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Restricted Success
EEB's appraisal of restriction under REACH

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CONTENTS

EXECUTIVE SUMMARY

Restriction is a powerful tool which holds great promise for mitigating exposures to hazardous substances in the EU. However, the restriction process is not the nimble and efficient policy tool that the REACH framers intended. In this report, we describe several important shortcomings of the restriction process as implemented today. It is worth noting that these shortcomings do not bear only on REACH, but also weaken the ability of restriction to support other high-level EU goals like the non-toxic environment strategy and the circular economy. We also outline recommendations for improvement to be considered under the current REACH review.

Since the REACH restriction process entered into force eight years ago, the pace of restrictions has increased only slightly, while the scope of the final restrictions has narrowed. Preparation of a restriction dossier places a heavy burden of data and evidence on the Dossier Submitter (DS), typically a Member State. In an ECHA survey of participants in the restriction process, roughly 80% of respondents indicated that the level of analysis required was unclear, and a similar number disagreed that the Committees' requests for additional information were reasonable. **These burdensome yet unclear requirements probably contribute to the slowdown of restrictions. Moreover, the requirements for evidence are not balanced between stakeholders.** Although the DS is held to very high standards for data and evidence, industry is not held to the same standards. Industry concerns are often accepted with little or no evidence.

The narrowing scope of restriction proposals is probably due in part to the heavy workload of dossier preparation, as well as to general uncertainty over the proper scope of a proposal. **However, the final restrictions are often deliberately narrowed by ECHA's committees, who regularly and arbitrarily modify the scope of proposed restrictions — usually weakening or undermining the proposals.** RAC and SEAC commonly add derogations (products or uses of the restricted substances which will not be covered by the restriction) to the restriction proposal, change allowable amounts or concentration limits, and modify the length of transition or permitted-use periods. Most of these derogations and changes appear to be attempts to assuage the concerns of industry, but the changes are too often entirely unsupported by evidence. Furthermore, despite the very heavy emphasis on quantitative calculations of risks and costs by the ECHA committees, the restriction proposals are not usually revised to assess the detailed impacts of these changes. To give just one example, the committees changed the allowable concentration limits in the PFOA restriction proposal from the 2 ppb proposed by the DS

to an entirely arbitrary 25 ppb (for PFOA and its salts), and 1000 ppb (for PFOA-related substances), without any evidence for the new numbers, nor any attempt to re-evaluate the consequent risks.

The restriction process as implemented places a strong emphasis on quantitative details, particularly in the analyses by the RAC and SEAC committees. The committees regularly base their decision on calculations that attempt to be highly precise — for exposures, risks, costs, or benefits. This leads to a focus on the quantities that we know the most about, and those that fit most easily into traditional risk assessment models, while leaving out the more difficult or less quantifiable concerns. In the BPA restriction, for example, the committees left out any assessment of hand-to-mouth exposure, despite the fact that their calculated risks were extremely close to ECHA's threshold, and the additional exposure term might well have put them over the top. **Presentation of such detailed numeric calculations creates a false sense of certainty about the proposal.** Yet there is no legal requirement in the REACH text for any such detailed assessment.

This desire for precision also leads to rejection of much modern science. In recent years, toxicologists have widely accepted the importance of non-monotonic dose-response, endocrine disruption, and other subtle problems of many ubiquitous chemical substances. **But the committees' desire for quantitation of risks means that they are likely to reject adverse health effects that cannot be easily characterised** — as when, for example, RAC rejected the dossier submitter's detailed analysis of endocrine-related outcomes of BPA exposure, preferring a more traditional risk assessment model. As a result, RAC's Derived No-Effect Level (DNEL) for BPA was 50 times higher than the figure used by the dossier submitter (France).

REACH requires restriction decisions to "take into account the socioeconomic impact of the restriction", and SEAC's role is to evaluate these impacts. **Unfortunately, in its desire to support its opinions with detailed quantitative analysis, SEAC relies far too much on a very narrow understanding of cost-benefit assessment.** In particular, SEAC appears to assume that the benefits must outweigh the costs — although this is not a requirement of cost-benefit assessment, nor is there any such requirement in the REACH text. SEAC's desire to calculate all costs and benefits of a restriction proposal leads directly to attempts to monetise the costs to human health and the environment, a challenge fraught with practical and moral concerns. For example, SEAC's analysis of the BPA restriction estimated the total costs of substitution at 20 - 60 Eurocents per working EU citizen per year, and pointed out that "no comments were received in the public consultation on possible affordability issues for industry". Despite this, SEAC deemed the proposed restriction "unlikely to be proportionate", since these small costs could outweigh the monetized benefits — which included lowering the risk of breast cancer in daughters of exposed workers.

While most of the effort involved in evaluating restriction goes towards detailed calculations, very little attention is given to another decision-making factor that is spelled out in the same sentence of the REACH text: "Any such decision shall take into account the socioeconomic impact of the restriction, including the availability of alternatives". **Alternatives assessment has evolved into a fairly mature and widely-accepted process, yet the availability of alternatives rarely plays much of a role in restriction decision-making.** Most commonly, the alternatives are assessed only in order to compare their monetary value with the non-restriction scenario. Because of SEAC's heavy emphasis on cost-benefit assessment, an alternative that is more expensive is assumed to be less acceptable, even if it has a greatly improved health and environment profile. Yet we interpret the REACH text to mean that the very existence of feasible alternatives should play a major role in the restriction decision.

The process of restriction could be made much smoother and quicker. We applaud the work of the Restriction Efficiency Task Force (RETF), which has identified 71 improvements to date, and we look forward to seeing those changes bear fruit. After a decade of REACH, it is time to update and clarify ECHA's guidance on restriction and on the roles of the committees. ECHA should define more carefully the appropriate roles of the committees, including when and how they may modify the restriction proposals, and what data is required to do so. The committees' opinions should include the most up-to-date science, even if — as with the endocrine-disrupting effects of BPA — that science is difficult to fit into traditional risk models. To reject such data, especially when it shows clear evidence of important effects , is inconsistent with REACH's clearly stated precautionary approach.

The biggest problems with restriction as it is currently implemented stem from the overemphasis on quantitative assessment of risks, benefits, and costs — none of which are required by the REACH text. Moreover, the presentation of very detailed numerical results of these calculations provides a false sense of certainty, when in fact the calculations may exclude entire routes of exposure(e.g., hand-to-mouth in the proposed BPA restriction), populations at risk, or socioeconomic factors that are not easily monetisable (e.g., biodiversity costs, or human pain and suffering). The demand for precision also leads ECHA to dismiss more nuanced and less easily quantified toxic mechanisms, like endocrine disruption, low-dose and non-monotonic effects, and cocktail effects.

The data requirements of the restriction process place a heavy burden on the dossier submitters. The burden of the assessment process could be greatly reduced by allowing for less heavily quantitative assessments. Prominently acknowledging and communicating uncertainties would provide a more honest view of the value of a restriction proposal. (The IPCC's reports for policymakers demonstrate one effective approach to presenting large amounts of data with very large ranges of uncertainty.) Moreover, we suggest that ECHA and the Commission should more often utilize the "fast-track" power granted to them under Article 68(2) in order to speed restrictions that are clearly proportional and/or affordable.

