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Evaluation of restriction reports and applications for authorisation for persistent substances in SEAC

1. INTRODUCTION

Persistent substances[1] are of specific concern due to their potential to remain and accumulate in the environment over long time periods. Persistent substances, therefore, have the potential to cause harm to both the environment and humans (either immediately or with a delay). This harm can stretch over several decades and generations, and could even be irreversible.

Experience from the past has shown that the effects of such accumulation are difficult to predict with sufficient reliability by testing or modelling. In the long-term, exposure via polluted environments is practically difficult to reverse, because an elimination of releases will not necessarily result in a measurable reduction in exposure – particularly for highly persistent chemicals. The properties of persistent substances lead to increased uncertainty in the estimation of human health and environmental risks when applying quantitative risk assessment methodologies. Therefore, a reliable "safe" (no effect) concentration in the environment, or when such level would be exceeded, can often not be established using the methods currently available. Hence, the quantification of risks is not foreseen in REACH for PBT and vPvB substances. Instead, emissions and subsequent exposures of humans and the environment throughout the life-cycle of the substance need to be minimised (Annex I para 6.5 of REACH).

Consequently, available information does usually not allow for a full quantitative assessment of the negative human health or environmental impacts or damages, because an assessment and a valuation of benefits of reducing emissions via a standard impact pathways approach[2] is not possible. Even if the precise relationship between emissions, exposure/risk, impacts and damage costs is not known, it cannot be ruled out that marginal damages are increasing in emissions or pollution levels, which means that damages will grow non-linearly over time.

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[1] The earlier versions of this approach explicitly covered only PBT and vPvB substances. As the approach has been succesfully used also for other persistent substances, the scope was widened to cover other persistent substances, where RAC considers releases as an appropriate proxy of the risks. These may include substances fulfilling the Annex XIII criteria for persistence, e.g. in addition to PBT and vPvB, persistent, mobile and toxic (PMT) and very persistent and very mobile (vPvM) substances, as well as substances fullfilling the criteria for identifying a persistent organic pollutant (POP).

[2] See European Commission, Directorate-General for Research and Innovation, Bickel, P., Friedrich, R., ExternE - externalities of energy – Methodology 2005 update, Bickel, P. (editor), Friedrich, R.(editor), Publications Office, 2005.

Therefore, the evaluation of the proportionality to the risks of the proposed restriction, or whether the socio-economic benefits of use of the substance outweigh the risks for an application for authorisation applying cost-benefit analysis (CBA) is challenging. Nevertheless, the Committee for Socio-economic Analysis (SEAC) still need to form an opinion on these cases. Other options which are able to reflect the socio-economic implications of persistence in evaluations of benefits and costs of measures for reducing emissions need to be considered.

Some elements of this approach for persistent substances are relevant also for other substances, such as substances with endocrine disrupting properties (ED)[3]. For these, dose-response functions or safe thresholds are usually also unavailable. Therefore, the impact assessment pathway approach cannot be applied or would be highly uncertain.

2. PURPOSE

The main purpose of this approach for evaluating persistent substances in SEAC is to ensure a **consistent treatment of the relevant socio-economic issues** in restriction proposals, as well as authorisation applications, to the extent possible. This will also make the opinion forming process in SEAC more efficient. Furthermore, Member States (MS) preparing Annex XV restriction reports and potential applicants working on applications for authorisation will better understand how the evaluation will be carried out by SEAC.

Whilst the proposed approach aims to enhance the consistency of Annex XV restriction reports and applications for authorisation, as well as SEAC opinions on those, by ensuring that certain information is available in all assessments for persistent substances, it should be noted that the intention of this document is not to limit the approaches and methodologies available to Dossier Submitters and applicants. If other approaches are used, SEAC will evaluate these on their own merits. Some other possibilities to approach the assessment are briefly described under section 4.

3. APPROACH

The challenges in quantitatively estimating the benefits of reducing emissions of persistent substances are well recognised. In addition, the difficulty in using only qualitative argumentation to evaluate the proportionality to the risks of restrictions and whether benefits outweigh the risks for authorisation applications is also acknowledged. Therefore, the approach of SEAC to evaluate persistent substances is based on the consideration of different types of information that should be available to assess potential impacts and their values.

