EEB
European Environmental Bureau

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Discussion starters to integrate chemicals into product policy

An assessment by Ökopol for the EEB

Introduction

The key guiding principle of the Chemicals Strategy for Sustainability[1] (CSS) published in October 2020 is to eliminate hazardous substances from products. The EU Green Deal[2] acknowledges that chemical pollution is detrimental to both human health and ecosystems. The design of products including the material composition, their production processes, their final treatment and controlled material loops play a key role in shifting towards a toxic-free environment in a circular economy. Effective measures include the substitution of hazardous substances and reducing the overall level of consumption.

However, to date, chemicals only play a minor role in product policy.

This briefing sets out key elements of future product legislation to ensure hazardous substances are avoided and substituted with safe alternatives. Where hazardous substances cannot be substituted, the key legal elements ensure that their content is minimised and disclosed to the relevant stakeholders.
The legislative elements are described irrespective of whether the EU Sustainable Products Initiative (SPI) results in an entirely new legislative framework or in amendments to existing legislation such as the Ecodesign Directive.

A separate briefing will identify effective measures to increase transparency throughout value chains to support achieving a toxic-free environment and realising the chemicals-related requirements of a future product policy framework ("product passport"). Therefore, the information flows are only briefly addressed here.

Important terms

- **Hazardous substances:** substances which may cause harm to human health or the environment due to their properties. This includes but is not limited to Substances of Very High Concern (SVHC) and substances meeting the criteria for classification under the Classification, Labelling and Packaging Regulation (CLP).

- **Product :** all goods on the market that neither fulfil the definition of a substance or mixture according to Article 3 number 1. and 2. of Regulation EC No. 1907/2006 (REACH) (i.e., is not a chemical like paint, cosmetics etc.) nor the definition of waste according to Directive 2008/98/EC Article 3 number 1. Products, therefore, are articles according to REACH Art. 3 number 3. and products composed of one or several articles (= complex articles). Articles can include also substances or mixtures as an integral part of the article and this unit will also be considered as a product.

- **Chemicals:** substances and/or mixtures

Our key recommendations

- **Recommendation 1:** Restrict the use of substances with properties of concern horizontally, conditional to the existence or newly enacted product-related legislation (vertical) defining derogations if these are necessary and justified.

- **Recommendation 2:** Define a work programme for the Commission with clear deadlines as to when product legislation must be in place that considers the requirements for chemicals, i.e. the generation of new product-specific policies and the revision of existing legislation.

- **Recommendation 3:** Define a process and criteria to efficiently assess and decide if derogations brought forward by sectors for a particular product or product group are justified, i.e. substitution by safer substances or through alternatives design is technically not feasible.

- **Recommendation 4:** Define review periods for derogations and require market actors to report on the use of their substances falling under the derogations.

1. Why should chemicals be integrated into the SPI

As part of its **Green Deal** published in 2019, the European Commission defined the ambition of Zero Pollution to achieve a toxic-free environment as a top priority. In the related communication, the Commission states that increased efforts are needed to eliminate existing and prevent new pollution, to protect citizens and the environment from the negative effects of chemicals in the future. It **highlights the need to cover chemical risks from products** and the necessity to consider combination effects that could result from the simultaneous presence of many hazardous substances, which may not always be evident if classical risk assessments are applied.

The Chemicals Strategy for Sustainability (CSS) adopted one year later implements and specifies the Green Deal's objectives. The CSS **aims to eliminate adverse impacts of chemicals** on human health and the environment, particularly from carcinogenic, mutagenic, reprotoxic (CMR) and immunotoxic substances as well as substances with negative effects on the respiratory, endocrine, reproductive or cardiovascular systems. In the CSS, the Commission highlights that human biomonitoring data show increasing amounts and varieties of chemicals in organisms.

The CSS explicitly announces the introduction of requirements to minimise the presence of hazardous substances as part of the Sustainable Product Policy Initiative (SPI). It specifies that such requirements should prioritise product categories that particularly affect vulnerable groups and that have a high potential for circularity. It also announces measures to increase transparency on the content of hazardous substances in products along their lifecycle under the SPI. These requirements will extend the ongoing initiatives to replace hazardous substances in products to a broader range of products and more types of hazards. Regrettable substitutions, where hazardous substances are replaced with substances of a similar hazard profile or with substances belonging to the "unknown territory of chemical risks"[3] as risk data is still lacking, should be prevented.

The **CSS fosters the development of safe and sustainable chemicals** to replace hazardous substances in products, thus preventing them from entering material cycles. This improves not only the state of human health and the environment but also accelerates the transformation of the economy towards circularity through the **prevention of (hazardous) waste** in the first place and improved recycling whenever prevention is not possible.

Companies providing alternatives that are **safe and sustainable by design** will have a **competitive advantage** and their market share will increase. Innovation for sustainability and knowledge gains will result from common substitution efforts in the industry. The Commission plans to amend several laws to ensure that hazardous substances are eliminated from products and processes as effectively as possible, which should support and help paving the way for safer alternatives.

According to a Commission survey in 2020, **more than eight in ten EU citizens are concerned about hazardous chemicals in everyday products**. More than 85 % are either worried about the environment or the health impacts of chemicals.[4]

Besides the risks, **hazardous substances in products cause additional costs for the disposal** and treatment of the products at their end-of-life phase when they become waste, which are generally passed on to society. This contradicts the EU's polluter pays principle[5] to a large extent.[6] If no hazardous substances were contained in products in the first place, these costs would be prevented, or internalised via the substitution efforts needed to detoxify products.

Apart from the information on SVHCs[7] in articles, there is **no transparency on the content of hazardous substances in products** along the supply chain. This prevents companies and consumers to make informed decisions and choose the least hazardous products. However, even if such knowledge would be available, products should be safe-by-design in the first place. Frontrunner companies with eco-labelled products show that hazardous substances can be replaced, and that safe and sustainable products are possible.

2. Problem analysis

Product legislation includes only a few requirements on the content of hazardous substances and/or acceptable material composition. Most of these provisions were either introduced due to specific health risks for the product users, e.g., to protect children from hazardous substances in toys[8], or due to the end-of-life treatment's inability to manage environmental and health risks, which is the case for e.g., electrical and electronic equipment[9] or batteries.

Decision-makers often rely on chemicals legislation to handle chemicals, including when they are incorporated into products. As the REACH instruments are neither sufficient to identify all relevant risks from hazardous substances in products nor to adequately address them considering the characteristics of many products, a regulatory gap exists, which may result in an insufficient level of protection.

The following sections on chemicals and product legislation briefly enumerate problems and issues which have prevented either:

- the successful substitution of hazardous substances in products; or
- the legal framework concerning hazardous substances in products from being consistent and effective.