A simpler assessment with better characterisation of uncertainty would provide a far more accurate view of a restriction proposal, with its knowns, unknowns, and potential benefits. **Such an understanding is critical if the ultimate decision-makers, the Commission and the Member States, are to make decisions that adhere to the core purpose of REACH: to use a precautionary approach to reduce risks to human health and the environment.**

ABBREVIATIONS

BPA	Bisphenol A
BPS	Bisphenol S
CBA	Cost-Benefit Assessment
CLP	Classification, Labeling, and Packaging
D4/D5	Octamethylcyclotetrasiloxane (D4) / Decamethylcyclopentasiloxane (D5)
decaBDE	Decabrominated biphenyl ether; Bis(pentabromophenyl) ether
DNEL	Derived no-effect Level
DS	Dossier Submitter
ED	Endocrine disruption
GLP	Good Laboratory Practice
MS	Member State
NP/NPE	Nonylphenol and nonylphenol ethoxylates
PBT	Persistent, bioaccumulative, and toxic
PFOA	Perfluorooctanoic acid
PNEC	Predicted no-effect concentration
ppb	parts-per-billion
PVC	Polyvinyl chloride
RAC	Committee for Risk Assessment
RETF	Restriction Efficiency Task Force
RMO	Risk management option
RP	Restriction Proposal
SEAC	Committee for Socio-economic Analysis
SVHC	Substance of Very High Concern
vPvB	Very persistent, very bioaccumulative

1 Introduction

The restriction process is the main mechanism within the REACH legislation designed to mitigate risks that chemical substances may pose to human health or the environment. The goals of restriction process are spelled out by Article 68: "When there is an unacceptable risk to human health or the environment," the text reads, the EU may decide to adopt or amend restrictions on "the manufacture, use or placing on the market of substances on their own, in mixtures or in articles." Restriction is one of the most important tools available to reduce the impacts of substances of concern. As ECHA has reported in their 2016 report on the operation of REACH and CLP,

> The annual human health related benefits from restrictions processed under REACH since 2009, were estimated at over EUR 700 million per annum. In addition, the adopted restrictions were estimated to reduce emissions of PBTs, vPvBs and other substances of concern by about 190 tonnes per annum. Furthermore, there were other positive impacts from the restrictions for at least 81 000 consumers and workers, the value of which could not be estimated. In specific cases, additional benefits, such as the avoidance of legal costs or re-insulation costs were evident.[1]

The aim of this report is to critically review the functioning of the REACH restriction process against its aims as described in the REACH legal text, and to thereby contribute to the current REACH Review undertaken by the Commission. Restriction holds great promise, and in the decade since it entered into force, the restriction has been an important tool for mitigating chemical risks in the EU. However, the REACH restriction process is not the nimble and efficient policy tool that the REACH framers intended. In this report, we will describe some of the current challenges to the proper use of the REACH restriction process, and present recommendations for improvement.

1.1 Background: The restriction procedure

The basic form of the restriction process is similar to Directive 76/769/EEC, which predates REACH, but which was incorporated into the REACH text. This motivation for incorporating restrictions into REACH is made very clear in REACH paragraph 84: "In order to accelerate the current system" (that is, under Directive 76/769/EEC). Indeed, this paragraph also refers to REACH restrictions as a "new accelerated restriction procedure". The drafters of REACH clearly intend restriction to be a process by which specific chemical risks can be simply and rapidly addressed.

The process of restriction is described by Articles 69-72 of REACH. If a Member State or the Commission believes that a substance "poses a risk to human health or the environment that is not adequately controlled and needs to be addressed", it may prepare a dossier outlining the proposal, in accordance with Annex XV. (In the case of the Commission, ECHA prepares the dossier.) Additionally, ECHA itself has the obligation to prepare a restriction dossier whenever it considers that the risk of SVHCs in products is not adequately controlled after the sunset date.[2]

After a conformity check by the ECHA committees, the registrants are notified of the proposed restriction, and a six-month public consultation begins. During this time, any interested parties may comment on the dossiers, the proposed restrictions, or the socioeconomic analysis.

At the same time, ECHA's Committee for

1 ECHA 2016. *Report on The Operation of REACH and CLP.* ECHA-16-R-08-EN. https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf

2 The date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted (REACH Article 58(1)(c)(i)) REACH Article 69(2).

Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) begin formulating their opinions. RAC's opinion addresses "whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment" (Article 70). SEAC, which evaluates "the suggested restrictions and on the related socio-economic impact", must first prepare a draft opinion, and publish it for a 60-day public consultation. (RAC's opinion is, unfortunately, not open for public comment.)

The final opinions are due nine months (for RAC) and one year (for SEAC) after the start of the initial public consultation. These are then submitted to the Commission, which then makes a decision, subject to the approval of the Member States at the REACH Committee. Decisions may include exemptions and date of entry into force.

It is important to note that restriction decisions must "take into account the socioeconomic impact of the restriction, including the availability of alternatives" [3]. However, the Commission's final decision on a restriction proposal need not meet any particular standard for socioeconomic impacts. In particular, REACH carries no requirement that a restriction's monetized benefits outweigh its costs. To further corroborate this point, Annex XV of REACH does not foresee as a requirement a socio-economic analysis in the proposal.

Finally, like all of REACH, the new restriction process is subject to the broader language and purpose of the legislation, which is grounded in the precautionary principle and which seeks to ensure that chemical substances "do not adversely affect human health or the environment". [4]

3 REACH Article 68(1)
4 REACH Article 1(3)

A NOTE ABOUT LANGUAGE

When describing the "correct", "proper", or "appropriate" use of the restriction process or of REACH in general, we rely on the language of Article 1(3): That the goal of regulation under REACH is to ensure that chemical substances "do not adversely affect human health or the environment", and that REACH is "underpinned by the precautionary principle".

2 Observed trends and challenges in the restriction process

2.1 Restriction has proven a valuable tool, but has not yet become the nimble and efficient process described by the REACH text.

The restriction process entered force on 1 June 2009, and the first restriction proposals were submitted ten months later. Since that time, 26 restriction proposals have been submitted, and 16 restrictions have been entered into Annex XVII. [5] The current average of 2 restrictions per year is a slight increase over the 1.7/year seen under the pre-REACH restriction regime.

This increase, although slight, is gratifying. We hope that the pace continues to speed up as the restriction process becomes more streamlined and efficient, ultimately becoming the "accelerated restriction procedure" foreseen by the REACH framers.

A small number of restrictions does not necessarily mean that the process is not working appropriately; there might be a variety of reasons for the slow pace. A useful analysis by Brandt [6] explored some of the reasons for the relatively slow pace of restriction. Brandt suggested, for example, that an increased reliance on safer chemistry would lessen the need for restrictions; or, that the bulk of chemical risks have already mitigated by previous restrictions and other regulations (like authorisation).

In looking over the set of chemicals that have been considered for restriction in recent years, however — including phthalates, Bisphenol A (BPA), Nonylphenol and nonylphenol ethoxylates (NP/NPE), lead in consumer articles, cadmium in paints, and decaBDE (decabrominated biphenyl ether), any of which may have ubiquitous consumer exposures — we do not believe these explanations to hold true. In addition, another indicator that restrictions should be more widely employed is shown by the results of compliance checks on registrations, which show that adequate control is not demonstrated for a wide number of substances, and therefore subject to restriction.

REACH restrictions, unlike those under the older process of Directive 76/769/EEC, may be submitted by a Member State. This is an important and well-utilised benefit of the new process. However, it places a very heavy burden on the dossier submitter, which must also respond to extensive follow-up requests from the ECHA committees. A 2016 discussion led by a number of member states concluded that,

> Another bottleneck in REACH where the burden of proof is at stake is the substantial work load of preparing restrictions. The challenging information demands from the committees RAC and SEAC, which are not based on the REACH requirements for such dossiers, are often mentioned in this context. [7]

The difficulty of these information demands is also demonstrated by the results of a survey undertaken by ECHA's Restriction Efficiency Task Force (RETF), which we discuss in more detail below.

Although there is obvious benefit in Member States being able to submit restriction proposals, it constitutes a transfer of responsibility and workload from ECHA and the Commission to the MS Competent Authorities. For example, before REACH the Commission was required to prepare justification and impact assessment documents for a proposed restriction. These requirements have been replaced by the Annex XV dossier, which in

5 Numbers courtesy of of ECHA staff.
6 Brandt, M. 2015. It's Not All About the Money: Why the Current Practice of SocioEconomic Analysis Used in Restriction Proposals Under the EU REACH Regulation Is Not Delivering.

