



Lessons learned from recent broad scope restrictions

Recommendations for Dossier Submitters

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ClientEarth[®]

Introduction

Broad REACH restrictions – i.e. of groups of chemicals or of a wide range of uses - are the future of chemical regulations, as recognised by the Council,¹ the Commission² and the European Parliament.³ Broad restrictions are the most effective option to ensure the protection of people and the environment from hazardous chemicals, speed up regulation and avoid regrettable substitution. They can also, however, be a challenging process. As well as unnerving for the Dossier Submitter, who naturally wants to ensure that the broad scope and set conditions make it through the process. The biggest threat is to have restrictions with very limited practical effectiveness, due to too many derogations and transitional periods watering down the initial ambition.

A lot can be learned from past broad restrictions (e.g. PFOA), to ease the preparation of the dossiers and ensure that the final proposal is not weakened by the regulatory process, i.e. RAC and SEAC opinion-making followed by the Commission's proposal. This report will specifically focus on the intentionally-added microplastics⁴ and PFHxA restrictions.⁵ That is because ClientEarth and EEB have followed those restrictions closely, as accredited stakeholders to the ECHA scientific Committees and contributors to the public consultations.

We have identified various hot spots - aspects that risk weakening the restrictions - from which we draw a series of useful lessons, on:

- 1) How to handle data gaps at the pre-submission stage;
- 2) How to make the dossier process-proof, especially considering the scope, derogations and the acceptable level of evidence; and
- 3) How to defend the dossier throughout the process.

This paper is not meant to give guidance on how to submit an Annex XV dossier - which ECHA already provides in a specific document.⁶ Rather, our goal is to provide authorities who intend to submit a broad restriction proposal with experience-based **practical tips on how to successfully manage the most difficult parts of the process.**

¹ Council approves conclusions on the EU Chemicals Strategy for Sustainability - Consilium (europa.eu).

² Chemicals Strategy for Sustainability, p. 10.

³ European Parliament, Resolution of 10 July 2020 on the Chemicals Strategy for Sustainability

⁴ Annex XV Restriction Report for intentionally-added microplastics: Microsoft Word - rest_microplastics_axvreport_en.docx (europa.eu).

⁵ Annex XV Restriction Report for undecafluorohexanoic acid (PFHxA), its salts and related substances: Annex XV reporting format 040615 (europa.eu).

⁶ See: RDDS - Batch Process 0.9 (europa.eu).

Significant improvements are expected to be made as part of the upcoming REACH reform. We will outline in complementary reports the changes that we think could contribute to make restriction a more impactful process, but also more manageable for the dossier submitters.

Lesson 1: If you lack information, ask for it as early as possible

1. How to handle data gaps at the pre-submission stage

Challenge

Broad restrictions often require authorities to look for information on the chemical and its uses beyond what is immediately available to them. Ideally, authorities should be able to clarify major data gaps before they submit the Annex XV dossier to ECHA. That way, they can assess early on the quality and credibility of the information they have. They can also identify potential remaining data gaps, which could be resolved through future consultations, and how they affect the assessment.

On the one hand it is a challenge to reach out to the right stakeholders and incentivise them to share information. On the other hand, handling potentially numerous comments coming in for broad restriction proposals can also be challenging, especially taking into account the tight timeline of the ECHA process.

Lesson learned

Important information was missing from the Annex XV dossier when Germany submitted its proposal to restrict PFHxA restriction in April 2020, despite the stakeholder consultation performed in 2018.⁷ This is visible from the questions raised in the consultation on the dossier launched by ECHA in March 2020 and the subsequent webinar organised by Germany to explain the call for evidence on 23 April.⁸ At this stage, it can be challenging to re-evaluate some of the

⁷ https://www.google.com/url?q=https://oekopol.de/en/topics/chemicals-policy/umfragen/survey-on-specific-pfass-c4-c7-and-other-fluorinated-substances-precursors-or-similar-substances-to-develop-a-restriction-proposal-under-reach/&sa=D&source=editors&ust=1632839725140000&usg=AOvVaw2M_18p-sklSkiFh0-xrLAp

⁸ The presence of significant information gaps is visible from the consultation launched by ECHA on the Annex XV dossier in March 2020.

main assumptions underpinning the dossier's overall conclusions, such as the emissions estimates.

