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Proposed approach to hazardous substance criteria development

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Summary: This paper presents the proposed approach to interpretation of Articles 6(6) and 6(7) of the Ecolabel Regulation (EC) 66/2010 during product criteria development. These articles have the objective of avoiding the presence of inherent hazards in ecolabelled products.

The approach outlined in this paper synthesises experience gained by the Product Bureau during product criteria development with discussion and feedback from Horizontal Task Force members between March 2012 and November 2013. Participants in the Task Force were Austria, CEFIC, Denmark, DG ENV, EEB/BEUC, Eurometaux, Germany and the UK. The overall approach retains its basis in the avoidance of hazards, but where substitutes are not yet available risk and exposure shall be considered in order to protect consumers.

The proposed approach presented in this paper is task-orientated and intended to achieve a high level of integration with the overall criteria development process, which takes a whole life cycle approach and indicatively aims to reflect the performance of the best performing 10-20% of products on the market. The proposal consists of a series of 6 interrelated tasks:

- Product definition and bill of components, materials and substances: A representative profile would be built up of the material and chemical composition of the product with distinguisment made between chemical mixtures, articles and complex articles constisting of component materials, small parts and devices. This would include preliminary substitution evidence from stakeholders.
- Substance and hazard class screening: An initial screening would be carried out of the product composition against the SVHC Candidate List, REACH Annex XIV and the Ecolabel hazard list for substances and hazards that are relevant to the product as a whole and its components and ingredients. The relevance of hazards along the products life cycle would also be identified.
- Product hazard substitution and green chemistry initiatives: A picture would be built up of the practical substitution potential demonstrated by the leading products on the market in order to define the ambition level for the criteria.

- Screening and investigation of derogation requests: A standard data collection form would be used to focus the screening and investigation of requests. A differentiation will be made between hazards by CLP Category and strict conditions will apply where derogations are made.
- Specification of criteria and derogation conditions: Tailoring and specification of the criterion and any specific derogation conditions according to the findings of Tasks 1-4.
- Specification of verification requirements: Tailoring and specification of the assessment and verification requirements according to the burden of proof required for the product and the nature of the product's supply chain.

The approach is grounded in a number of scientific principles identified by JRC-IPTS and based on, as far as possible, on consensus points from comments and discussions:

- Differentiation between chemical mixtures, articles and complex articles: The approach shall enable the distinction to be made between different forms of product and, in the case of articles, their component parts. CLP mixture rules shall additionally apply where relevant to the final product.
- Grouping of substances according to function: For the purposes of informing performance comparisons between substances and simplifying derogations it is proposed that, where appropriate, substances should be grouped by common function;
- Reflection of the substitution potential: The ambition level of the criteria for each product should reflect the substitution potential existing in the market, without compromising the quality and fitness for use of the product. Scientific evidence of substitutions should be gathered using a standardised data request form.
- Precautionary approach: This shall guide the evaluation of derogations and substance restrictions, especially if inherently safer products are available on the market. Decisions shall be made on a case-by-case basis and based on the latest scientific evidence.
- Prioritisation of the hazard classes: Whilst there were some calls for the list to be shortened the most practical interim measure would be to prioritise hazard classifications based on REACH Article 57 criteria, the CLP category of hazard and, where substitution is not possible, exposure pathways related to the specific product. Hazards would be screened following a modular approach reflecting the composition of the product and supporting the screening of mixtures, articles and complex articles. Mixture classifications would apply to final products that are mixtures.
- Setting of concentration limits: Where verifiable concentration limits would be used to restrict the use of derogated hazards, define cut-off limits for unintentionally added substances (impurities, contaminants and process residues), reflect the relative significance of components within complex articles.
- Streamlined and transparent derogation decisions: A streamlining of the process based on a standardised information data request pro-forma which would then be evaluated by JRC-IPTS and made available for scrutiny by a sub-group of stakeholders. Where relevant cross-product derogations from other products may be considered.
- Tracing of hazards along the product's life cycle: Where required, derogation conditions would be specified to address the point in the life cycle of the product where a hazard classification pose the most significant risks to the environment, consumers and workers.
- Verification to provide assurance: If Safety data sheets' (SDS) data is insufficient or poorly completed, if information is not available in ECHA databases or if evidence suggests that a supply chain may pose sufficient risks of non-compliance then stricter verification in the form of laboratory analysis of the final

product and/or components and ingredients by accredited laboratories would be required.

It is anticipated that supporting guidance notes could be developed in order to further support the criteria development process and to address open issues.

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In the first part of this paper we outline the proposed principles of compliance with the regulatory and logistical constraints of Ecolabel criteria development. We also present an overview of the proposed approach and how it would integrate with the main criteria development process.

In the second part we outline the proposed six step approach to hazardous substance criteria development, before highlighting open issues arising from the Horizontal Task Force for ongoing discussion.

The proposed grouping of the hazards according to their CLP Category and REACH Article 57 status, together with substitution and derogation data sheets *are included in an Appendix*.

1. Guiding principles for hazardous substance criteria development

The hazardous substance criteria in each product group must be developed in response to Article 6(6) and 6(7) of the Ecolabel Regulation (EC) No 66/2010. This states that the Ecolabel may not be awarded to products containing substances classified with certain types of hazard. The Regulation also sets out in pre-amble (7) a broader aim to:

> *[substitute] hazardous substances by safer substances, as such or via the use of alternative materials or designs, wherever it is technically feasible*

Moreover, the substitution of hazardous substances is a broader policy objective of the European Union to which the EU Ecolabel can contribute. This is highlighted in the proposal for a 7th Environmental Action Programme which under Priority Objective 3 seeks to *'safeguard EU citizens from environment-related pressures and risks to health and wellbeing'*. Objectives to be achieved by 2020 include:

> *Ensuring the combination effects of chemicals and safety concerns related to endocrine disruptors are effectively addressed, and risks for the environment and health associated with the use of hazardous substances, including chemicals in products, is assessed and minimised.*
>
> *Developing an EU strategy for a non-toxic environment, supported by a comprehensive chemical exposure and toxicity knowledge base and conducive to innovation of sustainable substitutes.*

The implementation of Articles 6(6) and 6(7) cannot, however, take place in isolation from the broader objectives of the Ecolabel Regulation and EU environmental policies on eco-innovation. In doing so there are a number of practical considerations relating to the ecolabelling process that must be considered. These include:

- The need to identify the products that indicatively reflect, indicatively, the best performing 10-20% on the market,
- The logistical constraints of the criteria development process as a whole and;
- The ability of Competent Bodies to verify compliance.

In order to reflect these broader considerations, which can be considered to constrain the scope of the hazardous substance criteria, we have sought to establish eight guiding principles with which the proposed approach must comply:

1. Front runner feasibility: The substance inventory shall reflect the best products on the market in terms of hazard substitution. Front runners should therefore be able to comply;

2. Integrating life cycle thinking: The approach shall reflect the relevance of hazards along the life cycle of the product. The overall environmental performance of the product shall also be taken into account when considering the potential for hazard substitution. In this respect LCA may be a complementary tool (see the technical note below);
3. Preventative action based on a precautionary approach Shall be a guiding element for evaluating derogations and substance restrictions, especially if inherently safer products are available on the market. Decisions shall be made on a case-by-case basis and based on the latest scientific evidence. This may be with reference to precautionary positions taken by Member States, the European Union [1] and/or international intergovernmental bodies.
4. Reference to EU policy tools: REACH and CLP shall be a key reference point used as an evidence base for substances and the prioritisation of hazards. Studies based on the product environmental footprint guide[2] should be used as a reference regarding the information on the product lifecycle assessment performance. It should be noted, however, that the objectives of REACH and CLP differ from the Ecolabel.
5. Proportionality within the workplan: The burden of criteria development shall not be disproportionate to the resources allocated to the rest of the criteria set e.g. discussions on a small number of substances should not dominate AHWG and/or EUEB meetings. All sub-tasks within criteria development shall be feasible within the Ecolabel policy cycle (e.g. approximate 1 year revision period)
6. Administrative burden: Verification shall be manageable from the perspective of criteria developers, applicants (industry) and Competent Bodies.
7. Verifiability: It shall be possible to meaningfully verify compliance with the criteria in a way that provides a high level of assurance to consumers, reflects the practical potential for applicants to obtain information from the supply chain and which excludes the potential for 'free riding' by applicants.
8. Horizontal applicability: The approach shall be applicable to all products regardless of their complexity, although aspects will require tailoring depending on the type of product and distinct functional requirements.

These eight tests have been applied to the approach in order to apply realistic checks and balances to the outcomes of the Task Force.

Technical note
Hazardous substances and LCA

Regulation (EC) No 66/2010 on the EU Ecolabel promotes products with reduced impacts during their entire life cycle. Article 6 highlights the importance of taking a whole life cycle perspective to the evaluation of the most significant environmental impacts, including:

- Impacts on climate change, nature and biodiversity,
- Energy and resource consumption,
- Generation of waste,
- Emissions to all environmental media, pollution through physical effects
- The use and release of hazardous substances.