7 REACH FORWARD: Priorities for Effective Regulation. 2016. Discussion paper policy conference Brussels 1 June 2016 – final version.

most cases is prepared by the MS CAs, who vary widely in their technical and workforce abilities to perform this work.

We note that the RETF has indeed worked to identify and reduce barriers and inefficiencies in the restriction process, having made 71 recommendations to date. We welcome these improvements to the process, and we look forward to seeing them bear fruit. While these steps can improve efficiency, however, they do not significantly lower the burden on the dossier submitter. As the 2016 Member State discussion pointed out,

> Practical steps and working procedures to streamline the restriction process and increase clarity on the information demands have been implemented to a large extent. These steps are helpful, but do not fundamentally change the situation, since information demands have not decreased. [8]

Finally, a preference by regulators for the authorisation process might explain the relatively slow pace of restriction. According to Brandt, this does appear to be the case to some extent. One reason for this is that listing a chemical under Annex XIV (requiring authorisation) does not require an SEA nor a Risk Assessment (RA) on the part of the regulators; whereas the restriction procedure, although not formally demanding an SEA under the legal text, has made it an effective requirement for a restriction proposal, greatly increasing the difficulty of the restriction proposal. In this way, the SEA requirement may be acting to slow the restriction process as a whole. Unfortunately, Brandt concludes that the resulting SEAs "are not well suited to support decision making as they assess only few policy options, consider only some impacts and do not address the more complex cases more thoroughly".[9] We address the SEA in more detail below.

8 REACH FORWARD: Priorities for Effective Regulation. 2016. Discussion paper policy conference Brussels 1 June 2016 – final version.
9 Brandt 2015

2.2 Since the implementation of REACH, the scope of restrictions has narrowed.

Brandt's analysis indicates that the scope of restrictions has narrowed considerably:

> While under the prior regime[10*] most restriction would fall in the category of "broad" (44%) and almost two-third of the restrictions either in "broad" or "very broad" (65%) under REACH almost half of the restrictions belong to the category "very narrow" (47%) and almost two-third of them either in "very narrow" or "narrow" (63%).

One likely reason for this is that **narrower restriction proposals require narrower documentation — of risks, of costs, of uses and alternatives, and of socio-economic impacts**. This likely indicates that the difficulty of the restriction process — perhaps especially the burden of the SEA — is limiting the ability of restrictions to address some risks. A second reason that restrictions have narrowed is because the ECHA committees regularly modify restriction proposals to restrict their scope. We discuss this concern next.

EXAMPLE: D4/D5

One example of a very narrow scope is the restriction of octamethylcyclotetrasiloxane (D4) and decamethylcyclopentasiloxane (D5). D4/D5 find use in a very wide range of products, from ingredients in alkyd paints and varnishes, to lubricants and anti-adhesion coatings, to consumer products including personal care products. D4 is very persistent, very bioaccumulative, and toxic (PBT and vBvP), while D5 is very persistent and very bioaccumulative (vPvB).[11] The proposed restriction applies to D4/D5 use in wash-off personal care products (PCP) in a concentration above 0.1 % by weight. This is an extremely narrow restriction for a very heavily used chemical that is PBT/vPvB (and which should probably be on Annex XIV): Less than 5% of D4/

10 i.e., Directive 76/779/EEC
11 Note: PBT and vPvB substances qualify to be listed under Annex XIV, as substances of very high concern requiring authorisation, under the criteria outlined by Article 57.

D5 is used in PCP,[12] and the restriction doesn't cover even that small amount, as personal care products with leave-on application such as hair gels and skin creams are excluded.

2.3 The committees regularly and arbitrarily modify the scope of proposed restrictions, usually weakening or undermining the proposals

A major challenge with the restriction process is uncertainty in the scope of the restriction. Once a restriction proposal (RP) has been submitted, it is reviewed by ECHA's RAC and SEAC committees. In recent restrictions, the committees have on several occasions substantially changed the scope of the restriction proposal — almost always leading to a much narrower scope than originally proposed.

These changes may occur in several ways:

- By the addition of derogations (i.e., products or uses which will not be covered by the restriction);
- by changes to amounts or concentration limits;
- and by changes to the length of transition or permitted-use periods.

Some changes to the scope may, of course, be necessary. However, these changes should be logical, defensible, and well justified. Instead, many of the committees' changes to scope appear to have been quite arbitrary.

EXAMPLE: PFOA

In 2014, Germany and Norway submitted a proposal to restrict PFOA and related substances that can degrade in the environment to PFOA. The restriction proposal would have banned use of these substances at concentrations greater than 2 ppb. PFOA is very persistent in the environment (vP), bioaccumulative (B), and toxic (T). PFOA is classified as toxic for reproduction (category 1B), affects cholesterol levels, and may cause cancer in humans. A recent review of the toxicity of perfluorinated compounds found adverse effects after developmental exposure, including immunotoxicity and endocrine disruption, at very low doses—thousands of times lower than the EU Tolerable Daily Intakes for PFOA.[13]

During the public consultation, some manufacturers argued that the 2 ppb concentration limit was too low, since PFOA and related substances may be present as impurities in the production of alternative chemicals (for example, the closely related chemicals called "C6"), and supply chains could be cross-contaminated with low levels of PFOA. Consequently, the committees proposed new limits of 25 ppb (for PFOA and its salts), and 1000 ppb (for PFOA-related substances). Although industry provided limited information on the content of PFOA and PFOA related substances in articles and mixtures, the limits proposed by ECHA's committees are 10 times higher than a revised proposal presented by the dossier submitter. Industry had supported these higher limits by saying that the original levels presented difficulties in chemical analysis, although it was expected that appropriate analytical methods would be available in two years. But the point remains that the new limits were arbitrarily chosen with little or no supporting data. Most importantly, the committees made no attempt to evaluate the revised limits for possible risks to health and environment, nor for any other impacts on

In recent restrictions, the committees have on several occasions substantially changed the scope of the restriction proposal — almost always leading to a much narrower scope than originally proposed.

12Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC). 2016. Background Document to the Opinion on the Annex XV dossier proposing restrictions on Octamethylcyclotetrasiloxane (D4) and Decamethylcyclopentasiloxane (D5).

13 Grandjean P, Andersen EW, et al. 2012. Serum vaccine antibody concentrations in children exposed to perfluorinated compounds [published erratum appears in *JAMA* 2012;307:1142]. *JAMA* 2012;307:391-7.

the efficacy of the restriction proposal.

In addition to changing the limits, the committees weakened the restriction proposal with numerous derogations. The original proposal included several derogations, such as for PFOA used in second-hand articles and for articles produced from recycled materials. After suggesting the new concentration limits, RAC then added a large number of derogations submitted by industry during the public consultation: derogations for substances used as isolated intermediates, for semiconductor photolithography processes, for photographic coatings, and for implanted medical devices. SEAC then added its own list of derogations, based on information from PFOA producers and users: For spare parts, for latex printing inks, for textiles treated for worker protection, for filtration systems, for non-implantable medical devices, for nano-coated materials, and for firefighting foams. In some cases these new derogations would permit the use of products containing PFOA for up to 20 years, or even without a time limit. Again, no justification about the environmental and health impacts of these derogations was provided by the committees.[14] These changes greatly undermine the goal of the restriction, which is to reduce global consumption and emission of PFOA.

SUMMARY

The arbitrariness of changes to the scope undermines the clarity, objectivity, and coherence of the restriction proposals. It is troubling that these changes are often made with little or no justification or motivation, and with little or no attempt to evaluate how the changes will impact the success of the restriction. In some cases—as in the PFOA restriction proposal—we believe that these changes greatly will reduce the effectiveness of the restriction in lowering risks to health and the environment.

Although the ECHA Committees regularly *reduce* the scope of the restriction proposal — sometimes very extensively — they have been very clear that they may not *expand* the scope of the proposed restriction. An example is the restriction of BPA. Although RAC recognised in its opinion that BPS poses a similar level of risk as BPA, ECHA rejected an NGO proposal to widen the scope to include BPS, arguing that it did not fall under the responsibility of the Committee. We believe that it is the responsibility of the committees under the REACH text to recommend the extension of the scope to other uses or to other substances, if evidence is gathered during the process that it would be necessary to do so. Alternatively, such a situation would be an ideal example for the enactment of a fast-track restriction under Article 68(2).

2.4 Weakening of restriction proposals undermines their critical role in achieving other EU goals, including the non-toxic environment and the circular economy

REACH, and its restriction and authorisation processes, are key elements in Europe's goal of achieving a non-toxic environment and a circular economy. But the committees' arbitrary weakening of restriction proposals poses a direct conflict to these larger goals by allowing more products to be produced, with higher levels of hazardous substances, and for longer periods of time. In addition to any threats to health and environment from first-generation use, these hazards create tremendous challenges for recycling and future use of products. A recent study produced for the EEB by ClientEarth concluded, [15]

> Policy makers must seek to limit hazardous chemicals from entering the material cycle in the first place. This is not only the best way to protect human health and the environment, but would also facilitate the future use of recovered materials for economic operators and thus the circular economy. Prioritising the full implementation of REACH and

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14 Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC). 2015. Opinion on an Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances. ECHA/RAC/RES-O-0000006229-70-02/F ECHA/SEAC/RES-O-0000006229-70-03/F.

15 ClientEarth. 2017. *Keeping it Clean: How to Protect the Circular Economy from Hazardous Substances*, p4.

other legislation restricting the use of hazardous chemicals will be necessary to achieve this objective.

Proper and forward-thinking management of hazardous substances is the first step in closing material loops and creating a resource-efficient economy for Europe. The slow pace of restrictions, and the numerous derogations and weakenings introduced during deliberations, undermines this critical step. Therefore, the ClientEarth report concludes that the EU must "accelerate the identification of SVHCs and inclusion of substances in the Restriction or Authorisation Lists." [16] Similarly, in a 2014 memo to the Council entitled "Key issues in chemicals policy on the road to a non-toxic environment", six member states (plus Norway) "call on the Commission to better integrate the regulatory instruments under REACH (restriction, authorisation), ensuring that problematic uses of chemicals are readily restricted following streamlined procedures." [17]

EXAMPLE: LEAD COMPOUNDS IN PVC

The proposed restriction on the use of lead compounds in PVC, currently under consideration, provides a forceful example of this concern. Although the quantities of lead used in PVC appear small, the proposal estimates that between 1,057 and 4,263 tonnes of lead were placed on the EU market in 2016 in PVC articles. [18] Clearly, the continued use of lead stabilizers in PVC will pose a grave challenge to the future recycling of this very common material.

2.5 The level of evidence required is unclear and unbalanced

In addition to changing nature of the scope, the use of evidence in the restriction process is also extremely variable. While it is difficult to generalize about the procedures followed by the Competent Authorities from the various Member States, we see clear patterns in the use of scientific evidence by the ECHA committees.

2.5.1 Giving privilege to GLP studies dismisses in practice independent scientific evidence

When reviewing evidence, RAC tends to privilege studies that comply with Good Laboratory Practice (GLP) standards. Many RAC members have experience with harmonised classification procedures, where standardized and GLP tests are normally preferred. However, it is important to note that GLP is a standard for management and registration of studies, developed to improve industry reporting of study results. GLP is not a measure of scientific quality, good study design, or correct interpretation of study data. Most independent academic studies do not follow GLP processes. By privileging GLP when analysing evidence to back a restriction proposal, RAC is in practice dismissing most of the independent scientific evidence provided by public authorities.

EXAMPLE: BPA

A very clear example was the selection of the result of the study by Tyl et al. on reproductive effects of BPA conducted under GLP standards and funded by industry as the starting point for the derivation of the DNEL when assessing the restriction of BPA in thermal paper. [19] This was the endpoint that the European Food Safety Authority (EFSA) had used in its assessment of BPA. However, RAC dismissed the systematic review carried out by the dossier submitter (ANSES, the French Agency for Food, Environmental and Occupational Health & Safety), which used independent academic studies considering mammary gland effects as starting point to derive the DNEL. The DS's analysis concluded that the general

16 ClientEarth 2017, p35.
17 General Secretariat of the Council, 2014. Key issues in chemicals policy on the road to a non-toxic environment: Information from the Austrian, Belgian, Danish, German, French, Dutch and Swedish delegations, and Norway, supported by the Croatian and Luxembourg delegations. 16361/14, p6. https://chemycal.com/news/3b86cfa4-6ce3-4f87-a410-3d24cdb6249d/2018_EU_strategy_for_a_non-toxic_environment_the_Council_calls_for_actions
18 Annex XV report for lead in PVC, p.27

19 Myers, vom Saal, et al. 2009. Why Public Health Agencies Cannot Depend on Good Laboratory Practices as a Criterion for Selecting Data: The Case of Bisphenol A. *Environ Health Perspect*. 2009 Mar; 117(3): 309-315. doi: 10.1289/ehp.0800173

public, not just workers, were at risk from BPA exposure. RAC's dismissal of the French studies had a major impact on the justification of the restriction proposal. While RAC has the obligation to take into account assessments from other EU Committees (like EFSA), it is not obliged to adhere to their conclusions, and we believe the French Competent Authority's evaluation was more relevant and more protective.

2.5.2 The level of evidence required is very uneven

There is a great deal of variation in the level of evidence required by ECHA from different actors. In particular, there is a large gap between evidence required of restriction dossier submitters to demonstrate risk or appropriateness of an Risk Management Option (RMO), and the level of evidence asked of industry when setting derogations, justifying substance uses, assessing alternatives, or the evidence required of industry to demonstrate adequate control when applying for authorisation.

MS / DS requirements

The requirements that must be met for a MS to submit a restriction proposal are very strict; the REACH FORWARD report noted especially the "challenging information demands from the committees RAC and SEAC". [20] These requirements appear to impact whether a restriction proposal is a submitted at all, and if so, how narrow it must be to satisfy RAC and SEAC. ECHA's Restriction Efficiency Task Force (RETF) provided vivid examples of this problem in their 2014 survey.[21] For example, on the statement, "I think that the Committees made reasonable requests for additional information", ***all*** of the non-Dossier Submitter ("Non-DS") respondents agreed to some extent, while nearly 80% of the Dossier Submitter (DS) respondents marked "do not agree" — the strongest possible response — and another 10% marked "disagree to some extent." **Evidently, the experience of actually preparing the dossier is far more involved, and the questions asked by the committees are far more difficult, than it appears from the non-submitter perspective.** It seems that one can't see how difficult a restriction proposal really is until one tries to write it — and get detailed questions back from the committees.

Similarly, for the statement, "To me it was clear how detailed the analysis needed to be for the Committees to develop the opinions", about 60% of Non-DS respondents agreed to some extent, while nearly 80% of DS respondents disagreed or mostly disagreed. **Again, the experience of the DS in fulfilling the committees' expectations is far more difficult than the non-DS — or, probably, than the ECHA committees or staff — believe.**

ECHA appears to see this problem of evidence primarily as an issue of the technical capacity of the MS.
There is certainly some evidence that MS capacity or lack of capacity is a major driver of restriction proposal submissions. For example, in the RETF survey, nearly 90% of Non-DS respondents agreed to some extent with the statement, "We hesitate to start the preparation of the Annex XV dossier due to the lack of competence in our CA."

These challenging demands for more and more detailed information place the burden of proof on public authorities to prove that a substance should be restricted. This is contrary to the goal of REACH.

However, it is clear from answers like those cited above that the problem is not simply one of technical capacity, but of the scope and depth of the data required from the dossier submitter. These challenging demands for more and more detailed information place the burden of proof on public authorities to prove that a substance should be restricted. This is contrary to the goal of REACH. The REACH text makes it clear that a precautionary approach is required in order to achieve a "high level of protection" of human health and the environment, and therefore that action should

20 REACH FORWARD p8
21 ECHA 2014. "Restriction efficiency task force: state of play" [presentation], 19 February 2014

be taken even when some doubt may exist. The burden of proof should be on industry, to demonstrate that the restriction proposals are not justified because the allowed uses are safe.

Industry requirements

By contrast, the committees often accept industry statements without evidence; and in many cases, this weak evidence is used to drastically and arbitrarily change the scope of the restriction proposal. In fact, some restriction proposals have been restricted or modified based on only simple requests by the regulated industry. A simple claim of cost or timeline, unsupported by evidence, should not so easily override the DS's considered opinions. Moreover, these last-minute derogations have typically not been evaluated by either the DS or RAC for risks, entirely circumventing the formal process for risk assessment.

Example 1

This was the case with the restriction proposal for the flame retardant decaBDE. During the first six-month-long public consultation, ECHA did not receive sufficient comments indicating the need for an exemption for the aviation industry, and concluded as well that there was not enough evidence to support a derogation for automotive spare parts. ECHA then opened a second public comment, asking specific questions about these two sectors as well as recycling, and received a small number of comments asking (as expected) for exemptions for auto spare parts and aviation. These claims were not critically evaluated by ECHA Committees, although alternatives were already readily available, and despite some evidence that the restriction would not be burdensome (for example, an indication from one major aircraft maker that decaBDE would be phased out by 2018).[22] In this case, not only did ECHA take the industry's comments at face value, but went out of their way to approach the industry, asking whether the industry might want additional derogations.

Example 2

In a parallel case involving the phthalates restriction, SEAC solicited information on automobile industry needs for derogations for spare parts, "opening a back door to the continued use of four phthalates, substances of very high concern, without an assessment by RAC of the risks that it may pose to Europe's population and environment."[23] This proposal came very late in the opinion development, after RAC had rejected in its opinion development process the derogation request for spare parts for vehicles already in use. The request has not been justified from a risk assessment point of view, and it concerns a potentially high volume of phthalates given the broad definition of "vehicle" (including buses, trains, planes, cars), the vast number of vehicles in use, and the long useful life of vehicles. The impact of this derogation on the risk reduction potential of the restriction could potentially be very high. SEAC should restrain from accepting such broad derogations, in particular at such a late stage of the opinion development process.

Moreover, these last-minute derogations have usually not been evaluated by either the DS or RAC for risks, entirely circumventing the formal process for risk assessment

2.5.3 The committees use inappropriately detailed analysis despite very weak data, leading to a false sense of accuracy

In a quest to provide the strongest possible evidence for their conclusions, the committees make extremely precise quantitative estimates even when there is very poor data available. Most scientists are trained to analyze data quantitatively, and non-scientist decision-makers are used to seeing the results of these analyses presented as numbers. Thus, there is a strong bias towards quantitative analysis. This often leads the experts on ECHA's committees to spend the greatest effort in a detailed analysis of familiar problems—while often ignoring important unknowns.

In evaluating the proposed BPA restriction,

22 EEB and IPEN, 2016, memo to ECHA on the decaBDE restriction proposal.

23 EEB comments during public consultation

for example, RAC spent a great deal of time and effort developing several models for the absorption of BPA through the skin of the hand. It reported the results of these models to three significant figures, and compared them with biomonitoring data. This gives the appearance, to the casual or nonexpert reader, that the problem is well studied and well understood. Yet the data that goes into these models is extremely poor: For example, one important parameter (skin absorption flow, F_{max}) ranges over more than an order of magnitude, while the length of exposure time ranges from 3, to 8, to 10, to 24 hours.[24] In other cases, RAC simplifies the analysis with averages values that may not be appropriate, as when using the "reference man" standard bodyweight of 70 kg when modelling pregnant women's exposure. RAC attempts to address these uncertainties by presenting "median" and "reasonable worst case" scenarios. (We note that no definition of or guidance on the preparation of a "reasonable worst case" scenario is available.) However, the wide range of input parameters, and the corresponding variation in model outputs, suggests that these models are of relatively little value despite the large investment in them.

This emphasis on detailed calculation puts pressure on the dossier submitter, ECHA, and the committees to simplify the analyses by omitting parts for which data is not available, or which cannot be easily addressed with numerical models. The final combined opinion on BPA, for example, includes this important footnote:

> The Dossier Submitter is aware that other routes of exposure to BPA such as hand-to-mouth contact are possible but was not able to evaluate them. It is conceivable, however, that hand-to-mouth contact could contribute to the exposure of workers and consumers to BPA from thermal paper. Due to the lack of information hand-to-mouth contact is not considered further in this opinion. [25]

That is, because of the difficulty in estimating it, the DS and ECHA omit any exposure to BPA resulting from hand-to-mouth exposure. Yet hand-to-mouth exposure has been studied extensively for many compounds, and is often a very significant source of exposure. This is particularly true for subcategories of exposed individuals, for example, smokers (who regularly touch their lips), or workers who might eat a meal or a snack during a shift. We admit that any attempt to quantify hand-to-mouth exposure would be difficult, but we think it would have been more valuable to create a rough estimate of this exposure — for example, a "reasonable worst case" scenario — rather than excluding it in favour of the an overly precise estimate for the single route studied by RAC.

The interpretation of these improbably precise figures is also fraught with problems. A risk characterisation ratio below 1 is dismissed by the committees as no risk, even though it might be quite close to 1 and might have significant uncertainties, as was the case in the BPA restriction proposal. A risk characterisation ratio just above 1, too, is sometimes minimized as demonstrating "little risk". Yet in either of these cases, the real-world variability among individuals will mean that some number of people, perhaps very many, are indeed subject to a risk that has been deemed unacceptable (RCR>1). A better presentation of the true uncertainties in the risk characterisation estimates, perhaps by graphical or Monte Carlo approaches, would lead to a more honest assessment of true risks in the population.

Our intention here is not to provide specific critiques of the methodology, but to emphasize that **the presentation of detailed numbers creates a sense of confidence in the analysis that is not justified by the data available**.

The presentation of detailed numbers creates a sense of confidence in the analysis that is not justified by the data available.

24 Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC). 2015. Opinion on an Annex XV dossier proposing restrictions on Bisphenol A. ECHA/RAC/RES-O-0000001412-86-56/F. ECHA/SEAC/RES-O-0000001412-86-82/F. p34

25 RAC and SEAC. 2015. Opinion on an Annex XV dossier proposing restrictions on Bisphenol A. Footnote, p7.

Moreover, the results are often biased against the restriction proposal. **For example, omission of some plausible routes of exposure means that the calculated risks represent only a minimum value of the total exposure burden.** Similarly, SEAC's cost-benefit calculations, although superficially precise, suffers from the typical weaknesses of cost-benefit analysis in being unable to properly monetize many of the most important and most human concerns (e.g., pain and suffering due to disease), leading to an assessment that underscore the quantifiable costs of restriction rather than the less-quantifiable benefits.

2.5.4 The committees' desire for precision leads to rejection of much modern science

The committees' desire for precision leads to their rejection of more modern, less certain, or less easily quantified data. In particular, RAC's attachment to calculating a precise numerical estimate of risk leads it to reject data points, like endocrine disruption, that don't fit its simple models. We give several examples.

NP/NPE

In its opinion on Nonylphenol and nonylphenol ethoxylates, RAC notes the strong evidence for endocrine disruption in fish (evidence is less clear in other species). However, RAC declines to use these effects in its risk analysis, saying, "these observations are not conclusively endocrine related since present knowledge prevents firm conclusions about a mechanistic link." But RAC's need for "firm" mechanistic data is at odds with REACH's precautionary approach. There is sufficient evidence of endocrine disruption that NP/NPEs have already been added to the candidate list of SVHCs for authorisation,[26] and RAC should recognize this evidence without an arbitrary requirement for more specific mechanistic data. Moreover, since NP/NPE is already classifed as reprotox under CLP,[27] this decision undermines the REACH goal of existing data and classifications where possible.

RAC's desire for precision in risk estimates leads it to question and ignore even its own conclusions. If there is in fact no safe exposure level, the substance should be treated as a non-threshold chemical. This was the approach taken by the DS: "the dossier submitter concludes that it is too difficult to derive a safe level for such substances and that covering ED effects by extra assessment factors in PNEC derivation would not be adequate (effectively meaning that no exposure can currently be considered acceptable)." [28] RAC, looking specifically at the fish ED evidence, concluded "that a PNEC lowered by about a factor of 5 (i.e. to 0.08 μg/L) might cover adverse ED effects," but then decided that it was "premature in this specific case to give an opinion on whether or not it is possible to derive a safe exposure level". Instead, while agreeing "that the ED-related generic arguments justify ED substances coming under particular scrutiny", RAC "pragmatic[ally]" chose the "traditional" PNEC for their calculations, despite concern that "the 'traditional' PNEC appears not to sufficiently cover the uncertainties identified".[29] Defining a threshold is one of the key challenges of endocrine disruption, but here RAC has argued itself in a circle. A better approach would have been to have used both the "traditional" and the lower PNECs, as well as the DS's approach, and providing the results of all three analyses to the Commission. Although more complex, this would have more transparently communicated the great uncertainties in the science.

PFOA

RAC took a similar approach in its risk characterisation of PFOA. Extensive epidemiologic studies have found associations between PFOA exposure and birth rate, and PFOA exposure and cholesterolemia. As expected of endocrine-mediated effects, these effects appear most prominently at low doses, and do not necessarily follow a traditional (i.e., monotonic) dose-response curve[30]. RAC

26 ECHA. Candidate List of substances of very high concern for Authorisation. https://echa.europa.eu/candidate-list-table
27 Summary of Classification and Labelling: Nonylphenol. https://echa.europa.eu/en/information-on-chemicals/cl-inventory-database/-/discli/details/20715
28 Committee for Risk Assessment (RAC). 2014. Opinion on an Annex XV dossier proposing restrictions on Nonylphenol and Nonylphenol ethoxylates ECHA/RAC/RES-O-0000005317-74-01/F. p8.
29 RAC 2014 Opinion on NP/NPE. p11.
30 Myers P. & Hesler W. Does 'the dose make

concludes that, "due to unclear adversity and uncertainties in dose-response, [these effects] cannot be used in the risk characterisation." Moreover, "Epidemiology studies on other endpoints (e.g. immunotoxicity) were submitted in the public consultation but these were also not considered robust enough to include in a quantitative assessment".[31] Here RAC has dismissed endpoints from human studies because they do not lend themselves to quantification using traditional models. A better and more transparent approach might be to qualitatively discuss this problem in the conclusions, highlighting for the Commission and the Member States the large and important uncertainties in the data.

BPA

The studies used by the DS as starting point to derive the DNEL of BPA were dismissed by RAC, as they didn't show simple (monotonic) dose-response curves, or showed effects at very low levels. RAC concluded, therefore, that these studies were considered "not to be robust enough to serve as critical study for the identification of a starting point for DNEL derivation. Therefore the effects will be accounted for in the setting of Assessment Factors". [32] As a result, RAC's Derived No-Effect Level (DNEL) for BPA was 50 times higher than the figure used by the DS (France). This discrepancy led RAC to conclude that there was no risk to the health of consumers. Again, an approach more consistent with transparency would have been to follow each approach separately, providing the results to the Commission and the Member States, and thereby clearly communicating the scientific uncertainty to the decision-making bodies.

Use of human biomonitoring data

RAC is particularly focused on biomonitoring data, which provides important but sparse data on real-world exposures. Unfortunately, in cases where most of the (often very limited) data shows exposures below the DNEL values, RAC uses this to demonstrate that there is no risk — although even a small percentage of the EU population exposed above the DNEL would constitute a significant number of people who might at risk. In our opinion, the biomonitoring data must be extensive and must consistently show exposures below the DNELs before it can be seen as evidence of no risk, in keeping with a precautionary approach. This is especially true if calculations from realistic exposure scenarios have indicated a likely risk.

SUMMARY

In each of these cases, RAC has acknowledged the existence of low-dose and/or ED effects, but has declined to use these effects in evaluating risks. These low-dose and often non-monotonic effects do not fit well with RAC's preferred risk assessment model. To be sure, these are subtle risks that are difficult to identify in epidemiologic data. But that is all the more reason that the limited epidemiologic data is in fact strong evidence of an association. Rather than replacing the DS's evaluation with their own, RAC and SEAC should clearly communicate the uncertainties to the decision-making bodies.

2.6 ECHA's evaluation of socio-economic impacts relies far too much on a very narrow understanding of cost-benefit assessment

In proposing a restriction, the dossier submitter typically performs a socioeconomic analysis (SEA), in accordance with the requirements of REACH: "Any such [restriction] decision shall take into account the socioeconomic impact of the restriction, including the availability of alternatives." [33] Although an SEA is not formally required of a restriction proposal, it is usually included: In RETF's survey, 100% of DS respondents said that they had prepared an SEA.[34]

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the poison? Extensive results challenge a core assumption in toxicology. Environmental Health News. April 30, 2007.
31 Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC). 2015. Opinion on an Annex XV dossier proposing restrictions on Perfluorooctanoic acid (PFOA), its salts and PFOA-related substances. ECHA/RAC/RES-O-0000006229-70-02/F ECHA/SEAC/RES-O-0000006229-70-03/F. p22.
32 RAC and SEAC 2015. Final BPA Opinion, p16.

33 REACH Article 68(1)
34 RETF, p18.

The purpose of the SEA is to assess the socioeconomic impacts of the proposed restriction. More specifically, the SEA contributes in the following ways: [35]

1. Justification that EU-wide action is required
2. Assessing whether the PR is the most appropriate
3. Refining the scope
4. Assessing in terms of net benefits and net costs

Annex XV, which describes the restriction dossier, reads, "The socio-economic impacts of the proposed restriction may be analysed with reference to Annex XVI. To this end, the net benefits to human health and the environment of the proposed restriction ***may be compared to its net costs*** ...". [36] However, throughout its guidance documents and its various opinions, ECHA — and particularly SEAC — seem to assume that the net benefits must exceed the net costs. For example, a 2016 ECHA report states, "There were two restriction proposals during 2011-15 where the Committees did not recommend to the Commission that a restriction be introduced: phthalates and cadmium in artists' paints. ***In these cases, the main reason was that the risk reduction for human health or the environment (benefits) was lower than the costs related to the restriction."*** [37]

Although ECHA and SEAC assume that the benefits must outweigh the costs, there is no such requirement in the REACH text. Article 68(1) simply says that the decision must "take into account the socioeconomic impact", not that it must impose a strict cost/benefit assessment. Nor does REACH Annex XVI, which lays out the details of the SEA process, contain any requirement or indication that benefits exceed costs. Indeed, Annex XVI provides broad latitude, saying, "the level of detail and scope of the SEA, or contributions to them, shall be the responsibility of the applicant for authorisation, or, in the case of a proposed restriction, the interested party. The information provided can address the socio-economic impacts at any level."[38] Rather, according to the ECHA guidance, "The SEA supports the justification that the proposed restriction is the best way of addressing the identified risks by providing a ***good overview*** of its socio-economic consequences to society as a whole." [39]

Indeed, a generic requirement that benefits exceed costs need not be an assumption of cost-benefit assessment — particularly in health and environment, where valuations are extremely uncertain. Moreover, this requirement leads directly to an inappropriate monetization of non-monetizable quantities like human life, as SEAC did in its BPA opinion. SEAC's break-even analysis required an estimate of the costs of various possible BPA-related diseases. (SEAC's discounted value for mammary gland changes, assumed to result in breast cancer 5.5% of the time, was €6,301.) [40] We find this type of comparison odious, but it is an almost necessary result of SEAC's adherence to cost-benefit assessment.
We need not recap the extensive literature critiquing Cost-Benefit Assessment (CBA). There are many cases where a CBA would not provide a legitimate assessment. For example,

• When costs of alternatives are overestimated (we believe that this is often the case);
• When costs of compliance or retooling are overestimated or overstated;
• When not all health/environmental impacts are known (commonly the case);
• When monetized benefits are underestimated (i.e., not all costs are included);
• When not all benefits can be assessed or monetized (e.g., pain and suffering due to disease);
• When not all benefits can be assessed or monetized (e.g., equity concerns).

In particular, the benefits of a restriction are usually very poorly estimated: Since the health effects are often poorly known, the monetized value of the health effects is an extremely low-quality estimate of the true benefits.

35 ECHA. 2008. Guidance on Socio-Economic Analysis – Restrictions, p25.
36 REACH Annex XV(II)(3) [emphasis added]
37 ECHA 2016. Report On The Operation of REACH and CLP, p107. [emphasis added]
38 REACH Annex XVI
39 ECHA. 2008. Guidance on Socio-Economic Analysis – Restrictions, p29.
40 RAC and SEAC 2015. Final BPA Opinion, Annex 5: Valuation Factors.

Moreover, since we want to restrict substances **before** they cause undo harm, it is usually the case that substances up for restriction (or even for authorisation) have not been fully evaluated for health risks. If additional health and environmental concerns are identified later — as is virtually always the case — then any early calculation of benefits **must always represent a significant underestimate**.

Another drawback for SEAC's opinions is that the committee focuses only on costs for the producer/user of the substance – and not the loss for the early adopters, those producers/ users of the alternatives who have already switched to safer alternatives. If the restriction is enacted, these innovative companies would be expected to gain the market share, assuming must be that the overall market remains the same. This seems an appropriate reward for companies who innovate in safer production, yet SEAC's opinions do not take it into account.

The narrow requirement that benefits exceed costs is equivalent to an assumption that society (in total) is not willing to pay any amount above the (total) monetized benefits. (Oddly, SEAC and ECHA often appear to use the term "proportionality" to mean "benefit > cost"; for example, "Comparing the socio-economic benefits to the socio-economic costs, the proposed restriction is considered unlikely to be proportionate." But CBA is not an appropriate assessment of proportionality, which includes a great many other factors.) The assumption that benefits exceed costs is ludicrous given that many benefits are not assessed at all and that costs are virtually always overestimated. Nor does it take into account the clear social willingness to absorb some costs of environmental and health legislation, as consumers do when purchasing "bio" products or by donating to cancer charities. (A far better approach might be to estimate the total social "willingness-to-pay" to reduce the health impacts; this will be even more difficult to monetize, but is certainly not zero.)

SEAC's opinion on BPA perfectly demonstrated the pitfalls of this type of assessment. The committee estimated the total costs of substitution at 20 - 60 eurocents per working EU-citizen per year, and pointed out that "no comments were received in the public consultation on possible affordability issues for industry". [41] Obviously, the restriction is "unlikely to have serious affordability concerns".[42] Despite this, SEAC deemed the PR "unlikely to be proportionate", since the costs outweigh the monetized benefits.[43] SEAC's conclusion makes a mockery of the process by assuming that society has zero willingness-to-pay to reduce the possible health impacts -- in this case, including breast cancer.

SEAC's conclusion makes a mockery of the process by assuming that society has zero willingness-to-pay to reduce the possible health impacts -- in this case, including breast cancer.

CBA is not the only tool that can be used to "take into account the socioeconomic impact of the restriction". For example, cost-effectiveness comparisons can provide much the same information without necessarily requiring all quantities to be monetized, and may be a better fit for ECHA's guidance that the socio-economic analysis "supports the justification that the proposed restriction is the best way of addressing the identified risks".[44] By comparison, the overarching cost-effectiveness mandate in the US requires that an agency "assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs".[45] **The benefits of a regulation may in fact *justify* its costs, even if they do not *exceed* its costs.** Moreover, the question of how much cost is acceptable is not

41 RAC and SEAC 2015. Final BPA Opinion, p72.
42 RAC and SEAC 2015. Final BPA Opinion, p72.
43 In this case, but equivalently, the thresholds set by SEAC's break-even analysis are unlikely to be reached given the costs assigned by SEAC to disease outcomes.
44 ECHA. 2008. Guidance on Socio-Economic Analysis – Restrictions, p29.
45 Office of Management and Budget. *Executive Order 12866* (1993). https://www.reginfo.gov/public/jsp/Utilities/EO_Redirect.jsp

Since the health effects are often poorly known, the monetized value of the health effects is an extremely poor estimate of the true benefits.

a scientific or economic decision but a political one, to be made by the Member States and the Commission.

In summary, ECHA's simplistic assumption that benefits must exceed costs is contrary to the principles of REACH and to the purpose of the SEA. Yet SEAC uses the comparison of monetised benefits and costs as the primary metric in most of its opinions, and, in fact, SEAC has previously responded to this critique by saying that CBA is "precisely the scope of SEAC's opinion making remit".[46] We disagree that cost-benefit is the only, or most appropriate, tool to assess socioeconomic impacts. ECHA and SEAC must find better ways to perform an SEA, and should avoid cost-benefit assessment—and monetization of the environment and human life—wherever possible. **Finally, we suggest that when an intervention is low cost—that is, when an intervention is expected to benefit health and environment and is "affordable", as was the case with the BPA restriction—a full assessment of benefits need not be done at all.**

2.7. The alternatives assessment process is greatly undervalued and underutilized

Although the use of alternatives assessment is spelled out somewhat more explicitly in the authorisation process than in the restriction process, it is clear from the REACH text that the existence of alternatives should play a role in a restriction decision: "Any such decision shall take into account the socioeconomic impact of the restriction, including the availability of alternatives." [47] It is unfortunate that SEAC's analysis of the socioeconomic impacts depends so heavily on CBA, with only a small fraction of the same attention paid to alternatives. In addition, as mentioned above, SEAC's analyses do not describe or quantify the benefits of a restriction proposal for those industries which have already taken the initiative to seek out and implement safer alternatives.

Part of the problem is a lack of guidance on the specific about "available alternatives". A recent review by ClientEarth concluded,

> Under Chemicals and Product legislation, restrictions are to be adopted or authorisations denied on the basis of whether feasible and safer alternative substances or technologies are available. However, this notion of 'available alternative' is not clearly defined or applied consistently. [48]

Additionally, the actual process of alternatives assessment itself is poorly defined. A 2016 report undertaken for ECHA by the Lowell Center for Sustainable Production found that "the quality and consistency of analyses of alternatives could be significantly improved", identified a number of specific problems, and made recommendations including "develop more detailed guidance or guidelines". [49]

A more detailed analysis of alternatives assessment (including non-chemical alternatives, alternative processes, rethinking design of products) is beyond the scope of this report. However, it is clear that restriction decisions would be better supported and more transparent if guidance were available on the practical development of an alternatives assessment, as well as on its use in making decisions on restriction.

46 Committee for Socio-economic Analysis (SEAC). 2015. Response to comments on the SEAC draft Opinion on the Annex XV dossier proposing restriction on Bisphenol A. p19.
47 REACH 68(1)

48 ClientEarth 2017, p31
49 Tickner & Jacobs, 2016. Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives.

EEB'S RECOMMENDATIONS

3.1 We must start by acknowledging the aim and the underlying principles of the REACH legislation.

Protection of human health and the environment

The overarching goals of REACH, as given in the preamble, are to "ensure a high level of protection of human health and the environment… while enhancing competitiveness and innovation." The first goal of REACH, therefore, is **to reduce risks to health and the environment**.

Substitution

A core goal of REACH is to "encourage and in certain cases to ensure that substances of high concern are eventually replaced by less dangerous substances or technologies".[50] Substitution — of dangerous substances or of substances of concern — will reduce risks and improve innovation.

Precaution

The actions of ECHA, its committees, the Commission, and the Member States, when considering restrictions, must more clearly acknowledge that REACH provisions are, as Article 1 asserts, "underpinned by the precautionary principle." The risk assessment must clearly identify and state the uncertainties as well as assess the consequences of the different risk management options proposed by ECHA. The committees need to better understand their role in the implementation of the precautionary approach.

Burden of proof

The shift of the burden of proof to industry is one of the main principles underlying the REACH text. ECHA should incorporate a more cautious approach in its opinion making processes, and should work to better balance the level of evidence demanded of Member states when submitting a restriction dossier — demanding at least as high a bar from industry when submitting evidence to prove safety, of the need for exemptions, and so on.

Innovation

Allowing the continued use of harmful or potentially harmful substances — for example, due to a derogation or to some other narrowing of a restriction proposal— undermines innovation towards safer alternatives within the EU chemicals industry. Continued use of these compounds reduces the motivation for industry to develop innovative, lower-risk alternatives which would increase competitiveness of the EU within the world market.

3.2 Acknowledge and better communicate uncertainty in the restriction process

The treatment of uncertainty is one of the biggest challenges in distilling and communicating scientific information. Critically, for any single chemical or endpoint, there is in many cases an extremely limited amount of data available. This problem is exacerbated by the fact that many new chemicals are introduced every year, and for most of them, only the most basic data required for registration is available. In addition, the complexities of modern toxicology — like nonmonotonic dose-response and endocrine disruption — provide substantial challenges for any attempt to apply traditional tools of toxicology and risk assessment.

ECHA, its committees, and the Commission are facing a difficult challenge when evaluating restrictions: Decisions must be transparent and well justified, despite the fact that the data may

> *RAC's incomplete models almost certainly represent a minimum estimate for exposure or risk… SEAC's cost-benefit analyses almost certainly understate the benefits of restriction.*

50 REACH paragraph 12.

be uncertain, and direct scientific evidence of harm is often difficult to come by.

As we have described above, the committees spend a great deal of time working on problems that are most familiar to them (e.g., monetization of costs, or detailed modeling of exposed skin area) while completely omitting the more difficult scenarios. This commonly leads to opinions that are unnecessarily detailed, while still being incomplete. By ignoring the more difficult or poorly understood aspects, **these incomplete models almost certainly represent a minimum estimate for exposure or risk**, despite the apparent accuracy of the models. Similarly, the difficulty of monetizing health and environment endpoints mean that **the cost-benefit analyses almost certainly understate the benefits of restriction**.

ECHA should encourage all actors, but especially the committees, to clearly represent their level of knowledge (for example, by using appropriate numbers of significant figures and confidence intervals) and to clearly communicate what information they are lacking, rather than allowing the false precision of limited calculations to drive decision-making. For example, if the BPA risk assessment ignores some exposure routes, that fact must be communicated clearly throughout, particularly in the conclusions and summaries—and unnecessary precision about those routes we do know about should be avoided. In cases where fundamental parameters are poorly known, or a wide range of values are consistent with the data, we encourage the committees to rely less on point estimates and more on distributions of parameters and model outcomes.

Finally, **we note that there is no mechanism by which interested scientists or the public may comment on RAC's calculations.** Although the REACH text does not require public comment on RAC's opinion, there is no reason that RAC shouldn't invite, and consider, comments from experts.

3.3 Incorporate modern toxicology into RAC's opinion-making procedure

RAC's preference for GLP studies prioritises industry over independent academic research, sometimes dismissing important scientific evidence. RAC's assessments are based on traditional principles of toxicology and risk assessment. Scientific knowledge generated over the last few decades, for example on endocrine disruption, cocktail effects, low dose effects, and non-monotonic dose response curves need to be better incorporated into RAC's opinion-making procedure.

3.4 Manage the burden of the restriction process, especially the SEA

The difficulty of first writing, and then defending, a restriction proposal is a major bottleneck to REACH's effectiveness. This problem has been discussed at length before,[51] but much more progress is needed. A large part of the problem is in the detailed quantification that the committees (albeit implicitly) require in order to develop an opinion. There are many places where quantification could be reduced without loss of information, in keeping with the precautionary underpinnings of REACH. For example, the SEA need not attempt to compare monetized costs and benefits of non-valuable quantities, when in some cases a simple narrative description of the risks would suffice. In other cases, as we suggest above, a clearly affordable restriction might be subject to less scrutiny if it can be reasonably expected to have benefits for health and environment.

...we encourage the committees to rely less on point estimates and more on distributions of parameters and model outcomes.

Taking this idea further, the 2016 REACH FORWARD workshop found "quite some support for the idea that regulatory processes, and in particular restrictions, could move on even without complete information." [52] Indeed, it is a fallacy to believe that we could ever have "complete information" on any substance,

51 REACH FORWARD
52 REACH FORWARD, p8.

and we do not have the luxury of waiting for data if we are to mitigate current risks in the EU. Today's process clearly spends far too much time calculating details of some aspects while almost entirely avoiding others. Detailed analysis of limited data should not be used to obscure the point that restriction is a policy, not strictly a scientific, decision.

3.5 Use the "fast-track" power of Article 68(2)

Article 68(2) gives the Commission power to "fast-track" a restriction proposal, avoiding most of the difficulties of developing and defining the proposal. Currently, proposals for textiles and construction materials under Article 68(2) are under consideration by the Commission. Although rarely used, this process has great potential to simplify the passage of the most clear-cut restrictions, where affordability or clear benefits indicate that a full review is unnecessary. We suggest that the BPA restriction might have fallen into this category; given the clear benefits, the well-characterised alternatives, and the extremely low cost, advancing this restriction under 68(2) would have saved the DS and the committees a great deal of time that might have been better spent evaluating more difficult proposals. Furthermore, if the committees do not have the power to expand the scope of a restriction to cover related substances – as was argued when we suggested adding BPS to the BPA restriction proposal – Article 68(2) gives ECHA the power to rapidly develop a parallel, fast-track restriction to prevent a looming "regrettable substitution".

3.6 Use registration dossiers to identify risks that are not adequately controlled

The REACH text makes it clear that inadequately controlled risks are unacceptable,[53] and that restrictions should be used to address these cases.[54] **We propose that registration dossiers that do not demonstrate adequate control of risks should automatically trigger the restriction process.** The registration dossier itself may already provide sufficient evidence to advance a restriction; alternatively, it may be used as the basis for the Commission to implement a fast-track restriction under Article 68(2).

3.7 Define more carefully the appropriate roles of the committees

RAC and SEAC have demonstrated broad power to modify restriction proposals. The source of this power is unclear, based on the REACH text's requirement that the committees prepare their "opinions". Regardless, the sweeping and arbitrary nature of these changes is of great concern. Trust in the process would benefit from clear instructions and guidance on the role and the limits of the Committees to modify proposals, and on the evidence needed to do so.

Further, although RAC and SEAC are tasked with providing their "opinions" these recommendations are then written into the restriction proposal and sent to the COM — effectively replacing the original proposal with an ECHA proposal. In this way, the proposal that reaches the COM does not necessarily reflect the scientific expertise, beliefs, or intention of the DS, while its over-reliance on quantification suggests more certainty than is warranted. Instead, the original DS proposal should be presented to the Commission and Member States side by side with the proposed modifications from the committees, and with estimated assessments of the impacts of those changes (particularly derogations). This would clarify the changes to the scope and efficacy of the original restriction proposal, and would highlight the justification (or lack thereof) behind those changes. It would also highlight (appropriately) the disagreements on fundamental scientific issues (e.g., the different approaches taken in calculating a DNEL) in a way that is currently obscured.

The ECHA committees are often referred to as "scientific committees", and their evaluations, opinions, and recommendations must be both transparent and well justified. However, it is important to recognize that the restriction process as a whole is not a

53 REACH Article 1(3) and Article 5.
54 e.g., REACH paragraph 29.

scientific process, but a policy process. **Clear communication of uncertainty, and of changes and derogations made by the committees, is critical if the process is to adhere to the core purpose of REACH: to use a precautionary approach to reduce risks to human health and the environment.**

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