3.1. Main elements for assessing costs and benefits

The starting point of the evaluation is the expected **emission reduction** of persistent substances of a proposed measure (i.e. the difference between a non-use and a continued use scenario in applications for authorisation, or a baseline and restriction scenario in restriction proposals) and the **compliance costs.** Hence, these should always be included to derive the cost per unit (e.g. kilogram) of emissions reduced,

[3] See SEAC note SEA-related considerations in applications for authorisation for endocrine disrupting substances for the environment, specifically OPnEO and NPnEO recognising the possiblity to report quantified release estimates complemented with contextual information on the releases to describe environmental risks.

which is equivalent to the average cost-effectiveness ratio of a measure[4]. In the unlikely case that releases cannot be estimated (and not even approximated using default release factors), reduced amounts of the substance used or placed on the market could be reported instead. However, in this case a justification for doing so needs to be provided and the implications of this change for the interpretation of the overall results of the assessment and the conclusions on proportionality should be discussed (including a justification for not using default release factors).

For persistent substances pre-defined emission targets that have been judged to be worth achieving do not exist. To assess whether the regulatory action results in net benefits for society, it is necessary to have a comparator or a "benchmark" on the level of costs per unit of emissions avoided that is deemed to be worthwhile taking when reducing emissions of persistent substances. This could be based e.g. on:

- previous studies on abatement or avoidance costs for persistent substances, including information on the cost of past regulations, or
- existing data on remediation or clean-up costs for persistent substances, or
- previous economic valuation studies which have looked at the benefits of reducing exposure to persistent substances.

Two studies are available suggesting benchmarks to be used in cost-effectiveness analysis for persistent chemicals[5]. Both studies are mainly based on historical cases of emissions that occurred in a specific geographical area during a given period of time. Hence, they do not establish generic benchmarks. In addition to that, some of the cost-effectiveness estimates are for the reduced amounts of substance used, instead of the amounts released. Overall, it does not seem to be currently possible to set any generic benchmark for the acceptable level of cost effectiveness that would be applicable to all persistent chemicals.

Recognising that neither SEAC nor decision-makers have been able to set generic benchmarks with the available empirical information, conclusions about proportionality of regulatory measures for persistent chemicals (where RAC considers avoided releases an appropriate proxy of the risks) will have to be made case-by-case. The restriction dossier or application for authorisation should include a comparison of the cost per kg of avoided emissions of previous regulatory actions to place the estimates in context with the cost per kg estimates of the case in question.

It is further suggested that, where available, qualitative information about the socio-economic costs and benefits of reducing emissions of persistent chemicals, or any other information which substantiates the societal acceptability of the measures proposed, can be used. SEAC expects, however, that the information and approach used to integrate qualitative information into the balancing of costs and benefits, and the assessment of proportionality, is well-motivated (i.e. sufficiently close to the case at hand) and traceable. More guidance regarding the qualitative description of the socio-economic benefits of reducing emissions is provided below under section 3.4.

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[4] If more than one measure is included in the assessment, measures can be compared and ranked according to the marginal or incremental cost-effectiveness ratio, denoting the *additional* costs for an *additional* unit of emissions avoided. See, for example, Karlsson, M. (1996): The decision-rules of cost-effectiveness analysis. PharmacoEconomics 9(2), 113-120.

[5] Oosterhuis F. and Brouwer R. (2015): Benchmark development for the proportionality assessment of PBT and vPvB substances; GROWTH (2016): Approach for Evaluation of PBTs Subject to Authorisation and Restriction Procedures in context of Socio-economic analysis (europa.eu).

3.2. Geographical boundaries of the assessment

Even if it is recognised that environmental impacts may occur inside and outside of the EU, the assessment of emissions reduced (or avoided stock in the environment, see 3.4.2), costs and proportionality should be based on the EEA. However, all significant changes in emissions because of the proposed restriction or application for authorisation should be reported, irrespective of where they occur. When relevant, it should be stated which changes in emissions are expected to occur inside the EEA and which changes are expected to occur outside the EEA. This global allocation of effects should at least be qualitatively described. This is of particular interest for substances classified as PMT or vPvM, which thus may accumulate outside the EEA. Moreover, as persistent substances are often retrieved in remote areas, a description of expected emissions (or emission reduction) outside of EEA may be of interest for the decision maker and could, therefore, be included in the discussion of impacts.

