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EU Ecolabel: Chemicals Task Force 2

Final proposals and recommendations

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Background:

The aim of this document is to present the final proposals and recommendations of the Chemical Task Force 2. The findings are organised according to each of the defined sub-tasks which formed the scope of the Task Force's work:

Issue 1: Criteria for complex articles

- Task 1.1 Developing an agreed terminology
- Task 1.2 How to define front runner performance?
- Task 1.3 Understanding when exemptions for reduced exposure to potential hazards may apply

Issue 2: The handling of derogation requests and related changes in CLP classifications

- Task 2.1 What flexibility does the Commission have?
- Task 2.2 Encouraging disclosure and identification of derogation needs
- Task 2.3 Determining classifications

For each task the background discussions and investigations undertaken by JRC with Task Force member's input are summarised.

Summary of the main <u>proposals and recommendations</u> arising from the EU Ecolabel Chemical Task Force 2.

Proposals and recommendations	Implications for the Ecolabel
Task 1.1 Developing an agreed terminology In the frame of the sub-task regarding "terminology" the following definitions were agreed to be used: o Article: means 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 o Complex object: means object made of two (or more) articles joined or assembled together either: – mechanically – using substance(s)/mixture(s) o Component article: means an article of complex object that is by itself integrated into a product that can be awarded with the Ecolabel *[applicable for very complex objects only]*.	o The definitions are to be used as a reference point by the Commission and all stakeholders.
Task 1.2 How to define front runner performance? To follow a defined decision making process in order to decide upon the most appropriate approach to application of the hazardous substance criteria for a particular product group based on: i. the potential presence of hazardous substances remaining in the final product, ii. the complexity of the supply chain, iii. the degree of control that applicants have over ingoing chemicals, and iv. the progress made by front runners in substituting hazardous substances. The implementation by applicants for the Ecolabel of an SVHC management systems shall be established as a horizontal requirement.	o Early discussions and decisions to be made at the EUEB level based on the best available information gathered by JRC, with the appropriate approach to be agreed by consensus. o JRC and CBs to work with license holder data and to identify/work with volunteer companies in order to validate how many mixture or article components/functional substances can be addressed and to also identify potential derogation needs.

Task 1.3 Understanding when exemptions for reduced exposure to potential hazards may apply To move the current exemption clause that is included in the hazardous substance criteria for articles into the derogation process. This is to ensure there are consistent, clear criteria and a transparent decision making process. A newly defined decision making process shall be used to evaluate exemptions. Exemptions for product groups that are articles may be given where substances are: o chemically modified, o immobilised within a matrix, Exemptions must be supported by accepted thresholds and the means to verify the form of modification or level of immobilisation.	o Greater input will be needed from industry stakeholders to justify and provide sufficient information on chemical modification and immobilisation in the context of the manufacturing processes for each product group. o JRC to present the findings from evaluations of this type of exemption (derogation) for final decision by the EUEB.
Task 2.1 What flexibility does the Commission have? Given that the Commission's Legal Service has confirmed there can be no flexibility in how derogations are adopted, the focus should instead be on improving the current process (see task 2.2).	*See the implications of task 2.2*

Task 2.2 Encouraging disclosure and identification of derogation needs It shall be checked/demonstrated during each criteria development process that at least two manufacturers with a credible market share or position as a front runner can comply with the proposed criteria. A stepwise process shall be followed to identify/prepare/check/evaluate derogation requests during a criteria validity period. It is proposed that derogations are treated with different levels of strictness depending on whether they are: i. a reclassification due to a change in classification rules (e.g. CLP ATP) ii. a reclassification or a new classification due to new toxicological evidence that is agreed on by REACH registrants and/or where this evidence informs a new harmonised classification iii. a derogation need that was not previously identified during a criteria revision process. Time frames shall be communicated to license holders during which relevant action should be taken.	○ JRC to carry out a detailed checking process with at least two manufacturers and report the findings ○ CBs to support JRC in carrying out the checking of hazardous substance criteria with manufacturers. ○ CBs, JRC and DG ENV to follow the stepwise process for the handling of derogations. ○ JRC, DG ENV and EUEB to refer to the approach laid down for the three different scenarios in which a derogation may be needed. ○ CBs to discuss/agree on the time frames for action and, if necessary, communicate these to license holders.
Task 2.3 Determining classifications A redesigned CLP classification 'decision tree' has been proposed. The revised decision tree reflects the potential situations that may arise during the JRC and stakeholders' review of the most readily available sources of classification data (SDS and C&L inventory) as well situations in which data gaps could be filled by additional data sources, if available. from the proposal has been check and agreed with ECHA and the Chemical Unit in DG ENV.	○ The final version of the decision tree to be used primarily by JRC, in conjunction with CBs and manufacturers/suppliers to reach a view on the CLP classification status of substances for the purpose of the hazardous substance criteria.

Contents

Issue 1: Criteria for complex articles

Task 1.1 Developing agreed terminology

Restrictions on hazardous substances used in EU Ecolabel products are specified in the articles 6(6) and 6(7) of the EU Ecolabel Regulation 66/2010. First of all, it is stated that the EU Ecolabel may not be awarded to **goods** containing substances or mixtures meeting the criteria for classification as toxic, hazardous to the environment, carcinogenic, mutagenic or toxic for reproduction (CMR) in accordance with CLP[1], nor to goods containing substances referred to in Article 57 of REACH[2]. The EU Ecolabel Regulation foresees certain situations when such substances may be derogated for specific categories of goods**,** with the exception of the SVHC, for which stricter requirements are set.

Interpretation and application of this criterion for different types of products revealed various practical difficulties. As far as products which are **mixtures** are concerned (e.g. detergents, lubricants, cosmetics), compositions of these products (i.e. lists of ingredients) can be obtained and checked for presence of classified substances above set thresholds (e.g. by an assessment of safety data sheets required for classified mixtures according to Article 31 of REACH). Still, this is not always straight forward due to confidentiality reasons and the fact that very often components of the formulations are mixtures as well (provided directly by suppliers without specified full composition).

Provision of such detailed information gets more complicated when we move from mixtures to **articles**, where the supply chains get longer and its different parts can be distributed geographically, like for instance textiles, shoes or furniture. So far there is only legal obligation to pass information down the supply chain on Candidate List substances present above 0.1% in an article (including each of those present in assemblies of more complex articles/objects). However, in case of **complex articles/objects** (i.e. electronic products) obtaining a full bill of materials and information on all classified substances (i.e. not only SVHCs) contained in products is very difficult, if not impossible at the current state-of-art. One needs to take into account not only the complexity of supply chains but also the number of component parts they are built of, which can be very substantial. Information on hazardous substances contained in goods, unless required to be specified by the law (e.g. notified, named on the label, etc.) is still very scarce. In addition, verifiability of this information needs to be also taken into account in the EU Ecolabel context (data availability, reliability and also related costs have to be considered). All this led to the common understanding that a different approach is needed for goods which are complex articles and not chemical mixtures or more simple articles.

In the last works on the EU Ecolabel criteria for **complex articles**, namely computers and notebooks and electronic displays, the requirement on hazardous substances was developed with focus on specific areas which can realistically be addressed in the current EU Ecolabel framework. This refers for instance to narrowing the scope to certain components of a product or restricting certain functional substance groups. The implementation of this approach for certain product groups such as electronic products gained the acceptance of the stakeholders, as a first step in the development of chemical requirements which could be implemented by industry and further revised and improved in the future. Stakeholders agreed to this more flexible approach based on the potential to deliver other important environmental benefits for the product group, namely in terms of resource efficiency (energy efficiency, extended life-time, recyclability, etc.).

Still, some needs were identified by the EU Ecolabel stakeholders in the area of **terminology** which should be used in order to ensure a harmonised formulation and interpretation of the criteria on hazardous substances across different products groups for **complex articles**. Therefore, in the following section a brief summary on existing definitions used in various pieces of relevant legislation

[1] 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, OJ L 353, 31.12.2008, p. 1.
[2] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, OJ L 396, 30.12.2006, p. 1.

(i.e. **REACH, CLP, RoHS**) is given, including also the terms used in the **European Court Judgement** on the interpretation of Articles 7(2) and 33 of Regulation (EC) No 1907/2006 on substances of very high concern present in articles, and the ECHA Guidance on requirements for substances in articles[3], which are both of relevance for products being **articles made out of several articles**. The existing definitions serve as basis for agreeing on the common terms to be used in the future in the EU Ecolabel criteria for articles.

1.1.1 Existing definitions from REACH, CLP and RoHS

Three pieces of legislation, namely REACH, CLP and RoHS, related to substances used in production processes and/or contained in products were analysed from the point of view of relevant vocabulary used. **CLP** and **REACH** focus mainly on substances and mixtures, but they also include a definition of what an **article** is:

*"**Article**: means 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".*

ROHs regulates the restrictions on use of certain substances in electric and electronic equipment (EEE), therefore the terms used in this act are focused mainly on such products. One definition included in ROHs can, however, be useful in the frame of the EU Ecolabel:

*"**Homogeneous material**: means 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"*

1.1.2 ECJ judgement and draft ECHA guidance

Article 7 of REACH ('Registration and notification of substances in articles') is worded as follows:

*"Any producer or importer of **articles** shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:*

(a) the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;

(b) the substance is present in those articles above a concentration of 0.1% weight by weight (w/w)".

This formulation raised a question what, in praxis, is considered an **article**; and in consequence – how far the obligation for notification reaches across the supply chain? Five Member States and Norway questioned the initial interpretation note of the Commission and the clarification provided in the ECHA guidance[4] that this obligation "*applies only if the substance of very high concern exceeds 0.1% in the entire article*".

The Court of Justice of the European Union analysed this query regarding the so-called '**complex' products** which are made up of a number of manufactured objects meeting the criteria laid down in Article 3(3) of the REACH Regulation, i.e. which mean they can be defined as articles.

In September 2015 a judgement of the court was released, in which it is stated that: *"Articles incorporated as components of a complex product must be notified to the European Chemicals Agency when they contain a substance of very high concern in a concentration above 0.1%".*

[3] Available online at: https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c.

[4] The 'Guidance on requirements for substances in articles', published by ECHA on 1 April 2011

Following the judgement of the court, ECHA updated the 'Guidance on requirements for substances in articles'[5], which was published in June 2017. In this guidance the term "**complex object**" is introduced and used instead of the "**complex article**" term. This choice was made due to the fact that "product" is often used in EU legislation to refer to chemical mixtures. "**Complex object**" refers to any object made up of more than one article. In complex objects, several articles can be joined or assembled together in various manners, i.e.: - two (or more) articles are **mechanically assembled**,

- two (or more) articles are joined together using a substance(s)/mixture(s).

Very complex object is also defined in the Guidance, as *a combination of simpler complex objects*, e.g. a computer, a mobile phone, etc.

1.1.3 EU Ecolabel Regulation

The EU Ecolabel Regulation refers to '**complex article**' (i.e. an article composed of many individual articles); however a definition of such an article could not be found in European law. For the purposes of the EU Ecolabel the following definition was suggested in the final paper summarising the agreements achieved during the work of the 1st EU Ecolabel Chemicals Horizontal Task Force[6]:

'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 EU Ecolabel Regulation also refers to '**homogenous parts of a complex article**' but also without defining them.

1.1.4 Terms and definitions proposed to be used in the context of the EU Ecolabel criteria

The Task Force members expressed strong willingness to use a harmonised and agreed vocabulary in the framework of the EU Ecolabel. After the analysis of the terms used in different pieces of the legislation and several rounds the feedback received to the first proposal, it is suggested to keep the terminology as simple and clear as possible. Therefore, the initially included terms of "coated article/complex object", "homogenous component part" and "very complex object" included in the initial proposal were decided to be removed.

The below definitions were considered relevant to be kept and used in a harmonised way across different EU Ecolabel product groups:

1) **Article**: *means 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*
2) **Complex object**: *means object made of two (or more) articles joined or assembled together either:*
    a. *mechanically*
    b. *using substance(s)/mixture(s)*
3) **Component article***: means an article of complex object that is by itself integrated into a product that can be awarded with the Ecolabel.*

This last term, i.e. component article was proposed to be used within the criteria development/revision process only for very complex articles /objects with long supply chain and where traceability of at least SVHC along the supply chain is ensured. A list of component parts, where necessary, should be defined within the process and included in the criteria document.

[5] Available at: https://echa.europa.eu/documents/10162/23036412/articles_en.pdf

[6] 'Findings of the EU Ecolabel Chemicals Horizontal 1st Task Force - Proposed approach to hazardous substance criteria development', February 2014

Task 1.2 How to define front runner performance?

Front-runner performance has been considered with a focus on how to screen for non-SVHC substances that remain in the final product and that possess at least one of the restricted CLP hazards that are defined for the horizontal screening of that particular product group at the sector level (section 1.2.2) or the individual company level (sections 1.2.3 to 1.2.6). However, with regards to SVHCs (section 1.2.1) it is recommended not to identify front-runner performance but instead to set minimum requirements for all EU Ecolabel license holders (except for product groups that are services).

1.2.1 Setting a common baseline for SVHCs

The horizontal screening and restrictions that apply to EU Ecolabel product groups (except for services) apply to both SVHCs and substances with at least one of a series of restricted CLP hazards. Screening and restrictions of SVHCs is well supported by (REACH) Regulation (EC) No 1907/2006, specifically in Articles 7(2) and 33 which set communication requirements for the presence of any SVHCs above 0.10% w/w. Clarification that these concentration limits should apply to individual articles in a complex article has been received following the judgement of the European Court of Justice of the 10 September 2015.While it is understood that the vast majority of suppliers do not (yet) have a management system in place that would allow for demonstrating ongoing compliance with the (growing number) of substances on the candidate list (SVHC), the lack of such systems can be perceived as undermining the credibility of the entire system.

With the legal situation now clarified, and concerns about credibility, it is recommended that the EU Ecolabel promotes the implementation of SVHC management systems for producers of EU Ecolabel mixtures, articles and complex articles for obtaining and updating SVHC declarations from suppliers. The maturity of such systems is anticipated to vary between product groups, but the intention is to identify from the outset of each criteria revision process the best practices amongst existing and potential license holders.

1.2.2 Front-runner potential at the product group level

The product group perspective is something that should be considered at the earliest stage possible in the criteria development/revision process. The main objective is to determine to what extent potential applicants and existing license holders are able to screen for and restrict the presence of hazardous substances in their goods. Factors such as the extent to which hazardous chemicals may remain in those final products, high profile consumer concerns, supply chain complexity and the extent to which hazardous chemicals are under the control of end product manufacturers must be considered. A proposed decision matrix could look as follows:

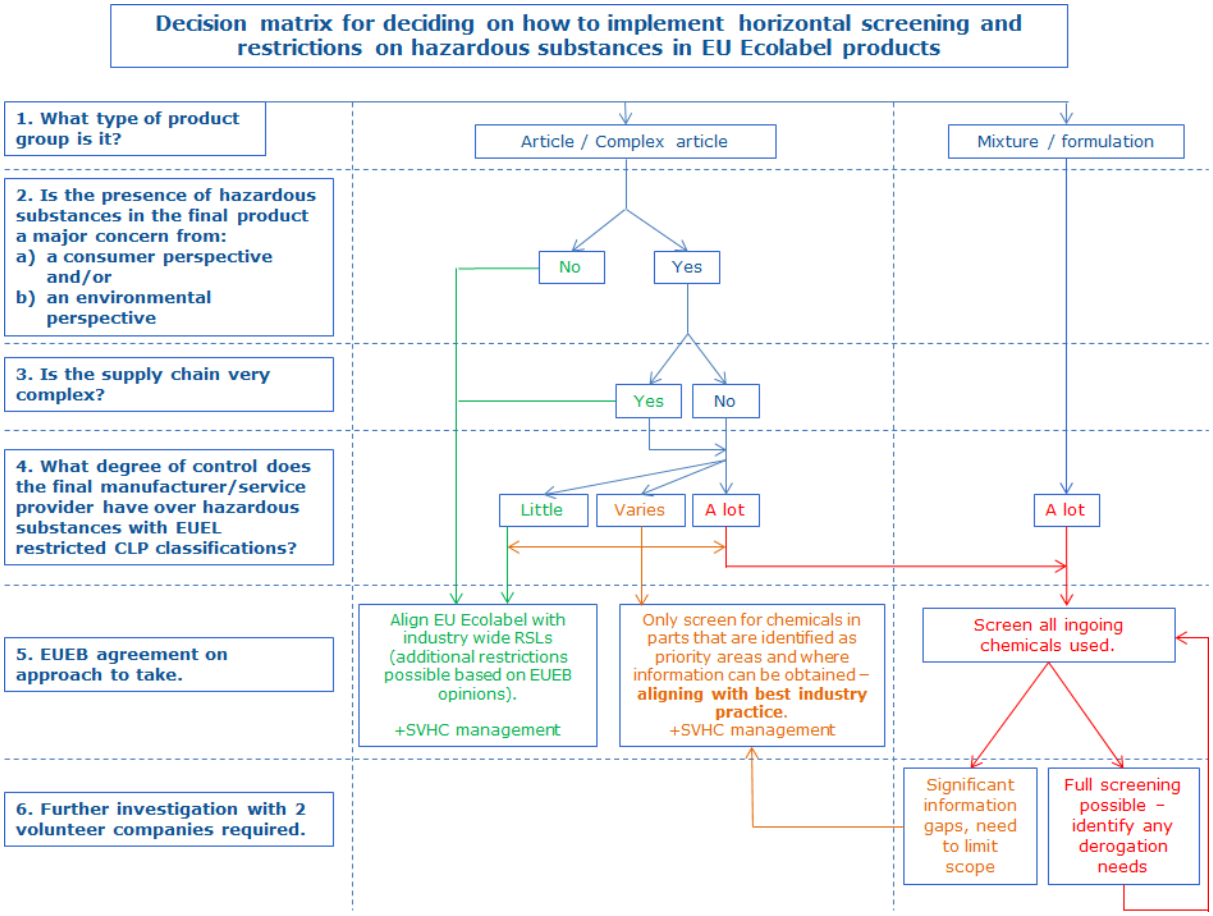


Figure 1. Decision matrix to consider front runner possibilities from a product group level perspective

All stakeholders should have an influence on the answers to the questions set out in steps 2, 3 and 4. The importance of inputs from consumer organisations is emphasised in answers to 2a) while evidence from the Preliminary Report carried out for a criteria revision could potentially provide a conclusive answer to 2b). Particular value would be given to industry stakeholders relating to the answers to questions 3 and 4.

As a general rule, the more complex the article, the more complex will be the supply chain. Even if the supply chain is complex, a route is left open to arriving at the requirement of a full screening approach just in case there are companies out there that are able to or trying to screen their entire supply chain.

When considering the degree of control that a manufacturer has over its supply chain, it is not only necessary to consider the complexity of the supply chain, but also the extent of SMEs involved in the sector. It is clear that larger companies will be able to exert a greater control on the supply chain than SMEs.

Ultimately, it will be the EUEB members who should agree on what approach should be taken in the research into hazardous substance screening and restrictions. A full screening approach can only be permitted if there are at least two companies that are willing to cooperate in the exercise. Depending on the results of this exercise, a full screening approach or a more limited screening will be recommended, together with any identified derogation needs.

1.2.3 Front-runner potential at the individual company or product line level

It is considered that this Task should focus on further development of the approach that was set out in Task 3 of the first Chemical Task Force recommendations. The sequence of tasks is illustrated in Figure 2 together with the content of Task 3 (see box 1.2.1).

Task 3 focusses on the need to define the current market potential for hazard substitution, at the sector level, the company level or the individual product line level for a product group. Preference should be given to the substitution level at the level of the individual product line where possible. This task is intended to inform the ambition level for the criterion and the need for derogations. The view was expressed within the Task Force 2 that there should be a stronger focus on identifying the substitution potential in each product group – referred to in Task 1.2 as a front runner profile.

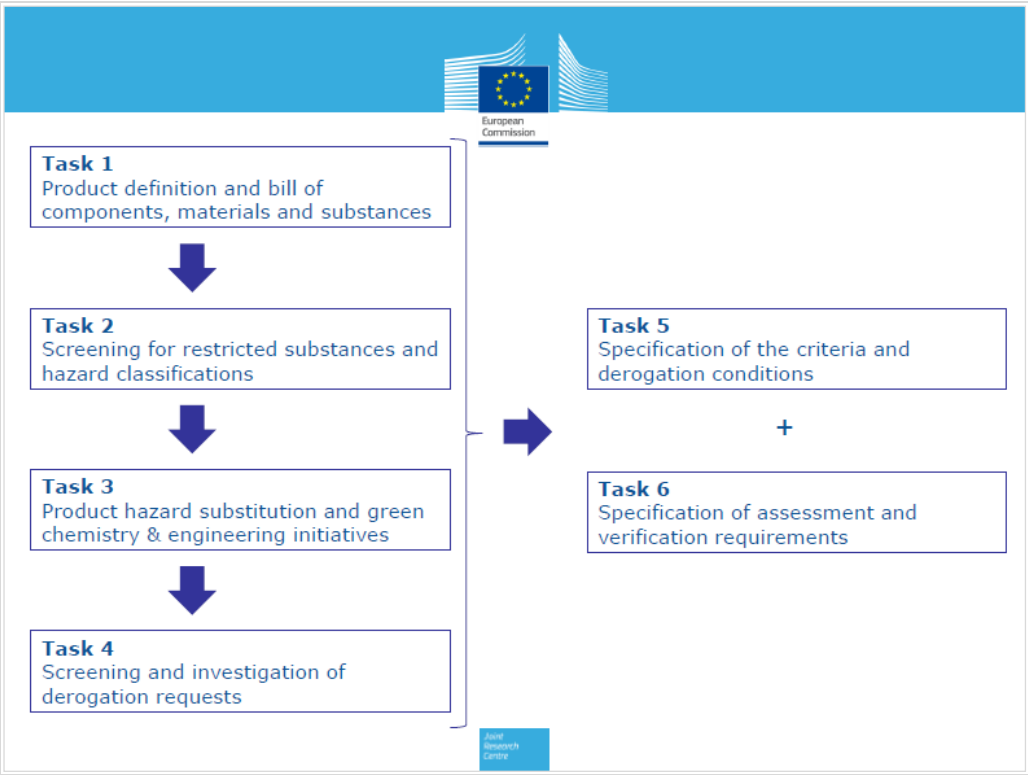


Figure 2 The six steps in hazardous substance criteria development (taken from first Chemical Task Force recommendations)

Box 1.2.1 Task 3 in the development of EU Ecolabel hazardous substance criteria

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*: 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.

- *Task 3b. Request for substitution evidence from stakeholders*: A call for evidence of substitutions shall be made to stakeholders. Submissions shall be made using the standard data format
- *Task 3c. Creation of front runner product hazard profile*: 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.

1.2.4 Examine the extent of the minimum boundary and burden of proof for the hazardous substance criteria

Earlier discussions suggest that distinctions such as 'tier 1' may not be relevant because important chemicals used to impart specific functions may be added to parts of an article several tiers along the supply chain. In these cases attention would have to focus instead on the commercial availability of substitute chemistry which can then be adopted along the supply chain. The situation will therefore vary by product and the way in which manufacturers communicate requirements along their supply chain.

It has been proposed by a task force member that an electronic SDS of specific chemical additives be requested from the supplier of the component. In this way at least an additional step will be introduced into the verification. It is also considered in some Member States that some form of testing of the final product is in this case necessary.

1.2.5 What would be the information needed to be collected in order to build a profile to define who are the 'front runners'?

Article 6(3b) of the Ecolabel Regulation states that *'the substitution of hazardous substances by safer substances, as such or via the use of alternative materials or designs, wherever it is technically feasible'* shall be considered in criteria development. The substitution of hazardous substances can apply equally to substances that do or do not remain in the final product. However, it is emphasised that the work of this task force focuses the application of horizontal screening for hazardous substances as per Articles 6(6) and 6(7). Consequently, focus is placed on the possible substitution of hazardous substances that remain in the final product. Much of the focus of screening studies and substitution initiatives has as a result tended to be on assessment of the possible of alternatives and their associated hazard and risk profile – as illustrated by the schematic of chemical substitution practice presented in Figure 3[7].

The most relevant examples of applied use of the hazard based approach adopted by the EU Ecolabel are the US EPA's Chemical Alternative Assessment (CAA) approach used in the Design for the Environment programme and Clean Production Action's Green Screen assessment tool. Both of these initiatives have successfully engaged industry in the assessment and screening of alternatives, as well as encouraging 'functional substitution' (as defined by Tickner et al [8]. Other examples of potential

[7] taken from Fankte.P, Weber.R and M.Scheringer, *From incremental to fundamental substitution in chemical alternatives*
assessment, Sustainable chemistry and pharmacy, 1(2015)1–8

[8] Tickner.J, Schifano.J, Blake.A, Rudisill.C and M.Mulvihill, *Advancing Safer Alternatives Through Functional Substitution*, Environmental Science Technology 2015, 49, 742−749

relevance to SMEs are identified by Oguzcan et al [9]. The most recent example of this approach being applied in the EU is the Danish EPA's screening of water repellent chemistry [10].