In the context of the microplastics restriction, ECHA found a way to mitigate the existence of data gaps by regularly updating the background document that goes along with the dossier, notably based on new information received. It did so on various occasions while the Committees were developing their opinions. It has adopted a similar strategy in the context of other restriction proposals, e.g. to restrict lead in ammunition for hunting, outdoor sports shooting and fishing. Doing so has the merits of providing flexibility to the dossier submitter when new relevant information turns up; however, any change should be transparent, logical, and well-justified.

Recommendation

- Ensure that **pre-submission consultations are widely disseminated to interested stakeholders**, for instance through sectoral and trade associations and journals, using ECHA registration and CLP notification databases, NGO networks, etc. It should be clear from the

Lesson 2: Incentivise the industry to provide information

consultation what type and amount of data is expected from the stakeholders – that would help dossier submitters better handle the number of comments submitted.

- **Ask for help as early as possible to identify and reach out to the right operators.** Trade organisations may not have access to specific information, or may not want to share it for strategic reasons. In that case, it is best to be in direct contact with the companies that will be most affected by the restriction, which can be a challenge. In that situation, ECHA but also some NGOs, like ChemSec, and other Member States may provide support in identifying and reaching out to the relevant importers, downstream users, or alternative providers.
- **Reflect clearly in your dossier what information you don't have** despite your efforts.
- Bear in mind that **you can always update the data from your dossier** if new information arises after you have submitted your proposal.⁹ This practice is acceptable only if the dossier submitter is clear on the reason and nature of the changes brought to the dossier. In particular, there should be transparency on the information source, a critical assessment of the data quality, and justifications if new derogations are proposed.

⁹ The ECHA Good practice guide on restriction explicitly states that "Dossier Submitters may complement the SEA along the opinion-making process, depending on which information will be available through the consultation on the Annex XV restriction dossier and on the specific requests from RAC/SEAC" (p. 4).

Challenge

It is challenging to overcome the data gap on the quantities and nature of use, emissions, and alternatives when industry refuses to collaborate. Even when asked early on, economic actors may not provide the information the authorities need. Industry might actually have an incentive not to cooperate, since late presentation of new data or requests for derogations directly to the Committees have been fruitful in the past. A related challenge comes from the fact that companies are oftentimes grouped in business associations, which makes it difficult to reach out and implicate them individually.

The dossier submitter must be aware of this strategy and anticipate it as much as possible.

Lesson learned

In the PFHxA dossier, the industry did not provide detailed information to the dossier submitter,¹⁰ or in the ECHA consultation.¹¹ Germany's estimations of emissions were later challenged by the same industry stakeholders. While emphasising that the overall lack of information made the "derivation of scientifically based conclusions challenging",¹² SEAC still supported the inclusion of several derogations and sector- or use-specific extended transition periods, requested during the consultation on the Annex XV report.¹³

Recommendation

- **Communicate as much as possible on why it is important for industry to collaborate.** Industry is not a homogeneous group – some companies might consciously aim to withhold information but others might simply not be aware of the ongoing process, or may want to contribute but do not know how. The restriction process can be perceived as quite remote and opaque from an external point of view. It is therefore key to communicate on the restriction

¹⁰ Annex XV Report for PFHxA, p.47: "One additional manufacturer contacted the Dossier Submitter late in the preparation process for this dossier asking for a derogation for the use of PFHxA-related substances in the production of fluoropolymers, fluorinated polymers and fluoroelastomers at his manufacturing facilities in the EU. *The manufacturer did not provide case specific data on possible socioeconomic consequences in case of a restriction.* The Dossier Submitter asked him to submit more detailed information in the public consultation of the restriction process."

¹¹ See Response to Comments documents, e.g. the response by the DS to Comment n*2962 regarding a derogation for PFHxA in products applied for the protection of professionals.: "The DS agrees that economic impacts will be affordable in general but *impacts on product longevity are not well understood.* However, the dossier submitter is not aware of robust scientific evidence suggesting significant impacts on product longevity, neither for private, lighter uses nor for professional, protective uses."