2.1 Chemicals legislation

Under the REACH Regulation, all substances must be registered by their manufacturers and importers if they are produced in amounts exceeding 1 t/a and per market actor. A chemical safety assessment (CSA) must be performed only for substances registered in amounts exceeding 10 t/a and per actor. Therefore, **for all low-volume substances, potential risks from their use in articles are not identified during registration and hence not managed in the supply chain.**
According to the CSS action plan, legislative proposals will be presented to extend the REACH registration requirements to ensure that the chemical safety of substances in volumes between 1 and 10 t/a is also assessed and that hazardous properties are identified, including immunotoxicity and neurotoxicity.

Some substances are not registered at all or are exempted from certain REACH provisions, such as polymers. Here, **hardly any information is available to assess and manage risk.**
However, the CSS foresees the inclusion of registration requirements for polymers under REACH in 2022.

CSAs drafted by registrants frequently suffer from **a lack of information** on hazards and on the use of substances. This **may lead to relevant risks being overlooked**. Furthermore, the **safety assessments of the service life and the waste stage of the products** within which the substance is contained, are (very) **generic** or not conducted at all.[10] This is another reason why risks from hazardous substances in products are neither identified nor managed in supply chains.
While according to the CSS more information on hazardous properties will be required for registered substances, it is currently unclear if and how information on their uses will be improved.
The versatility of products, their use conditions and waste treatment approaches suggest the need for a product policy framework targeting the service life of products and the chemicals contained therein.

Many of the substance **restrictions** in REACH Annex XVII directly or indirectly relate to products. However, they **cover a very minuscule share of all hazardous substances and products** on the market. Only a few broad substance bans exist that directly target (consumer) articles. Instead, the **substance-by-substance** (and use-by-use) **approach** of most restrictions may cause regrettable substitutions (e.g., BPA is replaced with BPS and BPF) and fails to incentivise a broad search for alternatives where only some (specific) uses are affected. The low number of restrictions is partly due to the need for Member State authorities or ECHA to demonstrate the existence of a risk that requires community-wide management.
The CSS plans to restrict substances with very hazardous properties (e.g., CMRs, PBTs) in consumer products based on a generic risk management. This means that the fact that a substance has a particular property triggers the need to exclude it

from the defined groups of products. The scope of hazardous properties which trigger such generic risk management may be extended in time.

The REACH authorisation process addresses the use of substances of very high concern (SVHC), with “use” meaning the handling, storage, application and incorporation into a product, etc. The presence of a chemical in a product is not a ”use”. Therefore, **SVHCs requiring authorisation** should in principle not be contained in EU-produced products, unless an authorisation was granted. However, **imported products may contain them**. The centralised authorisation scheme also targets individual substances and its implementation speed is limited by the capacities and resources of the Commission, ECHA, and national authorities. Currently, only 54 substances require authorisation[11].
Under the CSS a revision of the authorisation scheme is announced, although the details of the envisaged changes are unclear.

Exemptions to restrictions and authorisations are granted, although alternatives exist. The granted exemptions and authorisations are not always justified and weaken market actor motivation to substitute hazardous substances. They contribute to inconsistencies in legislation and the “patchworking” of requirements. Restriction exemptions and authorisations may also undermine the principle of requiring the same standards for virgin and secondary materials (such as the exemption for lead in recycled PVCs).
Discussions about possible changes to the restriction and the authorisation process and their implementation are ongoing.

The substitution of hazardous substances with safer alternatives may be time-consuming and cost-intensive and may not always pay off in a competitive advantage for innovative companies. Under the current conditions, it is often (perceived) economically more interesting to keep old solutions on the market as long as possible instead of initiating a fundamental change. This is supported by the fact that for most products only limited information on the ingredients is available and their buyers are therefore unable to make an informed purchase decision, even if there is a desire for less hazardous alternatives.

Although REACH was adopted already in 2006, **product suppliers are still not fully aware of their obligations** to communicate the presence of SVHC[12]. Furthermore, they are seldomly informed of and involved in the discussions about restrictions or authorisations, resulting in a lack of expertise in substitution processes that may be implemented “on short notice” and leading to regrettable substitution.

These high hurdles to substitution posed by the lack of end-user knowledge in substitution processes are further aggravated by the lack of disclosure of substances in products.

2.2 Product legislation

The General Product Safety Directive lacks specific requirements on chemicals in products and only demands the absence of immediate risks to product users. It does not address environmental risks at all. Tools to ensure the chemical safety of products are missing. Additionally, due to the product-focused risk definition, the directive fails to consider that consumers are exposed to various chemicals from various products, which could result in harm, including through combination effects.

The **Ecodesign Directive** is intended to complement existing directives and regulations, such as REACH or RoHS, and the presence of hazardous substances is to be considered when evaluating the potential for improving the environmental performance of a product group. However, although substances have been addressed in preparatory studies to a certain degree, **hazardous substances have in practise not been systematically assessed**, **nor** have they been **regulated** by product group-specific implementing measures.

Several product-specific legislation (e.g., toys, batteries, food contact materials) exists, but **not all products are covered by such product-specific legislation**. Moreover, the various **existing legal acts have different approaches to address** the content of hazardous **substances**: Some exclude substances via lists (e.g. RoHs), others exclude substances with certain classifications (e.g. Toy Safety Directive), and some only refer to standards with testing obligations but do not limit the content (e.g. Construction Products Regulation). The **chemicals-related requirements are not always consistent across product groups**, and some substances are prohibited in one application but are allowed in another. For example, some per- and polyfluorinated alkylsulfonates (PFAS) are restricted under REACH but are currently still considered safe for food contact under certain conditions. Some provisions, like those on CMRs in toys, have proven to insufficiently protect consumers[13].

The **legal patchwork is complicated, difficult to enforce** and fails to provide a clear signal to the chemical suppliers on the (types of) substance (groups) that are acceptable for inclusion in products and those that should be phased out (eventually).[14]

Hazardous substances in products may hinder recycling: As various products containing a multitude of hazardous chemicals are merged in waste streams, hazardous substances are carried over to secondary materials and dissipated with them. Ignorance of the chemicals content in products is due to a lack of (possibility to transfer) information to waste processors who are therefore unable to ensure proper sorting and treatment of waste. Therefore, either secondary materials are contaminated (no separate treatment of contaminated materials) or wastes are not recycled although they do not contain any hazardous substances.

2.3 Conclusion

Although the EU is equipped with some of the most advanced chemicals regulations in the world, the current chemicals and product policy does not ensure that products do not cause harm to humans and the environment, and [recent] data indicates an increasing effect of chemicals on human health and the environment.

Incentives for pro-active substitution of hazardous substances are missing; only the Ecolabel Scheme aims to reward frontrunners with an improved visibility on the market. Although the CSS will introduce several improvements to the legislative framework on chemicals, which will also positively affect the safety and sustainability of products, additional and stricter requirements are needed in the product legal framework itself to achieve a toxic-free environment.

Chemicals legislation does not adequately address all risks from hazardous substances in products and there are no consistent and sufficiently strong requirements on chemicals in the current product legislation. Therefore, it is important that a new element on hazardous substances is integrated into the SPI.