3.3. Time period of the assessment and discounting

Persistent chemicals can accumulate and remain in the environment and have the potential to cause damage to humans and the environment for long periods of time. The time period adopted in an SEA determines for how many years costs and benefits from reducing emissions of persistent chemicals will be taken into account. This implies that the time period for the assessment of costs and benefits needs to be chosen with care and be in a justifiable relation with the expected timing of costs and benefits, as well as related uncertainties.[6]

The usual assessment periods seen in past restriction reports (e.g. 20 years) may not adequately describe the timing and duration of the impacts of persistent chemicals. This warrants the use of time periods longer than 20 years for assessing costs and benefits. In particular, when environmental and health impacts can be assumed to be of an intergenerational nature, a time horizon of 30 or 50 years, or beyond, could be more appropriate. The time period chosen should always be transparently motivated in the restriction and authorisation dossiers.

Social discounting is applied to make costs and benefits that occur at different times comparable.[7] Using equal discount rates for costs and benefits is problematic mainly because of two reasons:

- Due to the on-going depletion of environmental resources, the relative scarcity of market and non-market goods (i.e. environmental goods and services) has been changing over time, causing the relative values of non-market goods to increase.[8] However, future prices needed for properly valuing environmental

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[6] For a discussion of the relevance of the time period see O'Mahony (2021): Cost-benefit analysis and the environment: The time horizon is of the essence. Environmental Impact Assessment Review 89.

[7] For a review of social discounting see Groom et al. (2022), The Future, Now: A Review of Social Discounting. Annual Review of Resource Economics 14, 467-491.

[8] It is widely acknowledged that environmental (i.e. non-market) goods – i.e. the biosphere and corresponding ecosystem services provided by the biosphere – are vastly declining at a global scale. In contast, the production of consumption goods (i.e. market goods), measured by the GDP, is growing (see, for example, Dasgupta (2021): Final Report - The Economics of Biodiversity: The Dasgupta Review - GOV.UK (www.gov.uk), chapter 4). Hence, goods have become more scarce compared to market goods. As a consequence, relative prices of environmental goods (i.e. the avoided environmental or health risks, representing the benefits in SEA for PBT/vPvB chemicals) and market goods (representing the costs in SEA of PBT/vPvB chemicals) change over time. Note that the relative scarcities will change when either the

goods and services in relation to market goods are often not known or not well-defined.
- Closely related to the first point, the substitutability between market and environmental goods and services is considered to be limited.[9]

In the specific case of a cost-effectiveness analysis, where the benefits of an emission reduction are not monetised, a lower discount rate could account for the possible changes in the relative prices of non-market goods in relation to market goods (as pointed out above).

For persistent substances SEAC expects the dossier submitter or the applicant to report the cost per kg of avoided releases where the costs are discounted with a positive discount rate.[10] For cases where impacts to human health and the environment can be expected to be long-term, i.e. of an intergenerational nature, SEAC recommends that benefits should be discounted with a different (i.e. lower) discount rate than costs. Recent scientific studies recommend to reduce the discount rate for non-market goods, representing the avoided environental or human damage (i.e. the benefits) in this context, by 1-2 percentage points compared to the discount rate used for market goods.[11] This is based on the assumption that the full time horizon of costs and benefits can be taken into account in an assessment. In the practical context of restriction proposals or applications for authorisation on persistent substances this may not always be possible. Considering that usually a finite time horizon will be adopted in the assessment, and to ensure consistency across dossiers, SEAC recommends to discount the benefits of a policy measure (approximated by avoided releases or stock estimates, see also section 3.4.2) with a zero discount rate as a default. If a dossier submitter or an applicant decides to use a different discounting approach (e.g. the use of declining discount rates), this should be made explicit and be well-motivated in the dossier. This can also be done as part of sensitivity analysis where the dossier submitter should give particular attention to the implications of different discount rates in relation to the time horizon adoted in the assessment.

