Consultation Questionnaire Exemption 10 of RoHS Annex IV

Table 1: Currently valid wording of the exemption

|  |  |  |
| --- | --- | --- |
| No. | Current exemption wording | Current scope and dates of applicability |
| IV-10 | Lead and cadmium in atomic absorption spectroscopy lamps | Applies to categories 8 and 9.  Expires on   * 21 July 2021 for category 8 other than in vitro diagnostic medical devices and category 9 industrial monitoring and control instruments. * 21 July 2023 for category 8 in vitro diagnostic medical devices. * 21 July 2024 for category 9 industrial monitoring and control instruments. |

Acronyms and Definitions

AAS Atomic absorption spectrometry

Cat. Category, referring to the categories of EEE specified in Annex I of the current RoHS Directive 2011/65/EU

Cd Cadmium

COM European Commission

CS-AAS Continuum light source AAS

CS-AAS Continuous spectrum AAS

CVG-AAS Chemical vapour generation AAS

EDL Electrodeless discharge lamp

EEA European Economic Area (EU 27 + Iceland, Liechtenstein and Norway)

EEE Electrical and electronic equipment

EU European Union

F-AAS Flame AAS

GF-AAS Graphite furnace AAS

HCL Hollow cathode lamp

Hg Mercury

IMCI Industrial monitoring and control instruments

LS-AAS Line source AAS, umbrella term for other types of AAS like CVG-AAS, F-AAS, etc.

Pb Lead

PE Perkin Elmer

X-free Not containing restricted substance X in the applications in scope of the exemption to be reviewed, i.e. X = cadmium and/or lead.

# Introduction

## Background

Bio Innovation Service, UNITAR-SCYCLE and Fraunhofer IZM have been appointed[[1]](#footnote-2) by the European Commission for the evaluation of applications for new exemptions and the renewal of exemptions currently listed in Annexes III and IV of the RoHS Directive 2011/65/EU.

Perkin Elmer (PE) et al. submitted a request the renewal of the above exemption for cat. 9 industrial monitoring and control instruments (IMCI) with a broadened wording for the maximum validity period of 7 years as detailed in the below table. The underlined phrase indicates the deviation from the current exemption wording.

Table 2: Requested exemption renewal

|  |  |  |
| --- | --- | --- |
| No. | Requested exemption | Requested scope and dates of applicability |
| *IV-10* | *Lead, cadmium, and mercury in atomic absorption spectroscopy lamps* | *Applies to category 9 industrial monitoring and control instruments.*  *Expires on 21 July 2031  (2024 +7 years)* |

The applicant was requested to respond to a clarification questionnaire prior to this stakeholder consultation to complete missing information. This questionnaire along with the exemption application and – if submitted – further information or supporting evidence from other stakeholders are accessible on the stakeholder consultation web page.

The stakeholder consultation is part of the review process for the exemption request at hand. It addresses third parties – not the applicants – to provide and to evaluate information and evidence according to the criteria listed in Art. 5(1)(a) of Directive 2011/65/EU.[[2]](#footnote-3)

Exemption IV-10 has never been reviewed since its adoption to Annex IV with the publicatiopn of the RoHS Directive 2011/65/EU in 2011.

## Summary of the exemption request

Line Source Atomic Absorption Spectroscopy (LS-AAS) systems use lamps which contain lead, cadmium, or mercury. The substance is used as a reference material in the cathode of the Hollow Cathode Lamps (HCL) or in the bulb of the Electrodeless Discharge Lamp (EDL). For detecting a substance, a reference material of the same substance is required, for example to detect cadmium, a reference cathode of cadmium is required in the HCL or a bulb containing cadmium in an EDL. The primary requirement of the lamp in a LS-AAS system is to generate a narrow emission line of the substance which is being measured. The narrow spectral line width optimises the conditions for absorbance by any atoms matching the reference substance, in the sample under test. The transmitted light detected enables the accurate calculation of absorbance and therefore the determination of the concentration of the substance in the sample.

There are no alternatives for using the substance under analysis as the reference material in HCL and EDL lamps. These are the only substances that produce the precise light spectra required in LS-AAS, for determining the concentration of the same substance in test samples.

