

**Assistance to the Commission
on technological, socio-economic
and cost-benefit assessment
related to exemptions from the
substance restrictions in electrical
and electronic equipment
(RoHS Directive)**

Guidance Document

Freiburg, 15 October 2012

**Öko-Institut e.V. – Institute for Applied Ecology,
Germany** (main contractor)

Carl-Otto Gensch

Yifaat Baron

Markus Blepp

Andreas Manhart

Katja Moch

**Fraunhofer Institute for Reliability and
Microintegration – IZM** (subcontractor)

Otmar Deubzer

**Öko-Institut e.V.
Freiburg Head Office**

P.O. Box 17 71
79017 Freiburg, Germany

Street Address
Merzhauser Str. 173
79100 Freiburg

Phone +49 (0) 761 – 4 52 95-0

Fax +49 (0) 761 – 4 52 95-288

Darmstadt Office

Rheinstr. 95
64295 Darmstadt, Germany
Phone +49 (0) 6151 – 81 91-0
Fax +49 (0) 6151 – 81 91-133

Berlin Office

Schicklerstr. 5-7
10179 Berlin, Germany
Phone +49 (0) 30 – 40 50 85-0
Fax +49 (0) 30 – 40 50 85-388

For the benefit of the environment, this document has been optimised for
double-sided printing.

Table of contents

1	Annex: GUIDANCE DOCUMENT	5
1.1	For whom this document is intended	5
1.2	Do RoHS exemptions concern me?	5
1.3	Criteria for exemptions	7
1.4	How do I apply for an exemption?	11
1.5	What happens once I apply for an exemption?	11
1.6	Everything you need to know about timelines for exemptions	13
1.7	Application format and elaboration of necessary documentation for submitting an exemption request	15
1.8	Further resources	15
1.9	Example	15
1.10	Contacts	15

List of tables

Table 1: Excerpt of Directive 2011/65/EU (RoHS 2) Annex III	7
Table 2: Definition of RoHS 2 exemption criteria	10
Table 3: Maximum validity period of exemptions under RoHS 2 as of 21 July 2011 unless a shorter period is specified	14

List of figures

Figure 1: Grounds for establishing if a product or article may qualify for a temporary exemption	9
---	---

1 Annex: GUIDANCE DOCUMENT

Standard application format and guidance document for RoHS exemption requests on the basis of Article 5(8) Directive 2011/65/EU

1.1 For whom this document is intended

This document is intended for economic operators of establishments responsible for putting electrical and electronic equipment on the European market, as well as establishments active in the development of materials and applications that may be used as part of such equipment. Economic operators may include:

- Manufacturers of electrical and electronic equipment and parts thereof
- Representatives authorized to act on behalf of manufacturers
- Distributors of electrical and electronic equipment
- Importers of electrical and electronic equipment

1.2 Do RoHS exemptions concern me?

The 2011/65/EU Directive¹ (henceforth RoHS 2) restricts the use of certain hazardous substances in electrical and electronic equipment placed on the European market. If an article falls under the scope of equipment given in the RoHS 2 directive, it should be regulated accordingly, thus ensuring that it does not include one of the restricted substances above a prescribed amount. The regulated substances are listed in Annex 2 of the Directive as well as the maximum tolerated amount of the substance permitted in any homogenous material from which the application is comprised. At present the list of substances and tolerated values includes:

- Lead (Pb), (0.1%)
- Mercury (Hg), (0.1%)
- Cadmium (Cd), (0.01%)
- Hexavalent chromium (chromium VI, Cr⁺⁶), (0.1%)
- Polybrominated biphenyls (PBB), (0.1%)
- Polybrominated diphenyl ethers (PBDE), (0.1%)

¹ Directive 2002/95/EC on the Restriction of Hazardous Substances came into force in January 2003 and was known as the RoHS directive. A recent recast in the form of Directive 2011/65/EU has brought into force the RoHS 2 regime, to which this document refers if not explicitly stating otherwise.

You should be aware that legislation may provide for adjustments of the list of substances and/or tolerated amounts from time to time, in correspondence with available scientific and technological developments.

