Exemption evaluation methodology manual

Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS (RoHS Pack 15 - Task 4, draft final)

Under the Framework Contract: Assistance to the Commission on technical, socio-economic and cost-benefit assessments related to the implementation and further development of EU waste legislation

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1. Executive summary – English

Under Framework Contract no. ENV.A.2/FRA/2015/0008, DG Environment of the European Commission requested a consortium led by Oeko-Institut to develop a methodology for supporting the assessment of exemption applications pursuant to the criteria in Article 5(1) of Directive 2011/65/EU (RoHS hereinafter).

The methodology developed has taken into consideration the practice applied in previous exemption evaluations performed under the RoHS Directive.

The methodology also provides elements for the comparison of quantified impacts, on the basis of life cycle analyses, in cases where the justification of an exemption is argued by the applicant relying on the third Article 5(1)(a) criterion.[1] This may be the case where the use of a RoHS substance may result in lower environmental impacts stemming for example from energy efficiency gains or of the use of recycled materials, in comparison to alternatives. The work has been undertaken by the Oeko-Institut and Fraunhofer Institute IZM.

[1] The criterion referred to: "*the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof*."

2. Task 4: Update of the exemption evaluation methodology based on RoHS Art. 5(1)(a)

Acronyms

LCA life cycle assessment

HMPS high melting point solder

EEE	Electrical and Electronic Equipment
REACH	Regulation No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
RoHS	Directive 2011/65/EU on the Restriction of the use of certain Hazardous Substances in Electrical and Electronic Equipment
SVHC	Substances of Very High Concern

2.1. Background and Basic Principles

The core objective of the exemption evaluation process is to assess whether an exemption from the RoHS Article 4(1) substance restriction is justified in the light of the criteria stipulated in RoHS Art. 5(1)(a). RoHS Art. 5 provides the base for the evaluation of exemptions, i.e. renewals of exemptions prior to their expiry following a request for renewal or for revoking of valid exemptions currently listed in Annex III or Annex IV of RoHS or requests for new exemptions. RoHS Annex III lists the exemptions that are applicable to electrical and electronic equipment under categories 1 to 11, listed in Annex I of the RoHS Directive. Annex IV lists exemptions that are applicable only to equipment under categories 8 (medical devices) and 9 (monitoring and control instruments).

RoHS Art. 5(1)(a) stipulates[2]:

1. *"For the purposes of adapting Annexes III and IV to scientific and technical progress […] the Commission shall adopt […] the following measures:*

[2] Different from the original wording in Directive 2011/65/EU, numbering has been added in brackets to the conditions specified under the reproduced Article 5(1)(a) text for clarity and easier referencing in following sections.

(a) *inclusion of materials and components of EEE for specific applications in the lists in Annexes III and IV, provided that such inclusion does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006* [referred to as the threshold criteria hereinafter] *and where any of the following conditions is fulfilled*:

- *their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable* [referred to as (I) hereinafter],
- *the reliability of substitutes is not ensured [referred to as* (II) hereinafter],
- *the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof* [referred to as (III) hereinafter].

Decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV and on the duration of any exemptions shall take into account the availability of substitutes and the socioeconomic impact of substitution [referred to as (IV) hereinafter].

Decisions on the duration of any exemptions shall take into account any potential adverse impacts on innovation. Life-cycle thinking on the overall impacts of the exemption shall apply, where relevant [referred to as (V) hereinafter];"

As stated in the Directive, the three conditions mentioned above (I, II and III) are to be regarded as alternatives, i.e. fulfillment of one of the conditions is sufficient to justify an exemption from the requirements of the Directive.

This document describes the current practice on how the above criteria are applied and operationalised in the technical assessments supporting the evaluation of exemption requests performed by a contractor for the European Commission.

