exemption request specific pages, accessible through the following link: <https://rohs.exemptions.oeko.info/exemption-consultations/2022-consultation-1> -> select exemption request through the tabs on the left).
- Clearly state whether the exemption requests are supported or whether no justification is apparent. To support your contribution, it is required to **provide relevant technical and scientific evidence** in accordance with the criteria listed in Article 5(1)(a). Explain the reasons why potential alternative materials, designs or processes are unsuitable with quantitative data wherever possible. If possible, **provide photographs or diagrams** to illustrate claims. Provision of third party data and information may be beneficial to further support your view. **Sources of information** should be referenced where possible.
- Provide your input to the consultation as early as possible in order to allow other stakeholders to comment.
- Exemptions to the RoHS Directive cannot be justified on the basis of confidential information. Should you wish such information to be used as a justification for an exemption, you need to give explicit agreement to the Commission and the project team to disclose the relevant information on their website.
- Nevertheless, comments shall be clearly marked **“NOT FOR PUBLICATION”** if they are not to be posted as comments on the consultation website. Please also refrain from submitting confidential and non-confidential information mixed in one document!
- Please refrain from submitting several identical comments in order to support a position / comment. It is more useful and efficient to include a cover letter stating that a submission is supported by several parties.
- Submit **compact and comprehensive information** instead of very large and extensive documentation. It will facilitate formulating the need for further information.
- It shall be noted that generic comments, statements, position papers and any additional request for exemptions will not be taken into account.

- **Do not submit new exemption requests.** New exemption requests as well as questions or remarks concerning results of former evaluations have to be addressed to the European Commission directly.
- Please be aware that it might be necessary to give a negative recommendation if important information is missing.
- Always include **your contact details** (or of the person responsible for further contact with name, organisation, email and phone number). The evaluation procedure will normally lead to further questions which we need to address to you directly.
- If you submit documents in **PDF-formats**, please make sure that text can be marked and copied selectively from these documents in order to avoid retyping (which is a possible source of mistakes) when summarising your arguments for the review report.

Interested parties are invited to send their comments by e-mail, at the latest on **19 May 2022**, to [rohs.exemptions@oeko.de](mailto:rohs.exemptions@oeko.de) or by post to:

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Responses submitted electronically will be posted on this web site as they are received, unless respondents specifically request that their contribution should not be published. In the latter case, responses should be clearly and visibly marked with the words **"Not for publication"**.