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physical availability of the non-market goods change or when peoples' preferences (e.g for preserving environmental quality) change. This can also occur if costs and benefits of regulatory measures stretch out over the same time horizon.

[9] See, for example, Polasky and Dampha (2021): Discounting and Global Environmental Change. Annual Review of Environment and Resources 46, 691-717, Weikard and Zhu (2005): Discunting and environmental Quality: When should dual rates be used? Economic Modelling 22, 868-878.

[10] See European Commission (2022): Better Regulation Guidelines and Toolbox (2022, https://commission.europa.eu/law/law-making-process/planning-and-proposing-law/better-regulation/better-regulation-guidelines-and-toolbox_en), tool 64 ('Discount factors); HM Treasury (2022, The Green Book (2022) - GOV.UK (www.gov.uk)), chapter A.6.

[11] See, for example, Baumgärtner et al. (2015): Ramsey Discounting of Ecosystem Services. Environmental Resource Economics 61, 273-296; , Drupp (2018): Limits to Substitution Between Ecosystem Services and Manufactured Goods and Implications for Social Discounting. Environmental Resource Economics 69, 135-158; Martinez-Paz et al. (2016): Pooling Expert Opinion on Environmental Discounting: An International Delphi Survey. Conservation and Society 14(3), 243-253; Nestico et al. (2023): A Dual Probabilistic Discounting Approach to Assess Economic and Environmental Impacts. Environmental and Resource Economics.

3.4. Accounting for differences between persistent substances in their potential to cause damage

3.4.1. Factors affecting damage potential

The potential for persistent substances to damage human health or the environment varies between the substances. This can affect costs and benefits of regulatory measures, and the evaluation of proportionality. Hence, in addition to quantified release estimates, specific factors or circumstances may also help to understand if and how a particular persistent substance would be likely to cause damage, for example, by considering toxicity potential, the environmental fate and exposure. The concern also varies with persistence (more persistent substances will likely increase the risk of intergenerational and irreversible effects), or with bioaccumulation potential. Furthermore, the combination of different hazardous properties is of relevance, for example, when a substance is classified as PBT or PMT.

This type of complementary information is relevant to describe situations where the properties of a particular persistent substance would be likely to cause more or less damage, e.g. when comparing the cost-effectiveness of policy actions involving different substances. It is expected that Member States preparing restriction reports and applicants drafting applications for authorisation consider such factors when carrying out their assessment either qualitatively (see also Section 4.2) or quantitatively (see further below), and report available relevant information. SEAC will take this complementary information into account case-by-case when assessing the impacts and proportionality of restriction proposals or applications for authorisation.

The list of factors below is not exhaustive, and not all factors are relevant for each persistent substance. Also, information on relevant factors may not be available. Nevertheless, the relevance of these factors for human health and environmental impacts, and how they affect the conclusions in restriction dossiers and applications for authorisation should be systematically considered by Dossier Submitters and Applicants. How this is carried out in practice depends on the approach taken to assess and balance the different impacts in each case.

The relevance of the **persistence** of the substance for the assessment is discussed in earlier sections of this document. Depending on the approach taken to assess the human health and environmental benefits of a regulatory action, additional contextual information on the persistence may be needed to describe the case. This could be based on e.g. half lives of the substance in different media or environmental clearance times.

Toxicity influences the damage potential of a specific substance. Substances which are, in addition to their persistence, known to have toxic properties can be assumed to be more harmful for human health and the environment than non-toxic substances. Furthermore, the type of toxicity and the potency may also point to a higher potential for causing adverse effects. For substances with a very high intrinsic toxicity or with a specific mechanism of toxicity, e.g. endocrine disruption, a description of ecotoxic or toxic effects and dose-response relationships (if available) can be of added value to better understand their possible socio-economic implications (in combination with persistence).

Another relevant factor is the **bioaccumulation potential** of a substance, which can lead to accumulation in organisms and along food chains over time. This is particularly relevant for humans and top predators. Also, organisms are vectors and carriers of substances and can transport them over distance and time. As such, bioaccumulation can contribute to long-lasting exposure, even if environmental concentrations are decreasing.