Homogeneous material means a material that cannot be mechanically disjointed or separated into different materials, by use of actions such as unscrewing, cutting, crushing, grinding and abrasive processes. A few examples² are listed below:

- A plastic cover is a "homogeneous material" if it consists of one type of plastic that is not coated with or has attached to it or inside it any other kinds of materials. In this case the limit values of the directive would apply to the plastic.
- An electric cable that consists of metal wires surrounded by non-metallic insulation materials is an example of a "non-homogeneous material" because the different materials could be separated by mechanical processes. In this case the limit values of the directive would apply to each of the separated materials individually.
- A semi-conductor package contains many homogeneous materials which include: plastic moulding material, tin-electroplating coatings on the lead frame, the lead frame alloy and gold-bonding wires.

Anyone who is involved with the production of such an article, be it for purposes of putting such equipment onto the market, for research activities concerning substitutes or for (legal) services around these issues, should be aware of the RoHS Directive.

In most cases, it will be companies that want to have legal certainty for their products that will need to check whether an existing exemption either applies or whether a new or amended one should be pursued. Also, some companies or research institutions might be involved in developing substitutes and would hence like to increase the incentives for them to be used, which is why they may like to apply for the deletion of an exemption.

If you would like to check whether your application falls under the RoHS 2 scope, you may find some guidance within the Frequently Asked Questions (FAQ) draft from 15 June, 2012 mentioned in section 1.8 of this document. Further questions may be referred to the European Commission by e-mail or post

contact details

or to the national authorities. A list of national authorities can be found here:

http://ec.europa.eu/environment/waste/weee/pdf/contacts_ms_rohs.pdf

² Examples are cited from: European Commission Directorate General Environment, 2006, "Frequently Asked Questions Document on Directive 2002/95/EC on the Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment (RoHS) and Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE)", cf. under http://ec.europa.eu/environment/waste/pdf/faq_weee.pdf

If you have found your application to be under the scope of RoHS 2, you may want to check if the criteria for exemption are applicable, to see if you have grounds for submitting a request for exemption. This should also be done if an exemption already exists but requires renewal or change of wording to cover additional similar applications, as well as in cases where you would like to apply for the revoke of an exemption, due to recent scientific or technical developments.

1.3 Criteria for exemptions

The directive³ includes a few criteria according to which RoHS 2 exemptions can be justified. This means that under specific circumstances, temporary permission, for placing EEE, which contains the RoHS 2 banned substances, on the EU market, may be granted. Such exemptions are then listed under Annexes III and IV of the directive. The following excerpt demonstrates how exemptions are listed in the directive annexes:

Table 1: Excerpt of Directive 2011/65/EU (RoHS 2) Annex III

	Exemption	Scope and dates of applicability
33	Lead in solders for the soldering of thin copper wires of 100 µm diameter and less in power transformers	
34	Lead in cermet-based trimmer potentiometer elements	
36	Mercury used as a cathode sputtering inhibitor in DC plasma displays with a content up to 30 mg per display	Expired on 1 July 2010
37	Lead in the plating layer of high voltage diodes on the basis of a zinc borate glass body	
38	Cadmium and cadmium oxide in thick film pastes used on aluminium bonded beryllium oxide	
39	Cadmium in colour converting II-VI LEDs (< 10 µg Cd per mm ² of light-emitting area) for use in solid state illumination or display systems	Expires on 1 July 2014

It should be noted that the criteria mentioned in the directive do not automatically justify an exemption but may rather be understood as the framework for your argumentation towards exemption justification. Assuming it can be shown that some of the criteria apply towards a certain application, the European Commission will still have the right of discretion in deciding if and under what circumstances the exemption should be granted.

One should also not assume that any single criteria can be seen as a minimum threshold that an exemption request must reach, but rather that respective argumentation towards the various points will be weighed and considered during the decision process.

Exemptions can be requested:

³ Directive 2011/65/EU, article 5(1)(a)

- First and foremost for applications, which contain RoHS 2 restricted substances above the amounts prescribed in Annex II of the directive (cf. section 1.2) – At present this is mainly relevant for applications previously considered out of scope and soon to be included, however if an in scope product is to newly be made available on the market or if you have just now recognized that your application is under the RoHS 2 scope it would also be relevant in your case.
- In cases where a change of wording of an existing exemption could be made to include a similar application with the same inherent compliance issues
- In cases where an exemption exists but is due to expire within ca. 18 months.