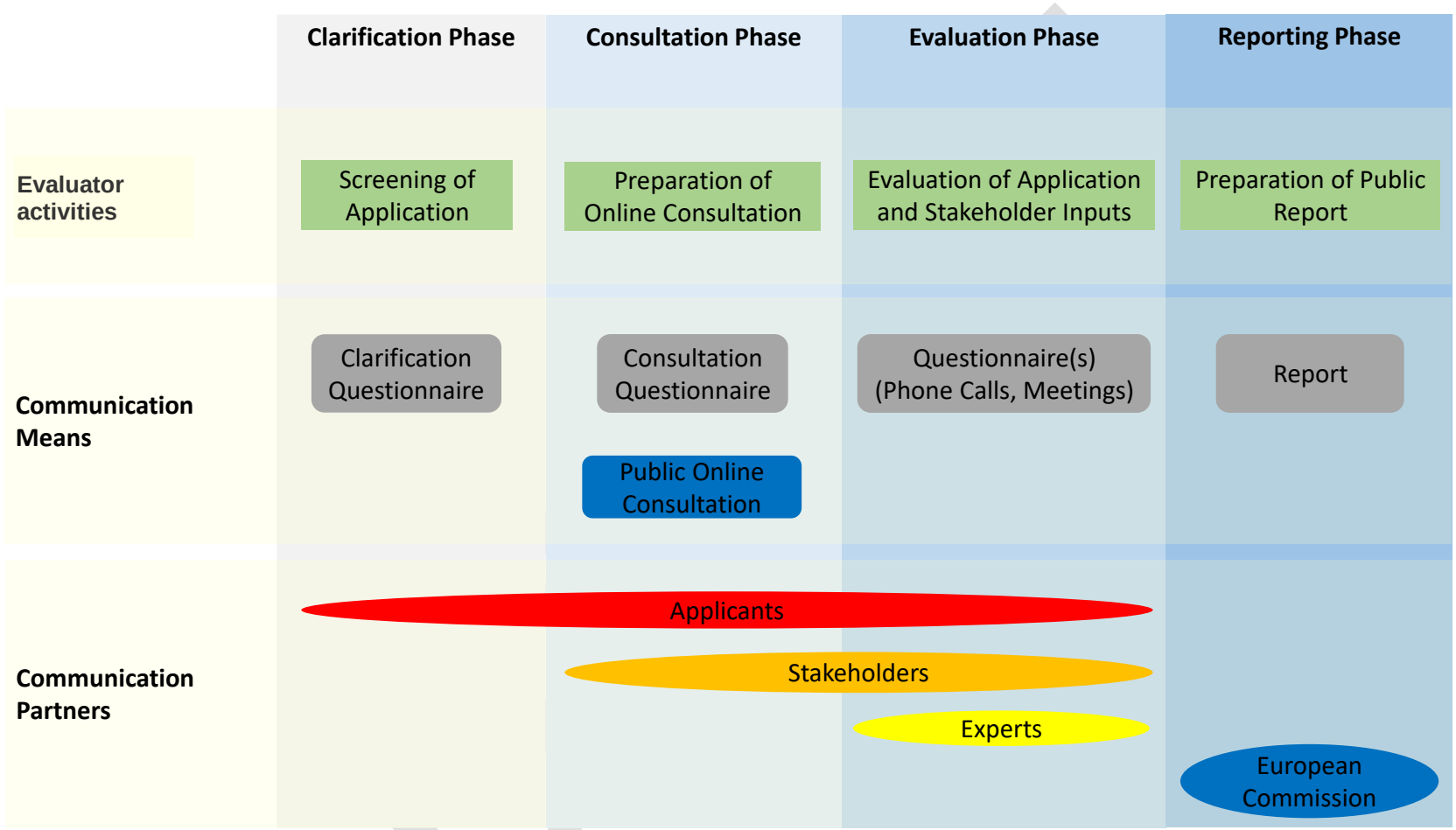
2.2. Overview of the exemption assessment

Applicants can request new exemptions, the renewal or revoking of exemptions listed in RoHS Annexes III and IV, providing information according to RoHS Annex V (Applications for granting, renewing and revoking exemptions). On the basis of the provisions specified under Article 5 of the Directive, the Commission receives requests for (granting, renewing, or revoking) exemptions that need to be evaluated in order to assess whether it is justified to grant the request in view of requirements of Article 5(1) being fulfilled the requirements order to grant.