The exemption wording has been amended to cover mercury. To date AAS lamps containing mercury have been covered under exemption III-4(a)(I – Mercury in other low pressure non-phosphor coated discharge lamps, where the application requires the main range of the lamp-spectral output to be in the ultraviolet spectrum: up to 15 mg mercury may be used per lamp. Due to the wide application scope of the III-4(a)(I) exemption and the use of mercury in AAS for the same technical rationale as outlined in this application, it would be preferable to cover its use in AAS lamps under exemtion IV-10. No technically viable alternatives to the use of these substances, in lamps in line source AAS systems, have been identified.

Analysis using LS-AAS has been an established methodology for over 50 years and is embedded in numerous European standards. The development of products to support these alternative methodologies and to qualify them for the wide range of established line source AAS applications is anticipated to take more than seven years and have significant implications on end users. Based on data from the Analytical Life Science & Diagnostic Association (ALDA) an installed base of approximately 5,000 LS-AAS systems in Europe[[3]](#footnote-4) is estimated.

**To contribute to this stakeholder consultation, please answer the below questions until 11 December 2023.**

**Please also see the applicants’ request form and clarification questionnaire response and – if submitted – further information on the consultation web page[[4]](#footnote-5).**

# Questions

1. Please let us know whether you support or disagree with the wording, scope and re-quested duration of the exemption. To support your views, please provide detailed technical argumentation / evidence in line with the criteria4 in Art. 5(1)(a). If applicable, please suggest an alternative wording and/or duration and explain your proposal.
2. The applicants discuss several analytical devices and whether and how they are (not) alternatives to AAS. Please provide information concerning these or possibly other technologies as to their potential to substitute or eliminate at present or in the closer future the use of the restricted substances in the application at hand so that the requested exemption could be restricted or revoked.
3. Please provide information as to research to find alternatives that do not rely on the exemption under review (substitution or elimination), and which may cover part or all of the applications in the scope of the exemption request.
4. Please provide a roadmap of such on-going substitution/elimination and research (phases that are to be carried out), detailing the current status as well as the estimated time needed for further stages.
5. As part of the evaluation, socio-economic impacts shall also be compiled and evaluated. For this purpose, if you have additional information on socioeconomic aspects that are expected to arise if the exemption is not renewed as requested, please provide details in respect of the following:
   1. What are the volumes of EEE in the scope of the requested exemptions which are placed on the market per year?
   2. What are the volumes of additional waste to be generated should the requested ex-emption not be renewed or not be renewed for the requested duration?
   3. What are estimated impacts on employment in total, in the EU and outside the EU, should the requested exemption not be renewed or be renewed for less than the re-quested time period? Please detail the main sectors in which possible impacts are expected – manufacturers of equipment in the scope of the exemption, suppliers, re-tail, users of MRI devices, etc.
   4. Please estimate additional costs associated should the requested exemption not be renewed, and how this is divided between various sectors (e.g. private, public, industry: manufacturers, suppliers, retailers).
6. Any additional information which you would like to provide?

**Please note that answers to these questions can be published on the stakeholder consultation website and in the review report. If your answers contain confidential information, please provide a version that can be made public along with a confidential version, in which proprietary information is clearly marked.**

**Please do not forget to provide your contact details (Name, Organisation, e-mail and phone number) so that the project team can contact you in case there are questions concerning your contribution.**

**It would be helpful for the review process if you could kindly provide the information in formats that allow copying text, figures and tables to be included in the review report.**

1. It is implemented through the specific contract 070201/2020/832829/ENV.B.3 under the Framework contract ENV.B.3/FRA/2019/0017 [↑](#footnote-ref-2)
2. Directive 2011/65/EU (RoHS) available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32011L0065:EN:NOT> [↑](#footnote-ref-3)
3. ALDA data covers: Western Europe, the UK, Scandinavia, Eastern Europe (Belarus, Bulgaria, Czechia, Hungary, Moldova, Poland, Romania, Russia, Slovakia and Ukraine), the Balkans (Cyprus, Greece and Turkey and the Baltics) [↑](#footnote-ref-4)
4. Consultation web page: <https://rohs.biois.eu/requests2.html> [↑](#footnote-ref-5)