You should keep in mind that the scope of RoHS was changed in the last recast and it is possible that an application that was previously exempt is now included in the scope. In such cases, a product that is already available on the market might require undertaking action for the approval of an exemption. Furthermore, the existing list of exemptions and the scope of RoHS 2 are always subject to changes. As a company you are always in the duty of keeping yourself updated in this respect and of verifying whether action is needed.

The directive states⁴ that exemptions may also be deleted from the Annexes if the conditions established through applicable criteria are no longer fulfilled. A request for deletion would then argue that the various criteria are no longer met. This could be relevant for you if your enterprise has developed or is representing a developer of possible substitutes for an application currently exempt.

The following diagram (Figure 1) will take you through the various criteria, to help you understand if you have grounds for requesting an exemption for your application.

This diagram may also be of assistance if you would like to apply for the renewal of an exemption that is close to the end of its validity; to apply for changing the wording of an on-going exemption so that it may cover additional similar applications or; to apply for the deletion of an existing exemption.

⁴ Directive 2011/65/EU, article 5(1)(b)

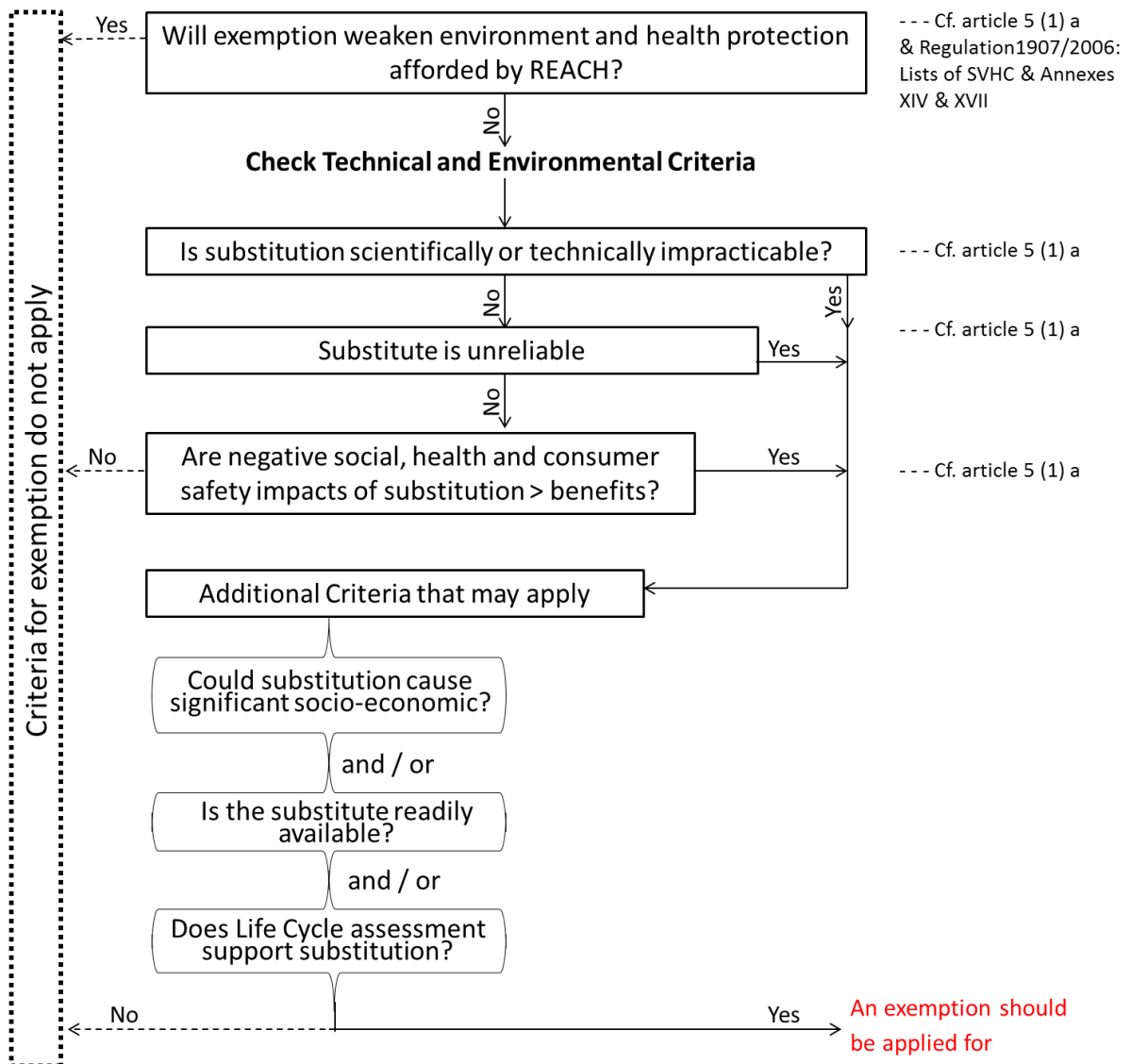


Figure 1: Grounds for establishing if a product or article may qualify for a temporary exemption