Following the submission of exemption requests to the Commission, a technical and scientific assessment is launched by the Commission (containing single or multiple exemption requests). The outcome of the assessment is a technical report providing an analysis on all relevant aspects related to the criteria listed in Article 5(1)(a) and including the consultants' recommendation.

Figure 2-1 illustrates the four different stages of the technical assessment including the actors and groups of stakeholders involved and the ways of communication and information exchange that have been applied over the past years.

Figure 2-1: Overview of the exemption assessment



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The next chapters describe in more detail the objectives and activities of the above phases.

2.3. The clarification phase

In the clarification phase, the consultants first screen the exemption requests to determine whether the application has been prepared according to the minimum information requirements listed in RoHS Annex V. This implies that the information submitted and the way it is presented is sufficiently complete, stringent and comprehensible so to understand:

- what the applicants request, i.e. which substance(s) and which components and/or materials are concerned,
- the technical background of the request, i.e. in which devices and components the substance is used and what the substance's functionality is,
- the applicants' justification why the substance cannot or should not be substituted or eliminated based on the criteria of Art. 5(1)(a),
- the proposed exemption wording including the requested validity period.

Where the information submitted in the request does not fulfil the Annex V minimum information requirements, the applicant shall be requested to complete missing information to ensure the above. Where information provided in response to such requests still does not sufficiently comply with the Annex V requirements to an extent which would prevent a successful conclusion of the assessment, this could lead to a recommendation to the Commission to not proceed with the assessment of such request.

The applicant is sent a clarification questionnaire and asked to answer the questions within a reasonable period, depending on the number and complexity of the questions. The response must be a written document that can be made publicly available for the purpose of the consultation to be performed in the next stage.

To summarise, the aim of this phase is to ensure that the information basis available is sufficient to allow a full understanding of the request by stakeholders in the consultation phase.

2.4. The consultation phase

A targeted online stakeholder consultation organised and hosted by the consultants via a dedicated website forms the core element of the consultation phase. This also fulfils the requirement of Article 5(7) that requires the Commission to "*consult economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations and make the comments received publicly available*". Stakeholders are invited to submit their comments concerning the requested exemptions. Relevant stakeholders, in accordance with Article 5(7), are notified per email about the start and the duration of the consultation and instructed on how to participate. This may include for example business associations representing manufacturers of the EEE or its components (OEMs and supply chain), manufacturers of the relevant substance, waste management operators, but also individual companies and operators. It is good practice to ask the applicant which other manufacturers of the equipment or materials in scope of the request are active on the market and to invite these to participate in this process. The consultation is

held on a publicly available platform and is usually held for a period of eight weeks, though longer and shorter periods may apply if necessary.

The consultants prepare a Consultation Questionnaire with the following main objectives:

- to collect stakeholders' comments and evidence as to whether they support, the respective request for exemption, its scope and formulation and its requested duration;
- to obtain information from stakeholders in order to assess whether the requested exemption is required, i.e. whether the substance for which the exemption is requested can be substituted or eliminated in the application(s) in focus of the exemption request.

After the consultation phase, the consultants start assessing the exemption requests in relation to the Article 5(1) criteria.

2.5. The evaluation phase

The evaluation of exemption requests strictly follows the criteria of Art. 5(1)(a) of the RoHS Directive, c.f. section 2.1 on page 7.