The EU Ecolabel thus covers both aspects related to environmental impacts conventionally evaluated through the LCA methodology and other "non-LCA" aspects related to health and

[1] European Commission, *Communication from the Commission on the precautionary principle*, COM (2000)1

[2] *Commission Recommendation of 9 April 2013 on the use of common methods to measure and communicate the life cycle environmental performance of products and organisations*

inherent safety of products.

The approach outlined in this document provides guidelines on how to handle and reduce hazards from substances and materials used in products included within the scope of the EU Ecolabel. This is mainly related to the analysis and screening of hazards associated to the products that, even with the state of art, are typically not fully assessed in LCA.

Some impact assessment categories conventionally included in LCA studies are directly (e.g. human toxicity) or indirectly (e.g. ozone depletion) related also to health issues, However, the LCA methodology typically characterises environmental burdens attributed to inputs and outputs from the product system and it does not analyse the hazards associated to a product, as done for instance in risk assessment. The identification of potential sources of hazard in LCA is constrained also by the resolution used in the definition of the product system (e.g. the cut-off limits set) and the representativeness of the lifecycle inventory data considered in the assessment.

The proposed approach to the restriction of hazardous substances could potentially be extended to include the application of LCA to evaluate if chemical substitution can lead to any environmental performance trade-offs. In this sense, the EC's reference is the Product Environmental Footprint guide, as described in the Commission Recommendation of 9 April 2013 on the use of common methods to measure and communicate the life cycle environmental performance of products and organisations.

The same recommendation point out that Environmental Footprint can be used to describe the existing pressures on the environment related to products and as such it can complement but not substitute other tools that have a different scope and objective (e.g. (Environmental) Risk Assessment, Health and Safety regulations at product level or related to safety at the workplace).

2. What Article 6(6) and (7) of the Ecolabel Regulation (EC) No 66/2010 require

The Ecolabel Regulation (EC) 66/2010 states that the Ecolabel may not be awarded to products containing substances classified with certain types of hazard. The Regulation as it is written takes an approach based on the substitution of inherent hazards as opposed to reducing the risk of exposure.

This requirement is set out in two Articles, the first of which, Article 6(6), refers to specific groups of classifications under the CLP Regulation (EC) No 1272/2008 and to substances which meet the criteria described in Article 57 of the REACH Regulation (EC) No 1907/2006.

Article 6(6) The EU Ecolabel may not be awarded to goods containing substances or preparations/mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR), in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures nor to goods containing substances referred to in Article 57 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency".

The Article 57 criteria are quoted in Box 2 below. They include Category 1A and 1B carcinogenic, mutagenic and reproductive (CMR) toxins as well substances that are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

Interestingly the wording of Article 6(6) does not state explicitly that the substances should already have been identified according to the procedure in Article 59.

Technical note
Criteria for Substances of Very High Concern (SVHC) (REACH Article 57)

(a) substances meeting the criteria for classification in the hazard class carcinogenicity category 1A or 1B in accordance with section 3.6 of Annex I to Regulation (EC) No 1272/2008;

(b) substances meeting the criteria for classification in the hazard class germ cell mutagenicity category 1A or 1B in accordance with section 3.5 of Annex I to Regulation (EC) No 1272/2008;

(c) substances meeting the criteria for classification in the hazard class reproductive toxicity category 1A or 1B, adverse effects on sexual function and fertility or on development in accordance with section 3.7 of Annex I to Regulation(EC) No 1272/2008;

(d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;

(e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;

(f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

The second article 6(7) does, however, recognise that in certain circumstances there may be a technical or environmental justification for still using a substance restricted by Article 6(6). It describes how specific categories of goods containing substances referred to in Article 6(7) may be derogated under certain conditions.

The prospect of derogation is, however, ruled out for Substances that have been identified as Substances of Very High Concern according to Article 59 of the REACH Regulation and which are present in the final product at concentrations higher than 0.1%.

Article 6(7) For specific categories of goods containing substances referred to in paragraph 6, and only in the event that it is not technically feasible to substitute them as such, or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall environment performance compared with other goods of the same category, the Commission may adopt measures to grant derogations from paragraph 6. No derogation shall be given concerning substances that meet the criteria of Article 57 of Regulation (EC) No 1907/2006 and that are identified according to the procedure described in Article 59(1) of that Regulation, present in mixtures, in an article or in any homogeneous part of a complex article in concentrations higher than 0,1 % (weight by weight).

3. Developing a consistent approach

In this section we outline the proposed approach to hazardous substance criteria development. The framework reflects as far as possible the consensus points arising from discussions and written feedback received from Task Force participants Austria, CEFIC, Denmark, DG ENV, EEB/BEUC, Eurometaux, Germany, Norway and the UK between March 2012 and July 2013. This was also supplemented by feedback received at the Ecolabel Competent Body Forum held in November 2012 and a compilation of the JRC-IPTS Product Bureau's experience to date with hazardous substances criteria development (see JRC-IPTS Chemical Task Force discussion paper 23rd October 2012).

The proposed framework consists of six tasks that follow a process. During this process stakeholder Ad Hoc Working Groups (AHWG's) and the EUEB would be consulted on key decisions such as derogations. The six steps are illustrated by Figure 3.1 below:

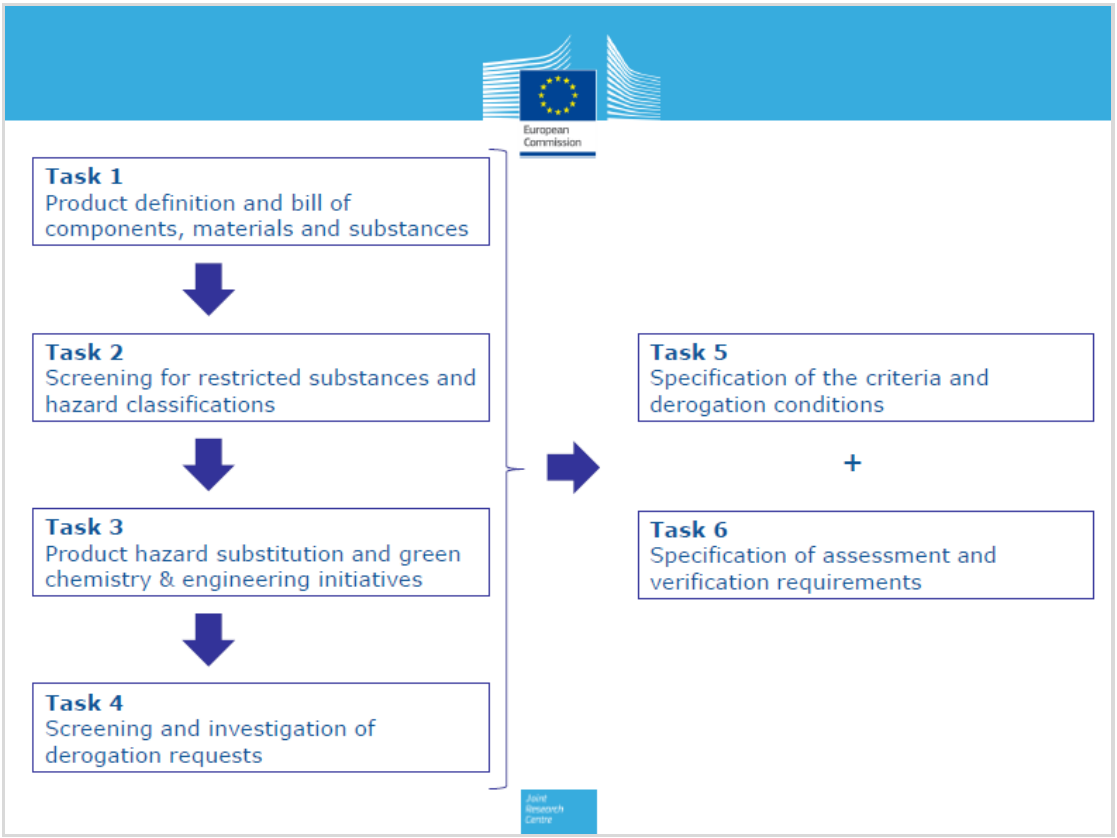

Figure 3.1 Proposed six steps in hazardous substance criteria development

Each phase is illustrated by a schematic together with a written description of the associated work packages and technical components. Whilst the six step approach implies a linear work process it is important to emphasise the interrelationships between the steps.

4. Integration with the criteria development process

It is intended that the chemicals approach is, as far as possible, integrated within the broader criteria development process. In this section we therefore highlight how the stakeholder participation during the process would be managed.

The process is envisaged as a series of tasks, some of which are interrelated. These are to be worked through sequentially as the criteria development process progresses. The process is intended to be iterative, relying on interaction with stakeholders via the Ad-Hoc Working Groups, Sub-Groups and bilateral communication. An overview of how the tasks are to be integrated within the criteria development process is presented in figure 3.2.