In order to be fully in line with REACH methodology and provisions, applicants for exemptions must follow the methodologies outlined in the ECHA Guidances on application for authorisation and socio-economic Analysis available under:

http://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf

and

http://echa.europa.eu/documents/10162/13637/sea_authorisation_en.pdf

These documents outline the criteria and tests to follow to determine the availability of substitutes and to assess socio-economic impact of substitution").

The directive also requires that impacts of an exemption on future innovation be considered when deciding on the duration of exemptions.

Table 2 below contains some further information as to how the various criteria should be understood:

Table 2: Definition of RoHS 2 exemption criteria

Element	Explanation
Threshold Criteria	
Exemption may weaken REACH afforded environmental and health protection	<p>An exemption may weaken REACH afforded environmental and health protection where REACH regulation already includes restrictions for the use of the substance in the application in question. Restrictions for substances and for specific uses of substances should be checked:</p> <ul style="list-style-type: none"> ▪ In the list of substances of very high concern (SVHC) and its respective candidate lists ▪ In Annex XIV of the REACH regulation that lists substances requiring authorization ▪ In Annex XVII of the REACH regulation that lists the restrictions of use for various substances <p>Note that REACH regulation may be updated from time to time to contain further annexes that may be relevant for checking existing restrictions.</p>
Criteria	
Substitution is scientifically or technically impracticable	A substitute material, or a substitute for the application in which the restricted substance is used, is yet to be discovered, developed and approved for use in the specific application (approval would be needed for example for the use of a substitute in medical devices).
Reliability of a substitute	The probability that EEE using the substitute will perform the required function without failure for a period of time comparable to that of the application in which the original substance is in use.
Negative environmental, health and consumer safety impacts of substitution outweigh benefits thereof	The impacts of substitution stand to be significantly higher than those attributed to the use of the restricted substance in the application in question, where environmental, health and consumer safety aspects are considered.
Additional Parameters	
Socio-economic impacts of substitution	<p>Substitution could cause adverse socio-economic impacts that should be considered in the evaluation of an exemption.</p> <p>A good example would be the impact of substitution for an application that is manufactured by big enterprises as well as small and medium ones. In such a case, the costs of substitution may have adverse effects on the market for the application, caused by the impacts on competitiveness and this may in turn affect employment in some regions.</p>
Availability of a substitute	The availability of a substitute to be produced and delivered within reasonable time in comparison with the substance originally used in the application. This includes the time required for manufacturing the application in which the original substance is in use. This could apply when a substitute exists "in the lab" but is still not available for use in the required amounts or qualities.
Life Cycle assessment on impacts of exemption	A life cycle assessment of the exemption would compare the consumption of various resources and the environmental impacts attributed to the use of the restricted substance and its possible

Element	Explanation
	substitutes in the various life stages of the application: production, distribution, use and waste management at end of product lifetime.
Impacts on innovation	Impacts that the duration of an exemption may have on future efforts for developing possible substitutes.

1.4 How do I apply for an exemption?

Once you have decided that you either want to request an exemption or the renewal, the amendment or the deletion of an existing exemption, you will have to do the following:

1. Use the checklist below to understand what information and data you need to compile before handing in a request.
2. Fill out the application form
3. Send the application form along with further documentation to the European Commission by e-mail or post:

contact details

4. Be ready to answer questions related to your request.

Checklist documentation

Research and provide documentation such as:

- Test results on the suitability of substitutes and any other technical / scientific documentation supporting your request – if possible and available, this documentation should be third party certified.
- Third party verified documentation such as life cycle assessment according to ISO 14040, ISO 14044, PCF, CBA etc.
- Roadmaps for the further technical development of RoHS 2 compliant substitute applications.
- REACH-relevant documentation such as registration, application for authorization etc.
- Documentation from suppliers on the availability or non-availability of substitutes
- Socio-economic data in as much detail as possible (see application form in Appendix 1 for the necessary categories and level of detail) and if possible and available, with third party certification.