¹² SEAC notes in its draft opinion (p. 30) that "supporting information for many of the derogation requests *is incomplete such that it makes the derivation of scientifically based conclusions challenging.* During SEAC opinion-making, stakeholders were encouraged to submit more information on specific points through the consultation. Some further information was received; however, *uncertainty remains.* This is largely due to the wide variety of uses and users, but also *due to the information received not being representative of all the different use situations and not giving a clear picture of the situation over the entire sector.*"

¹³ SEAC Draft Opinion on Annex XV Report for PFHxA, p. 26.

through various channels (ECHA, NGO networks, social media, local authorities etc.) and in laymen language. As many individual companies as possible should be able to get the information and feel empowered to contribute.

Lesson 3: Adequate evidence - the type and amount capable of substantiating the conclusions

- **Incentivise stakeholders to provide information early on**, by including under the restriction's scope all uses for which the need for derogation has not been justified by industry when preparing the dossier.
- **Firmly oppose during the discussions at RAC and SEAC any new derogation or change in the original scope that has not been thoroughly substantiated and explained transparently.**¹⁴ Obtaining a derogation is not a right, but a heavy burden - which requires industry to build a strong case during the ECHA process if they did not submit information early on.
- **Mention in the dossier who cooperated, and who did not, meaning who received the information but did not contribute.** This way, one can, at a later stage, stand up against derogations for which the industry did not provide information earlier.¹⁵
- **In case information is provided too late in the process** (e.g. at the very end of the Annex XV consultation), **ask ECHA to prolong the deadline for delivering the opinion** so that you have time to properly assess the reliability and credibility of the data.

2. How to make the dossier process-proof

How to get RAC and SEAC to accept the evidence collected

Challenge

When building a restriction proposal, authorities may be confronted with a huge amount of information, or no information at all. They enjoy broad discretion in assessing scientific evidence,¹⁶ but might doubt what type and level of information is sufficient to ensure the credibility of a

¹⁴ In line with the ECHA guidance: 7c4705d5-ad01-43ed-a611-06f1426a595c (europa.eu)

¹⁵ Industry is expected to cooperate with authorities and submit their substance's information. Recital 27 REACH states that "for purposes of enforcement and evaluation and for reasons of transparency, the information on these substances, as well as related information, including on risk management measures, should normally be submitted to authorities".

¹⁶ Case T-456/11 International Cadmium Association (ICdA) and Others v European Commission, Para. 45.

dossier in each context. An added difficulty is that industry often questions the validity of the proposed risk assessment, either by casting doubt on the reliability of the research, questioning the weighing or interpretation of the evidence, or presenting contradictory data.

The Court requires authorities to conduct their assessment in a way that is scientifically motivated, transparent and objective, allowing the final decision maker to “understand the ramifications of the scientific question raised”.¹⁷ In other words: authorities are not expected to collect exhaustive or perfect evidence. The requirement is to bring to the table “sufficiently reliable and cogent information”,¹⁸ i.e. information that is “factually accurate, reliable and consistent”, and “capable of substantiating the conclusions drawn from it”.¹⁹

The evidence collected must make the conclusion plausible.²⁰ It must not be exhaustive or perfect - that would actually go against the precautionary principle, consecrated in the Treaties and on which REACH is built. What matters most is the explanation of the method and why the evidence was considered as sufficient. In line with the general duty to state reasons,²¹ authorities are expected to explain why they reached a specific conclusion.

Lesson learned

On the one hand, the microplastics file is one for which extensive scientific information was available to ECHA. In such a data-rich context, ECHA did not consider or even refer to all existing studies. Using a weight of evidence approach, it showed that the evidence on risks is strong and coherent enough to support the conclusion of the dossier. ECHA carefully chose the key and supplementary studies that were relevant to support the conclusion that microplastics pose a risk to the environment.²² The large number of available studies but also the recent character of the studies chosen by ECHA convinced RAC of the credibility of the evidence with regard to the risk.²³ The fact that ECHA went beyond the assessment of the damage to the environment to consider additional concerns for health, with a view to further substantiate the unacceptability of the existing risk, served as a further argument for RAC to support the restriction.²⁴

On the other hand, German authorities faced significant data gaps when preparing the PFHxA restriction dossier. However, they reported those gaps in each part of their assessment by making

¹⁷ Case T-456/11 International Cadmium Association (ICdA) and Others v European Commission, Para. 52.

¹⁸ Case T-456/11 International Cadmium Association (ICdA) and Others v European Commission, Para. 52.

¹⁹ Case T-636/17 PlasticsEurope v European Chemicals Agency, Para. 58.

²⁰ Case T-636/17 PlasticsEurope v European Chemicals Agency, Para 58: “the evidence adduced by the applicant must be sufficient to make the factual assessments used in the act implausible” (emphasis added).

²¹ EU law makes it a requirement to give reasons not only for administrative but also for legislative acts, see Article 296, para. 2 TFEU.

²² Annex XV Restriction report for intentionally-added microplastics, p. 27.

²³ RAC Opinion, p. 50; p. 56; p. 63.

²⁴ Annex XV Restriction Report for intentionally-added microplastics, p. 23; RAC Opinion, p. 40.

clear where the evidence was missing, where it was available but insufficient to conclude, or where it was likely to be available in the future. For example, they alerted ECHA that the recent project by ECHA and the European Commission to study the use of PFASs in fire-fighting foams might bring new evidence.²⁵ Transparently signalling uncertainties and information gaps like this is good practice; it shows that the available evidence has been rigorously assessed and weighed.

Recommendation

- **Build a plausible assessment.** The requirement to respect scientific excellence as defined by the EU Courts, which must guide the interpretation of what is “enough and adequate” evidence under REACH, requires neither an exhaustive collection of data nor the absence of uncertainties. The dossier submitter just needs to build a plausible assessment, meaning:
 - In a data-rich context, you can set aside evidence, especially when saturation is reached, as long as you signify that you are aware of it and explain why and how.
 - In a data-poor context, data of very variable quality/reliability may be integrated in the overall weight of evidence, as long as the selection, ranking and weighting method is coherent and explained.²⁶ Any new scientific or technical knowledge that feeds into this set of evidence, regardless of the document from which it comes, can be taken into account.²⁷
- **Bear in mind the rules of scientific excellence,**²⁸ and notably make sure:
 - The evidence is factually accurate, reliable and consistent,²⁹
 - The evidence contains the information needed to assess the complexity of the situation at stake,³⁰
 - The evidence is examined in a careful and impartial manner,³¹
 - You rely on the most recent results of international research,³²
 - You draw adequately reasoned conclusions,³³ notably by making sure there is a logic between your assessment of the evidence and the conclusions.

²⁵ Annex XV Restriction Report for intentionally-added microplastics, p. 41.

²⁶ Case T-636/17 *PlasticsEurope v European Chemicals Agency*, Paras 166-171.

²⁷ Case C-499/18 *Bayer CropScience AG and Bayer AG v European Commission*, Para. 69.

²⁸ Case T-13/99 *Pfizer Animal Health SA v Council of the European Union*, Paras. 159 and 172.

²⁹ Case T- 257/07 *France v. Commission*, Para. 87.

³⁰ Case C-405/07 P *Netherlands v Commission*, Para. 55.

³¹ Case C-269/90 *Hauptzollamt München-Mitte v Technische Universität München*, Para. 14.

³² Case C-236/01 *Monsanto Agricoltura Italia SpA and Others v Presidenza del Consiglio dei Ministri and Others*, Para. 113; and Case C-192/01 *Commission v. Denmark*, Para. 51.

³³ Case C-269/90 *Hauptzollamt München-Mitte v Technische Universität München*, Para. 14.

- **Describe the method used to select the scientific evidence in a data rich context.** In the microplastics' file, ECHA included a summary of the available literature, and the methods used to prioritise them and score their reliability. The description included by the French authorities in their Annex XV dossier on the restriction of BPA in thermal paper is a good example.³⁴

Challenge

Lesson 4: Be transparent on the methodology your assessment relies on

For a proposal to be credible, the method used to assess the risk, but also the conditions and impacts of a restriction must be explicit. Meaning, it must be clear how the data was collected, ranked and weighed. The methodology must fit the specificities of the case at stake (properties of the chemical, types of uses etc.) and follow the applicable guidance, if any, e.g. if it is a PBT or vPvB.³⁵ A restriction proposal can easily lose credibility if it is not accompanied by a thorough explanation of the method, why it was chosen, and why it is reliable.

Lesson learned

In the context of the microplastics restriction dossier, ECHA provided a thorough explanation of the methodology it relied upon - quantitative, semi-quantitative or qualitative - depending on the type of data available.³⁶ Regarding the risk-assessment in particular, ECHA described why conventional threshold-based risk assessment could not be carried out for microplastics, and therefore why it used a combination of threshold, non-threshold and 'case-by-case' approaches.³⁷

Conversely, in the PFHxA restriction dossier, the dossier submitter did not systematically provide an explanation of the methodology and assumptions it relied upon, for example, to derive emissions estimates. The lack of clarity on the method used can cast serious doubt on the reliability of a dossier's conclusions, as RAC underlined in its opinion on the PFHxA dossier.³⁸

³⁴ ANSES ANNEX XV Restriction Report Proposal for a Restriction 4.4' isopropylidenediphenol (bisphenol A; BPA). Section B.5.0 The choice of the studies for BPA risk assessment.

³⁵ SEAC paper "Evaluation of restriction reports and applications for authorisation for PBT and vPvB substances in SEAC (2016)": af4a7207-f7ad-4ef3-ac68-685f70ab2db3 (europa.eu).

³⁶ Annex XV Restriction report for intentionally-added microplastics, p.35.

³⁷ Annex XV Restriction report for intentionally-added microplastics, pp. 72-73.

³⁸ RAC Opinion on Annex XV Report for PFHxA, p. 27: "the methodology used to calculate quantitative releases of PFHxA, its salts and related substances is concluded to be unreliable due to: - insufficient justification provided for the choice of assumptions made when constructing the exposure scenarios (including unsubstantiated deviations from and over reliance on worst-case (rather than reasonable worst-case) assumptions; - significant gaps in the reporting of the underlying data and calculation methodology; and - numerous inconsistencies in reporting between different sections of the Background Document."

Recommendation

- **Describe what method of assessment you have relied on and justify why**, notably in the light of the guidance of ECHA regarding both risk-assessment and socio-economic analysis. The method should be applied consistently throughout the proposal. That is all the more important as the actors involved in the process may all be experts (dossier submitter, RAC and SEAC members etc.), but they may not have the same expertise, and hence the same methodological approach.

Lesson 5: Acknowledge, assess and characterise uncertainties

- **Identify and highlight the gaps and limitations - if any - in the data, assumptions or the methodology relied upon**, for example by including a sensitivity analysis.

Challenge

All restrictions come with uncertainties but, due to their large scope, broad restrictions might contain more uncertainties than narrower ones. This is not an obstacle in itself,³⁹ however major uncertainties can block the ECHA process, in particular when RAC characterises the risk or when SEAC conducts the proportionality assessment. Committee members have no dedicated guidance, nor common training on how to deal with uncertainties.

It is important for the dossier submitter to clarify early on where remaining uncertainties are, their nature and what they entail for the overall restriction, in order to make the ECHA Committees' work easier. Depending on the type and extent of uncertainties, the decision-maker may need to resort to the precautionary principle.

Lesson learned

In the microplastics and PFHxA restriction dossiers, authorities have worked on describing major uncertainties and reducing them as far as possible.⁴⁰ Notably, the microplastics dossier lays out in a precise manner remaining uncertainties in the hazard, exposure and risk assessments.⁴¹ Both dossiers described uncertainties concerning the costs and benefits of restricting the use of the substance, while showing that a restriction was still the most proportionate action. In the

³⁹ The ECHA guidance on SEA in restrictions (p.24) sets that uncertainties need to be "addressed", meaning there must be an effort put into "defining and documenting uncertainty and its boundaries", "describing assumptions clearly" and "explaining the actions taken to reduce uncertainty".

⁴⁰ See notably the effort by Germany to describe the multiple uncertainties as part of the sensitivity analysis (Annex XV report for PFHxA, p. 78).

⁴¹ Annex XV Report for intentionally-added microplastics, pp. 32-73.

microplastics restriction, the dossier explains that the probability that humans could be exposed, in the present or in the future, and the irreversibility of the pollution justify the restriction. This argument plays an important role in convincing RAC and SEAC to support restrictions relating to environmental hazards.

In the single-use diapers restrictions, industry stakeholders were able to manufacture doubt on the risk assessment, the source of the pollutants and the availability of alternatives to such an extent that led RAC to conclude that the risk was not sufficiently demonstrated. As a consequence, SEAC contended that a conclusion on proportionality could not be reached.⁴² Similarly, in the PFHxA case, since RAC raised uncertainties on the magnitude of the risk, SEAC refused to conclude on proportionality, due to the difficulty in measuring the environmental benefits of emission reduction.⁴³

Uncertainties are an inherent part of risk-assessment and, more generally, of scientific research. For that reason, the mere presence of gaps in the assessment should not be a motive for rejecting a restriction. Unfortunately, RAC and SEAC opinions do not tackle uncertainties consistently in their opinions on different restrictions or authorisations. Therefore, providing as much clarity as possible on the type of uncertainty and their implications may help avoid a negative opinion.