3. Addressing chemicals in products effectively

A revised future regulatory framework aiming at the exclusion of hazardous substances in products must provide:

- clear and measurable objectives
- consistent and implementable requirements, regulatory processes and opportunities to involve the relevant stakeholders to ensure product specifics are considered
- communication obligations that increase transparency on the chemical content of products and
- a binding timeline for implementation.

These elements are indispensable for a consistent, predictable, and viable new or revised legislative framework.

To solve the key problems of regulating chemicals in products, it is essential that the regulatory framework applies consistently and to all types of (non-chemical)[15] products.

Due to the diversity of products, future horizontal restrictions of hazardous substances in products, such as those implemented on a voluntary basis in the EU Ecolabel Regulation[16], need to be linked to a derogation process that considers product-specific development cycles and related sector-specific substitution opportunities. It is also crucial to have a clear timeline for implementation and a definition of responsibilities of all actors. The framework must also provide mechanisms to assess and increase the level of ambition of excluding hazardous substances and/or the granting of product-specific derogations.

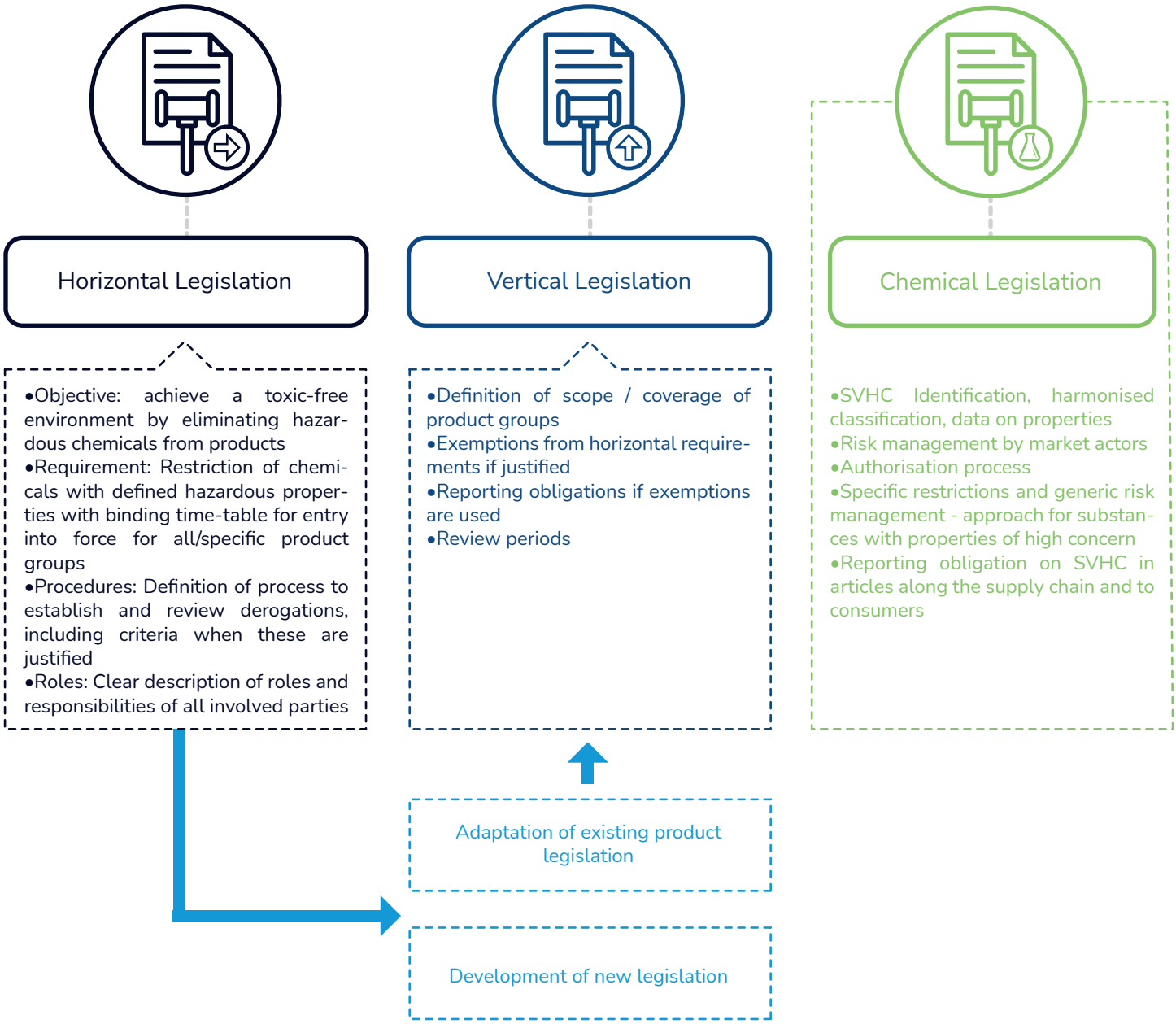
The legislation should directly apply to all relevant actors and products in all Member States, be harmonised and consistent. Therefore, **a regulation** and not a Directive **is the preferred option.**

3.1 Implementing the toxic-free environment objective in the SPI as a top priority

3.1.1 Regulatory approach

The future SPI framework must set out the overall aim of a toxic-free environment and safe and sustainable products using non-toxic chemicals as priority objectives. The structure of such a framework is illustrated in the following figure. Two options to implement this are discussed in the next chapter.

Figure 1: general scheme of the regulatory approach



The chemicals legislation defines a safety baseline via risk management communicated by market actors. The risk management must be based on safety assessments. The authorities manage risks via the authorisation and restriction process. It provides information to implement requirements on chemicals in the SPI.