For the assessment of exemption requests, information requirements stated in RoHS Annex V are of particular interest:

"[…]*(b) information on the material or component and the specific uses of the substance in the material and component for which an exemption, or its revocation, is requested and its particular characteristics;*

(c) verifiable and referenced justification for an exemption, or its revocation, in line with the conditions established in Article 5;

(d) an analysis of possible alternative substances, materials or designs on a life-cycle basis, including, when available, information about independent research, peer-review studies and development activities by the applicant and an analysis of the availability of such alternatives;

(e) information on the possible preparation for reuse or recycling of materials from waste EEE, and on the provisions relating to the appropriate treatment of waste according to Annex II to Directive 2002/96/EC;

(f) other relevant information;

(g) the proposed actions to develop, request the development and/or to apply possible alternatives including a timetable for such actions by the applicant;

(h) where appropriate, an indication of the information which should be regarded as proprietary accompanied by verifiable justification;

(i) when applying for an exemption, proposal for a precise and clear wording for the exemption;

(j) a summary of the application".

As part of this assessment, the consultants ascertain whether the applicant's justification for the exemption is comprehensible as well as scientifically and technically substantiated to allow conclusions on the practicability of substitution or elimination of the restricted substance. During the assessment process, the consultants communicate with the applicant mainly via questionnaires, until the practicability or impracticability of substitution or elimination is clarified. A stakeholder meeting (virtual or physical) may also be held where considered more efficient, however, the applicant or stakeholders are to summarise oral statements in writing as a means of documenting their input and ensuring transparency. The applicant has the general burden to substantiate as much as possible its claims (for example the impracticability of substitution and elimination) with evidence. A time period for providing the supporting information can be set by the consultant to enable performing the assessment. Based on all gathered evidence, the consultants conclude whether the exemption can be justified based on Article 5(1)(a) and recommend the Commission if it should be granted or not.

Consideration of stakeholders' information

In cases where the applicant is not the only manufacturer of the electrical/electronic component or EEE in the scope of the requested exemption, other relevant manufacturers are an important source of information.

These might provide relevant information in support or against the requested exemption as part of the stakeholder consultation or might be specifically contacted by the consultants as to their support or objection. In these cases, the consultant would seek to clarify if a component or product in the scope of the exemption request comparable in its functionality and other properties thereof can be manufactured without using the restricted substance, or not. If other manufacturers claim that substitution or elimination of the restricted substance is practicable, clear evidence confirming their claim will be sought.

Where such information is provided it is shared with the applicant, who is invited for a detailed justification in writing of his claim in the light of such new information. The situation will be clarified in the course of information exchanges and discussions between the applicant, the consultants and the other manufacturers concerned. In some cases, stakeholders may be asked to participate in teleconferences or meetings to support this process.

If needed, the consultants may also consult their network of experts for more information, or for identifying issues to be further clarified.

The following sections address each of these criteria separately, explaining consideration in evaluation their fulfillment. The focus is in relation to requests for

exemption renewal or for new exemptions, while requests for revoking exemptions are addressed more specifically directly below.

Revocation of Exemptions

Requests to revoke exemptions in principle also follow the procedures and conditions described below. Applicants have to plausibly explain and provide respective evidence that the conditions of Art. 5(1)(a)(I/II/III) are no longer fulfilled for a given exemption, i.e. that substitution or elimination of the restricted substance in the scope of the exemption, the revocation of which is requested, is scientifically and technically practicable and reliable and that it does not result in total negative environmental, health and consumer safety impacts that are higher than the application of the restricted substance.

In cases where other stakeholders raise objections against such a revocation in the online stakeholder consultation, the situation will be assessed following the approach described in the following sections sections of this chapter, resulting in a recommendation whether to revoke the exemption in line with Art. 5(1)(a)(I/II/III) or not.

If, during the stakeholder consultation, no other stakeholders express objections relating to the request for revoking the exemption, the consultants may, based on evidence provided by the applicant, recommend the Commission to repeal the exemption on the ground that substitution by non RoHS controlled substances or elimination are practicable, and that the original reason for the exemption has ceased to exist and the continuation of the exemption can no longer be justified under Art. 5(1)(a)(I/II/III).