1.5 What happens once I apply for an exemption?

Once you have handed in your request it will be processed in a standardized manner which is briefly described in this section.

First of all the request will be subject to a first check by the European Commission. Then the request will be technically and scientifically evaluated (this may be prepared by an external

consultant). Finally the request will go through a formal procedure within the EU institutions, in which a decision shall be made concerning its approval.

The directive⁵ describes in detail the procedure stages that need to be followed concerning requests for exemptions. These include:

- (A) The Commissions will acknowledge receipt of an application in writing within 15 days of its receipt. The acknowledgement shall state the date of receipt of the application;
- (B) The Commissions will inform the Member States of the application without delay and provide them with the application and any supplementary information;
- (C) The Commissions shall make a summary of the application available to the public;
- (D) The Commissions will evaluate the application and its justification

The evaluation of your request will include the following steps:

1. Completeness check (duly filled out application format, availability of all necessary documentation, contact details available).
2. First technical and scientific check (comprehension of request, validity of provided argumentation and information, identification of missing information).
3. Compilation of questions to the applicant if necessary.
4. Once the requested additional information has been received, the submitted information will be prepared for an online stakeholder consultation (compilation the application and additional information, references to former evaluations if applicable, questions to stakeholders, and preparation of consultation website). Note that a stakeholder consultation is usually held for a number of exemption requests in parallel and therefore will not necessarily take place adjacent to the completion of initial information.
5. Minimum of 8 weeks online stakeholder consultation with the goal to collect additional data and information and to inform stakeholders about the request.
6. Evaluation of consultation results and results of additional rounds of questions to the applicant and other stakeholders.
7. Drafting of a recommendation including the evaluation results and a justification on whether the request should be accepted or not.

Once the recommendation has been prepared, the European Commission will have to decide whether it follows the recommendation which could lead to an amendment of Annex III or IV (cf. Table 1 above). In this case, a draft Commission Delegation Regulation will be submitted according to the following steps:

⁵ Directive 2011/65/EU, article 5 (4)

- (A) Preparation of legal measure;
- (B) Consultation of Member States expert group for RoHS 2 delegated acts;
- (C) COM internal consultation and translation;
- (D) Notification of Council and Parliament;
- (E) Publication of legal measure in the Official Journal of the European Union.

It should be noted that The European Parliament and the European Council may object to a delegated act, and so to the decision concerning an exemption within 2 months of notification. This period may be extended to up to 4 months.

1.6 Everything you need to know about timelines for exemptions

How long do I need to wait for a decision concerning my application for exemption?

Once you have handed in a request it may take up to one and a half years before the procedure has been completed. You thus need to hand in a request in due time to make sure that you have legal certainty as soon as possible in order to be able to put your product onto the market.

The directive⁶ also lays down the obligation of the Commission to decide on an application for renewal of an exemption no later than 6 months before the expiry date of the existing exemption unless specific circumstances justify other deadlines. The existing exemption shall remain valid until a decision on the renewal application is taken by the Commission.

In case an exemption is to be deleted from the Annex, be it because the application for its renewal has been rejected or because the exemption is revoked, the directive⁷ specifies that it shall expire at the earliest 12 months, and at the latest 18 months, after the date of the decision. I.e. a transition period is foreseen to allow stakeholders to take appropriate action.

You should consider how these timeframes may affect the production and the placing of application on the European market in deciding when at latest to submit an application for exemption, should applicable substitutes not be available.

When at latest should I apply for an exemption?

If you are applying for a **new exemption**, you should apply no later than 18 months (cf. above); procedure completion may take a year and a half) before your application comes under the RoHS 2 scope. You should additionally consider how much time you will need to adapt production processes for the use of substitutes, should your exemption not be

⁶ Directive 2011/65/EU, article 5 (5)

⁷ Directive 2011/65/EU, article 5 (6)

approved, so as to avoid taking products off the market or postponing the distribution of a new application in the EU market.

If you would like to request the **renewal of an exemption**, the directive⁸ sets the maximum time limit for the application for exemption renewal at no later than 18 months before the exemption expires.