The **environmental fate** and **spatial distribution of releases** of a substance influences the geographical scale of the environmental contamination. This is likely to impact its damage potential, because the number of individual organisms, populations or ecosystems exposed, and the magnitude of (potential) clean-up or remediation costs, depends on a chemical's presence and (expected) exposure levels in the environment. **Mobility** and **potential for long-range transport** is therefore relevant to consider, e.g. indicated by physico-chemical properties and monitoring or modelling data. Information about the presence of the substance in remote areas, and time-trends of concentrations can be relevant as well.

Available information on current **exposure levels**, e.g. (bio)monitoring data, can support the overall assessment because it may indicate existing risks for exposed individual organisms and populations, in particular when being close to or above known effect levels. **Bioavailability** of the substance can also be relevant when evaluating information on environmental concentration levels.

A way to account for differences in damage potential between persistent substances could be a weighting of emissions, e.g. by scaling release estimates of each persistent substance based on its specific damage potential. This could help to highlight differences between persistent substances regarding their potential to cause harm, and to improve comparisons of emission estimates between different substances. There may be several methods to weigh emissions based on information about persistence, toxicity or bioaccumulation potential. However, SEAC considers the possibilities for weighting with available methods to be of limited practical applicability because:

- Numerical weights for relevant properties of persistent substances, e.g. for P. B and T, have not been defined in the context of SEA yet,
- the uncertainty introduced by applying available methods may outweigh their usefulness, also considering the uncertainties already present in emission and cost estimates,
- the information on the properties originates from a large variety of data types, which makes the comparison challenging.

Notwithstanding, Dossier Submitters and Applicants can choose to apply weighting, and SEAC will assess the methodology applied. For this, it is important that the method to construct the weighing is transparently described, and that the sensitivity of comparisons to the choice of a particular weighing scheme is tested.

3.4.2. Avoided environmental stock as a proxy for benefits

In addition to using releases, benefits of regulatory measures adopted on persistent chemicals can also be approximated by estimates of the avoided stock in the environment. Generally, the environmental stock denotes the pollution burden in the environment (in terms of the expected pollution mass or concentration[12]) resulting from emissions in any possible year. For a defined assessment period as adopted in an SEA, the total stock can be determined by aggregating stock estimates for all years of the assessment period.[13] The total avoided stock, then, is the difference between

[12] Note that the stock can be assessed for the environment as a whole (one-compartment approach), or for specific compartments (e.g. soil, air, marine/freshwater).

[13] See Gabbert et al. (2022): Can cost-effectiveness analysis of control measures for persistent chemicals be improved? A critical evaluation of approaches for assessing "effectiveness" - Journal of Industrial Ecology.

the stock under the baseline and a particular regulatory measure (i.e. the difference between a non-use and a continued use scenario in applications for authorisation, or a baseline and restriction scenario in restriction proposals). Stock estimates reflect the amount of yearly emissions that remain in the environment in every year of the assessment period, and from which impacts/damages can arise. Compared to emissions, estimates of environmental stock inform about the accumulation and perseverance of a persistent chemical in the environment over time. Furthermore, estimates of the environmental stock can account for other relevant factors, e.g. mobility and the distribution of a chemical across environmental media and spatial scales (if considered relevant). This can help to evaluate the impact/damage potential of a baseline scenario, and the benefits of regulatory measures reducing emissions.

The environmental stock can be assessed using available information about emissions and information about a chemical's persistence (when available). Furthermore, the dossier submitter should discuss existing pollution of the chemical(s) in the environment (i.e. the pre-intervention stock) even if this is not incorporated in the assessment of avoided stocks for the chosen time period.

Stock assessments have a long tradition in socio-economic analyses of pollution problems arising from persistent chemicals, for instance pesticide use, plastic pollution, and greenhouse gases[14]. Furthermore, stock assessments have already been used in previous restriction dossiers[15] as an indicator of the 'effect' of restriction options in cost-effectiveness analysis, complementary to using emissions.

4. OTHER POSSIBILITIES FOR THE ASSESSMENT

4.1. Stated preference-based (contingent) valuation of benefits

This approach involves surveys and choice experiments in which citizens are provided with a description of the possible reduction in human welfare-related impacts of chemicals, and are asked to state the monetary value that they would place on that reduction.