2.5.2. Compliance of the requested exemption with Regulation (EC) No 1907/2006 (threshold criterion)

Art. 5(1)(a)(I) (see section 2.1 on page 7) requires that the exemption, if granted, does not weaken the environmental and health protection afforded by Regulation (EC) No 1907/2006 concerning the **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **Ch**emicals (REACH), which regulates the use of chemical substances on the Union market. REACH, for its part, addresses substances of concern through processes of authorisation (substances of very high concern) and restriction (substances of any concern):

- Substances that may have serious and often irreversible effects on human health and the environment can be added to the candidate list to be identified as Substances of Very High Concern (SVHCs). Following the identification as SVHC, a substance may be included in the Authorisation list, available under Annex XIV of the REACH Regulation, the "List of Substances Subject to Authorisation", short "**Authorisation list**". If a SVHC is placed on the Authorisation list, companies (manufacturers and importers) that wish to continue using it, or continue placing it on the market, must apply for an authorisation for a specified use.
- If a Member State(s) or the European Chemicals Agency (ECHA), upon request of the Commission, considers the use of a substance (or compound) in specific

articles, or its placement on the market in a certain form to pose an unacceptable risk to human health and/or to the environment that is not adequately controlled, it shall prepare a restriction dossier. ECHA can also on its own initiative prepare a restriction dossier for any substance in the authorisation list if the use of that substance in articles poses a risk to human health and the environment that is not adequately controlled. These restrictions are laid down in Annex XVII of the REACH Regulation: "Restrictions on the Manufacture, Placing on the Market and Use of Certain Dangerous Substances, Mixtures and Articles". The provisions of the restriction may be made subject to total or partial bans, or conditions for restrictions, based on an assessment of the risks and the assessment of the socio-economic elements.

REACH Annex XIV and Annex XVII are essential for the evaluation of RoHS exemptions. If the substance in the scope of the exemption request is included in REACH Annex XIV, and/or its intended use is restricted in REACH Annex XVII at the time of the evaluation, it must be evaluated whether the environmental and health protection afforded by REACH would be weakened if the exemption would be granted under the provisions of RoHS.

Furthermore, substances which are subject to authorisation or restriction processes are also reviewed so that future developments may be considered where relevant.

2.5.3. Scientific and technical practicability of substitution or elimination and reliability of alternatives (criteria I and II)

Art. 5(1)(a)(II) allows an exemption to be granted if the elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II is scientifically or technically impracticable. For the purpose of the exemption assessment, 'elimination' is defined as avoidance of a restricted substance by changing the design or technology so that the material or component containing the restricted substance is no longer required. 'Substitution' is defined as replacing a restricted substance in a material by another substance.

The reliability of substitutes in Art. 5(1)(a)(III) is an inherent condition of the 'scientific or technical practicability of substitution or elimination' since a substitute whose reliability is not ensured is technically impracticable. If the substitute was not reliable, it would not be proposed as a viable alternative to the use of the RoHS restricted substance in question. It is therefore evaluated in this context and not separately. Nonetheless, in some cases, there may be substitutes that are suitable for a certain range of applications, but not for all (for example for general use but not for industrial use where conditions of use may demand more robust devices). Such aspects are to be considered in the assessment.

Assessment of fulfillment of this criterion

For the assessment of criteria I and II, it is of importance:

- To clarify the scope of applications to be covered by the requested exemption;

- To clarify the function of the RoHS substance within the application in terms of how the substance properties and qualities enable its function in the application;
- To clarify the availability (at present or in the future) and reliability of possible alternatives for the use of the RoHS substance in relation to options for substitution and elimination;

2.5.4. Impacts of substitution or elimination on environment, health and safety (criterion III)

Art. 5(1)(a)(III) justifies granting exemptions if the total negative environmental, health and consumer safety impacts caused by the substitution of the substance(s) addressed by RoHS are likely to outweigh the total environmental, health and consumer safety benefits thereof. Like for the impracticability of substitution and elimination and lack in the reliability of substitutes, applicants raising environmental, health and safety arguments to justify their exemption request need to provide the respective evidence, which in practice can be more challenging compared to technical evidence related to substitution and elimination. The holistic consideration of environmental and / or health and/or safety-related impacts requires a far more complex methodological approach and is a very data-intensive endeavor. Thus, it can be observed that where possible, applicants usually argue the justification of a request based on technical arguments for or against the scientific and technical practicability of substitution or elimination and the reliability of substitutes. In such cases, environmental, health and safety aspects may be raised to strengthen the argumentation. However, such impacts are less frequently presented as justification for exemptions than technical arguments as it is difficult to conclude as to fulfillment of this criterion without specifying the full range of related impacts.