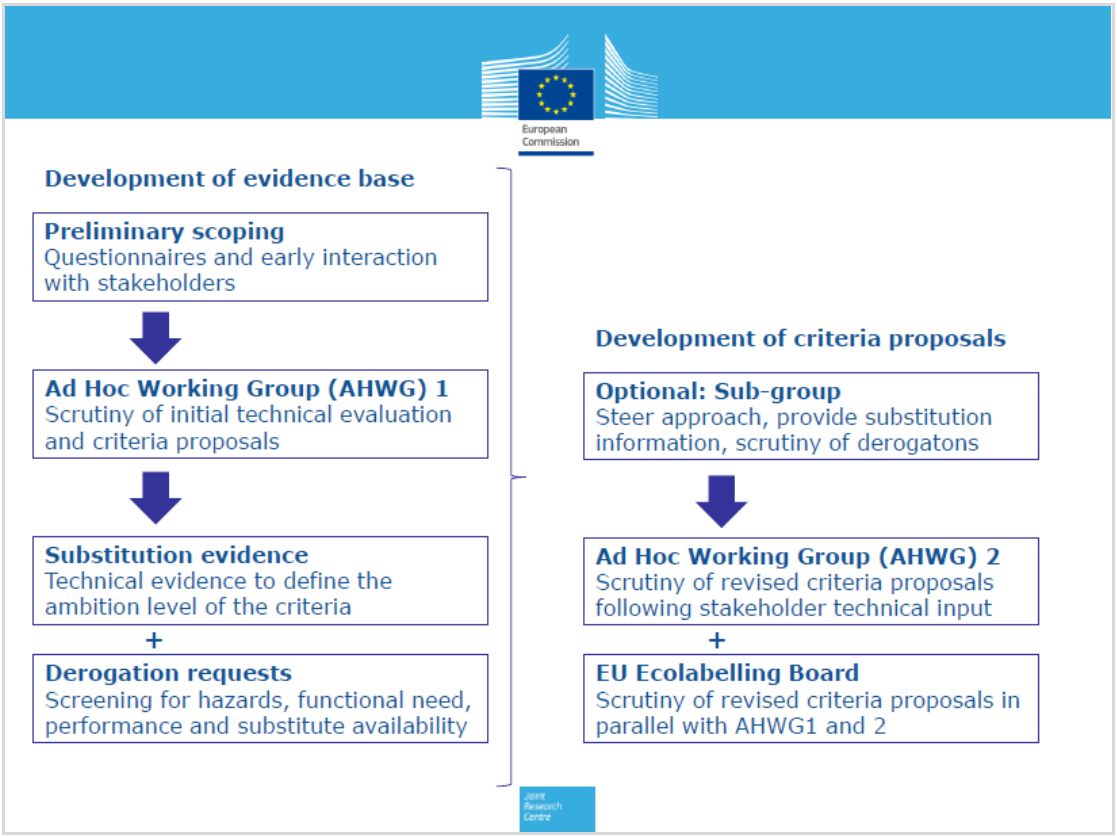

Figure 3.2 Indicative overview of the hazardous substance criteria development process

4.1 Preliminary scoping

Prior to the first Ad-Hoc Working Group (AHWG) meeting initial research would be carried out by JRC-IPTS to understand the product and the nature of any hazards that it might contain. This would be informed by questionnaires and early interaction with registered stakeholders. An initial summary of available knowledge of hazards that may be associated with the product would be presented in the draft technical background reports and at the first AHWG.

4.2 The option to establish a hazardous substance sub-group

It has been identified that during the detailed analysis of hazardous substances additional support may be required for JRC-IPTS (or other criteria developers) beyond the the Ad-Hoc

Working Groups (AHWG's). The option therefore exists to convene sub-groups for each product.

Product sub-groups of 5-6 stakeholders would meet in-between AHWG's, usually via phone conference, and their role would be to provide informed input into technical discussions and to steer the substitution and derogation analysis. They would be required to minute their discussions and to report their activities to the AHWG and EUEB.

Sub-groups would be constituted to ensure balanced representation and the presence of product/sectoral specific expertise. In addition to Commission representation a sub-group is proposed as being made up of 1-2 Member States, 1-2 front runner industry representatives, 1-2 NGO representatives and, preferably, an independent scientific expert ideally drawn from an EU scientific committee or as agreed by all representatives in the sub-group.

Process note
Hazardous substance stakeholder sub-group

- Sub-group of 5-6 stakeholders
- Aim is inform/steer criteria development between AHWG's
- Indicative representation: 1-2 Member States, 1-2 industry, 1-2 NGO, independent technical expert
- Steering of substitution identification and derogation analysis
- Report to AHWG and EUEB

4.3 Managing substitution evidence and derogation requests

The substitution of inherent hazards that may be present in consumer products with inherently safer substances, mixtures or materials is a key aim of the EU Ecolabel. It is therefore important that the potential to eliminate or minimise hazards with a product is fully investigated.

In cases where it has not yet proven to be possible to substitute hazards that are required to provide core functions of a product then derogations may be required.

During the criteria development process stakeholders shall therefore be invited to submit evidence in support of hazard substitutions made by manufacturers and the need for derogations of substances.

4.3.1 Substitution evidence

The focus of the EU Ecolabel is on the development of criteria that reflect the best performing products on the market. In order to determine an ambition level for the criteria that can be achieved by products in the market it is therefore important to understand the extent to which hazards can already by substituted.

The gathering of technical evidence on chemical substitutions made by manufacturers in order to minimise hazards and achieve inherent function is therefore an essential early step in the criteria development process. Further guidance is provided under Task 3.

A request for substitution evidence shall, in general, be made in the preliminary research phase and at the first AHWG followed by indicative conclusions on the state-of-the-art. A standard data collection form is to be used (see Appendix 2). A summary of the analysis of

substitutes shall be discussed within the sub-group, if formed, and ideally circulated to stakeholders before inviting derogation requests (see 3.3.2 and Task 3).

Process note
Substitution evidence collection

- Call for evidence in questionnaire (preliminary phase) and at AHWG1
- Use of standard data collection form (see appendix 2)
- Screening of evidence for scientific basis, market diffusion and product implications

4.3.2 Derogation requests

The potential for the continued use of substances under derogation from the hazardous substances criteria is described in Article 6(7) of the Ecolabel Regulation, which states that:

> *'…only in the event that it is not technically feasible to substitute them as such, or via the use of alternative materials or designs, or in the case of products which have a significantly higher overall environment performance compared with other goods of the same category, the Commission may adopt measures to grant derogations…'*

An opportunity is therefore given within each product group for industry to submit derogation requests for consideration by JRC-IPTS (or other criteria developers). This would usually be announced to stakeholders at the first AHWG but could also follow publication of the draft findings from the substitution analysis. A standard data collection form is to be used for requests (see Appendix 2).

Derogations shall be screened based on the nature of the hazards, the functional need and performance benefit from the derogation and the availability of substitutes. Further guidance is provided under Task 4. Requests received and draft decisions on whether derogations shall be granted shall be presented for initial discussion at the AHWG2, within the hazardous substance sub-group (if convened) and subsequently to the EUEB.

Process note
Call for derogation requests

- Call for evidence at or following AHWG1
- Use of standard data collection form (see appendix 2)
- Screening of based on functional need and the availability of substitutes

Task 1: Product definition and bill of components, materials and substances

Aim: To build-up a profile of the material and chemical composition of representative product(s) and their associated articles, including parts, devices and consumables, and/or ingredients.

Task 1a. Characterise the product

Timescale: Preliminary report

The first step would be to select and define a representative product or products and their possible bill of components, materials and/or substances. Here a differentiation shall be made between two main physical forms of product:

- Articles: Defined by REACH and CLP as 'an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition'. The article could be composed of further articles, parts, accessories, consumables and packaging;
  Examples: *printer, computer, bed mattress, shirt*

- Chemical mixture: Defined by REACH and CLP as 'a mixture or solution composed of two or more substances'. The composition could therefore include the different ingredients of the product that make up the products formulation, some of which may in turn consist of a number of mixtures or formulations.
  Examples: *soap, shampoo, paint*

In some cases the product may be a combination, for example, where the packaging (an article in itself according to REACH guidance) is required to contain a mixture e.g. soap, paint. This distinction shall also be used to determine whether packaging is included at this stage.

The Ecolabel Regulation refers to 'complex article' (i.e. an article composed of many individual articles) although this appears to have no definition in European law. For the purposes of the EU Ecolabel the following definition is suggested:

> *'An object composed of an assembly of different articles which during production is given a special shape, design, structure and component configuration which determine its function to a greater degree than does its chemical composition or its constituent articles'*

The Ecolabel Regulation also refers to homogenous parts of a complex article which could be interpreted to include, for example, homogenous plastic and metals components. Whilst no specific definition can be found in REACH or CLP, the RoHS Directive 2011/65/EU defines a homogenous material as:

> *'one material of uniform composition throughout or a material, consisting of a combination of materials, that cannot be disjointed or separated into different materials by mechanical actions such as unscrewing, cutting, crushing, grinding and abrasive processes'*

Moreover, a distinction may also be required between homogenous material components (e.g. textiles, foams, plastics, metal structures) and those that are individual *component devices,*

system components (e.g. fans, drives, processors) or *consumables* used within a product. In some cases component devices or consumables may also contain chemical substances that are intrinsic to their function e.g. battery electrolyte, printer ink cartridge.

An additional identification of complex articles containing component devices and/or consumables shall therefore be made. Moreover, and as in the case of imaging equipment, there may be distinguishment of small component parts or materials such as screws, clips and cables that form part of the assembly of an article.

An indicative characterisation of currently ecolabelled products into chemical mixtures, articles composed of materials and articles composed of materials and devices or system components is presented in Table 1.