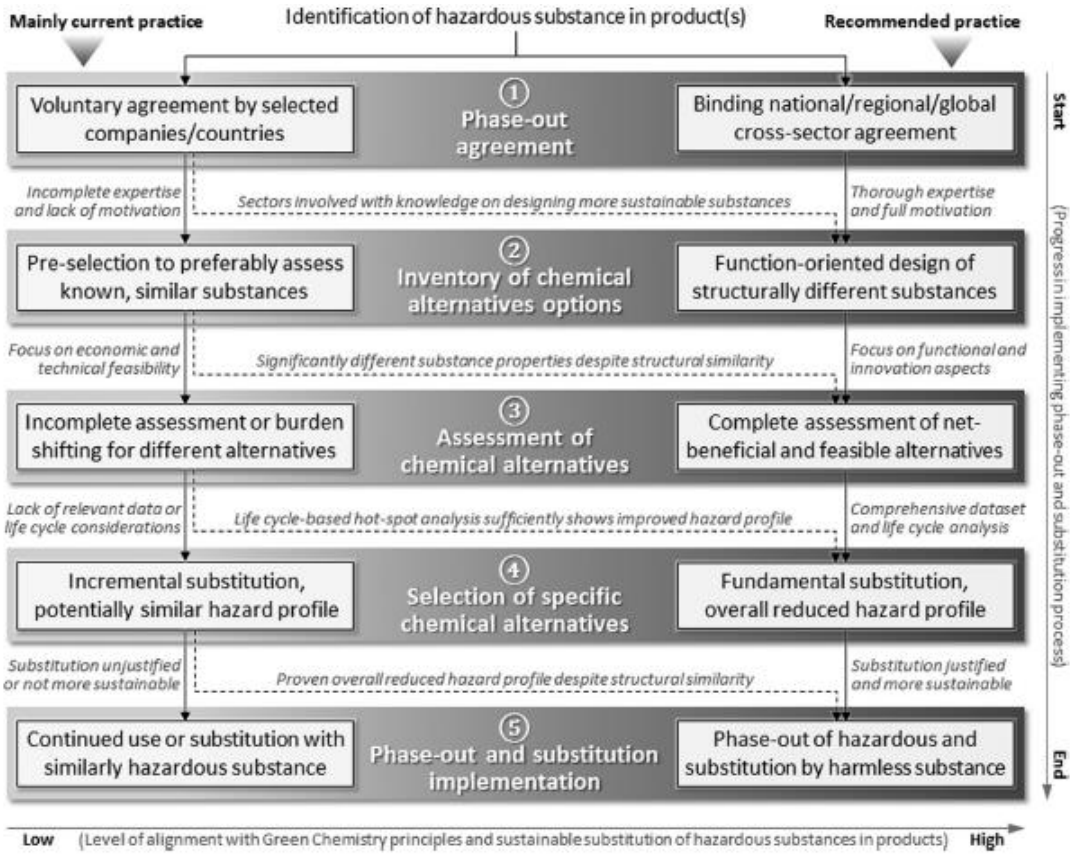


Figure 3. Current and recommended chemical substitution practices Source: Fantke et al (2015)

However, whilst a more complete picture of the substitute chemistry is essential in providing a scientific basis for dialogue with stakeholders, in practice it generally provides only limited information on the market significance of the substitutes identified. Moreover, requests made to stakeholders to provide evidence of substitute chemistry have, to date, generally received a limited response. Especially in product groups that are articles, it is understood that many front runners do not yet screen chemicals based on their hazard profile.

The JRC's recent experience in the development of hazardous substance criteria for EU Ecolabel suggests that chemical hazards are in practice controlled and managed in a number of different ways, both directly and indirectly, but with not all measures resulting in a 'functional substitution' based approach to product design:

'Direct' control of the supply chain

- *Restriction of 'phase out' substances* that have been identified as having health and/or environmental concerns at EU or international level and which may still only be the subject of voluntary agreements.
- *Declarations for the presence of Substances of Very High Concern (SVHCs)* which in some cases include subheadings for components/parts.

[9] Oguzcan.S, kruopiene,J and J.Dvarioniene, *Approaches to chemical alternatives assessment (CAA) for the substitution of hazardous substances in small and medium-sized enterprises (SMEs),* Clean Technology & Environmental Policy (2017) 19:361–378

[10] The Danish Environmental Protection Agency, *Alternatives to perfluoroalkyl and polyfluoro-alkyl substances (PFAS) in textiles,* Survey of chemical substances in consumer products No. 137, 2015

- *Raw materials* are selected or their concentration controlled based on their hazard profile, which in the case of mixtures can be identified from SDS (*e.g. paint preservatives*).
- *Components/parts* are specified based on their chosen chemistry based on substitution/product development work by the supplier (*e.g. Intel*)

'Indirect' control of the supply chain

- *Restricted substance lists* that identify controls and screening applied to components/parts which may also result in the auditing of suppliers. The substances restricted will have a hazard profile that can be determined (*e.g. control of carcinogenic PAHs in plastics and rubber*).
- *Communication of substitute chemistry* to the supply chain in order to facilitate the use of alternative chemistry in components/parts of an article. This is understood to be in the form of white lists that originate from the screening of substances (*e.g. shift to inorganic flame retardants*).

If best practice in a particular product-group is based on exposure-based, or blacklist-based approaches to substances instead of CLP hazard screening-based approaches, then the EU Ecolabel approach may not be adequate for correctly defining front runner performance. It could therefore be possible to identify manufacturers from a given market segment based on market share, and to then conduct a survey of their chemical management practices using a list of possible strategies as a prompt.

1.2.6 How should data to build a profile be obtained in order to ensure that it is a reasonable representation of the EU market position?

To date JRC criteria development has focussed on building up a picture of the hazards that may be present in a product – with a focus on either ingredients or components/parts, as well as functions. Two broad approaches have been tested out. Each has resulted in a set of derogations that define by hazard classifications which substances *can* still be used:

- Paints & varnishes:
  - ✓ A matrix of ingredients used in paint formulas was set up, starting with functions as headings and then inviting manufacturers to populate the matrix in an anonymised way. The manufacturers largely consisted of existing Ecolabel license holders.
  - ✓ This resulted in a hazard profile for a number of different substances that are used to provide the same function.
  - ✓ This in turn initiated dialogue with raw material suppliers about some of the functional substances and the derogation needs (e.g. preservatives).
- Computers and televisions:
  - ✓ A matrix of product components/parts was set up and specific functions associated with each component/part that require chemical additives or treatments identified.
  - ✓ For each function stakeholder information and literature was used to identify the range of substances used, including those that are considered to be being phased out/considered for phase out and those considered to be substitutes.
  - ✓ Literature produced by trade associations dealing with specific functional substances was particularly valuable (e.g. flame retardants)
  - ✓ Assessments of functional substances produced by peer agencies of ECHA (e.g. US EPA) was also valuable to help build an overall picture.

In general the overall knowledge of and access to information about the substances used in computers and televisions was much more limited than in the case of paints & varnishes, and as a result information had to be collected in an in-direct way and validated by asking manufacturers to review the proposals.

In both cases the result was a clearer picture of the alternatives, but each exercise also highlighted the need for better information on the market availability/take-up of the alternatives by the stakeholders who provided data (generally commercially sensitive), as well as the need for a consensus view on CLP classification for each substance.

To build a meaningful profile data would be needed to relate substitution activity to specific product types or market segments – *e.g. a substitute chemical may have been incorporated into a specific new model which has enabled it to be targeted at a specific receptive market segment.* However, this in turn relies on the involvement and co-operation of manufacturers.

1.2.7 Proposals and recommendations for discussion: how to define front runner performance

Especially considering the conclusions of the refit exercise relating to the challenges of implementing Article 6(6) in many product groups, it is proposed to have an initial product group level assessment to decide on firstly, the relative extent of hazardous substances and mixtures remaining in the final product and secondly, on the degree of control that manufacturers have on hazardous substances in the product.

If a full screening approach is chosen, it would be necessary to identify at least two companies (existing license holders or interested potential applicants) who are willing to fully co-operate with a hypothetical assessment and verification of the chemicals used in the manufacturing process. Such an assessment should, at the appropriate time, give a clear idea of whether a full screening approach is possible and also to help identify any derogation needs.

In cases where a full screening approach is not considered practical (for CBs, manufacturers and/or their suppliers), the EU Ecolabel requirements should limit the scope of the screening exercise to those areas that the applicant can control best and to where the presence of hazardous substances is of highest potential concern.

In cases where a decision is taken to align with targeting partial screening for hazardous substances, efforts should be made to identify the leading companies in the sector and what is currently achievable in terms of product stewardship regarding hazardous substances because this may differ significantly from one product group to another, even when the same materials are involved.

In exceptional cases where full or even targeted screening is not deemed practical, the horizontal EU Ecolabel requirements for hazardous substances could simply align with industry compatible restricted substance lists plus a commitment to the non-use and supply chain screening for SVHCs. In this case, it would be clear that the market distinction of such an EU Ecolabel product group would have to be made in other criteria areas.

Task 1.3 Understanding when exemptions for reduced exposure to potential hazards may apply

The interpretation of Article 6(6) for product groups that are mixtures can follow a simple 'in-can' approach, based on the quantities and classifications of added ingredients. However, in product groups which are articles, the following clause has also become relevant in the interpretation of Article 6(6) because of doubts about what extent the added substance or mixture remains in the final product and the potential risk of exposure to the consumer:

"...shall not apply to substances or mixtures which change their properties upon processing (in other words, substances which become no longer bioavailable or undergo chemical modification) such that the identified hazard no longer applies."

This text is too general and is open to misunderstandings and abuse. Consequently, the aim of Task 1.3 is to try to explain what this clause should really mean and how it can fit into the general approach for screening substances that have restricted CLP hazards in EU Ecolabel products that are articles.

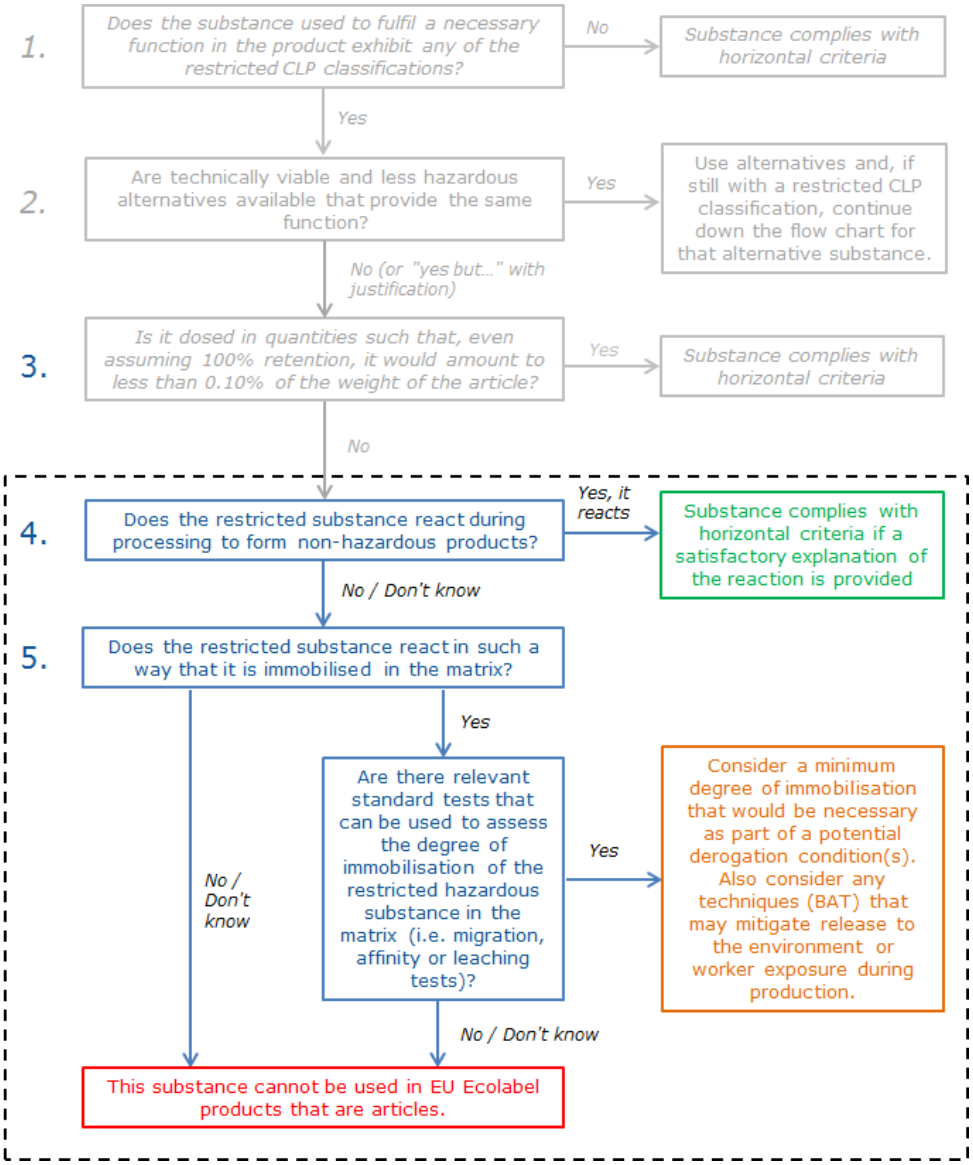


Figure 4. General approach proposed for screening substances against the horizontal CLP restrictions for EU Ecolabel products that are articles.