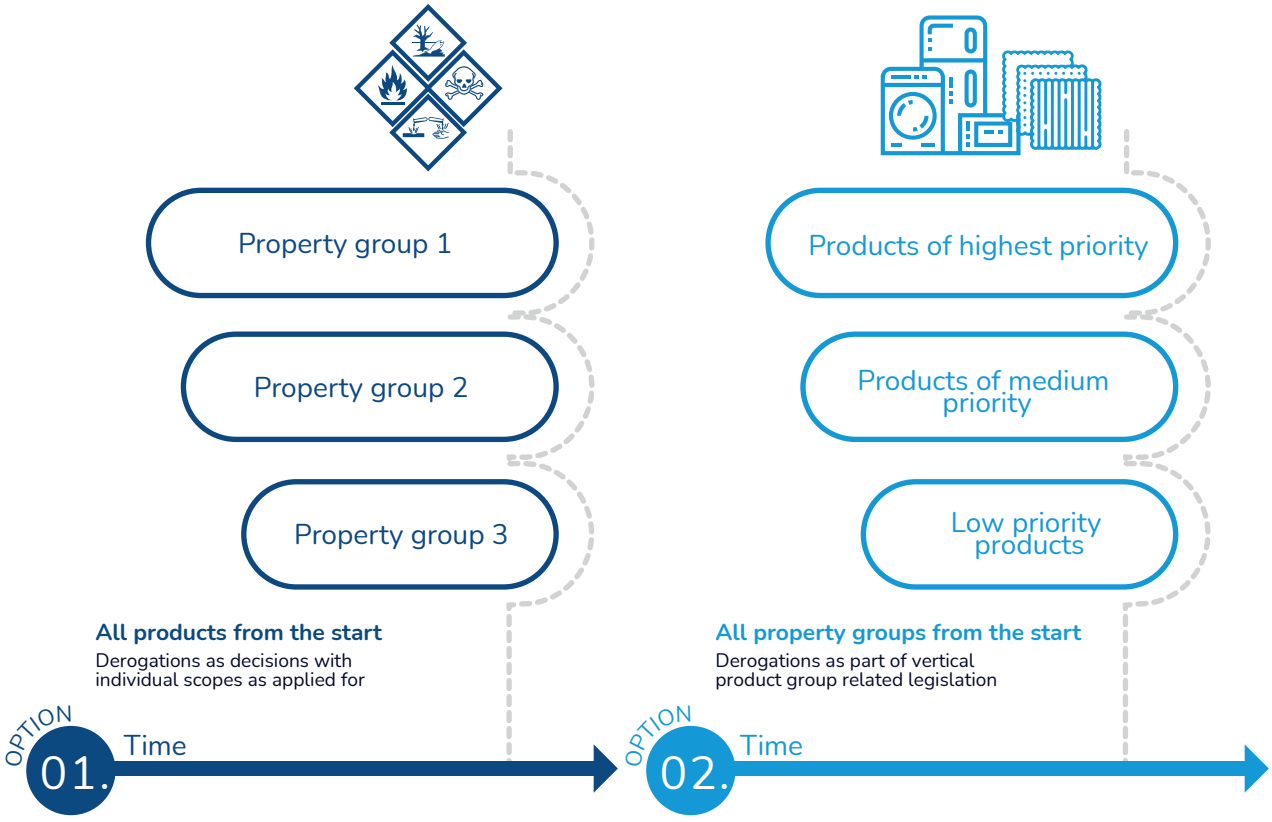
Horizontal legislation should define the requirements on chemicals as well as the criteria for and the process of derogating from them. The vertical product legisla-

tion, may contain derogations from the horizontal requirements, which are developed according to the process and criteria outlined by the horizontal legislation. Derogations should be regularly reviewed. **Vertical legislation could be based on the adaptation of existing legislation, or new legislative initiatives per product group**. This approach resembles that of the EU Ecolabel's Article 6[17] and derogation process.

3.1.2 Options to implement the regulatory approach

There are two main regulatory options as regards timing and process. The first optiond restricts the use of substances with more and more hazardous properties over time and applies to all products on the market. The second is to implement a process that over time phases product groups into the restriction of all hazard groups (cf. next figure). Eventually, the result of either option will be the same but the implementation process differs.

Figure 2: Two options to implement the regulatory approach



Option 1: Step-wise phase-in of hazard group restrictions for all product groups

The main requirement of the SPI is a horizontal restriction of substances that have certainhazardous properties. Starting with the most severe hazards (e.g. SVHCs), the scope of hazards is gradually extended to further hazardous properties over time (e.g. neurotoxicity, chronic aquatic toxicity) in accordance with the priorities of the CSS. The restriction covers all products equally.

The market actors may apply for derogations from the restriction and have to prove whether exemptions are justified. Exemptions are time-limited and subject to regular reviews. Vertical legislation with exemptions would include an obligation for the market actors to report on the use of the restricted substances.

Option 2: Step-wise phase-in of product groups to horizontal restriction of all hazard groups

The second option for horizontal legislation requires the absence of substances of all hazard groups, according to the CSS with immediate effect but initially only in certain product groups. The other groups are phased in over time. The entry into force of the restriction is triggered by the existence of vertical product legislation.

The need for and the nature of derogations are specified during a process similar to that for the implementing regulations of the Ecodesign Directive[18], where the vertical product legislation is developed that will trigger the need to comply with the horizontal restrictions. Derogations address hazard groups. Table 1 compares the core characteristics of the two options.

Table 1: Comparison of Option 1 and Option 2

	Option 1	Option 2
Substance phase-out in horizontal legislation	Step-wise entry into force of hazard groups over time: first group 1 followed by group 2 and last group 3	Substances of all property groups are restricted in all product groups from the point in time when vertical product legislation exists (new or adapted existing legislation)
Consequences of phase-out requirements	Substance groups are likely to be dealt with one by one in time	Producers have to consider substances of all groups from the start
Phase-in of requirements for products	All product sectors are affected by the restriction after the initial transition period	Horizontal legislation defines when product legislation is to be in place, including provisions on chemicals. Vertical product legislation is developed first for high priority products (exposure potential)
Flagging of the need for derogations	Industry or Member States flag the need for a derogation to the Commission, the Commission organises the process to assess and decide on a derogation application by the sector	In the development process of vertical product legislation, derogation needs are identified
Outline of the derogation process	Product sectors develop a derogation application and submit it to the Commission including justification of the derogation need	The Commission, product sector and Member States organise a process of assessing sector-wide derogations in the context of the background study for vertical product legislation
Derogation scope	Product sectors define for which product groups or parts thereof the restrictions are derogated	Within the derogation process, the scope of derogations is defined by all involved stakeholders
Decision on derogations	The Commission, together with the Member States Committees decides on derogations and implements them	The decision on derogations is embedded in the decision on the vertical product legislation
Review of derogations	All derogations are reviewed regularly, e.g., every 5 years	All derogations are reviewed regularly, e.g., every 5 years. Where useful, the review could be aligned to review of the entire vertical legislation

	Option 1	Option 2
Pros	The most hazardous substances are immediately restricted in all product groups Simultaneous restriction across all sectors creates a strong stimulus for developing alternatives Sectors may inspire each other Clear orientation for industries regarding the time frame of the phase-out	The most problematic exposure potentials are addressed via the highest priority product groups, such as textiles. Clear timeline for when all requirements apply to a product sector The derogation process considers all hazard groups from the start, resulting in an efficient initial and complete assessment of products which can later be "only amended". Transparency on the content of hazardous substances in products is required from the beginning. Clear start of sector activities and process guidance by the Commission increases chances that all sector actors, including SMEs, can follow the process
Cons	The degree of organisation of the derogation process depends on the market sector initiatives No focus on sectors or products with a risk of disparities between well organised and less well-organised sectors and companies Inefficiencies likely due to the phased process for properties (several derogation rounds) Risk of lacking resources due to ignorance of the number, type and level of detail of derogations on the side of all stakeholders Risk of high incompliance due to industries failing to manage derogation processes with a consequent loss of credibility of the legislation	Risk that the Commission lacks resources to implement the ambitions time plan defined in the horizontal legislation. The development of vertical legislation requires consideration of all hazardous substances, implying a high complexity and level of ambition in the initial phase of the SPI implementation

Both options have the same ultimate ambition, but their implementation process differs. Due to the higher degree of organisation of the derogation process as well as the expected overall efficiency gains from addressing all relevant hazard properties from the start and sector-wise, we consider Option 2 to be better implementable than Option 1.