Table 1 Indicative characterisation of currently ecolabelled products

Mixtures	**Articles composed of materials**	**Articles composed of materials and devices**
Paints and varnishes Lubricants Soaps and shampoos All-purpose cleaners Hand dishwashing detergents Detergents for dishwashers Laundry detergents I&I Laundry Detergents I&I Automatic Dishwasher Detergents Soil improvers Growing media	Textiles Footwear Bed Mattresses Sanitary tapware Toilets and Urinals Absorbent Hygiene Products Hard floor coverings Textile floor coverings Wooden floor coverings Wooden furniture Newsprint Copying and graphic paper Printed Paper Products Converted paper products Tissue paper	Light sources Imaging equipment Televisions Personal and notebook computers Hydronic Heating generators Heat pumps *Associated consumables:* Batteries Ink cartridges

Task 1b. Build-up a bill of components, materials and/or substances

Timescale: Preliminary report

Depending on the nature of the product characterised in Task 1a a more detailed chemical composition and/or a bill of materials and component devices shall be put together. Sources of information could include manufacturers, literature, peer reviewed studies and LCA bills of materials. The main focus shall be on identifying where chemicals are used to impart specific functions to the final product.

A distinction shall be made between primary functions that are intrinsic to the product and secondary functions that may be introduced in order to meet additional, new consumer expectations. This will serve to better inform discussions with the stakeholders about the relative importance of the product having certain functions.

Coatings, treatments and additives applied to components in order to carry out a specific function shall be identified, including their indicative concentrations on the final product. Because of the potential risk of contamination component materials containing recycled content shall also be identified for all products.

Articles that are, or can come into direct contact with the consumer, as well as where there is potential for a direct exposure of consumers to substances that may be released from the product into the environment shall be identified. Where alternatives do not exist this will enable consumer concerns that are substantiated by evidence of exposure pathways can be addressed as a priority.

In the case of complex electrical devices the scope of analysis of the bill of components shall be more limited in order to make verification more feasible. The focus shall be on primary material components, component devices (or 'system components') and their sub-components from tiers 1 and 2 of the supply chain which then form part of the final assembly of the product. Smaller components used to fix together the product may be excluded based on a product-specific weight threshold.

Task 1c. Develop an initial understanding of the supply chain

Timescale: Preliminary report

The evidence gathered for each product should be sufficiently detailed to enable the relative significance of intermediate suppliers, and the ability of applicants to obtain information from their supply chain, to be determined. This shall include identification of different parts of the supply chain that feed into the final product e.g. biocide manufacturers, dye houses, polymer manufacturers, component manufacturers, formulators.

Decision-making basis for Task 1: Product definition and bill of components, materials and substances

Decision component	Outline of methodology
1.1 Distinguish between articles and mixtures	Existing REACH and CLP definitions shall be used to make a basic distinguishment, as well being used to determine the inclusion of certain articles e.g. packaging.
1.2 Contact with the consumer	Priority identification of product articles that are in direct contact with the consumer or from which, based on evidence, there is potential for dermal, ingestion or inhalation exposure of the consumer or dispersion into the environment during the use phase. This shall be used to prioritise substance and hazard restrictions, but may also be used to tailor derogations in cases where no substitutes are available and the risk posed is minimal (see task 4b).
1.3 Potential exposure of workers	Identification of where in production and recycling facilities there may be potential for exposure of the workforce.
1.4 Concentrations required to fulfil product function	Determination of the concentrations of substances required in components, ingredients or the final product in order to fulfill specific, required functions. This information can form the basis for case-by-case concentration limits and the evaluation of substitution potential (see Task 2).
1.5 Packaging inclusion as an article	Packaging shall always be considered within the bill of materials if it is considered an intrinsic part of the product i.e. the packaging is an article which is required during the functional life of the product e.g. shampoo bottle.
1.6 Secondary materials	Material with a recycled content shall be prioritised in Ecolabel products unless there is scientific evidence demonstrating the circulation or concentration of specific hazardous contaminants or impurities that may pose a risk to the consumer. The European end-of-waste criteria for polymers [3] shall be used as a minimum performance requirement for the minimising of any hazards that may be present unless there is evidence in relation to specific contaminants or impurities.

[3] JRC-IPTS, *End of waste criteria – studies on specific recyclable waste streams,* http://susproc.jrc.ec.europa.eu/activities/waste/

1.7 Supply chain knowledge and applicant control	The inclusion of certain components or ingredients may be determined based on the level of applicant control of the supply chain. This shall be determined based on nature of the hazards that may occur and the significance of the component or ingredient.

Task 2: Screening for restricted substances and hazard classifications

Aim: To identify substances and hazards from the SVHC Candidate List, REACH Annex XIV, Article 57 substance screening and Member State intentions. that are relevant to the product functions as well as related component materials, devices and mixtures. To identify points in the life cycle of the product where hazard classifications associated with substances that may be in the final product are the most relevant.

Task 2a. Priority screening for Article 57 and 59 substances

Timescale: Preliminary research/AHWG1

Screening of the product would be carried out as a priority for substances that meet the criteria of Article 57 of REACH which, according to Article 6(6)/6(7), shall be subject to the strictest requirements to exclude them from products. In some cases the cut-off limit for derogations referred to in Article 6(7) may be lowered to 0.01%, for example for products to which the consumer has direct exposure e.g. rinse-off cosmetics.

This shall include reference to the SVHC Candidate List, REACH Annex XIV, ECHA evaluations (including ongoing evaluations arising from the Community Rolling Action Plan) and other relevant Article 57 substances that may be identified and/or prioritised for action by the European Commission such as the establishment of a priority list of endocrine disruptors. Wherever possible the associated function carried out by the substances shall be identified.

On a precautionary basis restrictions made by other national regulatory systems, such as in the USA, together with the positions of international intergovernmental organisations such as the OECD, WHO and IARC may be taken into account.

Task 2b. Screening for hazard classifications

Timescale: Preliminary research through to post-AHWG1

Screening of the product's composition for hazards as summarised in Table 2 and with reference to Task 2a and the EU Ecolabel hazard listing (see Appendix 1). Wherever the possible the function carried out by the substances shall be identified.

Explanatory note: A modular approach to screening

Table 2 describes a modular approach to the screening of products, allowing for the screening to be adapted to the distinct composition of each product. Criteria developers should:

1. Identify which components or ingredients are relevant to the products, depending on whether they are an article or a mixture,
2. Then carry out the screening according to the rules in Table 2 and according to the scope indicated in the checkboxes,
3. Where required apply horizontal screening to a mixture or an article - as described in points h (process residues and contaminants) and i (chemical additives, coatings or treatments).

This approach allows for a level of flexibility which reflects the wide range of products for which hazardous substance criteria may be developed.

This task will enable a better understanding of the hazard classifications that may be relevant to the product. It can also help distinguish between hazard classes on the basis of health or environmental impacts, the category of hazard and those hazards that may be relevant along the products lifecycle (see Task 2c). Cut-off thresholds of 0.10% shall be used in general for components of articles and 0.010% for products that are chemical mixtures. The lower threshold for mixtures is justified by their potential for wide dispersal in the environment. In some specific cases lower thresholds may be justified based on hazards and exposure.

For products with a significant number of possible ingredients and process chemistries this task is difficult but could be taken in several iterative steps. A practical approach would be to apply first this exercise to a 'business as usual' product case studies to capture the most commonly and widely used substances. This sample could be compiled using a combination of industry, Member State and independent expertise supplemented by relevant scientific literature. This can then be compared with the substitutions evidence from Task 3.

Though it is difficult more precise information regarding the specific applications and functions of substances will significantly assist in verifying the scope of any derogation. For example in paints & varnishes derogations proposed distinguish between indoor and outdoor applications.

It is proposed that for complex articles there would be the option to exempt certain homogenous material components and mixtures according to Article 23 and Annex I point 1.3.4 of the CLP Regulation (EC) No 1272/2008. This states that:

> *Metals in massive form, alloys, mixtures containing polymers and mixtures containing elastomers do not require a label according to this Annex, if they do not present a hazard to human health by inhalation, ingestion or contact with skin or to the aquatic environment in the form in which they are placed on the market, although classified as hazardous in accordance with the criteria of this Annex.*

Other homogenous materials, or parts from which they are manufactured, as identified in Table 2 could also be considered. This exemption would not apply if hazardous coatings, treatings or additives of concern are identified as having been applied to the polymer, or if specific concerns were to be identified in relation to the recyclability of the material or an end of life phase.