Life Cycle Assessment (LCA) is one method which could be used to derive results supporting this kind of justification for exemptions. However, it has to be borne in mind that LCA only addresses potential environmental impacts throughout a product's life cycle (see EN ISO 14040:2006). Health and safety aspects are not covered by this method. Against this background, applicants and other stakeholders have to take into consideration whether other methods or a combination of methods (e.g. risk assessment, exposure assessment, safety analysis, etc.) could be more appropriate to cover health and consumer safety impacts caused by substitution, in order to support or object a request for exemption or its revocation.

LCA is an internationally harmonised and standardised method. Whereas EN ISO 14040 sets out the principles and provides a framework for such analysis and EN ISO 14044 provides specific requirements and guidelines for application of the analysis method. Several requirements depend on the intended use of the results. The most extensive requirements, especially with regard to reporting as well as in relation to the need for a formal critical review, have to be met in those cases where LCA studies include comparative assertions intended to be disclosed to the public. In the case of supporting or refusing a request for exemption, both criteria apply: the results have to be publicly available and the LCA necessarily implies the comparison between a situation with / without use of the requested exemption at hand.

The ISO standards allow several methodological choices and leave some room for implementation, e.g. the selection of impact assessment models etc. Against this background, additional requirements based on the EU methodology on Product Environmental Footprint (PEF)[3] are introduced below in order to provide conclusions from LCA studies that are reproducible, comparable and verifiable. It is noted that at the time of writing of this manual, the Commission methodology on PEF is specified as a suggestion for methodology improvements. Once this initiative is transferred to a Commission Communication, the weighting approach of PEF could be applied (based on available specific PEF-CR category rules or on the general PEF approach).

Further product specific specifications such as typical bill of materials (BOM) and standardised conditions of usage are available for different product groups in the context of the Ecodesign Directive, which provides consistent EU-wide rules for improving the environmental performance of products.

Based on these preliminary considerations, LCA studies intended to be considered in relation to Art. 5(1)(a)(IV) shall meet the following requirements. In accordance with the PEF methodology, the terminology is defined as follows:

- The term "shall" is used to indicate what is required from a LCA study intended to be used to support or to object a request for exemption.
- The term "should" is used to indicate a recommendation rather than a requirement. Any deviation from a "should" requirement has to be justified by the applicant or stakeholder who uses LCA studies in the exemption context.
- The term "may" is used to indicate an option that is permissible without further justification.

Requirements:

- The data to be used for the LCA study shall be in accordance with the exemption considered/ requested in relation to (i) time-related coverage, (ii) geographical coverage, and (iii) technological coverage of the exemption and relevant substitutes. In particular, the comparison must be representative in terms of the technologies used and their state of development over time.
- As generally results of LCA studies strongly depend on data and assumptions in relation to energy supply and recycling, the LCA shall comply with the modelling requirements on electricity use and end of life modelling of the EU PEF methodology.
- The LCA shall take into account a comprehensive set of impact categories and should use the 16 PEF impact categories and models, including the characterisation factors provided.

[3] The requirements are based on both, the Recommendation 2013/179/EU on the use of common methods to measure and communicate the life cycle environmental performance of products and organisations and the recently published suggestions for updating the PEF method (Zampori and Pant, 2019).