3.2 Prioritising substances for phase-out

Both options should group hazard properties into three groups, in line with Article 6 of the EU Ecolabel Regulation. To allow some flexibility as to the use of substances, the derogations from restrictions refer to hazard groups rather than individual substances or substance properties. The groups should also fit in an overall time-frame in which an ultimate phase-out is to be achieved by ending all derogations.

Table 2 shows the three priority groups as defined in the Ecolabel Regulation. Under the SPI, also more groups or another grouping of hazards could be envisaged.

Table 2: Possible hazard groups

Current EU-Ecolabel approach (adapted)[19]
Group 1: Properties to be phased-out of products with priority[20]
• Candidate list of SVHC[21]
• Harmonised classification as carcinogenic, mutagenic or toxic for reproduction, Category 1A and 1B, PBT, EDC, PMT[22]
Group 2: Properties for phase-out to which stricter conditions shall apply Derogations may be granted more leniently than for group 1 in the initial implementation phase but are handled with stricter conditions than Group 3
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
• Acute toxicity, Category 1 and 2
• Specific target organ toxicity (STOT) Category 1
• Respiratory and skin sensitisation (where applicable) Category 1
• Hazardous to the aquatic environment Category 1 (acute and chronic) and 2
• Hazardous to the ozone layer
Group 3: Properties for phase-out of lower priority Greater flexibility may be applied to derogations and longer review periods be granted
• Acute toxicity Category 3
• Specific target organ toxicity (STOT) Category 2
• Hazardous to the aquatic environment Category 3 and 4 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)

Hazard-based substance exclusions come with a specific challenge to take a definite decision as to whether a substance fulfils a hazard criterion or not, where no harmonised classification exists or a substance is not listed on the candidate list. The self-classifications often differ between the various substance manufacturers and importers[23] and, although the market actors should agree on a classification, this hardly ever takes place due to a lack of respective obligations. Moreover, the available hazard information from testing under REACH may be insufficient to classify a substance, resulting in “no classification due to lack of data” (underestimation of hazardousness).

To implement and control the hazard-based exclusion requirements, a hazardous property should be deemed to exist if it is notified by at least one notifier to the classification and labelling inventory[24]. For substance properties that are not reflected by a classification category (yet), a procedure is needed on how to decide on whether or not the property applies (currently PBT/vPvB, EDC, PMT but also others that might become relevant in the future).

An information collection element in a product regulation would duplicate REACH registration. Therefore, the obligations under the CLP[25] to review “available" data from registrations as well as distributors of substances and mixtures should be used instead.

3.3 Justification of derogations from the horizontal restrictions

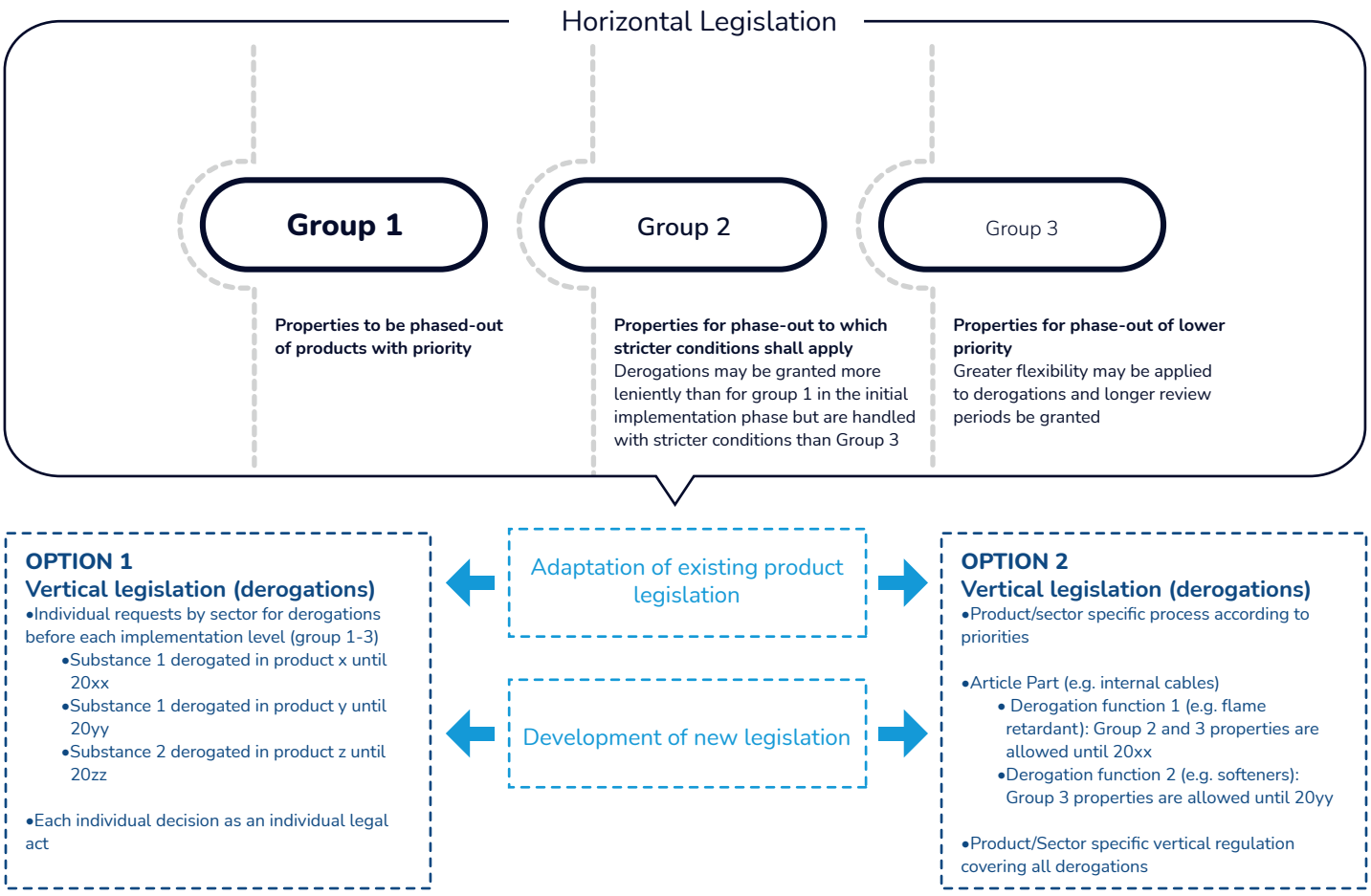
In their application for a derogation, the product sectors have to demonstrate that

1) the continued use of a (group of) hazardous substance(s) is necessary (essential use) and
2) that no suitable alternatives are available

In some cases, exceptions may be justified in order to give market players time to introduce suitable alternatives. However, these periods should be clearly limited in time and based on targeted alternatives in order to ensure genuine adaptation of products.