Table 2. Indicative product screening guide

Component or ingredient	Screening scope and rules	REACH Article 59 Candidate List SVHCs and Article 57 substances (Group 1)	Screening against the EU Ecolabel hazard list Groups 2 and 3	Criteria applying to substances grouped by function	Possible exclusion unless specific hazards and risks are identified	Consideration of potential for release during use or disposal
Chemical mixtures						
a. Chemical ingredients (cross reference with h)	○ Substances present at a concentration of >0.010% and which are required to carry out specific functions within the product mixture. ○ Mixtures present at a concentration of >0.010% and which are required to carry out specific functions within the product mixture.	✓ ✓	✓ ✓	✓ ✓		
b. Organic and mineral constituents (cross reference with h and i)	○ As for chemical ingredients but a different concentration cut-off limit may be applied ○ Residues, contaminants and internationally added substances	✓	✓	✓		
c. Final product mixture (with reference to a. and h)	○ Reference to the CLP mixture rules for hazards that may be present in the product.	✓	✓			

Articles and their component parts						
d. Homogenous material components or parts *(also to be screened for h and/or i)*	○ Homogenous material components could include those made from metal, glass, polymer, wood, stone, ceramic, cardboard ○ Metals, alloys, polymers and elastomers which may be excluded from labelling according to Article 23 and Annex I point 1.3.4 of the CLP Regulation (EC) No 1272/2008 ○ Recyclate shall be screened for potential hazardous contaminants and shall, where applicable comply with EU end-of-waste criteria. These include the following conditions; - Recyclate shall not contain restricted substances and/or SVHC's at concentrations of >0.10%.	✓			✓	
e. Complex component devices *(also to be screened for h and/or i)*	○ Identification of chemical additives, coatings or treatments of high concern that have a specific required functions or properties associated with sub-components of the device (e.g. solvents, flame retardants, coolant)	✓		✓		
f. Connectors, fixtures and adhesives	○ Homogenous material components such as screws, clips and cables that are used to assemble articles. ○ A weight threshold may be applied if agreed by consensus ○ Chemical formulations that are used to assemble articles e.g. adhesives. See also a.	✓ ✓	 ✓		✓	
g. Consumables *(also to be screened for a)*	○ Chemical substances or mixtures that are intended for release (e.g. ink in a cartridge) ○ *or* which play a functional role within the device (e.g. electrolyte in batteries)	✓ ✓	✓ ✓			✓ ✓

Horizontal screening requirements for mixture or articles						
h. Residues or contaminants	○ Substances from upstream processes that identified that may remain in or on the final product at equal to or greater than following concentrations: - In articles equal or greater than 0.10% (e.g. auxiliaries from textile processes) - In mixtures equal or greater than 0.010% (e.g. shampoos, paints, detergents) ○ Pollutants present in waste-derived materials and recyclates that may be carried into the final product. Specific concentration limits may be set for identified substances.	✓	✓			
i. Chemical additives, coatings or treatments	○ Screening of d and e for the presence of substances of concern. ○ The focus shall be on those applied, reacted or added to homogenous materials, parts or sub-component devices in order to impart functions or properties (e.g. dyes, biocides, flame retardants)	✓	✓	✓		

The Classification & Labelling (C&L) inventory cross-referenced to the ECHA database for registered substances and REACH dossiers shall be used as a starting point for screening, subject to further investigation of contradictory self-classifications. This shall include reference to scientific evidence and classifications from further afield, for example by the US EPA.

In general the classifications for individual substances and, where available from SDS, classifications for the ingredients of mixtures that are themselves ingredients shall be the main reference point during the screening for hazards.

For products that are themselves mixtures the CLP rules for the classification of mixtures with aquatic environmental hazards, acute toxicity, and specific target organ toxicity (STOT) shall be applied. Final product mixture classifications will require consultation with manufacturers in order to determine the relative significance of different ingredients to the final product (mixture) classification.

For polymers in some cases there may be a classification of the final material. Where the polymer is formed from monomers and other functional additives that are classified, their presence on the final product as well the relevance of the hazard along the life cycle of the

polymer may be considered. For example, in terms of handling in the workplace, recyclability or other end of life phases.

Task 2c. Tracing of hazard hot spots along the product life cycle

Timescale: Between AHWG1 and AHWG2

Once the nature of hazard classifications that may be associated with substances or substance groups contained within the product are better understood (as described in Task 2a and 2b) their relevance along the life cycle of the product can be determined. Expert technical literature (including LCA literature) and industry input will be required to assist in this process. The findings may be useful in the formulation of derogation conditions (see Task 6).

The reason that a substance carries a hazard classification may not always relate to the final product. It may instead relate to the potential exposure of workers (during the production phase), consumers (during the use phase) and/or the fate of the substance in the environment (during production, use or end-of-life phases). The transformation of the substance once it is dispersed in the environment with, under conditions that reflect a probable life cycle of the product for the period of the criteria validity (e.g. 3 years), may also create the potential for the formation of hazardous breakdown products, for example in the case of certain flame retardants and perfluorinated substances.

If other stages in the life cycle of the product are identified as being relevant then evidence shall be gathered relating to the risk of exposure of receptors to the hazard. In the case of the use phase, and where substitutes are not found to be readily available, the findings from toxicological studies and exposure assessments may be required to substantiate any potential exposure of the consumer.

Decision-making basis for Task 2: Screening for restricted substances and hazard classes

Decision component	Outline of methodology
2.1 Article 57/SVHC Candidate List screening	Priority identification of substances of concern from the most current Candidate List. Priority listings of Article 57 substances by the European Commission shall also be checked for relevance e.g. endocrine disruptors, CMR, PBT/vPvB. On a precautionary basis restrictions made by other national regulatory systems, such as in the USA, together with the positions of international intergovernmental organisations such as the OECD, WHO and the UNEP may be taken into account. Substances already restricted or authorised under REACH in the EU may still be listed in the criteria where it may have been identified that best available production practices are not being used at manufacturing sites outside of the EU and/or there may be risks that they may be present as a contaminant in the raw material.
2.2 Sectoral and international regulation of substances	The existence of the specific sectoral regulation (e.g. cosmetic products, RoHS, WEEE), offical scientific opinions (e.g. the Scientific Committee on Consumer Safety (SCCS)) and the scientific positions of international intergovernmental bodies (e.g. OECD, WHO) shall be taken into account.
2.3 Use of the Classification & Labelling inventory for screening	Classifications that are notified but not yet harmonised can be referred to but conflicting classifications shall be cross-checked with the ECHA database for registered substances.
2.4 CLP cut-off limits for contaminants and residues	CLP rules shall be reflected in the application of cut-off concentration limits for the presence of unintentionally added contaminates and/or production process residues. A limit of 0.10% shall apply for components of articles and 0.010% for mixtures. Lower thresholds may be applied for certain substances based on evidence of specific hazards or specific CLP concentration limits.

2.5 CLP rules for metals and alloys	Article 23 of Regulation (EC) No 1272/2008 and Annex I point 1.3.4 provides derogations for metals and alloys from labelling if they do not present a hazard in the form they placed on the market. This could be extended to also ensure that there is no assessed risk or evidence of exposure during the recycling and/or final disposal of the product. Limit values established in the REACH and CLP Regulations for the migration of substances from metals or alloys shall be referred to where relevant.
2.6 Classification of mixtures	This shall be applied to products that are mixtures and according to the CLP rules. Information shall be gathered from manufacturers in order to prioritise the contributions of ingredients to final classification.
2.7 Screening for ready-made mixture classifications	In the case of complex product mixtures classifications for the individual ingredients of ready-made mixtures shall generally be referred to unless they are not listed on an SDS. Where this information is not available then mixture classifications shall apply.
2.8 Sensitisers and allergens	Hazard classes H317 and H334 shall be added to the list where they are relevant to potential consumer exposure from the product. Reflecting the 2nd ATP of CLP distinction could, in the future, be made between 1A and 1B classifications. Where, according to Article 57(f) of REACH sensitisers, are shown to be of equivalent concern to SVHC's they shall be subject to strict requirements.
2.9 Identification of the most probable exposure paths	Critical analysis of evidence from ECHA evaluations, Member State evaluations, industry stakeholders, BREF's, peer reviewed scientific literature and NGO's shall be used to identify potential exposure relating to substances of concern that are present in the product and their specific hazard classifications.
2.10 Transformation and bioavailability	The physical form of the substance on the final product and the potential for exposure of the consumer shall be defined based on scientific evidence relating to the process chemistry used to manufacture the product and the potential for migration or leaching/migration of a substance from the final product. Scientific evidence of the potential for the formation of hazardous breakdown products shall also be taken into account, including in downstream life cycle phases e.g. in recyclate, landfill, incineration.

2.11 Identification of leaching/migration from the product	Where the potential for leaching/migration from an article is identified, for example into the sewerage system (e.g. upon washing), indoor air (e.g. paint) or to the skin (e.g. from a coating), then product specifications and standards shall be identified that minimise or prevent leaching/migration. Acceptable levels of leaching/migration could be determined based on (as relevant to the product) existing restrictions in regulation, ISO or EN standards, exposure studies and/or scientific committee opinions.
2.12 Identification of workforce exposure	Where workforce exposure is identified as being relevant then sectoral occupational exposure limit values shall be identified as a possible basis for derogation conditions. The strictest, sector-specific OELV shall apply taking into consideration the working conditions of the countries that are relevant for this production stage (i.e. working hours = exposure time).
2.13 Identification of upstream or downstream releases of hazardous substances to the environment	Where environmental hazards are identified then the relevance of discharges from manufacturing sites and widely dispersive discharges during the use phase shall be investigated. These could include emissions to air and water. The transformation of substances once they have been released to the environment shall also be a consideration. Consideration shall also be made of possible end-of-life scenarios in order to manage exposure that may arise from specific disposal routes e.g. Electronic waste treated outside of the EU. Evidence would be required on a case-by-case basis of the significance of such disposal routes to products in the EU market. Exposure paths that may arise from other waste treatment routes shall be considered (e.g. leachate from landfill, dioxins from incineration). The potential for the accumulation of hazardous substances in recyclate shall also be considered.