So far, **only few studies have become available** examining the willingness-to-pay for reducing environmental impacts of persistent chemicals. For assessing the willingness to pay (WTP) for reducing health or environmental impacts caused by persistent chemicals, some contingent valuation studies exist[16]. However, given the lack of information on the precise change of impacts resulting from emission reductions, valuation scenarios which appropriately capture the complexity of the environmental or human health impacts of persistent chemicals are difficult to develop. Existing studies have not been able to sufficiently capture the complexity of the impacts of persistent chemicals and applying existing WTP estimates could lead to considerable bias in the assessment of monetised benefits. Therefore, existing WTP estimates may not be directly applicable to benefit estimation of reducing emissions of specific persistent chemicals addressed in restriction dossiers or applications for authorisation. Still, they can provide complementary insight into the potential avoided environmental or health damage when reducing emissions of a specific persistent

[15] See ECHA (2019): Restriction Report on D4, D5 and D6 and ECHA (2019): Restriction Report on PFHxS, its salts and PFHxS-related substances.

[16] See e.g. at https://echa.europa.eu/support/socio-economic-analysis-in-reach; Holmquist et al. (2018): How information about hazardous fluorinated substances increaseswillingness-to-payfor alternative outdoor garments: A Swedish survey experiment. Journal of Cleaner production 202, 130-138; Shahsavar et al. (2020): Willingness to pay for eco-friendly furniture based on demographic factors. Journal of Cleaner Production 250.

chemical. This supplementary information could, then, be used to better inform comparisons between different policy actions. Future studies may overcome the current shortcomings and could, then, be taken into account as well.

4.2. Qualitative evaluations of impacts

Dossier submitters may also consider providing an evaluation of the impacts of any proposed restriction option or of an application for authorisation that largely rests on qualitative, narrative arguments.

However, there are no agreed criteria by which such argumentation could be made and moreover, the approach would still face the difficulty of assessing scale or degrees of economic welfare change (benefits), in a commensurate way with costs, such that it would not be able to provide an unambiguous conclusion regarding proportionality to the risks. Furthermore, a qualitative argumentation has a risk of double counting of impacts, which should be considered in the assessment. The SEAC approach to assessing qualitative information was agreed in 2022[17], and it describes how SEAC would evaluate qualitative information when presented in a restriction dossier. However, the approach recognises that the lack of quantitative elements in the assessment needs to be justified, and it can only be seen as complementary information to the approach outlined in section 3 of this document.

5. DEALING WITH UNCERTAINTY

Uncertainty, i.e. a situation characterised by inadequate, partial or lacking information, making it impossible to predict occurances of certain outcomes, is a key element of socio-economic analysis which can affect the size and reliability of cost and benefit assessments of risk management measures on persistent substances. Therefore, dossier submitters need to transparently identify and describe relevant types of uncertainties. SEAC recommends the use of sensitivity or scenario analysis to further illustrate the effect(s) of uncertainties, noting that also other approaches may exist.[18] Based on the uncertainties identified, the sensitivity or scenario analysis should compare relevant scenarios and should discuss the implications of uncertainties on the assessment of impacts, and on the conclusions about proportionality[19]. Where possible, a discussion of the probability of the scenarios assessed may facilitate and underpin the conclusions drawn by SEAC.

6. POTENTIAL UPDATES OF THE APPROACH

Based on developments in the methodologies to evaluate the socio-economic impact of regulating persistent substances and experience gained from using the current approach, SEAC may update the approach when needed.

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[17] SEAC approach to evaluate cases with qualitative information is available at https://echa.europa.eu/support/restriction/how-to-prepare-an-annex-xv-report/general-instructions.

[18] For a discussion of the relationship between uncertainty, risk, ambiguity and ignorance, and an overview of approaches to address uncertainty, see Bond et al. (2015): Managing uncertainty, ambiguity and ignorance in impact assessment by embedding evolutionary resilience, participatory modelling and adaptive management. Journal of Environmental Management 151, 97-104.

[19] See e.g. to the Guiding principles for uncertainty analysis in Annex XV Restriction Reports.