- If the exemption considered relates to products which are covered by implementing measures according to the Ecodesign Directive (e.g. lighting, displays), LCA studies shall take basic definitions in relation to BOM and condition of usage into consideration.
- The LCA reports submitted shall comply with the reporting requirements of EN ISO 14044, section 5.1 to 5.3. The report shall include the identification of hotspots to be understood as (i) most relevant impact categories, (ii) most relevant life cycle stages, (iii) most relevant processes, and (iv) most relevant elementary flows.
- The LCA study shall include a critical review according to EN ISO 14044, section 6.3. This means that the critical review has to be carried out by interested parties. The chairperson of the review shall select at least one representative of the EU Commission as a member of the group of interested parties.
- The scope of the critical review shall be documented according to the requirements of ISO TS 14071.

2.5.5. Availability of substitutes and socioeconomic impact of substitution (criterion IV)

Article 5(1)(a)(V) stipulates that "*Decisions on the inclusion of materials and components of EEE in the lists in Annexes III and IV […] shall take into account the availability of substitutes and the socioeconomic impact of substitution*." According to Art. 3(25), the "'*availability of a substitute means the ability of a substitute to be manufactured and delivered within a reasonable period of time as compared with the time required for manufacturing and delivering the substances listed in Annex II*."

In respect of the 'availability of substitutes' and 'socio-economic impact of substitution', the European Commission's Frequently Asked Questions Document for RoHS[4] specifies that "*an exemption cannot be based on these parameters only. These are not considered to be as significant as the three criteria mentioned above. If a criterion is fulfilled, the parameters may subsequently influence the decision-making*."

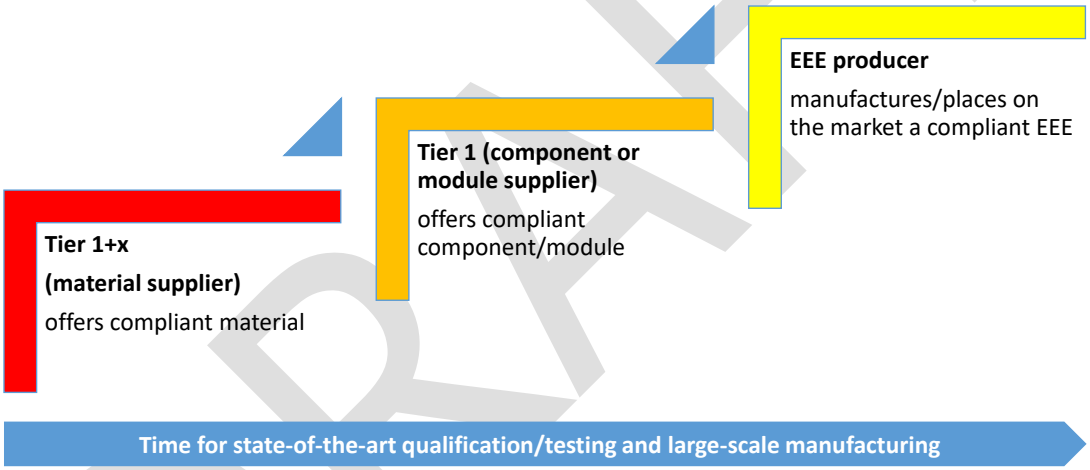
Where lacking information does not allow ascertaining the fulfillment of criteria (I-III), but where data suggest that the socioeconomic impacts of substitution or the limited availability of the substitutes might reach a level where impacts are comparable to the scientific and technical impracticability of substitution or elimination, i.e. resulting in a market supply gap, or in outweighing the total environmental, health and consumer safety benefits of the substitution.In such cases, an exemption might be justifiable in line with Art. 5(1)(a) based on socioeconomic impacts or the non-availability of the substitute.