The cut-off limit of 0.10% w/w is a practical threshold that can effectively be applied to the horizontal screening of hazardous substances in articles. It should be noted that the horizontal screening should be considered as a type of minimum safety net and that there is always the possibility to place tighter restrictions on specific hazardous substances and mixtures either by requiring their non-use in production lines or restricting their presence to levels well below the horizontal 0.10% w/w limit in articles or 0.010% w/w in mixtures. Any relevant restrictions below these generic limits, based on adequate and reliable scientific information as per Article 10 of the CLP Regulation (EC) No 1271/2008, should be flagged by stakeholders and addressed in separate standalone criteria.

However, the presence of any SVHC in EU Ecolabel products, even below the generic limits mentioned above, should not be permitted at any level unless specifically derogated. Even in cases where a derogation for an SVHC is agreed, the maximum quantity of that SVHC may not exceed 0.10% w/w in articles or 0.01% w/w in mixtures. Another potential deviation from the generic limits could potentially be for individual hazardous

Starting from the point where that restricted hazardous substance can be hypothetically considered to be present in an article above the acceptable concentration limit (generally 0.10% w/w for articles), there are a number of points to consider (i.e. 3, 4 and 5 in **Error! Reference source not found.**).

- Do not start to consider factors such as chemical modification or physical immobilisation unless it is clear that there are justifications[11] for not using less hazardous alternative substances for the same function.
- Chemical modification, due to its potentially simpler explanation, should be considered **before** physical immobilisation. However, considerations such as completeness of the reaction and the potential reversibility of the reaction may be relevant.
- Physical immobilisation should only be considered if there are standard tests that can be used to objectively assess the degree of immobilisation **AND** if a minimum acceptable immobilisation can be agreed upon as a derogation condition.

All of these points should be considered during the criteria development process and especially when potential needs for derogations are flagged up. In cases where new derogations are identified for published EU Ecolabel criteria for a particular product group, the same logic should be applied to any potential amendment to the Decision. In both cases, it is ultimately the EUEB that decides on the final criteria or amendment proposals via a formal voting procedure.

1.3.1. Some common examples of chemical modification

One common basis for the consideration of chemical modification is that it must always be associated with the breaking and/or creation of covalent bonds. Changes only relating to the formation of hydrogen bonds or weak Van der Waals forces should not be considered as sufficient chemical modification.

However, in reality the reaction chemistry may be extremely complex, depend on the processing conditions and be difficult to explain. Consequently, it is especially important to try to offer real examples of when a sufficient degree of chemical modification could be (or could not be) considered as having been achieved such that hazardous substance effectively no longer exists in the final article.

Sufficient degree of chemical modification	Insufficient degree of chemical modification
Polymerisation: Many examples possible, including the formation of polyethylene from ethylene via addition polymerisation or the formation of nylon 510 from pentamethylene diamine and sebacic acid by condensation polymerisation. **Wet Strength Agents based on epichlorohydrin:** These are cationic polymers that impart an essential wet-strength function to tissue paper via homo-crosslinking (new polymer to polymer bonds) and via co-crosslinking (new covalent cellulose fibre to resin bonds). **Bleaching chemicals:** In the pulp and	**Dyestuffs and pigments:** These are used to impart a desired colour to the product. While a number of auxiliary chemicals such as fixatives (chemical bond possibly formed) and solvents (physical evaporation) in a dye formulation can be argued as no longer remaining in the final product, the actual colourant remains visible and so should not be considered as chemically modified. As a general rule, dyestuffs should be considered as not chemically modified except in specific cases where supporting evidence can be provided (e.g. reactive dyes that form covalent bonds in textiles). **Plasticisers:** Substances which are incorporated into a polymer material to increase its flexibility, softness, distensibility and workability. Plasticisers modify the end properties of polymers for a wider range of applications. Careful selection of the plasticizer structure and molecular weight is needed to ensure that intermolecular forces (dipole-dipole interaction, dispersion forces, Van Der Waals forces, hydrogen bonding …) are developed with the

[11] Justification for not using less hazardous alternatives should be related to considerations such as efficiency of function and associated environmental benefits (e.g. a TiO_2 pigment with a restricted CLP hazard may deliver the same opacity for a coating layer that is 4x thinner than non-classified zirconium dioxide or 100x thinner than a coating with calcium carbonate or barium sulphate. See: http://www.european-coatings.com/Raw-materials-technologies/Titanium-Dioxide-Ruling-opacity-out-of-existence

paper industry, these are generally oxidising agents that react to impart an essential degree of brightness to the pulp and paper. Chemicals such as chlorine dioxide and sodium hypochlorite or used to oxidise lignin by polarising aromatic rings (replacing H for Cl) and opening C to C double bonds amongst other reactions. **Reactive flame retardants**: For example organophosphorus flame retardants in epoxy resins where the P forms a covalent bond with –OH groups of cured epoxy resins.	plastic polymer, limiting to a significant degree potential plasticizer migration, while ensuring retained flexibility over time and harsh aging conditions. Although plasticisers are effectively embedded in the plastic matrix, they should not be considered as chemically modified since their presence in the article is not fixed by covalent bonds and they may migrate from the matrix during the use stage under certain conditions. **Additive flame retardants:** These chemicals are added to impart a minimum ignition resistance to the treated article. As with plasticisers, their presence in the article is not fixed by covalent bonds and they may migrate from the matrix during the use stage under certain conditions.

When a non-hazardous chemical is formed by the reaction of at least one hazardous chemical (e.g. many examples of monomer → polymer) it is important to consider the quantity of residual hazardous substance that may remain. Although such residues will generally be well below the threshold of 0.10% w/w that is recommended for the horizontal CLP restrictions in EUEL products that are articles, possible further restrictions going below 0.10% w/w could be considered on a case-by-case basis in standalone criteria.

1.3.2. Considerations relating to physical immobilisation

Physical immobilisation cannot be used as a justification of compliance with Article 6(6), but it can potentially be used as a derogation condition that would allow for the presence of a CLP restricted hazardous substance in an EU Ecolabelled product that is an article. However, it is emphasised here that before thinking about derogation conditions, some pre-requisite justifications for a derogation must also be made in the first place (e.g. no technically feasible alternative or net environmental benefits).

The terminology used relating to the degree of physical immobilisation may vary depending on the exposure path and end target. Terms such as bioavailability and bioaccesibility focus on end targets that are biological organisms whereas terms such as leaching and migration may relate to releases to specific targets such as food or to the wider environment in general. To better understand how limited mobility / bioavailability can be assessed, the following areas have been consulted and investigated:

1. An explanation of the terms "bioacccesible" and "bioavailable".
2. A simplified framework for linking bioaccesibility to exposure scenarios.
3. Real examples of assessing bioaccesibility or potential for emission to the wider environment.

The final aim is to produce recommendations on how different substance groups could be assessed in terms of their potential migration and release during the use phase of the product. Efforts to assess the potential release of hazardous substances after the End of Life of the article will depend on the assumed disposal route (e.g. illegal dumping, landfill or incineration) and potentially go beyond the boundaries of manufacturer responsibility. One aspect is to consider if a substance will leach into the aqueous phase in a landfill, another aspect altogether is where that leachate may go (i.e. is the landfill lining a suitable barrier).

Following a review of literature and current practice the term bioaccessibility has been identified as being more relevant than the term bioavailable, at least in relation to the practical evaluation of the migration of substances from products.

1.3.3 An explanation of the terms "bioaccessible" and "bioavailable"

The exemption clause mentioned at the beginning of section 1.3 refers to the term "*not bioavailable*", which is closely reflected by Art. 12(b) of the CLP Regulation where it says:

"*conclusive scientific experimental data show that the substance or mixture is not biologically available and those data have been ascertained to be adequate and reliable*;"

The CLP text is not particularly clear. Determining the bioavailability of a substance is extremely important in determining the potential for toxic effects of a hazardous substance in a particular exposure scenario and will typically require some degree of *in vivo* evidence from toxicokinetic studies that relates the form of the substance used with concentrations of that substance and/or its metabolites found in body fluids and/or target organs. A practical alternative technique, which can be used as an estimate of potential bioavailability, is to measure the "bioaccessibility", which can be measured by *in vitro* methods.

Bioavailable: the extent to which a substance is taken up by an organism and is "available" for metabolism and interaction.

Bioaccessible: the fraction of a substance that dissolves under surrogate physiological conditions and therefore is "potentially available" for absorption into systemic circulation.

There is a proven track record of using bioelution tests as a means to measure the bioaccessibility of metals, for example in migration tests stipulated in EN 71-3 for toys and in EN 1811 for nickel release from consumer articles.

Table 1. Examples of relationships between bioeluants and exposure simulation in bioelution tests

Exposure simulation	Bioeluant used (Henderson et al., 2014)
Oral ingestion	10mg sample per 50ml gastric simulant (i.e. HCl at pH 1.5) at 37°C for 1 hour agitation + 1 hour resting
Inhalation routes	100mg of particles <10µm in 50ml interstitial fluid simulant (i.e. Gamble's solution at pH 7.4) at 37°C for 24 or 168 hour agitation + 3-5 minutes resting
	100mg of particles <10µm in 50ml lysosomal fluid simulant (i.e. a defined mixture of Na, Ca and Mg salts plus citric acid, glycine and formaldehyde at pH 4.7) at 37°C for 24 or 168 hour agitation + 3-5 minutes resting
Dermal contact	100mg sample in 50ml sweat simulant (i.e. a mixture of NaCl, urea and lactic acid at pH 6.5) at 30°C for 24 or 168 hour agitation + 3-5 minutes resting

To date, there is no formal standard that sets out methodologies for assessing the bioaccessibility of hazardous substances via bioelution tests. There is work ongoing with a view to validating bioelution protocols developed by the metal industry as an OECD standard. There is understood to be interest from within the Commission in linking reliable bioelution tests to the CLP Art. 12(b) definition of bioavailability.

Conclusion: Bioaccessibility is a good and practical way forward in evaluating the bioavailability of hazardous substances in EU Ecolabel articles. Experience is growing but still limited to mainly metals. A harmonised approach to testing would help a lot but even before then, bioelution data should be able to be considered as part of potential derogation conditions.

1.3.4 A simplified framework for linking bioaccessibility to exposure scenarios

Before deciding on what type of bioaccessibility data could be relevant for any particular derogation request, it is first necessary to consider what the most relevant exposure scenario(s) is/are. The general REACH guidance for environmental release categories that relate to products that are articles (10A, 10B, 11A and 11B) are quite general and only distinguish between (i) low release and high/intended release and (ii) indoor or outdoor use. Consequently it may be useful to consider a framework that is more applicable to individual articles, be that as a simple product or articles within a product that is considered as a complex article.