Task 3: Product hazard substitution and green chemistry & engineering initiatives

Aim: To develop a picture of the practical substitution potential for hazards incorporated within the product, as well as the chemical management systems used for production processes and supply chains for products that represent indicatively the best on the market in terms of environmental performance, as defined in the EU Ecolabel Regulation.

This should be used to inform the ambition level for the criteria and the need for derogations. It shall also ensure that substitutions do not result in an inferior product. Where substitutes exist but have a low market share then the selectivity of the criteria set and the fitness for use of the product shall be important considerations.

Task 3a. Initial scoping of evidence

Timescale: Preliminary report/AHWG1

Case studies of substitution initiatives, inherently safe product chemistry and substance restrictions that have been implemented for products available on the EU market shall be compiled. They shall indicatively represent the best performing products on the market in term of environmental performance (i.e. they should not be niche products) and wherever possible the core functions associated with the substitution shall be identified. Greater market selectivity by reflecting the chemistry of the best performing products would require discussion of the implications for the potential market penetration of the label and agreement at EUEB level.

To provide the widest possible coverage evidence should be gathered from manufacturers, industry associations, ecolabels, governmental initiatives, independent studies/papers and NGO initiatives. The evidence base from other Ecolabel schemes shall be used as a reference point but shall be checked for geographical and market relevance. Evidence shall be screened for its scientific basis regardless of the source.

Table 3. Indicative scope of evidence collection

Information source	Scope of evidence collection
Governmental initiatives	○ Substance group-specific stewardship initiatives
Manufacturers and industry associations	○ Sectoral or product-specific restricted substance lists ○ Substance-group specific screening exercises ○ Supply chain protocols
Ecolabels	○ Scientific evidence regarding hazardous substances ○ Geographical relevance of the label and market uptake
Peer reviewed studies	○ Scientific papers ○ Sectoral or product-specific studies
NGO initiatives	○ Case studies of industry initiatives

Task 3b. Request for substitution evidence from stakeholders

Timescale: Preliminary research questionnaire and at the AHWG1

A call for evidence of substitutions shall be made to stakeholders. Submissions shall be made using the standard data format (see Appendix 1). They shall then be screened for their scientific basis, with reference to REACH/CLP dossiers and life cycle considerations, and for any potential impact on the fitness for use and/or functional requirements of the product. The market diffusion of the substitution shall also be a consideration, with reference to the indicative target market share for the EU Ecolabel. Substitutions could include process changes that eliminate hazardous residues from the final product.

Summary of evidence requirements for substitutions

- Characterisation of the substance, material or process innovation
- CLP/GHS (the Globally Harmonised System) classification status
- Technical and functional performance
- Evaluation of the hazard profile and environmental performance compared to the substances substituted The relevance of the hazard substitutions along the life cycle of the product
- Market availability and technical maturity

Task 3c. Creation of front runner product hazard profile

Timescale: Follow-up from AHWG1 to be refined with sub-group and later in AHWG2

The findings from Task 1 and Task 2a/b shall be synthesised into an initial overview of the front runner product chemistry or product green engineering.
This overview shall be used in Task 4 to inform whether derogation requests are appropriate, particularly for more significant hazards.

Depending on the information available, and the extent of activity in the product sector, the focus for this task could include substances and their hazards (if classified) that are used to fulfil specific functions in relation to specific components and materials (e.g. plasticisers, flame retardants) or ingredients (e.g. preservatives, surfactants, colourants).

Where information on substitutes is limited then this shall be supplemented by substance and hazard restrictions that have been implemented by manufacturers, either independently or in response to ecolabel criteria.

Decision-making basis for Task 3: Sectoral hazard substitution and green chemistry initiatives

Decision component	Outline of methodology
3.1 Scientific evidence supporting substitutions	A standard data collection form is to be used with stakeholders and case studies will also be screened accordingly. Substitutions shall demonstrate a reduction in their inherent hazards compared to typical products on the market. Reference shall be made to REACH/CLP evidence requirements, life cycle considerations, potential impacts on the fitness for use and functional requirements of the product based on the actual use of the substitute, and relevance in the market.

Task 4: Screening and investigation of derogation requests

Aim: To investigate derogation requests that may relate to specific materials, substances or groups of substances. This process shall be based on the best available scientific knowledge on the potential hazard, product function and the potential for substitution including, if available, market information.

Task 4a. Call for derogation requests from stakeholders

Timescale: AHWG1 through to AHWG2

Following the AHWG1 and the analysis of substitutions stakeholders shall be invited to submit derogation requests for substances that are classified with hazards but for which no suitable alternative exists. A standard template has been developed that stakeholders shall use to submit evidence (see Appendix 1). Unless otherwise requested derogation requests shall be made available within the Technical Report for the product group.

Summary of evidence requirements for derogation requests

- Current CLP/GHS classification and regulatory status
- Concentration on/in the final product
- The technical and functional need for the substance in the final product
- Existing evidence and dossiers and relating to its specific application in this product group
- The relevance of the hazard classifications along the life cycle phases of the product
- The market availability, technical maturity and hazard profile of potential substitutes

Task 4b. Screening and investigation of derogation requests

Timescale: AHWG1 through to AHWG2

Derogation requests for substances or groups of substances shall be investigated. Submissions from industry together with findings from Task 2 and 3 shall be used to support this process. The investigation shall take the form of a screening of the best available scientific and industry knowledge on the potential hazard, the need for the specific function and the potential for substitution.

Differentiation shall be made between hazards, and the decision to permit a derogation or not, according to their Status as Article 59 or 57 substances and/or their Categorisation under CLP, as described in the summary note below and as listed in Appendix 2. The hazards are split into priority hazards to which strict rules apply and lower level hazards to which more flexibility may be applied. The rules take into account as a priority:

- the functional need for the substance/substance group;
- the potential for substitution as defined by front runner ‘green chemistry’;
- classification of the final product (if it is a mixture) and;
- the scope to impose derogation conditions along the life cycle of the product.

The inclusion of skin and respiratory sensitiser hazards in the EU Ecolabel hazard list for a product group will be based on whether there is potential for consumer exposure, either through extended periods of skin contact with the product (e.g. textiles) or the potential for respiratory exposure to particles, vapours or fumes during use (e.g. paints and varnishes).

Summary note

Rules for the differentiated treatment of hazards

The following rules shall apply to hazards when considering derogations. Hazards have been grouped in order to reflect their CLP Category and the REACH Article 57 criteria. In some cases combinations of hazards change the grouping of a substance. All rules for each group of hazards shall be taken into consideration and flexibility is generally only to be applied where no substitutes are available (with reference to Task 3).

Group 1: Hazards subject to complete restriction

Hazards addressed: Substances that meet the criteria of Article 57 of REACH and/or have been entered onto the SVHC Candidate List.

The following rules shall apply to hazards in this group:

- the substance shall not be present in mixtures, in an article or in any homogeneous part of a complex article;
- No derogation shall be granted where the substance is present at concentrations of greater than 0.10% (weight by weight) in mixtures, in an article or in any homogeneous part of a complex article.
- In some cases the Article 6(7) concentration limit for derogations may be lowered to 0.01%, for example for products to which the consumer has direct exposure e.g. rinse-off cosmetics.

This group includes Category 1A and 1B CMR hazard classifications under CLP, endocrine disruptors, neurotoxins and sensitisers of 'equivalent concern'.

Group 2: Priority hazards for restriction

Hazards addressed: CLP CMR Category classifications, CLP Category 1 and 2 acute toxins, Category 1 STOT, Category 1 allergens.

The following rules shall apply to hazards in this group:

- Where in combination with these hazards a substance is very persistent, persistent, very bioaccumulative or bioaccumulative, according to the definitions in Annex XIII of the REACH Regulation, it shall be treated according to the rules in Group 1 substance.
- Derogations are permitted if:
  - there is a functional need for the substance;
  - if there are no substitute materials, substances and production processes which are technically feasible and available on the market;
  - the substance is present in mixtures, in an article or in any homogeneous part of a complex article at concentration of less than 0.10% (weight by weight).
- Any derogation shall be accompanied by conditions relating to identified exposure routes along the product life cycle.
- Differentiation between Category 1A and 1B skin or respiratory sensitisers, as introduced by the 2nd ATP of CLP, could be made subject to the availability of test

data and evidence for exposure paths. In this case the general approach would be that:

- CLP Category 1A skin sensitisers and 1A and 1B respiratory sensitisers would be subject to prioritisation (Group 2);
- CLP Category 1B skin sensitisers would be examined on a case by case basis but could be subject to greater flexibility (Group 3).

Sensitisers identified as of equivalent level of concern to SVHC's according to Article 57(f) of REACH would be treated as Group 1 hazards.

