Essential use & EU law

Making judgement on acceptable risk fairer, easier and more transparent

The definition of what is an acceptable risk always involves value judgements on what is essential to society. They implicitly influence the scientific assessment of the hazardous properties of the substances and of the exposure patterns, as proven time and again.[1] They explicitly ground the final decision on when to allow potential harm. And if the criteria set in law allow decision makers to make an arbitration on what is essential to society transparently, easily and fairly, then the final decision is more understandable, legitimate, effective and efficient.

But the current criteria do not deliver this result because they mostly rely on a cost-benefit analysis which results in a hyper technical and resource intensive process that favours business as usual.[2]

Therefore, the criteria used by decision makers to identify acceptable risks must better reflect their need to consider what is essential to society quickly and transparently, by setting a common approach on how to make this arbitration grounded in the essential use concept (ESU).

[1] See the synthesis of the evidence on this by Renn, O. Risk governance. Coping with uncertainty in a complex world, Routledge, 2008 – for ex. P. 44. The synthesis of social research on risk governance offers great insights on the approach and methods to use by public authorities when attempting to integrate broader social considerations in risk decision-making process. His summary of the criteria used universally by humans as heuristics to evaluate risk is particularly useful. See also the seminal work of Sheila Jasanoff, see here, including "Controlling Chemicals, the politics of Regulation in Europe and the United States, 1985.

[2] "Socio-economic assessment and REACH authorisation. The mismatch between law and practice", ClientEarth, 2021. See also: Keith Miller, "Quantifying Risk and How It All Goes Wrong", Hazards 28, Symposium Series No 163, IChem (2018); Franck Ackerman, Pricing the priceless, cost-benefit analysis of environmental protection, p 1568; Cass R. Sunstein, "Is Cost-Benefit Analysis for Everyone?," 53 Administrative Law Review 299 (2001); Baruch Fischhoff, "The realities of risk-cost-benefit analysis", Science 2015, Vol. 350, Issue 6260, aaa6516, DOI: 10.1126/science.aaa6516.

Why is an essential use approach needed?

REACH authorisation – improved legitimacy, effectiveness and efficiency

The essential use approach described below would solve several key issues of the current authorisation process.

1) Limit the number of applications

The resources needed for the authorisation process, by companies and public authorities, should be used only for the cases where a deep focus on the substitution efforts and remaining emissions and exposure is needed. They should not be spent on non-essential uses – either because the use is not critical (luxury) or because there are alternatives (shampoo without microplastics). We explained how the REACH authorisation process could be rebuilt in this way in our Demand #3 and Demand #4 for REACH reform).

Excluding such cases would have advantages for companies and public authorities. For companies, it is a clear signal to substitute, that saves them from risking resources in the authorisation process. For authorities, it gives a clear mandate to reject abusive applications without a full, resource intensive examination and with full legitimacy.

2) Streamline the analysis of alternatives

In the current system, there is no pre-set acceptable loss of technical performance. The analysis of alternatives is entirely dependent on the narrow perspective of the applicant and its customers.[3] This is the main obstacle to the proper consideration of market changes and of the high concerns raised by the use. The essential use concept can help define what is an acceptable loss of performance to break the deadline (see figure 1 below).

REACH restrictions – improved predictability, legitimacy, effectiveness and efficiency

REACH obliges the submitter of restriction dossiers to "take into account the socio-economic impact of the restriction, including the availability of alternatives" (Art. 68) but leaves considerable discretion on how to do so.

The complexity of defining a tailored approach in each case led to the default selection of the predominant method for assessing benefits – a cost-benefit analysis favouring a quantitative approach - which some of the indicative elements listed in Annex XVI hint at. This approach and the way it is applied amount to considering any production of goods or services as beneficial for society (which does not mean that the benefits will be systematically considered as proportionate to the risk), because it contributes to the economy (jobs, sales, competitiveness, etc.). It is based on a value judgment: that retaining jobs and goods in the EU is *at least* as important as preventing harm to health or the environment.[4] It is also based on an often wrong assumption – that no other jobs and goods will come up from the safer pathway. The selection

[3] See Christoph M. Rheinberger and Matti Vainio, Benefit-Cost Analysis in EU Chemicals Legislation: Experiences from over 100 REACH Applications for Authorisation, 2018, Journal of Benefit Cost Analysis, 9(1):1-24.
[4] See SEAC Opinion on Gruppo Colle Application (Sodium Dichromate), p.20-22. https://echa.europa.eu/documents/10162/f6cfd792-8986-c451-8ada-d5ba4f2c2649.

of this approach resulted in a de facto - and so undebated, unexplained and non-transparent – adoption of the vision of the socio-economic authorisation route as a **profitability preserver**.