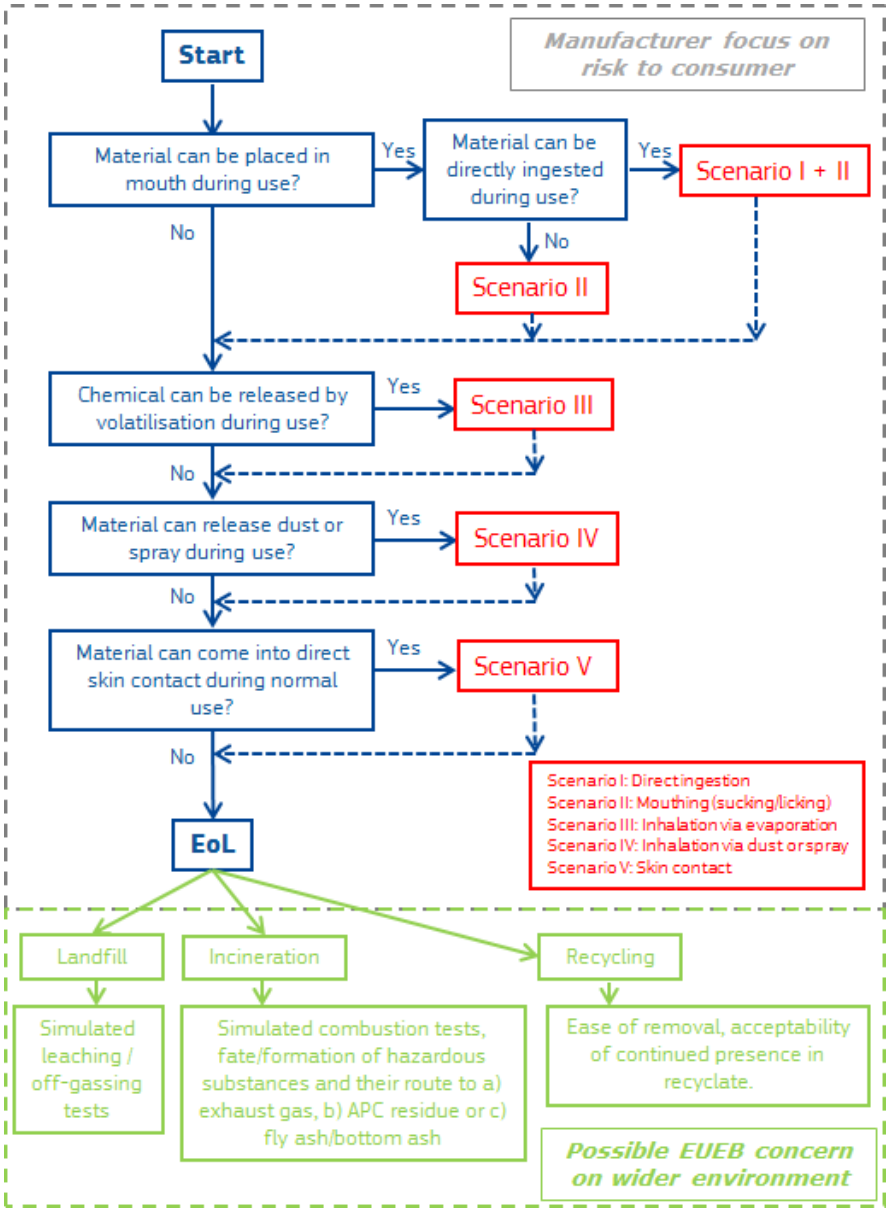


Figure 5 Exposure scenario decision tree (manufacturer scope adapted from RIVM, 2008)[12]

The grey section of the above decision tree has been modified from that published by RIVM (which was specific to toy products). The wording can now, in principle, be applied to any article in an EUEL product that contains Art. 6(6) restricted hazardous substances in order to determine what bioaccessibility tests would be most appropriate as part of supporting evidence for a derogation request.

However, it is also possible that the EUEB decides that the allowed presence of an immobilised hazardous substance in an EU Ecolabel product presents a risk to the wider environment after its use. In order to address such concerns, the potential further evidence that should be considered is provided in the green box.

[12] Van Englen et al., 2008. Chemicals in Toys. A general methodology for assessment of chemical safety of toys with a focus on lements. RIVM (The Institute for Public Health and the Environment).

1.3.5 Real examples of assessing bioaccesibility/potential for emission to the wider environment

Bioaccessibility is just one potential way to assess the degree of physical immobilisation of a hazardous substance in an article and is relatively new. Other assessments that relate to migration or leaching are better established and in some cases are already established in EU Regulations. This section aims to provide a number of relevant examples:

Material	Substances, standards and brief test details
Paper	Dye bleeding. EN 646. 50mm x 20mm paper samples are placed in between two unstained glass fibre papers that have previously been immersed in one of four test fluids (DI water, acetic acid (3% w/v), alkaline salt solution or vegetable oil. The paper sample is held for 10 min, 4h or 24h at 23°C depending on the contact time or for 30 min at 90°C in water or at 120°C in oil to simulate contact with hot moist or fatty food. The degree of bleeding is measured by comparing any stains on the glass fibre papers with the ISO grey scale. Scores of 1 (poor) to 5 (very good) are generated.
Leather	Colour fastness: EN 11640. One side of a dry or wetted leather specimen at least 100mm x 20mm is rubbed with a piece (15mm x 15mm) of reference wool felt under the pressure of a 500g (for soft leather) or 1000g (for normal leather) finger with a rubbing motion of 35-40 mm and at a rate of 40 cycles (one forward + one backward motion) per minute. The felt may be wetted previously with an artificial sweat solution (specifically for wet rubbing resistance). The degree of fastness is measured by comparing any stains on the leather with the ISO grey scale. Scores of 1 (poor) to 5 (very good) fastness are generated. Minimum standard scores to reflect good fastness have been set based on the number of cycles, which can range from 20 to 500, and depending on the type of leather to be tested and if wet or dry felt is used.
Metal	Nickel in electroplated steel or in stainless steel. EN 1811. The article (of known surface area) is submerged in a closed container with an artificial sweat solution at pH 6.5and temperature 30°C for a period of one week. The total quantity of solution added should be approximately 1ml per cm^2 of sample surface area. The dissolved Nickel concentration is then measured by ICP-MS or ICP-OES and results converted into $\mu g/cm^2$/week.
Plastics	Bisphenol A. Regulation 10/2011 methodology (but ongoing discussion about what might be considered as unacceptable migration in different food contact materials). For migration from water bottles, an appropriate methodology would include a migration study for 10 days at 40°C. The test should be repeated three times on the same plastic and results from the third test compared to acceptable limits, in units of mg/dm^2 of contact surface or in mg/kg food simulant.
Toys	Various metals and organic tin. EN 71-3. Three categories of migration limit are set based on the nature of the toy material and its use. In heterogeneous toys, samples of different materials or colours are analysed separately. Category I and II toys: the material is mixed with a solution of hydrochloric acid at pH 1.0-1.5, liquid to solid ratio of 25 or 50, at temperature of 37°C and for a period of 1 hour prior to being filtered and analysed by ICP for the metals and by other defined methods for organic tin and Cr(III) and Cr(VI). Category III samples: The same procedure as Category I or II toys but always with a liquid to solid ratio of 50. Migration is expressed in units of mg/kg of sample.

While the approach to the migration of around 1000 substances in food contact materials (as per Regulation (EC) No 10/2011) is very comprehensive, the detail about choice of methodology is quite complex in order to capture all the different potential exposure routes for food contact. Apart from food contact materials, clear examples of limits for the migration of specific hazardous substances and associated methodologies are quite scarce. In the table above, the immobilisation requirements for dyes are only indirect measures of the immobilisation of the colourant.

Issue 2: The handling of derogation requests and related changes in CLP classifications

Task 2.1 What flexibility does the Commission have?

2.1.1 Approach

The legal service of the Commission was consulted to explore the flexibility on handling of derogation requests and related changes in CLP classifications:

Request for legal opinion on possible alternative to grant derogations from Article 6(6) of Regulation (EC) No 66/2010

Framework

The EU Ecolabel Regulation (EC) No 66/2010 sets out the process for developing and revising ecological criteria that are applicable to all relevant EU Ecolabel product groups. After going through a delegated procedure, the criteria for each product group are published as a Commission Decision. Any amendment to that Decision has to go through a delegated procedure once again.

*Article 6(6) of Regulation (EC) No 66/2010 requires that EU Ecolabel product shall not contain hazardous substances with certain hazard classifications. Article 6(7) then refers to the possible derogation, under specific described conditions that are laid down, of certain hazardous substances from the provisions of Article 6(6). In relation to how derogations shall be granted, Article 6(7) says that "**the Commission may adopt measures to grant derogations from paragraph 6**" and furthermore it is noted that "**those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 16(2)**". Article 16(2) refers to the supporting role of the EU Ecolabel Regulatory Committee as a scrutiny committee in accordance with the procedure described in Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC.*

The recent evaluation of the EU Ecolabel Regulation highlights the need to develop a practical 'modus operandi' for the implementation of article 6.6 and 6.7, which is considered as a potential obstacle for higher uptake of the scheme.

Existing approach to grant derogations

*To date, potential justifications for derogations for the presence of hazardous substances are consulted on separately for each product group. Proposals for derogations are evaluated by DG Joint Research Centre and DG Environment, before a proposal to accept or reject a derogation is presented to the EU Ecolabel Board for an indication as to voting intentions, before then being presented to the EU Ecolabel Regulatory Committee as part of a formal procedure of **amendment of the Decision setting up the criteria** (published in the Official Journal). This process usually lasts **between 13 and 18 months in total** (clarify and evaluation of the derogation request, formulation of a proposal, followed by 4-6 months for formal adoption by the Commission).*

Difficulties of existing approach

Hazardous substances are derogated based on their hazard classification, but the hazard classification of substances can change with time as new toxicological data becomes available and ATP (Adaptation to Technical and scientific Progress amending the CLP Regulation) are published to reflect changes in the underlying rules of the GHS (Globally Harmonized System of Classification and Labelling of Chemicals). These changes can potentially render previous derogations listed in the Decision invalid (because the derogation is linked to both the substance and its hazard classification), resulting in the need to start the amendment procedure.

It is very difficult to identify all of the possible derogation needs during the criteria development process. In practice, the need for some derogations are identified only after the original Decision is published and potential license holders have examined the criteria in detail. The length of time

required to evaluate and adopt an amendment to the original Decision can create a considerable delay and associated period of uncertainty for license holders of ***up to 18 months****. This can create a barrier for EU Ecolabel uptake in some product groups.*

Finally, amending existing Decisions presents a major potential administrative workload for the Commission, and for Competent Bodies with most EU Ecolabel license holders, as each relevant license would need to be re-evaluated. This serves to confuse potential applicants.

2.1.2 Proposed alternative to current practice:

In order to make the derogation approval process more efficient to be able to respond to industry request within a more reasonable period, it would be proposed that the Decision setting criteria refers to a ***separately managed*** *'derogation list' for each product group that can be updated to reflect:*

i. *future changes to the CLP classification rules,*
ii. *new CLP classifications of specific substances, and*
iii. *derogations requested during the criteria validity period*

The list would not be published in the Decision, although an explicit reference would be made to it in the Decision with a mechanism[13] *described in which the relevant EC services (incl. DG JRC, DG ENV) with Member States would identify, evaluate and come to a decision on derogation needs and requests for hazardous substances that have been communicated by new applicants or existing license holders. The derogation list would be put together and evaluated by DG JRC and DG ENV based on a number of technical criteria agreed with Member States.* ***The list would be endorsed by the EU Ecolabelling Board on a regular basis (every 6 months) and published by the Commission on the EU Ecolabel website.***

2.1.3 Questions to the legal services

Could you please provide legal advice as to whether Article 6(7) of Regulation (EC) No 66/2010 could be interpreted in a way that allows for the proposed approach for granting derogations?

Moreover, we would welcome advice as to whether existing precedents in EU law could support our suggested interpretation and proposal.

Specific legal questions we have in relation to the request are as follows:

- *Could the 'measures' referred to in Article 6(7) be interpreted as the inclusion of a legal reference to a (periodically updated) derogation list in a Decision for a product group?*
- *Does the EU Ecolabel Regulation allow the use of the regulatory procedure with scrutiny for granting derogations in the way as presented in paragraph 2 of section 4 above?*
- *To what extent does the EU Ecolabel Regulation allow us to go in the above proposed direction for simplifying the procedure for granting derogations?*
- *What are the other possible ways to simplify the procedure for granting derogations on the basis of existing precedents? e.g. REACH Candidate List*

2.1.4 Response received from the legal services

Following submission of the above questions to the Commission's legal service, the following response was received:

Article 6(7) sets out that, if the substantive conditions in that paragraph are met, the Commission may adopt measures to grant such derogations, and that those measures shall be adopted in accordance with the regulatory procedure with scrutiny. This approach provides for the required legal certainty and ensures that the derogation is legally binding. As explained in

[13] Similar to art. 59 of REACH that applies to the list of Candidate list of SHVC (Substances of Very High Concern) published on the ECHA website

Recital 17, the measures necessary for the implementation of the Regulation should be adopted in accordance with Council Decision 1999/468/EC on the procedures for the exercise of implementing powers conferred on the Commission, which introduced the regulatory procedure with scrutiny. Thus, ***to grant derogation in accordance with Article 6(7), the Commission has to act on the basis of the regulatory procedure with scrutiny.*** *The publication of a separately managed "derogation list" for each product group on the EU Ecolabel website does not satisfy the criteria of that provision.*

<u>Conclusion</u> of the consultation with legal services

It can be concluded following the consultation with the Legal Services that at present there is no flexibility in relation to the need for derogations to be individually granted on the basis of the regulatory procedure with scrutiny i.e. the EU Ecolabel Regulatory Committee.

In the light of this response, proposals have been formulated for **how the current derogation process – both during criteria development and criteria validity periods - could be streamlined and improved**. These proposals are outlined in **Section 2.2.2**.

Task 2.2 Encouraging disclosure and identification of derogation needs

2.2.1 How could this be done for other potential and current applicants/front runners, and how could companies be engaged better during the revision process?

In the experience of the JRC during the criteria development process a 'reality check' can be made with the co-operation of manufacturers. This does rely on them being willing to spend time to check with suppliers, but can be a useful way of identifying potential problems or barriers in advance.