Hazards addressed: CLP Category 1 and 2 hazards to the aquatic environment

- Derogations are permitted only if no substitute materials, substances and production processes are technically feasible and are available on the market;
- Derogations may be permitted taking into account the following factors:
  - If there is a functional need for the substance
  - if European legislation authorises the use of substances classified with these hazards and relevant substance-specific risk assessments have been carried out that relate to the products applications and anticipated end-users;
  - if direct exposure to the aquatic environment is not foreseen during the products lifecycle.
- For widely dispersive mixtures in which exposure may take place, it may be appropriate to restrict any derogation to specific uses only, as well as potentially placing conditions on:

  - Concentrations of specific hazardous substances in the final product,
  - The biodegradability and/or bioaccumulation of the hazardous substance(s),
  - Manufacturing processes that may result in aquatic pollution by the hazardous substance(s);

Group 3: Hazards to which greater flexibility may be applied

Hazards addressed: CLP Category 3 and 4 hazards to the aquatic environment, CLP Category 3 acute toxins, Category 2 STOT. The following rules and derogation considerations shall apply to hazards in this group:

- The applicant shall clearly demonstrate that the substances or substance groups are necessary to provide a necessary function (which may relate to form, durability, process chemistry etc..) and that other less hazard substances are not used as substitutes. The availability of substitute materials, substances and production processes shall be also taken into consideration.

Where hazard derogation requests are to be considered for groups of substances, then as far as possible this shall be supported by up-to-date evidence on the availability of alternative product processes and chemistries e.g. solvent reduction on a final textile product by moving from screen printing to digital printing. This could be compiled from a number of technical sources including IED BREFs, REACH dossiers, market intelligence, industry associations and trade literature.

Explanatory note
Defining 'substance groups based on function'

Where appropriate, common functions may be used as the basis for identifying and grouping substances that impart a function to the final product. Within such a group there may co-exist several different chemical mechanisms to impart the function. There could also co-exist several different technical options for incorporating the function.

For example, flame retardancy can be incorporated into textile fabrics as a surface coating, as an additive to individual fibres or by modification of the fibre polymers. The common characteristic is a mechanism to reduce flammability. A grouped approach makes it possible to compare not just the different potential hazards but also the different technical options.

Task 4c. Check for possible cross-product derogations

Timescale: Preliminary report, through to AHWG1 and AHWG2

The applicability of derogations made for other product groups shall be checked based on the distinct characteristics and functional needs of the product, e.g. nickel in stainless steel, dyes to provide colour, flame retardants to meet regulatory requirements.

Task 4d. Decision-making on derogation requests

Timescale: presentation to AHWG2/EUEB

Once requests have been received they shall be evaluated against the background of the substitution evidence gathered from Task 3 and cross-checked with other relevant scientific evidence gathered during the process. As a rule derogations shall be as specific as possible, applying only where a certain function is required and at a specified concentrations.

Requests shall also be shared with the hazardous substance sub-group, which may include an scientific experts from EU committees. Based on all the available information JRC-IPTS shall formulate a preliminary opinion on the derogations submitted, including initial proposals for derogation conditions. This shall then be shared within the sub-group and the AHWG2 before a final opinion is then presented to the EUEB for final decision.

Decision-making basis for Task 4: Streamlined investigation of derogation and substitution requests

Decision component	Proposed methodology
4.1 Hazard distinguishment and prioritisation	The hazard classifications shall be treated differently based on the categories of hazard and according to the three groups described in Section 4: - Group 1: SVHC's and Article 57 substances are subject to the strictest conditions, - Group 2: Category 2 CMR hazards and all other Category 1a, 1b and 2 hazards shall be restricted at concentrations greater than 0.10% and shall be subject to strict derogation conditions. - Group 3: Category 3 and 4 aquatic hazards, Category 3 acute toxins and Category 2 STOT may in general be subject to more flexible derogation conditions. Group 2 hazards that are also vP, P, vB or B shall be treated as Group 1 hazards.
4.2 Comparison at a substance group level	Derogations requests shall be considered in the context of different options to achieve the same function. For this purpose substance groups can be defined. These shall allow for the comparison of different chemistries and mechanisms that can be used to achieve the same function.
4.3 Cross-product derogations	The applicability of derogations from other product groups shall be checked for their relevance based on the distinct characteristics and functional needs of the product.

Task 5: Specification of the criteria and derogation conditions

Aim: To tailor and specify the criterion and any associated derogation conditions according to the findings from Tasks 1-5.

Task 5a. Structuring and formulation of the criterion

Timescale: First draft for the AHWG1 and/or the AHWG2

The criterion text shall be tailored according to the findings of tasks 1-5. In doing so a balance shall be achieved between horizontal consistency across the product groups and the specific needs of the product group. The main elements of the criterion (or criteria) could include, as a general guide:

- Priority substance restrictions: Specific reference to substances that meet the criteria in Article 57 of REACH and which have been identified according to the process in Article 59 of REACH (the Candidate List);
- Hazard restrictions: Overall rules describing how listed CLP hazards are to be restricted for substances and, where relevant, final product mixtures;
- General restriction list: A material and substance black list (REACH based together with more significant CLP hazards). Complementary to this a reference to substitute ('white') lists could also be used where European authorisation processes exist (e.g. biocides) or where the EU Ecolabel has developed listings (e.g. DID list);
- Substance and hazard derogations: If required, a substance and/or hazard derogation list, which shall also specify concentration limits, hazard classifications and any broader derogation conditions;
- Assessment and verification requirements: Information requirements in order to verify compliance with the criterion.

Task 5b. Specifying derogations

Derogations agreed by the stakeholder group and the EUEB shall be listed in the criterion. They shall be as specific as possible, with the criteria specifying the function or product category to which they apply.

Where they are verifiable concentration limits shall be specified as part of derogation conditions. These shall be specified based on the information gathered during tasks 1, 2 and 5, with options including:

a) Cut-off limits for contaminants and impurities (as discussed under Task 2),
b) Reference to generic or specific CLP concentration limits for hazards which are non-additive, for example, sensitisers;
c) The use of scientific evidence to set specific concentrations for substances that have an M-factor for aquatic hazards;
d) The contribution of specific identified hazards to the final product classification for mixtures;
e) Concentrations defined by the required function of the product.

In the case of e) it is possible that the concentrations required to fulfil a function may exceed generic CLP concentration limits for specific hazards, in which case a higher limit may be required. This could, in certain cases, be permitted as long as there was sufficient evidence

that the consumer would not be placed at risk, environmental impacts would be minimised and that appropriate derogation conditions are in place.

Task 5c. Setting derogation conditions

Derogation conditions shall reflect the need to minimise pollution or exposure to the hazard along the products lifecycle. Moreover, they shall be tailored to the distinct characteristics of each substance group – for example, reference could be made to functional requirements of the product, occupational exposure limits at manufacturing sites, measures to minimise leaching or dispersed pollution from the product, design for recycling, durability standards and/or BAT techniques.

Decision-making basis for Task 5: Specification of criteria and derogation conditions

Decision component	Proposed methodology
5.1 Horizontal consistency	The criteria shall consist of a number of basic elements that ensure consistency of structure and approach across product groups (see above).
5.2 Concentration limits that reflect the significance of articles or ingredients	Concentration limits may be adjusted or used as cut-offs for specific groups of substances or components based on their significance to the final products classification, final product function, exposure pathways or components.
5.3 Concentration limits that exceed generic CLP limits	Concentration limits may exceed generic CLP limits for specific hazards but not for SVHC's or Article 57 substances where there is scientific evidence that the substance in the form it takes on the final product does not present a risk of exposure to hazards either in the use phase or the end-of-life phase of the product (see Task 6).
5.4 Derogation conditions: Reference to BAT techniques	Where hazards are identified in Task 4 as being linked to process control, wastewater discharges and/or aerial discharges from production sites and BAT techniques exist for which clear evidence exists of their potential to control exposure then these shall be specified as conditions. It is important here that the applicant has control and/or influence so as to ensure that these conditions are fulfilled.
5.5 Derogation conditions: Reference to workplace OELV's	Where hazards are identified in Task 4 as being linked to workplace exposure then OELV's shall be identified as a means of limiting exposure. This condition shall only be applied where there are no EU-wide OELV's. The strictest limits identified from countries that are relevant to the supply chain for the product sold in the EU shall apply.
5.6 Derogation conditions: Migration and diffuse pollution	Where hazards are identified in Task 4 as being linked to potential migration from the product during use and where this may then lead to diffuse pollution hazards conditions may be specified that minimise migration/leachability along an identified pathway.
5.7 Derogation conditions: End-of-life options	Where hazards are identified in Task 4 reference shall be made to end-of-life options in order to manage specific disposal routes for which evidence exists of their relevance to products in the EU market. Design for recycling or dismantling criteria shall be identified as a positive basis for derogation conditions. Again, it is important that the applicant has a certain control and/or influence so as to ensure that these conditions are fulfilled.

Task 6: Specification of verification requirements

Aim: To tailor and specify the assessment and verification requirements according to the burden of proof and reputational risk identified for the product.

Task 6a. Specification of the verification conditions

Timescale: AHWG2/EUEB

Once a better understanding of the verification issues and risks associated with the product has been developed it should be possible to specify the verification requirements. In doing so the burden to Applicants and Competent Bodies shall be weighed up against the benefit to the Ecolabel.