Derogations should refer to the use or function of a product or product component rather than an entire product group. They should consider sector/product specific aspects in their justification to be time-limited and may include conditions. Each derogation should trigger a reporting requirement for the identity of the substances used in accordance with the derogation, which applies by default (see figure below).

Figure 3: Implementation of derogations from horizontal chemical requirements under option 1 and 2



In accordance with the principles of the CSS, derogations are only possible if no suitable alternatives exist for an "essential use".

Essential uses are considered uses that provide a societally needed functionality or product. Criteria for essential uses will be developed at EU-level and largely determine the use of chemicals in products in the future.[26]

Safe and sustainable by design alternatives are not hazardous and may be a chemical or non-chemical solution (such as a different design that makes a substance use unnecessary) that can replace a hazardous substance and ensure the functionality of the product. Hence, chemicals of equal or higher toxicity than the hazardous substance are not an alternative. Less hazardous substances are at least a gradual improvement and are therefore generally considered alternatives if no safer alternatives are available.

Derogations can be justified by a complete lack of alternatives (no availability) or if the available alternative(s) are not suitable. The main reasons for non-suitability are an association of alternatives with so significant "other" environmental burdens that the benefit of reduced (eco-) toxicity from substitution is considered disproportional to the costs of other environmental and health burdens.
Derogations could also be justified if the available alternatives are only less hazardous and their use would cause disproportionate ecological and economic burdens compared to the benefit of a slight risk reduction. An exemption may be justified until a safe and sustainable by design solution is identified instead of investing resources in a suboptimal short-term solution.

Criteria are needed to support decision making on the "suitability of alternatives" regarding which "other" environmental burdens are relevant and **if and** when they **can** overrule the priority of a toxic-free environment. As this is a general issue in balancing environmental goals against each other, the criteria should be consistent with other sustainability policy goals.

3.4 Defining conditions of the horizontal restrictions

Implementable and enforceable exclusion criteria must be specific and unambiguous both to industry actors and the enforcement authorities. The following sub-sections outline different options of how the conditions could be defined and set out some pros and cons of the various options.

3.4.1 Threshold values

The restriction of substances in the three hazard groups could be linked to the following conditions:

1) No intended use is allowed (document check)
Substances with restricted properties may not be intentionally added to a product (along the entire life cycle). Compliance is to be demonstrated via documentation and/or supplier declarations (e.g. the new 'product passport')

Advantage: compliance proof and enforcement do not require measurements; supply chain actors are individually addressed to refrain from the use of hazardous substances
Disadvantages: hazardous substances may be present from various (unintended) sources

2) **Concentration limit** (% w/w) either one threshold for all hazard groups or different thresholds according to the hazard groups (i.e. higher thresholds for lower priority properties)
The presence of substances with hazardous properties above the concentration threshold is prohibited. Compliance is demonstrated and controlled by measurements.
Advantage: coverage of all substances regardless of origin, including from non-intended use
Disadvantage: proof of compliance and enforcement very costly and cumbersome, requires at least knowledge on a suspected substance otherwise not targeted.

3) **Mix of option 1 and 2**
Advantages and disadvantages of both options combined.

3.4.2 Reference unit of thresholds

If the restrictions are based on concentration thresholds, a reference unit has to be defined to which they apply. The type of unit determines the achievable level of protection and influences the ability and efforts of the article supply chain to implement the provisions. Furthermore, reference units are needed to define the application of exemptions.

The options are:

- **No reference unit (entire product)**

This option is only needed if the threshold value is "no intended use" or if an exemption should apply to the entire product (could be applicable to mono-material products like textiles).

- **Per homogeneous material/article**; i.e. proof of compliance to be provided by the material or the article producers of all individual parts of a product

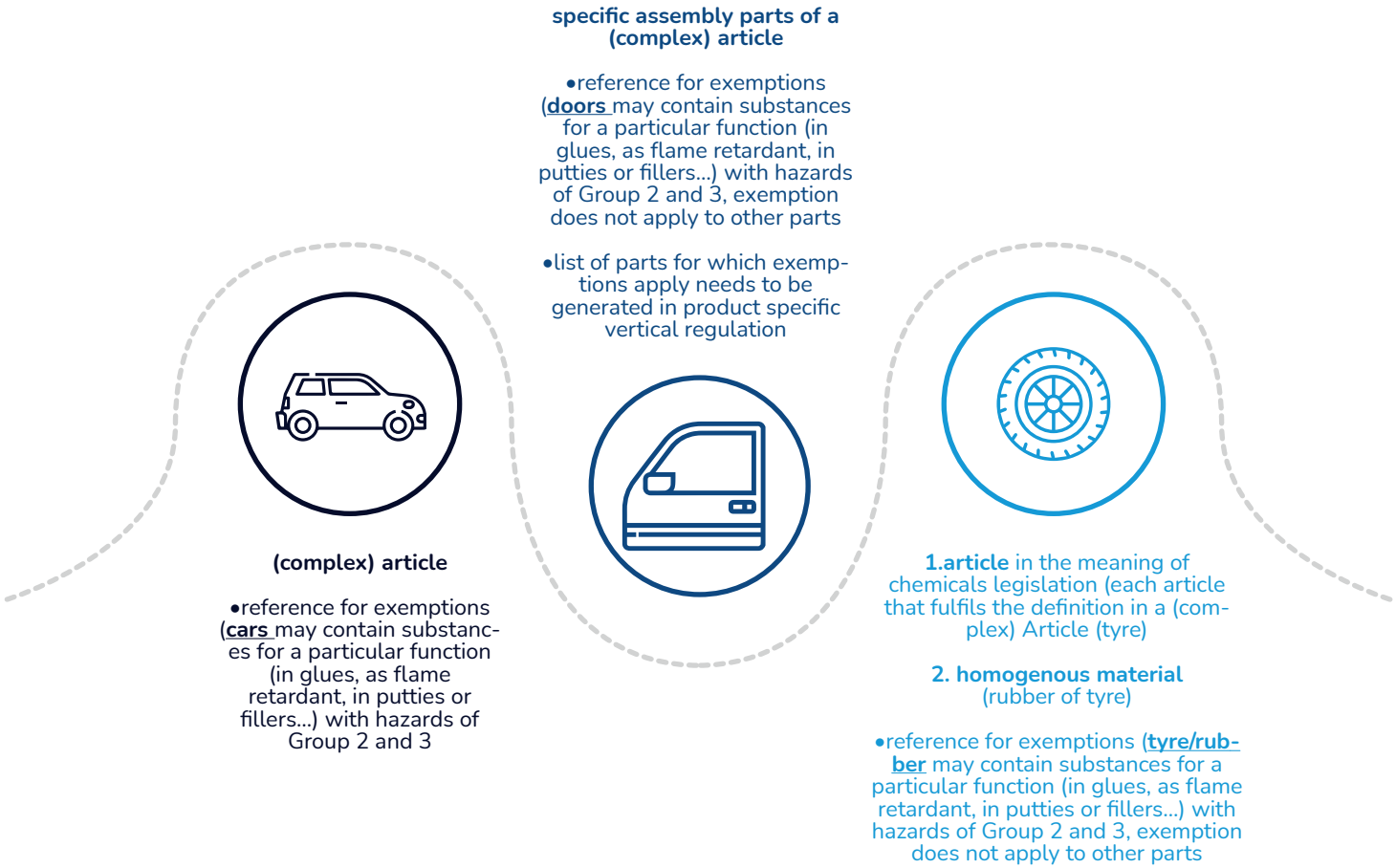
Advantage: high level of protection, incentive for material producers to standardise their materials (towards low hazardous substance content); if based on articles – compatibility with REACH reporting obligation on SVHCs in articles and the SCIP database.
Disadvantage: CBI constraints, many individual proofs of compliance needed