Some front runners are not able for confidentiality reasons to discuss openly and instead can only review proposals and say yes/no to whether they could comply with them. This can be frustrating because they would tend to be a target group for attracting new license holders.

The shortcoming is that this approach is only generally possible once the criteria are further advanced, and also usually with a focus on particular functions or components of a product, because it is time consuming. It is also supposes that the product group has sufficiently committed stakeholders.

There could be the potential to extend this exercise also to Competent Bodies, who for some products have a comprehensive knowledge of what is feasible. This could take two forms:

1. a CB could check the criteria based on their knowledge of existing applicants, or
2. a CB could arrange checks directly with specific license holders.

2.2.2 How could the process be better organised in order to gather the necessary information?

In terms of REACH and RoHS processes these appear to be very strictly defined in terms of the timescales, the substances in question and the criteria for assessment. Because they are not voluntary the participation is high, reflecting the needs of the broader spectrum of the industry for a product group(s). A lesson could be that with a pre-study by JRC it could be possible to focus attention on specific derogation areas/functions/substances, rather than putting out a general call for derogation needs, which is what has been done up until now and generally has not worked.

In Task 1.2 an evidence matrix approach that JRC has used for both mixtures and articles was outlined. An example of a component/material data system has also been cited by a task force member (see screen grab in figure 6 below). In both cases the approach has been based on a matrix which can be provided to stakeholders. They can then be invited to enter information, if necessary on a confidential basis, which could for the Ecolabel be shared with JRC, CBs, sub groups and/or stakeholders.

From experience so far using a matrix approach the emergent information tends to define the ambition level of the criteria i.e. it represents the limit of what is known about the product. The matrix can be structured by function or by components, although the experience is that a matrix usually ends up being re-organised by function to avoid duplications.

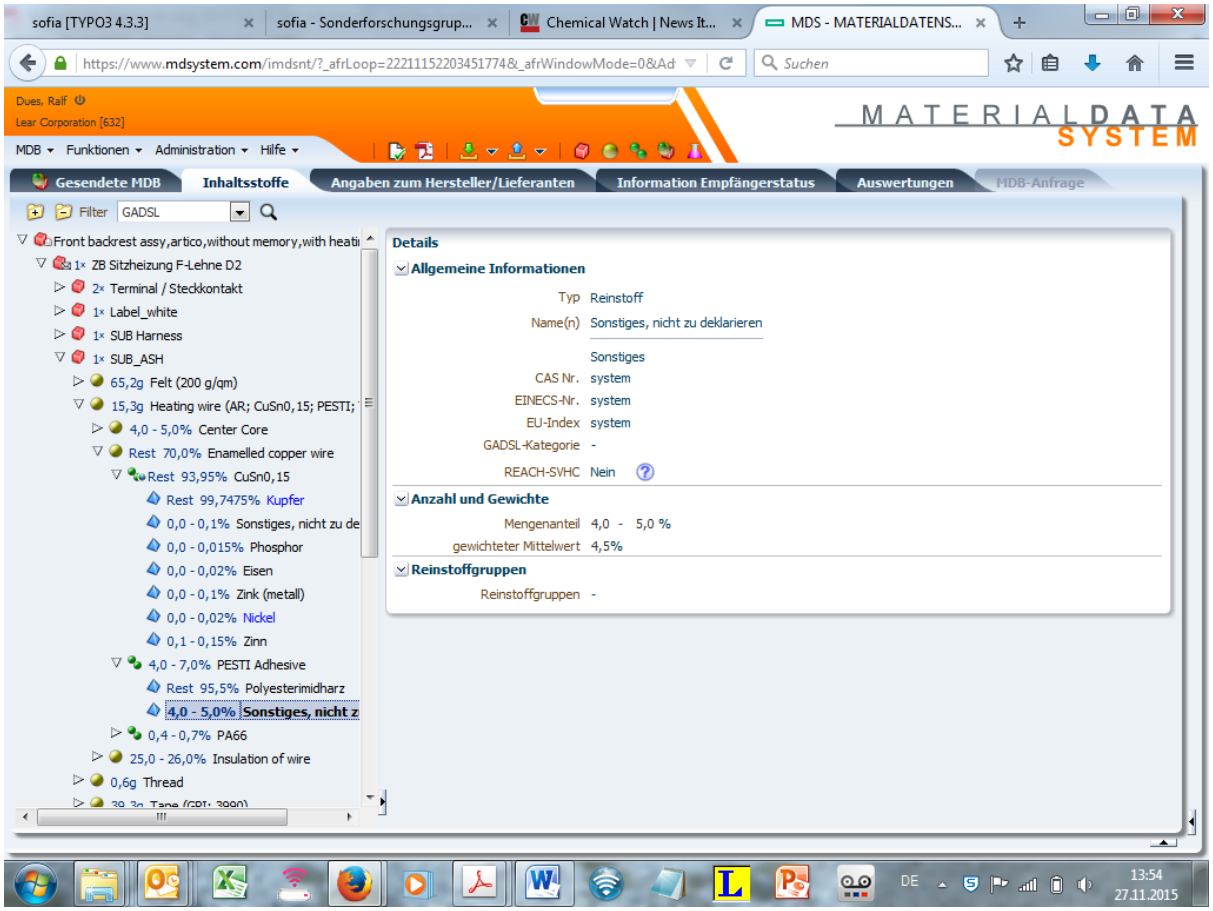


Figure 6 Material Data System screen grab

2.2.2 Proposals and recommendations of the Task Force: Encouraging the disclosure and identification of derogation needs

2.2.2.1 Improving the identification of derogation needs during the criteria development process

It is proposed that during criteria development process a 'reality check' is always carried out with the co-operation of manufacturers. This checking process has a number of objectives. The primary objective is to ensure that the ambition level of the criteria is achievable by front runners, as has already been referred to under Task 1.2. The *golden rule* of the check will be that at least two manufacturers with a credible market share or position as a front runner can comply with the criteria. However, a secondary objective is to help improve the identification of derogation needs.

This process is to be carried out directly by the JRC with the co-operation of stakeholder manufacturers willing to disclose the necessary information and Competent Bodies, who for some products have a comprehensive knowledge of what is feasible based on data they already hold from applications for licenses granted. The co-operation between JRC and CBs could be in two main forms:

1. a CB checks criteria compliance based on their knowledge of existing applicants, or
2. a CB could arrange checks directly with specific license holders who are willing to co-operate and disclose the necessary information.

There is already good evidence that these processes can proactively help identify and differentiate the hazard profiles of different products and formulations, as well identifying where derogation needs may exist, even in the case of leading front runners.

2.2.2.2 Streamlining and improving the derogation request process during a criteria validity period

In the case of derogation requests that take place during the criteria validity period, it is proposed to focus on improving the submission and evaluation period for derogations. This is in part due to the substantial effort which is required to evaluate a new derogation request in isolation from a criteria development or revision process, and the demand from those that submit derogations for a clearer and more efficient process.

Concerns have also been raised that the process for identifying and processing derogations currently lacks a clear structure and process, starting from identification by a manufacturer and their discussions with CBs, and continuing through to the collation of these requests for evaluation by DG ENV and the JRC. It is also important that JRC receives all the relevant information to enable it to efficiently carry out an evaluation.

An underlying issue relating to agreement on classifications has also been identified during 2017 by the JRC. Depending on the conclusions reached by different manufacturers and CBs on a substances classification, this may lead to a loss of time during the process or even a realisation that a derogation may not be needed in the first place.

It is therefore proposed to develop a stepwise process with the aim of providing clarity on how derogation requests can be identified->formulated->checked->evaluated, so that all those involved can play a role in ensuring that there is an efficient process.

Proposed process for identifying and processing derogation requests

1) Submission of a request by a license holder or their supplier to a relevant Competent Body
    - ✓ CB to communicate what is needed by JRC to make the evaluation: Derogation form, SDS, JRC classification check rules (the 'decision tree'), relevant background data
2) Checking of the request by the relevant Competent Body
    - ✓ CB to check for the completeness of the request and that CLP classification is consistent (using the decision tree in task 1.3)
3) Competent Body forwards the request to DG ENV and JRC for consideration
4) JRC the makes a quick check of the completed derogation form and the classification
5) Evaluation initiated (if still required) with a short technical review and including a survey of CBs, license holders, lead trade associations and the NGO representative.
6) Technical discussion of the findings from the evaluation in the Competent Body Forum, including interested parties and with final checking if deemed necessary. The EUEB shall also be updated on progress.
7) Decision to be made by the Commission as to whether to present the derogation for voting by the Regulatory Committee.
8) Proposal with technical justification formally submitted to the EU Ecolabelling Board for discussion and then, if there is the necessary support, the Regulatory Committee for voting.

To support this stepwise process it is proposed that periodic deadlines are established by which derogation requests must be submitted to the Commission. It is also recommended that in order to support the first two steps a toolkit/guidance is provided to all Competent Bodies on how to handle derogation requests as they arise. This could comprise:

- ✓ When/how to submit them

- ✓ Checklist of relevant information and documentation needs
- ✓ Quick check items (e.g. to confirm CLP classifications)
- ✓ Clarification on how to approach different types of derogations (see section 2.2.2.3)

2.2.2.3 Addressing CLP reclassifications during a criteria validity period

The Chemical Task Force 2 has discussed and identified, based on experience, three possible situations where derogation requests may arise during the validity period of a criteria set. It is proposed that a differentiated response is adopted in each instance:

1) **Reclassification** due to a **change in classification rules** (e.g. CLP ATP)
2) **Reclassification or a new classification** due to **new toxicological evidence** that is agreed on by REACH registrants and/or where this evidence informs a new harmonised classification
3) No reclassification but the **derogation need was not previously identified**

Proposals on how to handle each case are set out below.

In all cases the wording of the hazardous substance criteria is considered important by task force members. This is because it should state that the CLP classifications to take into account in assessing applications for a license shall be those at the time of award. This then provides a starting point for considering the implications for current license holders and the extent to which the burden is placed on them to respond.

In practice the time frame stipulated in the ATP for any change coming into force and also for licenses to be updated with new information – for example, if substitutions are made or derogations are needed - will be important to take into consideration and could be used to define transitional periods.

Case 1: Reclassification due to a **change in classification rules** (e.g. CLP ATP)

In the first case the approach is recommended as being less stringent, given that all license holders may automatically be affected. If the implications are significant then, as was the case for detergents, the Commission could take the initiative and develop a block derogation request.

Case 2: <u>Reclassification</u> due to **<u>new toxicological evidence</u>**

In the second case the approach is recommended as being more stringent, particularly if the reclassification reflects test results and self-classification conclusions that were already used/adopted in SDS by some manufacturers.

It is proposed that in this case that all CBs notify affected license holders and set a deadline for adaptation. The emphasis would be placed on substitution of the affected substance, but the opportunity would also be given to make a derogation request. The timeframes for adaptation and any associated updates to licenses should be discussed/formulated at the CB Forum before being tables for discussion/agreement at the EUEB This is to ensure that all license holders across the EU are treated the same.

If it becomes clear that a derogation is needed for most license holders then the time frame for a decision on the derogation and its subsequent adoption could be used to define a transitional period.

Case 3: <u>No reclassification but the **derogation need was not previously identified**</u>

In the third case a derogation request will need to be made, unless a substitution can be made within an agreed timescale for updating of the license.

Recognising that for more complex products it may be difficult to identify all derogation needs within the frame of a criteria development/revision process, a period of 'grace' (e.g. 2 years) could be allowed following the date of the criteria coming into force. During this time a license would not be revoked if a derogation need was to come to light.

Task 2.3 Determining classifications

2.3.1. CLP hazards decision making tree: The background to its setting-up

The decision tree was originally developed in order to determine which substances or hazard classifications should be derogated for use in the EU Ecolabel for Computers and Televisions product groups.It was considered important to consult with ECHA in order to identify key factors to take into account during the evaluation of different sources of hazard classification evidence and to then use this to develop a decision making tool in order support the process.