If you would like to **change the wording of an existing exemption** you should take notice of the validity period as mentioned above, especially if there exist, within the exemption, a few clauses setting unique validity periods that depend on application specifics (for example voltage, size, material components, etc.).

If applying for the **revoke of an existing exemption**, you may apply immediately, so long as substitutes will be ready and approved for use in applications, should the request be approved. Though the procedure for reviewing and reaching a decision concerning a request may take up to 18 months, it could also take less and then an additional 12-18 months would be granted as transition period for manufactures to update production lines for the use of applicable substitutes.

How long will an exemption be valid?

The directive⁹ regulates the maximum validity period of exemptions:

Table 3: Maximum validity period of exemptions under RoHS 2 as of 21 July 2011 unless a shorter period is specified

Category Annex I	Maximum validity period for <u>new exemptions</u>	Validity period for existing exemptions where <u>no expiry date is specified</u>	Validity period for existing exemptions where an <u>expiry date is specified</u>
1-7, 10, 11 (not applicable to Annex IV exemption)	5 years	22 July 2011 - 21 July 2016	22 July 2011 - specified date
8, 9 (medical and monitoring and control devices)	7 years	22 July 2014 - 21 July 2021	22 July 2014 - specified date
8 (in vitro diagnostic medical devices)		22 July 2016 - 21 July 2023	22 July 2016 - specified date
9 (industrial monitoring and control instruments)		22 July 2017 - 21 July 2024	22 July 2017 - specified date

Assuming that the conditions set out in the exemption criteria are still fulfilled, the validity period of an existing exemption may be renewed by means of application for renewal.

⁸ Directive 2011/65/EU, article 5 (5)

⁹ Directive 2011/65/EU, article 5(2)

You should also be aware that if your application is to be included into the RoHS scope in the near future, the granted validity period only starts “running” once the application comes into scope.

1.7 Application format and elaboration of necessary documentation for submitting an exemption request

The application form can be found in the Annex below [### add link in final document ###]. It has been formulated to assist applicants in understanding the various details that should be included in an application.

Applications should be submitted in digital format.

It should be specified if parts of an application, or parts of further information supplied throughout the evaluation process, are confidential. It is strongly recommended to submit confidential and non-confidential material in separate documents. Additionally, it should be noted that as confidential material cannot serve as official information in support of an exemption request (or its renewal, amendment or deletion), where possible, it should be refrained from.

1.8 Further resources

In 2012 a RoHS Frequently Asked Questions (FAQ) document draft was published by the European Commission. It includes information that may be of assistance concerning various issues such as:

- The main changes introduced by the recast of RoHS (RoHS 2 regime)
- Information concerning the transposition of the directive into force
- Clarifications concerning the RoHS 2 scope, terms and definitions and other specific issues
- Questions concerning compliance

The document may be found under:

http://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf

1.9 Example

###Once document is finalised, add an example that can be followed by the applicant (this may be located in an appendix)###

1.10 Contacts

###Name and contact information of an official Commission contact###

Exemption Request Form

Date of submission: _____

1. Name and contact details

1) Name and contact details of applicant:

Company: _____ Tel.: _____
Name: _____ E-Mail: _____
Function: _____ Address: _____

2) Name and contact details of responsible person for this application (if different from above):

Company: _____ Tel.: _____
Name: _____ E-Mail: _____
Function: _____ Address: _____

2. Reason for application:

Please indicate where relevant:

- Request for new exemption in:
- Request for amendment of existing exemption in
- Request for extension of existing exemption in
- Request for deletion of existing exemption in:
- Provision of information referring to an existing specific exemption in:
 - Annex III
 - Annex IV

No. of exemption in Annex III or IV where applicable: _____

Proposed or existing wording: _____

Duration where applicable: _____

Other: _____

3. Summary of the exemption request / revocation request

4. Technical description of the exemption request / revocation request

(A) Description of the concerned application:

1. To which EEE is the exemption request/information relevant?

Name of applications or products: _____

a. List of relevant categories: (mark more than one where applicable)

- | | |
|----------------------------|-----------------------------|
| <input type="checkbox"/> 1 | <input type="checkbox"/> 7 |
| <input type="checkbox"/> 2 | <input type="checkbox"/> 8 |
| <input type="checkbox"/> 3 | <input type="checkbox"/> 9 |
| <input type="checkbox"/> 4 | <input type="checkbox"/> 10 |
| <input type="checkbox"/> 5 | <input type="checkbox"/> 11 |
| <input type="checkbox"/> 6 | |

b. Please specify if application is in use in other categories to which the exemption request does not refer: _____

c. Please specify for equipment of category 8 and 9:

The requested exemption will be applied in

monitoring and control instruments in industry

in-vitro diagnostics

other medical devices or other monitoring and control instruments than those in industry

2. Which of the six substances is in use in the application/product?

(Indicate more than one where applicable)

Pb Cd Hg Cr-VI PBB PBDE

3. Function of the substance: _____

4. Content of substance in homogeneous material (%weight): _____

5. Amount of substance entering the EU market annually through application for which the exemption is requested: _____

Please supply information and calculations to support stated figure.

6. Name of material/component: _____

7. Environmental Assessment: _____

LCA: Yes

No

(B) In which material and/or component is the RoHS-regulated substance used, for which you request the exemption or its revocation? What is the function of this material or component?

(C) What are the particular characteristics and functions of the RoHS-regulated substance that require its use in this material or component?

5. Information on Possible preparation for reuse or recycling of waste from EEE and on provisions for appropriate treatment of waste

1) Please indicate if a closed loop system exist for EEE waste of application exists and provide information of its characteristics (method of collection to ensure closed loop, method of treatment, etc.)

2) Please indicate where relevant:

- Article is collected and sent without dismantling for recycling
- Article is collected and completely refurbished for reuse
- Article is collected and dismantled:
 - The following parts are refurbished for use as spare parts: _____
 - The following parts are subsequently recycled: _____
- Article cannot be recycled and is therefore:
 - Sent for energy return
 - Landfilled

3) Please provide information concerning the amount (weight) of RoHS substance present in EEE waste accumulates per annum:

- In articles which are refurbished _____
- In articles which are recycled _____
- In articles which are sent for energy return _____
- In articles which are landfilled _____

6. Analysis of possible alternative substances

(A) Please provide information if possible alternative applications or alternatives for use of RoHS substances in application exist. Please elaborate analysis on a life-cycle basis, including where available information about independent research, peer-review studies development activities undertaken

(B) Please provide information and data to establish reliability of possible substitutes of application and of RoHS materials in application

7. Proposed actions to develop possible substitutes

(A) Please provide information if actions have been taken to develop further possible alternatives for the application or alternatives for RoHS substances in the application.

(B) Please elaborate what stages are necessary for establishment of possible substitute and respective timeframe needed for completion of such stages.

8. Justification according to Article 5(1)(a):

(A) Links to REACH: (substance + substitute)

1) Do any of the following provisions apply to the application described under (A) and (C)?

- Authorisation
 - SVHC
 - Candidate list
 - Proposal inclusion Annex XIV
 - Annex XIV
- Restriction
 - Annex XVII
 - Registry of intentions
- Registration

2) Provide REACH-relevant information received through the supply chain.

Name of document: _____

(B) Elimination/substitution:

1. Can the substance named under 4.(A)1 be eliminated?

Yes. Consequences? _____

No. Justification: _____

2. Can the substance named under 4.(A)1 be substituted?

Yes.

Design changes:

Other materials:

Other substance:

No.

Justification: _____

3. Give details on the reliability of substitutes (technical data + information): _____

4. Describe environmental assessment of substance from 4.(A)1 and possible substitutes with regard to

1) Environmental impacts: _____

2) Health impacts: _____

3) Consumer safety impacts: _____

⇒ Do impacts of substitution outweigh benefits thereof?

Please provide third-party verified assessment on this: _____

(C) Availability of substitutes:

a) Describe supply sources for substitutes: _____

b) Have you encountered problems with the availability? Describe: _____

c) Do you consider the price of the substitute to be a problem for the availability?

Yes No

d) What conditions need to be fulfilled to ensure the availability? _____

(D) Socio-economic impact of substitution:

⇒ What kind of economic effects do you consider related to substitution?

Increase in direct production costs

Increase in fixed costs

Increase in overhead

Possible social impacts within the EU

Possible social impacts external to the EU

Other: _____

⇒ Provide sufficient evidence (third-party verified) to support your statement: _____

9. Other relevant information

Please provide additional relevant information to further establish the necessity of your request:

10. Information that should be regarded as proprietary

Please state clearly whether any of the above information should be regarded to as proprietary information. If so, please provide verifiable justification:
