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Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC

1. INTRODUCTION

PBT and vPvB substances are subject to restriction and authorisation. Quantification of impacts is not currently possible for most PBT/vPvB substances, which makes 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[1] for an application for authorisation challenging. Nevertheless, the Committee for Socio-economic Analysis (SEAC) still needs to form an opinion on these cases.

This document outlines the approach for the evaluation of restriction dossiers and applications for authorisation for PBT and vPvB substances in SEAC. Based on future developments in methodologies to evaluate the socio-economic impacts of PBT and vPvB substances and experience gained from using the current approach, SEAC may update this approach.

2. PURPOSE

The main purpose of the approach for evaluating PBT and vPvB substances in SEAC is to ensure a consistent treatment of the relevant socio-economic issues in restriction proposals as well as authorisation applications. 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 it is hoped that the proposed approach will enhance the consistency of Annex XV restriction reports and applications for authorisation by ensuring that certain information is available in all assessments for PBT and vPvB substances, it should be noted that the intention of this document is not to limit the approaches and methodologies available to MSs and potential applicants. If other approaches are included in an application for authorisation or Annex XV restriction report, SEAC will evaluate these on their own merits.

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[2] Cost-effectiveness analysis (CEA) is widely used to support decision making by determining the least cost means of achieving pre-set targets or goals. It is often defined in terms of finding the minimum cost of meeting a specified physical outcome. CEA does not require monetising the benefit of achieving a target, but the disadvantage is that it provides no assurance that achieving any target will result in net benefits.

3. BACKGROUND

PBT and vPvB substances are of specific concern due to their potential to remain and accumulate in the environment over long time periods. Historical cases have shown that the effects of such accumulation are unpredictable in the long-term and that exposure is practically difficult to reverse, because an elimination of releases will not necessarily result in a measurable reduction in exposure. The properties of PBT and vPvB substances lead to increased uncertainty in the estimation of human health and environmental risks when applying quantitative risk assessment methodologies. As such, a “safe” (no effect) concentration in the environment cannot be established for PBT and vPvB substances using the methods currently available, and the quantification of risks is not foreseen in REACH.

Consequently, the data on P, B and T properties does not often allow for quantitative assessment of the human health or environmental impacts. Therefore, the valuation of benefits via the assessment of the impacts on the environment and human health – the standard ‘impact pathways’ approach to benefits assessment for chemicals – is not possible, and other options for benefits assessment need to be considered. These options could include:

- Stated-preference based (contingent) valuation of benefits. This approach involves surveys in which members of the public are provided with a description of the possible change in human welfare related impacts, associated with a specific reduction of PBT or vPvB substances, and are asked to state the monetary value that they would place on that reduction. However, given the lack of information on the change in impacts, credible valuation scenarios are difficult to develop, such that survey respondents may effectively be left unclear as to the nature and scope of the impacts for which monetary valuation is required. Although contingent valuation studies have been undertaken for decades and are well established, very few such studies have so far been undertaken to value the benefits of PBT or vPvB reduction. Even if the difficulty in quantifying PBT and vPvB impacts makes this approach attractive, the current state of the evidence base does not seem to allow it to be applied as the main approach to benefit estimation by the dossier submitters, applicants or SEAC.

- Provision of only a qualitative, narrative argumentation in favour or against the proportionality to the risks of any proposed restriction or whether the socio-economic benefits of use of the substance outweigh the risks for an application for authorisation. 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.

4. APPROACH

The challenges in the valuation of the benefits of reducing emissions of PBT and vPvB 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 PBT and vPvB substances is based on the consideration of different types of information available on potential impacts and their value. Information on compliance costs and emissions form the starting point of the assessment and should always be presented in the dossiers.

4.1. Cost-effectiveness analysis as a basis of the framework

SEAC will consider in its evaluation of PBT and vPvB cases all the available evidence. A cost-effectiveness analysis[2] based on emissions reduction of PBT or vPvB substance and the compliance costs should be included in the dossier. In other words, one basis of the evaluation should always be the cost per unit (e.g. kilogram) of emission reduced.

Even if it is recognised that environmental impacts may occur inside and outside of the EU, the cost-effectiveness estimates should be based on the emission reductions and corresponding costs relevant for 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 EU and which changes are expected to occur outside the EU. This global allocation of effects should at least be qualitatively described.

For PBT and vPvB substances target levels or goals that have been judged to be worth achieving do not exist. In fact, REACH promotes the reduction of the impacts by requiring the minimisation of releases and environmental and relevant human exposure (Annex I para 6.5 of REACH). To assess whether the regulatory action results in net benefits for the society, it would be desirable to have a comparator or a "benchmark" on the level of costs that are deemed to be worthwhile taking when reducing emissions of PBTs and vPvBs. This could be based e.g. on:

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

VU (Vrije Universiteit Amsterdam) conducted a project for the development of a benchmark for regulatory decision making under REACH for PBT and vPvB

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substances[3]. Within this project information was gathered on the costs of reducing 8 (groups of) PBT substances. Where possible, this cost information is related to decision making on PBT reduction. If a certain proposed measure has been rejected due to excessive costs per unit of reduction of a PBT substance, this can be seen as an indication for society's 'maximum willingness to pay'. The exceedance of this cost level might then be considered to be disproportionate in comparable future cases as well. Clearly, this approach rests on a number of assumptions and neglects any differences e.g. in properties between PBTs. Although the project did not result in a specific suggestion for a benchmark, it can be seen as a first step towards benchmarking.

Based on the available information, it does not seem to be currently possible to set any benchmark level for the acceptable level of cost effectiveness or other indicator of benefits that would be applicable for all PBTs and vPvBs. The existing studies are mostly based on historical cases of emissions that occurred in a given geographical area during a given period of time. The studies may estimate the adverse socio-economic impacts (damage costs) of such specific pollution occurrences but do not establish general damage cost functions. Ex-ante costs (i.e. the cost of avoiding emissions in the first place, for example by substituting a PBT substance with a less hazardous alternative) can differ a lot from ex-post costs (i.e. the cost of cleaning up or repairing damage from emissions that have already occurred), even for the same substance. Furthermore, some of the cost-effectiveness estimates are for the reduced amounts of substance used, instead of the amounts released.

SEAC has not been able to set benchmarks with the available information. This does not exclude the possibility that SEAC would be able to do it in the future.

4.2. Differences between PBT/vPvBs in their potential to cause damage

The potential for PBT and vPvB substances to damage human health or the environment varies between the substances. This is due, for example, to differences in the potency of toxicity and the exposure concentrations. Ideally, the damage potential of different PBT and vPvB substances could be weighted. Any such weighting would allow SEAC to take into account the damage potential of a substance quantitatively in the cost-effectiveness analysis when assessing the proportionality to the risks of restriction or whether the benefits outweigh the risks for an application for authorisation. In other words, to have specific acceptable levels of cost (benchmarks) for each PBT or vPvB substance.

The current framework takes into account differences in emission factors between different substances and uses. However, it appears evident that it is not currently possible in practice to further weight the damage caused by different PBT and vPvB substances. A quantitative weighting method may have additional value in a relative way, i.e. qualitatively in a comparison between different substances, but a systematic approach to weight the damage that would be applicable for all the cases does not currently exist. The weighting with available methods is not possible or meaningful quantitatively because:

- the uncertainty introduced by applying the available methods would outweigh their usefulness considering also the uncertainties already present in emission and cost estimates,

[3] Oosterhuis F. and Brouwer R. (2015): *Benchmark development for the proportionality assessment of PBT and vPvB substances* available at http://echa.europa.eu/documents/10162/13647/R15_11_pbt_benchmark_report_en.pdf

- a single numerical value e.g. for persistence or bioaccumulation, has not in most cases been identified for PBT and vPvB substances, and

- the information on the properties originate from a large variety of data types, which makes the comparison challenging.

Given the problem of undertaking quantitative weighting, the starting point for the SEAC evaluation is that a unit of emission (e.g. kg) of any PBT or vPvB substance is considered to be the same in terms of the potential damage to human health and environment.

While weighting on the basis of (expected damage) is not currently possible systematically using numerical approaches, it is often feasible to describe factors or situations where the properties of a particular PBT or vPvB would be likely to cause more or less damage. Examples of such factors and situations are listed in Annex 1. These include the possibility to use information on P, B and T properties.

This type of complementary information may be relevant in specific cases. It is expected, that applicants drafting applications for autorisation and Member States preparing restriction reports consider factors and situations, such as presented in the Annex 1, when carrying out their assessment, and when relevant report the available information in their dossiers. When complementary information is presented, SEAC will take it into account case-by-case.

5. POTENTIAL UPDATES OF THE APPROACH

Based on developments in the methodologies to evaluate the socio-economic impact of regulating PBT and vPvB substances and experience gained from using the current approach, SEAC will update the approach when needed. For example, further development of the list of qualitative descriptors or situations with more or less potential to cause damage (Annex 1), or a more systematic way to qualitatively or quantitatively consider these factors by SEAC could become available.

Annex 1: List of potential factors or situation for case-by-case consideration

This annex lists factors or situations that may indicate that the particular PBT or vPvB substance would be likely to cause more or less damage. The list includes suggestions received from the individual members of the PBT Expert Group of ECHA. It should be noted that the list is not exhaustive, and not all the factors (if any) are relevant for specific PBT of vPvB substance, for example, because the information may not be available. Based on this kind of factors, it may be possible to develop a more systematic PBT case profiling to be used as part of the framework.

- Environmental fate/distribution:
    - a high potential for long-range transport, as proven by monitoring or modelling data or half-life in air > 2 days
    - number of environmental media/compartments affected
- Characteristics, size and dynamics of the substance stock and flow in society/the environment:
    - level of persistency (e.g. half lives in different media), environmental clearance time
    - overall tonnage used/tonnage emitted per year and the current trend
    - use pattern (how widespread use?)
    - potential accumulation of the substance in articles/the technosphere
    - data on historical use/emissions
- Exposure:
    - (measured) exposure levels (e.g. (bio)monitoring data) and, in particular, increasing/decreasing trends or findings in remote areas
    - specific factors affecting the irreversibility of exposure (information on extremely high bioaccumulation potential)
    - environmental bioavailability of the substance
    - high levels of the substance in humans and the top of food chains, resulting from the effective accumulation of the substance in organisms and the slow elimination (not from high releases)
- Hazard potential:
    - the substance fulfils additional criteria of properties of concern, e.g. it is PBT but also vP
    - characterisation of toxic effect, potential toxicity of degradation products
    - overall uncertainty of available data
    - high potential for ecosystemic effects
    - a very high intrinsic toxicity
    - QSAR comparison

Some factors may be systematically approached using QSAR estimates as indictors of P, B and T. This could differentiate between the intrinsic PBT potential of a unit emission of a substance, and thereby improve on the simplified approach that 1 kg of emission of any PBT or vPvB substance is equally damaging. However, for the foreseeable PBT/vPvB restriction cases, e.g., decaBDE, PFOA/APFO, QSARs cannot be applied effectively.