The resulting first version of the decision tree is presented in the figure below:

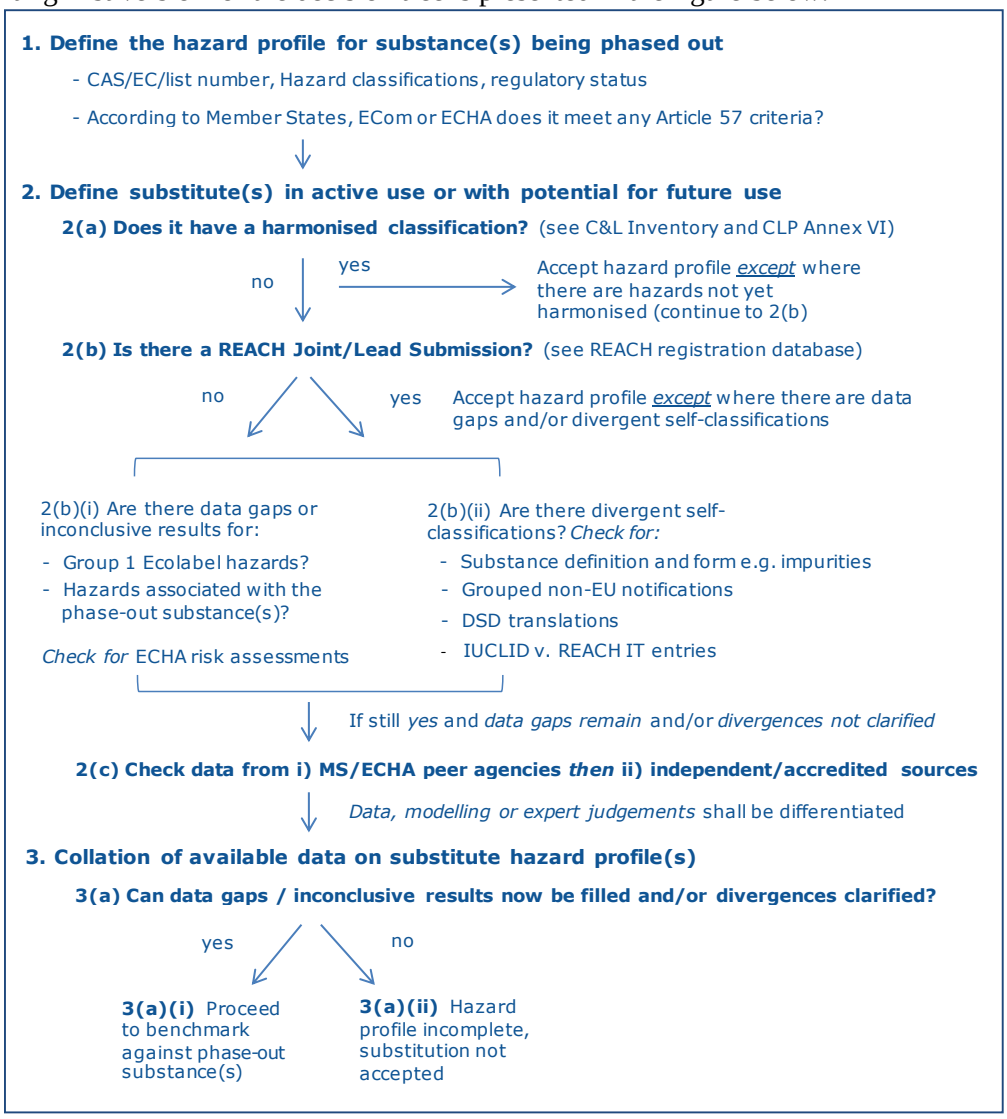


Figure 7 Version 1 of a 'decision tree' for hazard profile determination for potential derogations/substitutions (elaborated under the revision of EU Ecolabel for Computers and Televisions product groups)

This tool was then used by JRC to determine hazard classifications for the substitute flame retardants and plasticisers identified. In addition the main elements of the decision tree where used to redraft the assessment and verification text of the EU Ecolabel for computers.

2.3.2 Task Force member's feedback on the current Decision tree:

A stakeholder stated: *In the case of harmonised classification new data justifying more severe classification should not be disregarded.*

ECHA was further consulted and they considered that if a stricter classification than that made under CLP is to be considered then harmonised classifications should receive priority. Moreover, they commented that the decision tree supposed a deep understanding of the REACH data requirement, interpretation of hazard data and classification criteria. All of these aspects require in principle a lot of expertise and careful considerations before answers to the various steps of the tree can be given. Care should therefore be taken if someone who is not necessarily qualified to make such expert judgements tries to use it. It was also pointed out that the way the decision tree is presented at the moment is very narrow, as it is only written as if it will be used for potential substitutes, whereas it may be necessary to use it more widely – for example, substances that may be phased out.

2.3.3. Revised Decision Tree presented in briefing paper 4 (May 2017)

Considering that there might be the situation where there is no harmonised classification for substances being phased out, a hazard determination process should be followed as well for these substances and not only for potential substitutes. It is therefore proposed to reformulate the decision tree to convert it in a general tool to determine the hazard profile of relevant substances independently of their status (e.g potential substitutes, substances being phased out, existing substances that need derogations, etc…).

It is considered that the decision tree should be a tool that helps users (JRC, stakeholders, CBs potential applicants) to find out hazard classification of substances in general during the revision process and once the text is in force. The rules in relation to the derogation and/or restriction of hazards are specified in the criteria text; therefore the decision tree should work as a tool to find out hazard classifications and not to define the substitution or derogation rules. In addition as far as possible the reformulated decision tree should be simplified and made more users friendly to help all potential users to deal with it.

All EU Ecolabel hazards statements for a specific substance must be assessed through following steps (Fig.8):

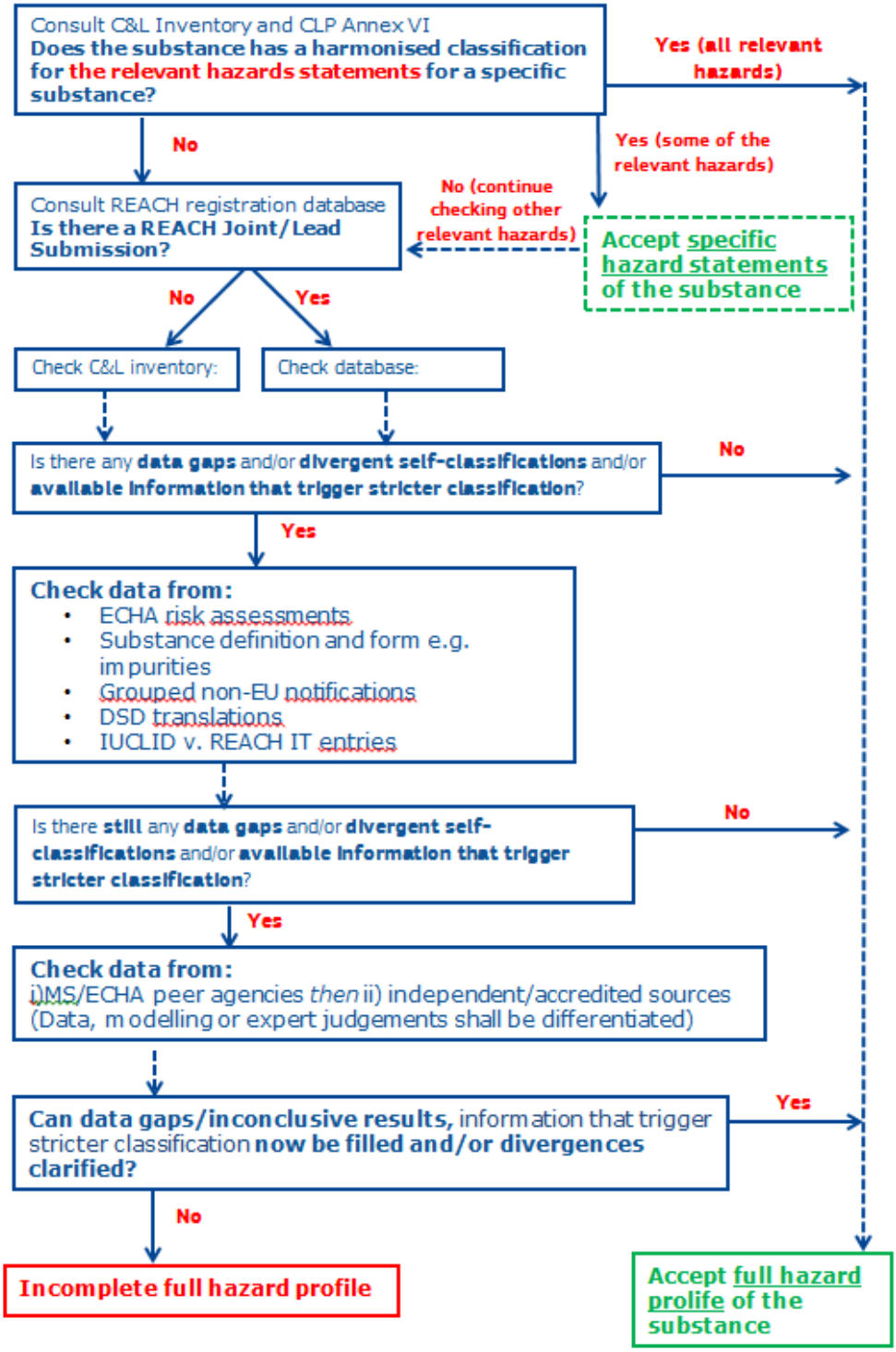


Figure 8. Revised decision tree for hazard profile determination

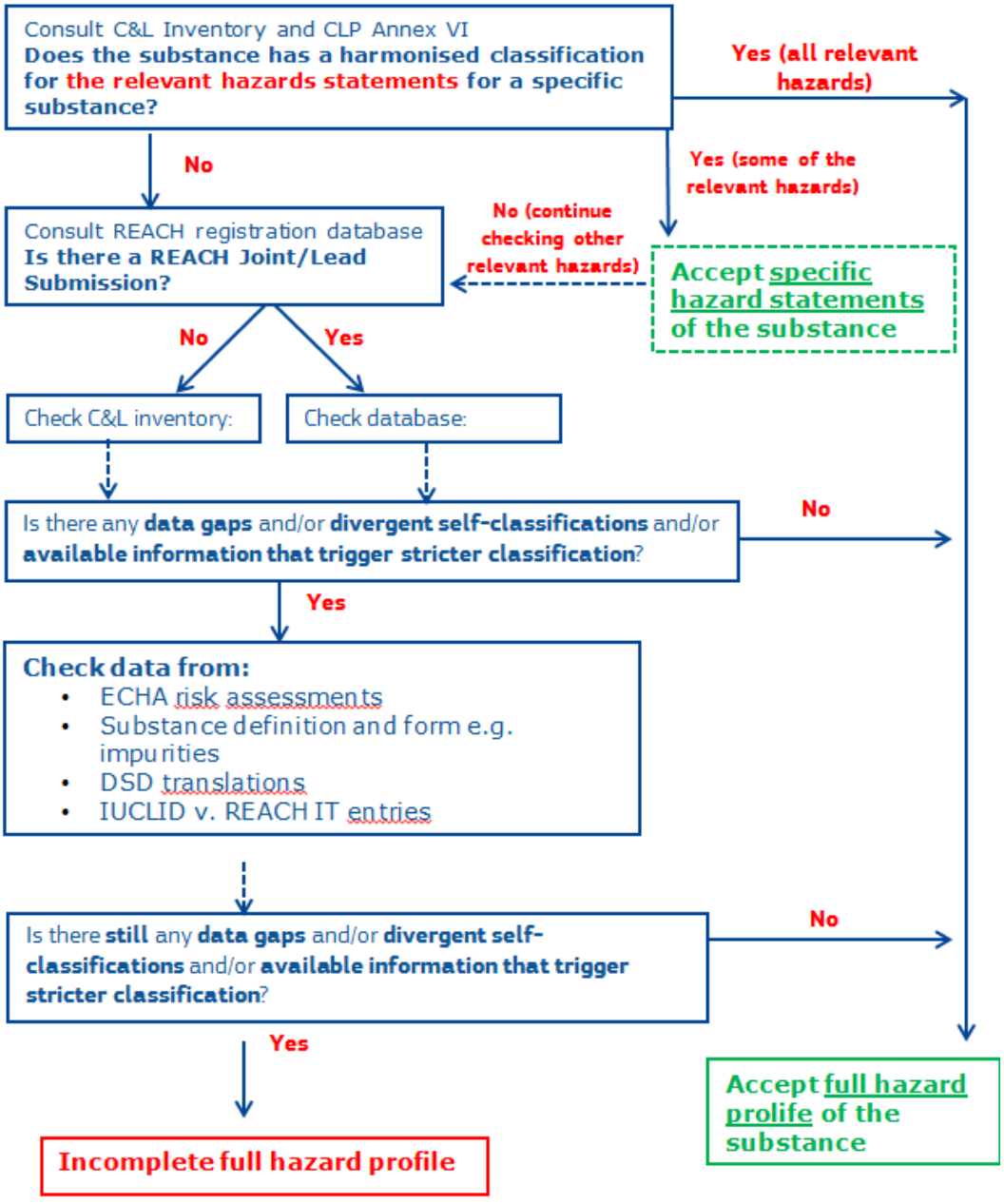
2.3.4 Task Force member's feedback on the revised Decision tree:

- While TF members agreed that it could be used to look at the level of uncertainty associated with a substance classification, they were sceptical about how far the applicants/CBs would actually have the capacity/expertise to make a conclusion (i.e. do the work of ECHA).
- ECHA flagged areas where there is a significant disparity in classification information between different submissions and considering other possible regulatory approaches for these substances.