The broad discretion also led to two other adverse results. First, it led to excessive public resources being spent in justifying the phase out of the most harmful substances. Second, it placed the dossier submitter on fragile ground – the dark side of discretion. By not having an explicit legal basis to eliminate non-essential uses, it created fears of court challenges. All this resulted in extra public resources spent and undue protection of business-as-usual.

Creating an explicit mandate for dossier submitters (ECHA or Member States) to use an essential use approach to design their dossiers will, if associated with a useful guidance, help increase transparency, predictability and legitimacy and might help save public resources.

The essential use grid would help sort out uses under restriction to avoid abusive derogations and transition periods. It also ensures that truly complex cases are analysed in depth, and under a process that obliges companies to provide meaningful information (by sending the essential uses requiring more than 6 years transition to the authorisation process – see the brief for our Demand #4 for REACH reform).

In other sectoral regulation – a transparent grid for legislative choices

EU sectoral regulations that are concerned with the use or presence of chemicals in products and processes may gain from the essential use grid. Contrary to REACH, which covers any use, sectoral laws target specific uses. Because the end uses are already known, the essential use approach should be a tool first used by the co-legislator rather than, as for REACH, in the hand of the authorities in charge of implementation. Indeed, for some sectors, it can be easily concluded *ex ante* that there are no essential uses of the most harmful substances.

Such a grid could indeed help the EU legislators to implement the expansion of the generic risk approach promised by the Commission (exclusion by default of the most harmful substances), by supporting the identification of:

- The sectors in which no derogations should be granted (for ex. toys, as there exists without doubt products and ways to play without the presence of the most harmful substances).
- The sectors in which limited derogation could be granted, by pre-identifying specific needs that could be considered as critical upon further assessment (for example, in cosmetics, protection from UV light for specialised sunscreens).
- The conditions to fulfil for a derogation to be granted, including the threshold of acceptable technical loss for the analysis of alternatives.

In summary, contrary to REACH, it is possible in sectoral laws for the co-legislator to pre-sort the needs that may be considered as essential uses. In order to avoid heated, complex and lengthy debates at the implementation stage, it is indispensable for the co-legislators to do so.

How would it work?

As wonderfully explained by the recent publication on chemical pollution overshooting planetary boundaries, the expansion of the chemical universe has long exceeded the containment capacity of chemical regulation.

Therefore we need to go from a specific to a generic approach in the main steps of chemical regulation. What it means in practice is that a series of presumptions and assumptions are used:

- Hazard assessment: application of a group approach, which is a rebuttable presumption that similar substances have similar properties.
- Exposure assessment: application of a generic risk assessment approach, which is a presumption that some categories of use lead to unacceptable exposure or material contamination - for example consumer, professional or other wide dispersive uses.
- Risk management: an application of automatic consequences, including bans, attached to groups of substances with similar properties for some categories of uses – for example, carcinogens are banned from toys.
- Socio-economic impact of the ban: treating the impacts of banning non-essential uses as acceptable by default.

Whatever the final version of the ESU is, it must support the adoption of a generic approach as the only tool able to give back to public authorities the capacity to bring chemical pollution within the planetary boundaries.

Situations concerned

The most harmful substances may be present in production processes as well as products and materials for three reasons.

- Contamination - for example, legacy substances in recycled materials.
- By-products - for example, the substances present in plastic because of reactions between its chemical ingredients.
- Intention – their technical function provides a performance to the product or process.

The Chemical Strategy promises to eliminate all non-essential uses of the most harmful substances, making the essential use concept (ESU) a sorting tool for what must go immediately, and what can legally stay a bit longer. In practice ESU can help with intentional uses and by-products, but not contamination.

Essential use – but what is a use?

The term essential use refers to the function of the chemical. But this question may be answered at different levels as it concerns what the chemical does, why it is used and why it matters.

What it does – this is the micro level, relating the technical function, the performance brought.