A key factor to consider in specifying verification criteria will be the risk that non-compliance poses to the consumer. Product testing shall only be specified if there are clear environmental or health risks and if the substance group is of a high level of concern. Here a distinction shall be made between the assessment and verification of applications and ongoing surveillance of licenseholder compliance.

Articles shall receive a specific focus because information on the classification of ingredients in mixtures tends to be more readily available. In any case the cost and burden to the applicant should also be weighed against the additional benefits for the Ecolabel.

A hierarchy of verification shall be followed which reflects the quality of information available to the applicant via suppliers and reputational risks that may exist along the supply chain. Derogation conditions may require specific forms of evidence or testing which would need to be specified separately. The options presented in table 4 shall form the basis for the verification hierarchy.

Figure 4. Indicative hierarchy of verification options

Level 1: Self-declaration *Products of relevance:* Mixtures, articles where the production formulas for substances applied to the product can be identified.
Product verification option 1a: Self-declaration by the applicant on the basis of SDS data and evidence compiled in accordance with REACH Annex II
Product verification option 1b: Self-declaration provided by sub-suppliers on the basis of SDS data compiled in accordance with REACH Annex II if this is required to substantiate the composition of articles, materials, consumables or mixtures,

Continued over the page

Level 2: Stricter verification *Products of relevance:* Articles where information on material or device components is not readily available but where there is knowledge of substances being applied, articles where a risk has been identified of hazards being present in the final product.
Product verification option 2a: Final product testing by the applicant, which could be carried out on a risk basis for distinct product lines or specific sub-components. Examples may include where suppliers change during a license period, where triggered by complaints or reports from consumers or where there are scientifically justifiable concerns about specific substances that are in the public eye. Testing shall be carried out according to the specified test methods by accredited laboratories.
Product verification option 2b: Site visits by Competent Bodies or their representatives. This option is specified within the Ecolabel Regulation and applicants may be required to contribute to expenses incurred. This option could be used from time to time on a spot check basis to verify general capability to achieve consistent compliance, as well as implementation of specific derogation conditions e.g. BAT techniques.
Supply chain verification option 2c: The combination of conditions will vary according to the nature of the products supply chain and the relevance of hazards along the product's life cycle. Verification will therefore need to be tailored but must also, where possible, minimise the burden to applicants and Competent Bodies: o Workplace health and safety: Annual monitoring data verifying compliance with OELV's o Wastewater and air emissions pollution control: Annual monitoring data verifying compliance supported by evidence from IPPC/IED permits. o BAT techniques: Process performance data supported by documentary and site-specific evidence of equipment having been installed and operated. o Product performance: Reference to appropriate ISO, EN or member state standards and associated performance benchmarks. Where possible these conditions shall be transferred to standalone criteria in order to avoid overcomplicating the hazardous substance criteria.

Decision-making basis for Task 6: Specification of verification requirements

Decision component	Proposed methodology
6.1 Final product testing	Final product testing shall in general be carried out where: - there exists clear evidence of systematic risks of non-compliance, - where the substance group is of a high level of concern - and/or where suppliers may change during a license period.
6.2 Accredited laboratory testing	Where possible testing shall be performed by laboratories that meet the general requirements of European Standard EN ISO 17025 or equivalent.
6.3 Acceptance of equivalent test results and methods	Where appropriate, test results obtained for other certifications or clients may be used if they are equivalent (e.g. Oeko-Tex 100 for textiles). Test methods other than those indicated for each criterion may be used if their equivalence is accepted by the Competent Body assessing the application.
6.4 Life cycle verification (derogation conditions)	Life cycle-related derogation conditions shall be verified against existing European reference standards, OELV's or BAT techniques. Monitoring data, documentary evidence and photographic evidence shall, where appropriate, form part of the verification requirements.

Appendices

Appendix 1 Hazard class differentiation

Group 1: Hazards subject to complete restriction

Scope: Substances present in mixtures, in an article or in any homogeneous part of a complex article that meet the criteria of Article 57 of Regulation (EC) No 1907/2006 or that are identified according to the procedure described in Article 59(1) of that Regulation. This shall include the hazards listed below, as well as endocrine disruptors, neurotoxins and sensitisers of equivalent concern.

Carcinogenic, mutagenic or toxic for reproduction	
Category 1A and 1B	
H340 May cause genetic defects (R46)	
H350 May cause cancer (R45)	
H350i May cause cancer by inhalation (R49)	
H360F May damage fertility (R60)	
H360D May damage the unborn child (R61)	
H360FD May damage fertility. May damage the unborn child (R60, R60/61)	
H360Fd May damage fertility. Suspected of damaging the unborn child (R60/63)	
H360Df May damage the unborn child. Suspected of damaging fertility (R61/62)	

Group 2: Priority hazards for restriction to which stricter conditions shall apply

Additional rule: Substances that, in combination with these hazards, are also very persistent, persistent, very bioaccumulative or bioaccumulative, as defined according to Annex XIII of the REACH Regulation, shall be treated as Group 1 substances.

Carcinogenic, mutagenic or toxic for reproduction	
	Category 2
	H341 Suspected of causing genetic defects (R68)
	H351 Suspected of causing cancer (R49)
	H361f Suspected of damaging fertility (R62)
	H361d Suspected of damaging the unborn child (R63)
	H361fd Suspected of damaging fertility. Suspected of damaging the unborn child (R62/63)
	H362 May cause harm to breast fed children (R64)

Acute toxicity	
Category 1 and 2	
H300 Fatal if swallowed (R28)	
H310 Fatal in contact with skin (R27)	
H330 Fatal if inhaled (R23/26)	
H304 May be fatal if swallowed and enters airways (R65)	

Specific target organ toxicity (STOT)	
Category 1	
H370 Causes damage to organs (R39/23, R39/24, R39/25, R39/26, R39/27, R39/28)	
H372 Causes damage to organs (R48/25, R48/24, R48/23)	
Respiratory and skin sensitisation (where applicable)	
Category 1	
H317: May cause allergic skin reaction (R43)	
H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled (R42)	

Hazardous to the aquatic environment	
Category 1 and 2	
H400 Very toxic to aquatic life (R50)	
H410 Very toxic to aquatic life with long-lasting effects (R50/53)	
H411 Toxic to aquatic life with long-lasting effects (R51/53)	
Hazardous to the ozone layer	
H420 Hazardous to the ozone layer (R59)	

Group 3: Hazards to which greater flexibility may be applied

Acute toxicity	
	Category 3
	H301 Toxic if swallowed (R25)
	H311 Toxic in contact with skin (R24)
	H331 Toxic if inhaled (R23)
	EUH070 Toxic by eye contact (R39/41)
Specific target organ toxicity (STOT)	
	Category 2
	H371 May cause damage to organs (R68/20, R68/21, R68/22)
	H373 May cause damage to organs (R48/20, R48/21, R48/22)

Hazardous to the aquatic environment *	
	Category 3 and 4
	H412 Harmful to aquatic life with long-lasting effects (R52/53)
	H413 May cause long-lasting effects to aquatic life (R53)

* flexibility may be applied only if the fate of the product is not in the aquatic environment (e.g. in paints and soaps where there is the potential for wide dispersive release into the aquatic environment)

Appendix 2 Derogation requests and substitution evidence: Data collection fields

2.1 Common information requirements

1. Chemical substance name(s)	
2. CAS, EC or Annex VI numbers	*The CAS No shall always be provided*
3. Current EU regulatory status	*E.g. notified, on or proposed for the SVHC candidate list, registered, authorised*
4. CLP Classifications from the EU Ecolabel hazard listing	*Please specify the source and evidence for the classification(s).*
5. Proportional contribution to final product classification (for mixture ingredients)	*This is relevant for mixtures where the CLP rules shall be used to classify the final product mixture.*
6. Existing scientific evidence and risk assessments relating to the substance	*E.g. REACH dossiers, ECHA evaluations, peer reviewed scientific research/screening exercises.*
7. Functional need and significance to the final product	*What technical function does it provide and why is it needed? The need for the substance to be present in the product shall be detailed based on specific consumer requirements or standards.*
8. Typical concentration in the final product and specific components or articles	*This should be indicative include ranges where this varies according to function.*

2.2 Additional information required for derogation requests

1. The relevance of the hazard classification(s) along the life cycle of the product (e.g. manufacturing, use, disposal)	*Where the risks of exposure to the hazard may occur e.g. workforce exposure, wastewater release, consumer exposure. Scientific evidence relating to risks of exposure.*
2. Market availability of alternatives and the potential for substitution	*Market availability and technical status of alternatives – why are they currently not suitable? This shall be substantiated with technical evidence*

2.3 Additional information required for substitutions

1. Comparative evaluation of environmental performance	*Identification of substances that can/have been substituted and supporting evidence of the improvement for specific hazards i.e. CLP classifications, reference to scientific research/screening exercises.*
2. The relevance of the hazard substitution along the life cycle of the product (e.g. manufacturing, use, disposal)	*Evidence of where the greatest improvement potential along the lifecycle can be detected e.g. through reduced workforce exposure, wastewater release, consumer exposure.*
3. Compliance with product performance and functional requirements	*Verifiable evidence that the substitute fulfills the same functional requirements and technical needs e.g. fitness for use test results, specifications*
4. Market diffusion and technical maturity	*Evidence of the market availability and technical maturity of substitute(s)*