- Proposed to "cut" the decision tree at the point where it starts looking at data gaps.
- Priority to harmonised classifications will be kept.
- Due to limited expertise, data gaps would need to be accepted to certain extent.
- Questioned whether data gaps should be accepted in potential substitutes of existing hazardous substances.

2.3.5 Revised decision tree included in briefing paper 5 (December 2017):

Against this background the decision tree was modified further and simplified as follows:



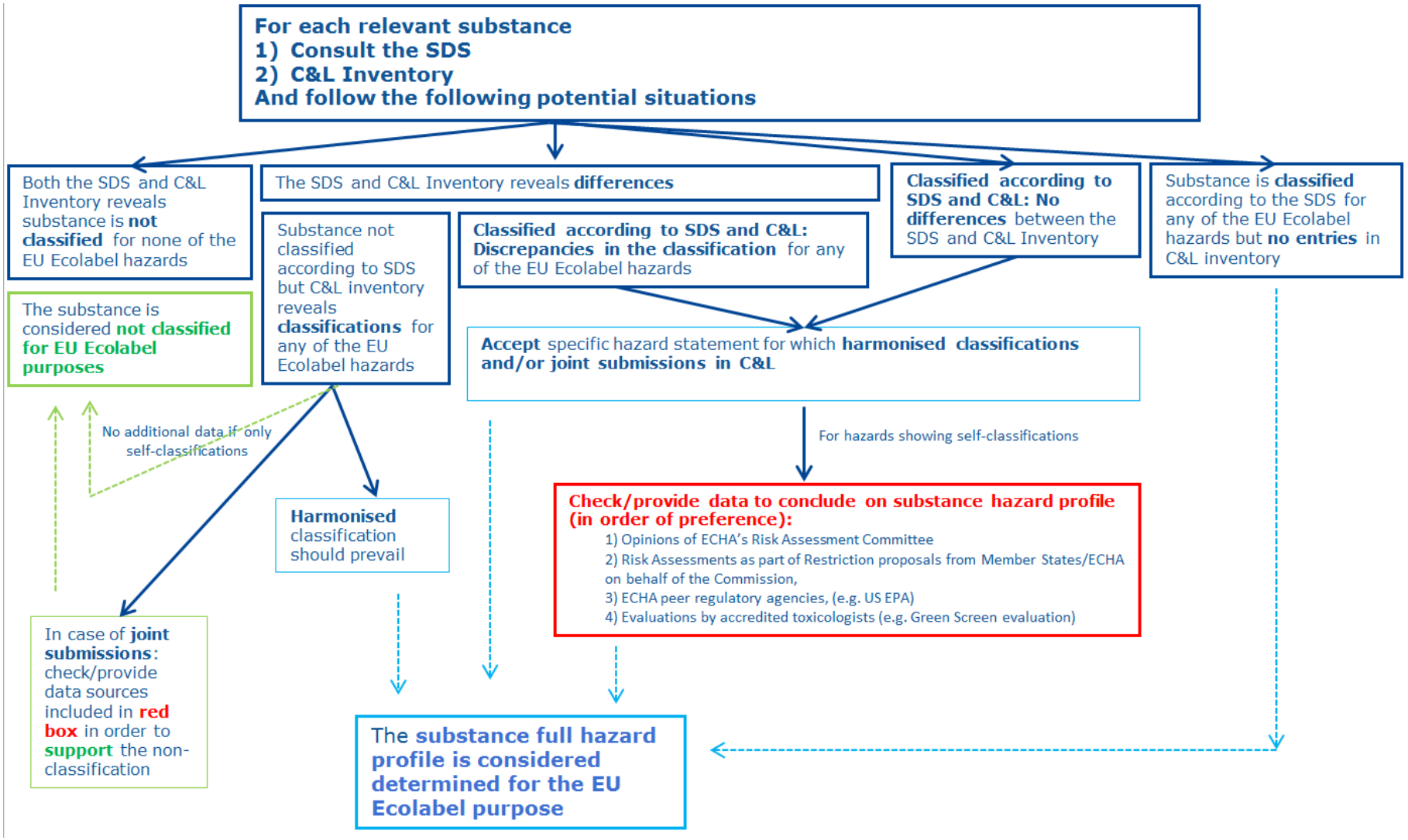
2.3.6 Redesigned Decision Tree (January 2018)

ECHA expressed difficulties on understanding how the decision tree works in practice and how could be implemented by its expected users. In addition, another TF member suggested reflecting the use of SDS as information source.

Against this background, the tree has been redesigned (see figure below). The idea is to have a clearer decision tool that better reflects the potential different situations that applicants/Competent Bodies may be confronted with, in relation to the evidence they find in preliminary sources of data (SDSs and C&L inventory), when they proceed for EU Ecolabel application/assessment.

The modification aimed also to make clear in which situations, considered of 'less confidence" (i.e. self- classifications in C&L for potentially classified substances according to SDS and potentially non-classified substances according to SDSs but classified according to joint submissions in C&L), applicants/Competent Bodies are proposed to be asked to go a step further and to provide/check additional data (red box in the tree).

Considering that there are considerable changes in the tree, at this stage it is expected to have additional feedback in order finalise it.

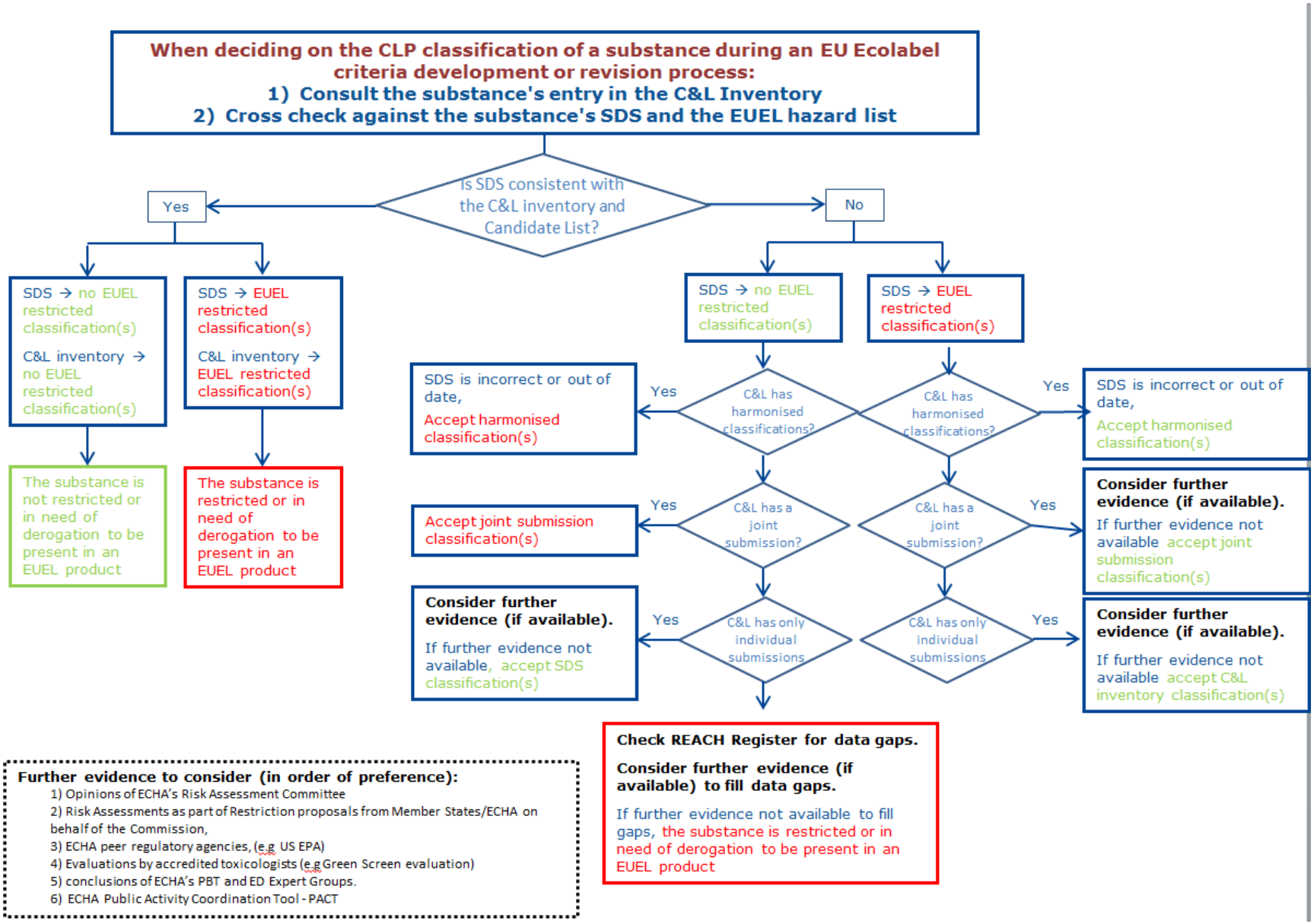

For each relevant substance
1) Consult the SDS
2) C&L Inventory
And follow the following potential situations
Both the SDS and C&L Inventory reveals substance is not classified for none of the EU Ecolabel hazards
The SDS and C&L Inventory reveals differences
Classified according to SDS and C&L: No differences between the SDS and C&L Inventory
Substance is classified according to the SDS for any of the EU Ecolabel hazards but no entries in C&L inventory
Substance not classified according to SDS but C&L inventory reveals classifications for any of the EU Ecolabel hazards
Classified according to SDS and C&L: Discrepancies in the classification for any of the EU Ecolabel hazards
The substance is considered not classified for EU Ecolabel purposes
Accept specific hazard statement for which harmonised classifications and/or joint submissions in C&L
No additional data if only self-classifications
For hazards showing self-classifications
Harmonised classification should prevail
Check/provide data to conclude on substance hazard profile (in order of preference):
1) Opinions of ECHA's Risk Assessment Committee
2) Risk Assessments as part of Restriction proposals from Member States/ECHA on behalf of the Commission,
3) ECHA peer regulatory agencies, (e.g. US EPA)
4) Evaluations by accredited toxicologists (e.g. Green Screen evaluation)
In case of joint submissions: check/provide data sources included in red box in order to support the non-classification
The substance full hazard profile is considered determined for the EU Ecolabel purpose

2.3.6 Final Decision Tree (June 2018)

The feedback received by Task Force and EUEB members with regards this Decision Tree revealed that majority of the members are concerned about the capacity/expertise of applicants and Competent Bodies to use/check additional data (further to SDSs) in order to determine the hazard profile of substances.

Against this background, as final recommendations of the Task Force it is suggested that the Decision Tree for hazard profile determination is **to be exclusively used during the revision process** (not in the assessment and verification) **by JRC and experts involved in the revision** of the relevant product group.

ECHA and Chemical Unit in DG ENV feedback have been consulted in order to finalise the Decision Tree. The Decision Tree is proposed to be a dynamic tool, that can be updated as JRC makes more use of it and gains more experience.


When deciding on the CLP classification of a substance during an EU Ecolabel criteria development or revision process:
1) Consult the substance's entry in the C&L Inventory
2) Cross check against the substance's SDS and the EUEL hazard list
Is SDS consistent with the C&L inventory and Candidate List?
Yes
No
SDS → no EUEL restricted classification(s)
C&L inventory → no EUEL restricted classification(s)
The substance is not restricted or in need of derogation to be present in an EUEL product
SDS → EUEL restricted classification(s)
C&L inventory → EUEL restricted classification(s)
The substance is restricted or in need of derogation to be present in an EUEL product
SDS → no EUEL restricted classification(s)
SDS → EUEL restricted classification(s)
C&L has harmonised classifications?
Yes
SDS is incorrect or out of date,
Accept harmonised classification(s)
C&L has a joint submission?
Yes
Accept joint submission classification(s)
C&L has only individual submissions
Yes
Consider further evidence (if available).
If further evidence not available, accept SDS classification(s)
SDS is incorrect or out of date,
Accept harmonised classification(s)
Consider further evidence (if available).
If further evidence not available accept joint submission classification(s)
Consider further evidence (if available).
If further evidence not available accept C&L inventory classification(s)
Check REACH Register for data gaps.
Consider further evidence (if available) to fill data gaps.
If further evidence not available to fill gaps, the substance is restricted or in need of derogation to be present in an EUEL product
Further evidence to consider (in order of preference):
1) Opinions of ECHA's Risk Assessment Committee
2) Risk Assessments as part of Restriction proposals from Member States/ECHA on behalf of the Commission,
3) ECHA peer regulatory agencies, (e.g. US EPA)
4) Evaluations by accredited toxicologists (e.g Green Screen evaluation)
5) conclusions of ECHA's PBT and ED Expert Groups.
6) ECHA Public Activity Coordination Tool - PACT