Why it is used –medium level, relating to the purpose of the product or process to which the performance is brought.

Why it matters – macro level, relating to the service provided to society by the product or process.

The ESU approach requires to look at those three levels to grasp the full picture.

Table 1 – The three functional levels of chemicals in products and processes – adapted from Tickner et al.[5]

Functional level	**Chemical in product** Bisphenol-a in thermal paper	**Chemical in process** Methylene chloride in degreasing metal parts
Chemical function Industrial performance of the chemical – what it does	Chemical developer	Solvent degreaser
End use function Purpose of the product/process – the applications for which the chemical is used – why it is used	Creation of printed image	Degreasing
Societal function Societal service provided by the product/process – why it matters	Providing a record of sale to a consumer	Contaminant-free metal parts needed for corrosion-resistant cars

Under the ESU grid, the use of a very hazardous chemical may be acceptable only if it is critical on those three functional levels. That requires to ask: how critical is the performance for the application? How critical is the application for the societal service? How critical is the societal service? For each level, the existence of an alternative will have a considerable role to play in the conclusion on the criticality. In other words: if there is an alternative at any level of function, a use cannot be essential. However, the analysis of alternatives is more complex, more technical and resource intensive at a micro (chemical function) than a macro level (function as service), which is why the macro level should be the first filter.

For example, let's say that microplastic in shampoo helps to take grease off hair. It is easier to conclude that it is not needed because there are many shampoos without microplastic that do the job, than to assess which chemical component ensures the highest scalp degreasing performance.

[5] Tickner J. et al. "Advancing Safer Alternatives through Functional substitution" Environmental Science & Technology, 2015.

The criteria

The source

<u>Decision IV/25</u> adopted by the parties to the Montreal Protocol

1. The use of a controlled substance should qualify as "essential" only if:

    a) It is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and

    b) There are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health.

Criteria 2 (a) and (b) of Decision IV/25 must not be forgotten**.**

2.

    a) requires a minimisation of the use of the substance of concern in any case (even when considered essential).

    b) considers the implication for the entire supply chain beyond the users – the manufacturers of the substances are allowed to maintain their activity only if the existing stocks (banked or recycled) are not sufficient to satisfy the residual demand linked to essential use, considering the "national" consumption for essential use and beyond ("*also bearing in mind the developing countries' need for controlled substances*").

The Decision also specifies that the "*steps necessary to ensure that alternatives and substitutes are available as soon as possible for the proposed essential use*" must be considered.

The meaning

The clear cases

The Montreal Protocol, the work of Cousins et al.[6] and many EU regulations (albeit implicitly) offer indications of the sectors or types of uses that are non-essential: luxury, convenience, leisure, cosmetics, toys or decorative products.

Health and safety are the least contentious sectors of the other side of the spectrum. The NGO ChemSec developed an interesting series of questions that can support an effective decision making process on essential use.[7]

The grey areas

The task becomes difficult when attempting to define more precisely the other uses considered essential under the Montreal Protocol, those "*critical for the functioning of society (encompassing cultural and intellectual aspects)*".

[6] See their <u>2019 article</u>, and the follow up in <u>2021.</u>
[7] See <u>https://chemsec.org/publication/chemical-strategy/when-is-it-justified-to-use-very-hazardous-chemicals/#so-what-could-the-essential-use-determination-process-look-like</u>.

The reference to the core human needs as categorised by social research might in that regard be useful.[8] In this debate, it is critical to keep in mind that human needs can be material (subsistence) or immaterial (affection). Material human needs cannot be fulfilled without material satisfiers (food). Immaterial needs are mostly fulfilled by non-material satisfiers (a hug, an expression of empathy).

Material satisfiers may support the fulfilment of immaterial needs (a sympathy card, for example) but are rarely a precondition to its fulfilment. For example, it is true that decorating one's home can serve the human needs for creation, identity or affection. However, it is also true that these immaterial needs may be fulfilled by an infinite number of immaterial and material means.

Therefore, claims attempting to qualify the use of a substance of concern in a product or process fulfilling an immaterial need as essential must be presumed to be unfounded. This calls into question whether we should define uses supporting traditional and religious practices as potentially critical for the functioning of society (e.g. use of hazardous incense in churches during religious ceremonies). Traditional and religious practices are recognised under the Montreal Protocol as potentially critical. However, these exceptions must concentrate on the material needs absolutely indispensable to these practices.

The only exception must be critical infrastructures, as mentioned by the Commission, that supports both the fulfilment of material needs (transport of food) and immaterial ones (visits to loved ones).
Reciprocally, when the SVHC is critical to a product or activity indispensable to the satisfaction of a material need (subsistence and protection mostly, via food, water, housing, medical and security services, communication and transport), it should be submitted to a lower level of scrutiny.

Excluding purely economic arguments from essentiality

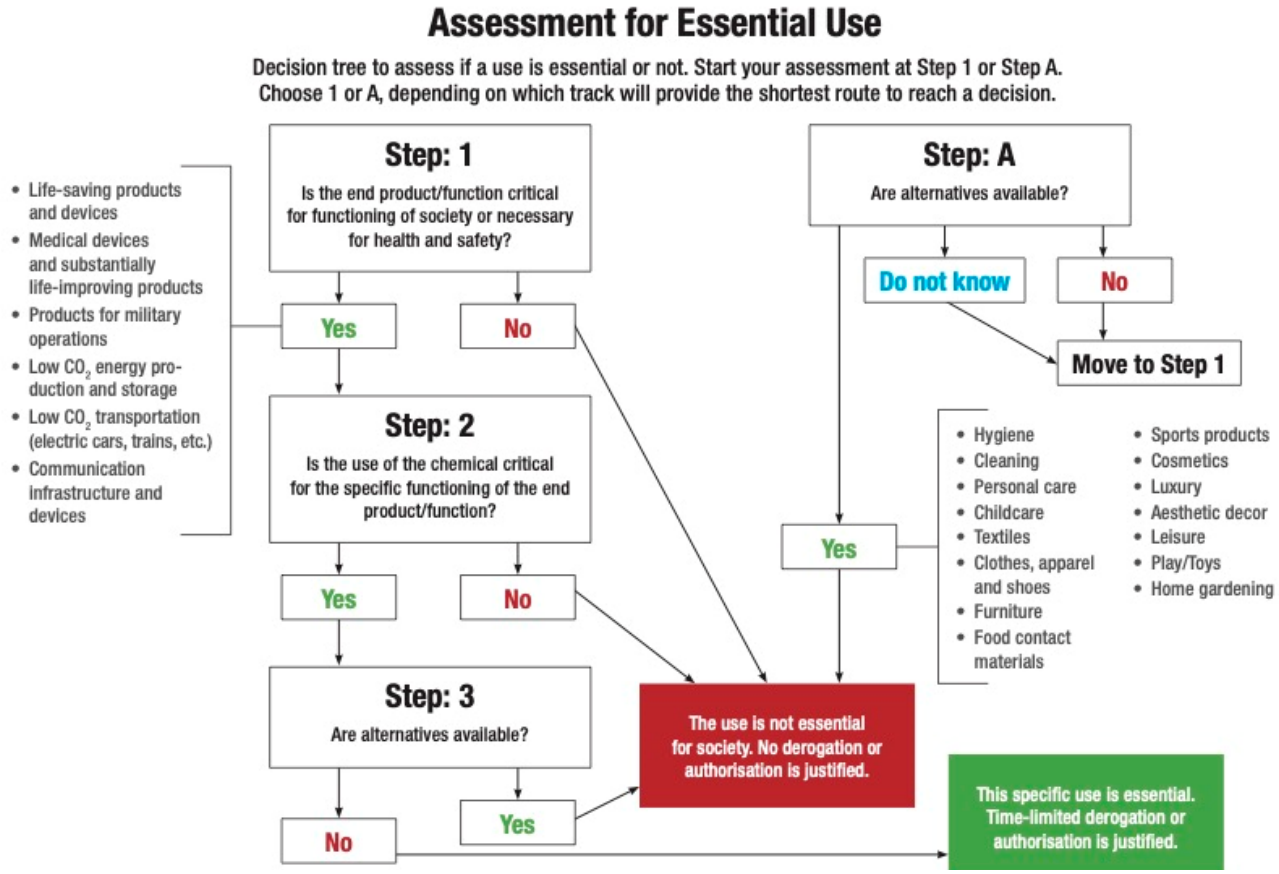
Any company may have the incentive to claim that the use that is being restricted is somehow essential, or likely to become essential in the future. This kind of argument is already brought forward by companies applying for authorisations for substances that have been classified as being of very high concern.[9] Under the Montreal Protocol discussions on essentiality have often been driven by economic arguments.[10] The 9th Meeting of the Parties to the Protocol in 1997 allowed critical use exemptions for uses of methyl bromide, when the lack of availability of methyl bromide for that use would result in a significant "market disruption". It should be made clear from the start that market disruption is not sufficient to establish essentiality. It is only when the market disruption would impact the satisfaction of an essential material human need that an exemption may be considered.