- **Per assembly of articles in a product**, i.e. set of articles that as a unit perform a function (in the overall product)

Advantage: medium level of protection, experience from Ecolabel Regulation can be used; lower efforts to demonstrate compliance
Disadvantage: reference unit has to be specifically defined for different product groups to avoid ambiguous interpretations[27]; substitution can be implemented at the level of "functional units", which might be easier on a part level by design changes;

- **A mixture of the above**, i.e., making general exemptions with a reference unit of articles and specific references based on assemblies of articles

Figure 4: Potential options for the reference for the verification of the absence of hazardous substances and the implementation of exemptions.



Although chemicals legislation uses limit values in relation to the smallest article by definition[28], there are problems with implementation as shown by the problems with the implementation of e.g. the information requirements according to Article 33 of REACH. The here proposed legislative approach requires the absence of substances with hazardous properties in products and exemptions may be granted for required functions. Therefore, exemptions should refer to assemblies or certain parts of a complex article where a certain functionality is required. When developing vertical legislation, assemblies and parts of complex articles, to which exemptions shall apply can be directly listed. This makes the scope of an exemption clear and allows flexibility for each product group.

3.5 Derogations from the restrictions

The vertical product regulation applicable to product groups should define which derogations from the restrictions are allowed. The sequence of developing vertical product legislation should follow the prioritisation of product groups as outlined below.

3.5.1 Prioritisation of product groups

To implement Option 2, the sectors or product groups should be prioritised with

regard to the time, when vertical product legislation is developed because the restrictions can only be implemented when it is ensured that all essential uses remain available. Vertical product legislation with the necessary derogations must be introduced step-by-step, considering the available resources of all involved actors. **The sequence of developing vertical legislation and the time for entry into force must be defined in the legislation to ensure a predictable and binding process and the ability of all actors to get involved.**

Existing legislation should be adapted in parallel to the introduction of new product groups. When revising existing rules, any derogations from the horizontal exclusion criteria must be implemented timely.

The following criteria should guide the selection process of priority products:

- **High priority:** product groups with high exposure potential for human health and the environment, in particular to vulnerable groups and/or product groups, where the content of hazardous substances currently prevents or significantly hinders recycling
- **Medium priority**: product groups with medium exposure potential for human health and the environment but placed on the market in high volumes and product groups, where recycling efficiency could be improved if hazardous substances were phased out
- **Low priority:** product groups with low exposure potential for human health and the environment placed on the market in low volumes and product groups, where recycling destroys and/or separates hazardous substances.

The phase-in of product groups must balance the need for time for the regulatory process of identifying and defining potential derogations for essential uses. On the other hand, the toxic-free environment ambition demands an ambitious overall timetable. Obviously, the selection of product groups for vertical regulation may also depend on other criteria stemming from the implementation of other requirements in a Sustainable Products Initiative.

3.5.2 Developing vertical legislation and timeframe

The Commission should drive the development of vertical legislation in line with the phase-in scheme for products defined in the horizontal legislation. Vertical legislation should be implemented in the form of Regulations to create a harmonised internal market with synchronous implementation and include the derogations from restrictions as one of the provisions related to the product group. The horizontal restrictions for specific products should only enter into force once the related vertical legislation is in place.

The definition of derogations requires a procedure and criteria to ensure consistency across legislation. The procedure implemented under the EU Ecolabel Regulation has proven feasible and functional and should therefore be also applied under a future SPI framework: sectors identify and justify the need for a derogation, which is assessed and approved in a common process by the applying sector, the Commission and Member States, as well as third party stakeholders such as NGOs or academics. This is manageable for all involved parties and places the burden of

proof on the industry. The procedure should follow the criteria defined in the horizontal legislation to decide whether any exemptions are acceptable.

Any decision to justify a derogation should be based on the assessment of the availability of suitable alternatives. In a first step of the process, the market actors request a derogation by specifying the functionality and the product (component) for which it is needed. Based on the list of requested exemptions, all actors of a sector and third parties are invited to present their technical solutions currently applied for the functionalities in question (determination of the status quo in the sector) and to propose alternatives (determination of progress). Finally, the Commission checks if the functionality is essential and if suitable alternatives are missing and/or carry disproportionate burdens. Based on this, the Commssion decides whether a derogation should be included in the vertical legislation. A derogation is implemented by lowering the priority group of hazard properties or specifying which hazard properties may be used. If e.g. an exemption request concerns priority group 1, the use of substances fulfilling the criteria of the priority group 2 would be allowed.

If product-specific legislation already exists, such as on toys or batteries, a case-by-case assessment should determine whether this legislation can be fit under the umbrella of the horizontal restrictions, whether any adaptations or an entirely new framework is needed. It may also be necessary to introduce provisions excluding certain product types from the horizontal restrictions until adaptations are implemented.

The default setting for the review process of the exemptions should be defined in vertical product legislation, e.g. every 5 years. Where it is useful and acceptable, longer or shorter reviews may be applied in vertical legislation

4. Recommendations

To unlock the unprecedented potentials of the upcoming Sustainable Product Policy legislative framework to contribute to the EU target of a toxic-free environment, the following is recommended:

1) Include the toxic-free environment objective into product legislation to strengthen the goal and align legislation.

2) Develop a horizontal restriction of substances with hazardous properties that applies to all products wherever specific legislation exists. The restricted hazardous properties should reflect the priorities of the Chemicals Strategy for Sustainability.

3) Define a work programme for the Commission with clear deadlines for the development and entry into force of vertical product legislation that triggers the horizontal restriction requirement. Products with high exposure potentials should be phased in first.

4) Define and organise a process for developing the vertical product legislation, including a common definition of derogations for essential uses where no suitable alternatives exist. The criteria defining essential use and whether or not an alternative is suitable should reflect respective provisions in other (existing) policies, such as the Chemicals Strategy for Sustainability or sustainable investment legislation. Involve all relevant stakeholders in the process.

5) Require market actors using derogations to report their use of substances to gather information for the regular review of derogations and other provisions.

5. Expected impact

Implementing a phase-out of hazardous substances in an increasing number of product groups as outlined above will substantially improve human health, the environment, and the economy. Due to the manifold products on the market, no quantitative effects can be described.