[4] See: https://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf, pg. 25

2.5.6. Assessing the duration of exemptions

Article 5(1)(a)(VI) requires decisions on the duration of an exemption to consider adverse impacts on innovation and life-cycle thinking. Recommendations as to the duration of an exemption shorter than the maximum period are justified if substitution or elimination of the restricted substance in the applications in scope of the exemption is expected to be possible within a shorter time period. Applicants sometimes already mention upcoming RoHS-compliant solutions in their exemption application. Stakeholders may also address such solutions during the stakeholder consultation, or the consultants may come across such alternatives in the course of the evaluation. Provided these solutions for substitution or elimination are scientifically and technically practicable, it may still be justified to grant the exemption for a certain time, mainly for testing and qualification, the duration depending on the stage of development and where in the supply chain the solution is available. Figure 2-2 and the following explanations illustrate the situation.

Figure 2-2: Compliant solutions in the supply chain and duration of exemptions



Source: Own illustration

1. Substitution or elimination have been practiced successfully on material supplier level

   - A supplier offers a compliant material, which, however, needs to be tested or qualified in the supply chain, i.e. in the component or module in which it shall be used, and in the EEE.
   - Example: A new type of lead-free solder which can replace lead high melting point solder (lead HMPS, c.f. exemption 7 (a) listed in Annex III).

2. Substitution or elimination have been practiced successfully on component or module level

- A manufacturer of a component or module has successfully substituted or eliminated the restricted substance, but the component/module still needs to be tested and qualified for use in EEE.
- Example: The new type lead HMPS has been tested and qualified for die attach.

3. Substitution or elimination have been practiced successfully on EEE producer level

    - A producer of EEE can apply the compliant component or module in EEE, but is not yet ready for industrial scale production.

Since producers are responsible for the reliability and safety of their products, the time for state-of-the-art testing and qualification needs to be taken into account when deciding about the duration of exemptions. The earlier in the supply chain substitution or elimination has been practiced, the more time may be required to allow for testing and qualification of the compliant solution up to the use in EEE. Additional time may also be required for the industrialisation and production ramp up of the compliant product and also for recertification of equipment which may be a condition for marketing in some sectors (e.g., medical devices).

According to Art. 5(1)(a), "Decisions […] on the duration of any exemptions shall take into account the **availability of substitutes** and the **socioeconomic impact of substitution**" and "[…] any potential adverse **impacts on innovation**. Life-cycle thinking on the overall impacts of the exemption shall apply, where relevant".

RoHS Art. 3(25) defines the *"availability of a substitute' as […] the ability of a substitute to be manufactured and delivered within a reasonable period of time as compared with the time required for manufacturing and delivering the substances listed in Annex II*". Lacking availability of substitutes could, for example, occur in cases where substitution is in principle possible, but the industrial scale production is still in the ramp up phase resulting in undue delivery times in the supply chain. In such a case, an exemption could be granted for a period after which it is foreseeable that the substitute will be available.

Socioeconomic impacts of relevance for the duration of an exemption could arise, for example, if the use of a substitute requires the requalification of staff to warrant its safe and reliable use. Another possibility could be that the cost of substitutes is prohibitively high in the initial phase until foreseeably more than one manufacturer produces the substitute, thus spurring competition and decreasing prices. In such cases, an exemption could be renewed or granted for a certain time despite of scientifically and technically practicable substitution or elimination.

Negative impacts on innovation could emerge if a substitute is in development and expected to be market ripe within a few years. Specifying a shorter duration in this case would ensure that the assessment is revised when the substitute becomes available to clarify if the exemption is still needed or if it can be revoked.

2.6. The preparation of the Report

After the evaluation has been closed, the consultants prepare a report for the Commission providing the following core information:

- the technical background of the requested exemption;
- the applicants' and other stakeholders' justification why the exemption is required and should be granted;
- other stakeholders' justifications and arguments why the exemption from their point of view is not required and should therefore not be granted;
- the consultants' assessment of the presented evidence and arguments and of their relation to Article 5(1)(a) – here additional information retrieved from publicly available sources or through contact with relevant experts and professionals is also to be assessed;
- the consultants' recommendation for the requested exemption(s) including the wording and an expiry date.

The Commission might ask the consultants for feedback and clarifications on technical and other aspects, or adjustments of certain aspects e.g. regarding how the requirements of Art. 5(1)(a) were applied. The report as approved is published.