Questions to assess – the sequence matters

The assessment of essentiality is a series of questions, and those that will be the harder to answer depends on the specificities of the context. For example, it can be very easy to know whether there is an alternative (is there a toy without carcinogenic chemicals?) or very hard (is there another way than chromium trioxide to guarantee corrosion free plane breaks?).

[8] See for example Tim Jackson, Nic Marks, "Consumption, sustainable welfare and human needs—with reference to UK expenditure patterns between 1954 and 1994" Ecological Economics, Volume 28, Issue 3, 1999, Pages 421-441 offers insight on what might be considered essential material human needs, which offers useful guidance when definition essential uses. Their work relies on the Max-Neef and Maslow categorisations of human needs, themselves useful.
[9] AmChamEU position paper on Essential Uses.
[10] Brian J. Gareau, "Sociology in Global Environmental Governance? Neoliberalism, Protectionism and the Methyl Bromide Controversy in the Montreal Protocol", *Environments*, Department of Sociology, and the International Studies Program (2017).

So the order of the questions should be flexible, for the easiest eliminating question to always been asked first. This is what is proposed in this decision-tree by ChemSec:



Increasing the speed, legitimacy and efficiency of the process must be the goal of the concept. It must aim at transforming the process into an easier road to environmental and health protection. However, essentiality can be a hot topic. Depending on how it is done, ESU can bring a better system or weaken it by opening the door to more exceptions or by stalling the decision-making process.

How to assess alternatives

The burden of proving that there is no alternative must be on companies

In the context of the Montreal Protocol, the Handbook on Essential Use Nominations[11] provides detailed guidance on the preparation of essential use nominations under the Montreal Protocol and the rationale behind the authorisation of each exemption. It shows, in particular, that the review process for essential use exemptions is made stringent by placing a relatively heavy burden of proof on the applicant. This approach could help frame the implementation of the essential use concept in the EU.

And the burden is high. The Parties are instructed to exercise "the utmost diligence" in the assessment of essentiality. The scientific panel ("TEAP") in charge of the case-by-case assessment will not evaluate nominations that identify a "*perceived essential use, but do not request a specific quantity of controlled*

[11] See at: https://ozone.unep.org/sites/default/files/data-reporting-tools/EUN-Handbook2009.pdf.

substance for a specific consumption and/or production exemption". The TEAP does not hesitate to refuse a request when there is evidence that even one alternative product is available.[12]

The final decision is not based on information by companies only

The assessment of alternatives under REACH suffered from the overreliance on applicant's information and barriers in the participation of alternative providers.[13] Fees need to be raised to conduct market surveys, in addition to better information requirements and the power to ask questions to applicants and their competitors.

Need for agreement on acceptable loss of performance and acceptable cost

Not allowing the use of the most harmful substances when an alternative is available is common sense and protects frontrunners. But, in practice, the consensus dies as soon as the performance needed by the alternative is discussed. The lesson from REACH is that whether there is an analysis of alternative is rarely a yes/no question.

The applicants tend to argue that nothing less than the performance of the substance of concern will do, alternative providers argue that the performance is sufficient considering the end use. Under REACH authorisation, the applicants' arguments were most often taken at face value, especially when they related to – even undocumented – customer preference.

Therefore, to make ESU work, a way out of the deadlock must be found. Several key elements are needed:

- An agreement that it is acceptable for an alternative to be more costly and/or less performant than the substance of concern, as long as the end-function is preserved.
- A common understanding of what availability means, in terms of economic and practical access to the alternative.
- A common understanding of what is an acceptable loss of performance (which still has not been set under REACH). ESU offers a perfect matrix to conceptualise what an acceptable loss of performance is. As supported by ESU, the level of performance required depends on its criticality for the end use function as well as the importance of the end use.

For the criticality of the technical function, it could be helpful to have indications of what could be considered as a high, medium or low level of criticality – see Table 2:

[12] See the case of China asking for the use of 4.57 tonnes of CFCs to produce manufacture sodium cromoglycate metered dose inhalers. The TEAP explained that: "*for this category when there is one CFC-free product available*. *Last year MTOC indicated that it would recommend the nominated quantities for one last year to facilitate transition to CFC-free products during 2014. MTOC is unable to recommend the requested CFCs (4.57 tonnes) to manufacture sodium cromoglycate MDIs in 2015 because alternatives are or will be available*". See May 2014 TEAP Progress Report p. 13.

[13] See our report with ChemSec - How to find and analyse alternatives in the Authorisation Process – ChemSec.

Table 2 – indicators for high, medium of low criticality of the technical function for the end use function

Criticality of technical function for end use function	High	Medium	Low
Indicators	No product or process with similar function available without the substance of concern Regulatory standards require the level of performance granted by the substance of concern	The process or product exists without the substance of concern, but is less performant or widely available	The process or product exists without the substance of concern but is more resource intensive

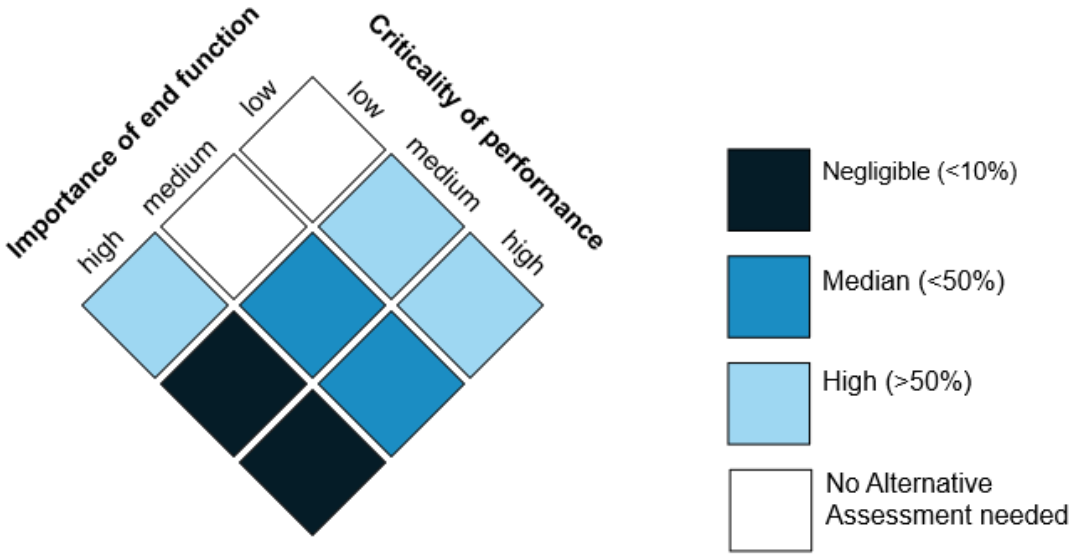
For the importance of the end function, we could similarly adopt indicators to distinguish between high, medium and low importance – see Table 3:

Table 3 - indicators for high, medium and low importance of the end use function for the societal function

Importance of end use function for societal function	High	Medium	Low
Indicators	Product or process is life saving Medical devices and products improving life substantially Communication devices and infrastructure Low CO^2 energy and transportation solutions	Critical enabler of product or process of high importance	Marginal support to product or process of high importance

The determination of what is an acceptable loss of performance (high loss, medium loss or low loss) can then become a function of both – see Figure 2 below:

Figure 2: Determination of the level of acceptable loss of performance considering the criticality of the technical function and the importance of the end use.



The allowed transition – conditions and length

The possibility to allow transition for essential use should not undermine the goal – the elimination of the most harmful substances – or the development of alternatives. They also must protect people and the environment. Therefore, they must be submitted to the following conditions:

- As short as possible, 10 years maximum, with a mid-term review if over 6 years.
- Obligation to minimise emissions and exposure in the application of best practices.
- Obligation to monitor, track and report the use, presence, exposure and emissions.
- Obligation to pay a fee, increasing every year.
- Under REACH – must be submitted to authorisation if longer than 6 years, or in the case of serious uncertainties related to risk or substitution.

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