Reduced emissions of hazardous substances should lead to improved **human and environmental health**, resulting in **savings of public health spending, environmental remediation** and not least **preventing the loss of (quality) of life**. Additionally, the absence of hazardous substances in (waste) products is assumed to **increase the compliant reuse and material recycling** at high material quality standards. According to ECHA's impact assessments[29] of restrictions, these **benefits are likely to outweigh the substitution costs** by far.

The regulatory push to substitute hazardous substances in products should:

- Promote the development and use of innovative and sustainable alternatives, resulting in increased competitiveness of enterprises on the (global) market and an improved ability of the sectors to adapt to changing product demands
- Accelerate changes in the market shares of product suppliers due to ceasing (parts of) the business, (inability or lack of willingness to substitute, high costs etc.)
- Include increased enforcement efforts, in particular, to control imported products
- Lead to a reduced market for hazardous substances, which may increase the prices of these substances in the remaining sectors, including for essential uses

Overall, the impacts are difficult to quantify not only due to the high number of (hazardous) substances used in the production of products but also due to the fact that chemicals requirements will be increased also by chemicals and waste policies. Furthermore, similar developments can be observed in other regions of the world, which will also have effects on the (global) markets.

Eventually, the development of safe and sustainable products is inevitable and hence, a consistent framework with clear goals, timelines and criteria defining which uses of hazardous substances are considered essential will make changes predictable and manageable.

References

[1] European Commission COM(2020) 667 final "Chemicals Strategy for Sustainability Towards a Toxic-Free Environment", https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2020:667:FIN

[2] European Commission COM(2019) 640 final „The European Green Deal", https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2019:640:FIN

[3] https://www.eea.europa.eu/signals/signals-2020/infographics/the-unknown-territory-of-chemical-risks

[4] https://ec.europa.eu/commission/presscorner/detail/en/IP_20_331

[5] See Article 191 Treaty on the Functioning of the European Union, consolidated version https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:12012E/TXT

[6] In the CSS the societal costs due to chemical exposures are estimated as high. For example, the estimated costs from PFAS alone are in the order of magnitude of 52-84 billion Euro per year across the EU (based on Nordic Council (2019): The Costs of Inaction. A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS, 2019) http://norden.diva-portal.org/smash/get/diva2:1295959/FULLTEXT01.pdf. The EEA quotes costs due to exposure to EDCs in its report "The European environment — state and outlook 2020, Knowledge for transition to a sustainable Europe" that EDC might cause health effects of EUR 157 billion annually (based on Trasande, L. et al. 2016 Burden of disease and costs of exposure to endocrine disrupting chemicals in the European Union: an updated analysis https://doi.org/10.1111/andr.12178). The EEA report also states that remediation of environmental media is often technically impossible or too expensive, so effects are in practice often irreversible (EEA 2020 https://www.eea.europa.eu/publications/soer-2020/at_download/file).

[7] Substances of Very High Concern identified according to the formal procedure of Article 57 REACH and officialy listed on the Candidate list according to Article 59 of the same regulation.

[8] DIRECTIVE 2009/48/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 June 2009 on the safety of toys

[9] DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment
The RoHS Directive is normally attributed to waste legislation, it actually affects the placing on the (EU) market by defining minimum requirements regarding the absence of substances in the covered products.

[10] It is not fully clear at which point in the lifecycle registrants may stop the safety assessment, due to unlear cut-off criteria in the legislation. Furthermore, generic exposure models for articles and waste treatment that could be used by the registrants are missing.

[11] Over the last 11 years, Annex XIV successively expanded since 2009

[12] According to REACH Art. 33 product (article) suppliers must inform their customers of the presence of SVHC contained in the article above 0.1% w/ww. They must also answer consumer requests about the content of SVHC in products within 45 days and free of charge if an SVHC is contained above 0.1 % w/w.

[13] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020SC0287

[14] Under the CSS it is intended that the criteria for inherently safe chemicals are developed, which may give more guidance in the future.

[15] Chemical products are better addressed by the chemicals regulations, e.g., REACH, the Biocide and Plant Protection Products Regulation.

[16] This article is a horizontal ecolabel award criterion for any product and requires that substances with certain hazardous properties are not contained in the product. The Ecolabel Regulation also defines a process for derogations. These provisions were elaborated by two multi-stakeholder working groups with the participation of representatives from industries, NGOs, the Member States, and the Commission. The provisions are implemented in the definition and revision of EU-Ecolabel criteria (cf. EU-COM, JRC 2014

"Findings of the EU Ecolabel Chemicals Horizontal Task Force, Proposed approach to hazardous substance criteria development" and EU-COM, JRC 2018 "EU Ecolabel: Chemicals Task Force 2, Final proposals and recommendations).

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[18.] The vertical legislation not only includes the derogations from restrictions but any other ecodesign parameter for the product group, such as energy consumption or carbon footprint

[19.] The criteria have been established in a working group "Chemicals Horizontal Task Force" led by the JRC and the Commsiion (DG ENV) and with contribution from the industry stekholderes and representatives of MS authorities and consumer and environemental NGOs. The results have been published in a document 2014 "Findings of the EU Ecolabel Chemicals Horizontal Task Force - Proposed approach to hazardous substance criteria development"

[20.] As default no derogations are granted on group level but only very specific.

[21.] The CSS supports the extension of the candidate list to EDC and PMT substances, therefore PMT will have high relevance for this group as well

[22.] These requirements already cover the higher relevance given to EDC, neurotoxins and sensitisers in the CSS, the implementation of criteria to identify these hazards will support the identification of such substances, furthermore, the introduction of new classification categories under the CLP for EDC, PBT/vPvB and PMT will increase visibility of such substances in markets and thus simplify the implementation of a substitution requirement

[23.] The notified classifications differ over a large range for individual substances, as is evident from the classification and labelling inventory

[24.] This corresponds to a precautionary approach and is based on the assumption that market actors have no interest in overclassifying a substance.

[25.] In accordance with Chapter 1 of Title II Identification and verification of information (Articles 5-8)

[26.]The CSS states that: "These criteria will guide the application of essential uses in all relevant EU legislation for both generic and specific risk assessments;" It is not clear at this stage what this exact concept will cover and whether it will be applicable across the full range of hazard categories, without imposing a disproportionate burden on market actors. Depending on the concrete discussions in the field of chemicals law, further adjustments may be necessary.

[27.]However, this reflects the current supply practices for complex articles and might therefore be better implementable than the current REACH requirement of Article 33 or the SCIP database

[28.]Based on the once an article – always an article (O5A) interpratation of the application of Article 33 and 7 and the definition in Article 3 number 3. of REACH (see EUGH decision on case C-106/14 https://eur-lex.europa.eu/legal-content/de/TXT/?uri=CELEX:62014CJ0106

[29.]ECHA (2016): Cost and benefit assessments in the REACH restriction dossiers. Helsinki. https://echa.europa.eu/documents/10162/13630/cost_benefit_assessment_en.pdf/b780a657-b4aa-4274-8c74-3a80bae8e883

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