Recommendation

What we recommend is to **consistently acknowledge uncertainties throughout the dossier** in line with the recommendations of the Restriction Task Force⁴⁴ and the Court's most recent case-law,⁴⁵ notably by:

- **Identifying gaps in the analysis**, i.e. determine what is not known and its implications. This will enable ECHA Committees to understand what level of evidence is missing and whether it is possible to solve the uncertainty within a reasonable timeframe.
- **Characterising the type and level of uncertainty.**⁴⁶ For example, the dossier submitter could distinguish between data gaps, ambiguous or contested data and true uncertainties linked to the complexity of the matter. Dossier submitters need to be precise on what these uncertainties relate to, whether they are minor or major, and how they were taken into account without threatening the plausibility of the conclusion that an unacceptable risk exists. Making this clear will facilitate the work by RAC and SEAC and give authorities the means to

⁴² SEAC Draft Opinion on substances in single-use baby diapers, p. 45.

⁴³ SEAC Draft Opinion on Annex XV Report for PFHxA, p. 59.

⁴⁴ 'Description of uncertainties in the evaluation of restriction proposals' RTF document (Dec. 2020) [0472008c-62c9-7b82-c71e-1bf318891c39](https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:0472008c-62c9-7b82-c71e-1bf318891c39) (europa.eu).

⁴⁵ Case C-389/19 European Commission v Kingdom of Sweden, in particular Para. 35.

⁴⁶ By referring for example to the work done by the European Environment Agency (EEA) in its report "Late lessons from early warnings".

defend the dossier in case uncertainties are considered by ECHA Committees to affect the overall proportionality of the restriction.

Lesson 6: Define the scope as precisely as possible

- Where uncertainties are linked to ranges of values such as confidence intervals, **conducting a sensitivity analysis after the assessment may be useful**, to account for more and less plausible outcomes.
- **Reaching out to ECHA or stakeholders for supplementary information** or expertise when big data gaps persist.
- **Asking for a precautionary approach when major uncertainties remain**, but where the existing evidence shows that a risk of serious or irreversible harm cannot be ruled out. This could help support the proportionality of the measure. To resort to the precautionary principle, the risk may not be merely hypothetical. Depending on the level of evidence, it may be sufficient to resort to the preventive approach. For example, when the existing evidence shows there is a need to prevent exposure.⁴⁷

How to handle the broad scope

Challenge

Broad scopes are indispensable, but politically sensitive. It is imperative to be explicit on what they include, and what they do not include.

Lesson learned

The broad scope of the microplastics restriction - all intentionally-added microplastics, across uses and polymers - set a crucial precedent.⁴⁸ Because the scope is all-encompassing, it was immediately criticised by industry stakeholders for being disproportionate to the objective. For example, that triggered discussions on how to define a “microplastic”, and what polymers it should include. Industry stakeholders notably suggested that soluble or ‘natural’ polymers deserve to be excluded from that definition.⁴⁹

⁴⁷ Case T-392/02 Solvay Pharmaceuticals v Council [2003] ECR II-4555, paragraph 129

⁴⁸ RAC Opinion on Annex XV Report for intentionally-added microplastics, p.7.

⁴⁹ RAC made the discussion on scope definition explicit in its opinion (Combined RAC and SEAC Opinion on the Annex XV Report for intentionally-added microplastics, p. 15): “RAC notes that the scope of the restriction is set by several sets of criteria which may require careful interpretation in some cases to decide if a particular polymer is in or outside of the scope of the proposed restriction (e.g. biopolymers, swellable polymers, soluble polymers)”.

The more precisely authorities explain the scope of the restriction (e.g. by being clear that “all uses” are by default included), the better equipped they will be to answer any questions raised during the development of ECHA’s scientific opinion. A good practice - adopted by ECHA in the microplastics dossier - was to conduct a detailed market analysis which included an identification of potential novel uses. That way, industry may not ask for derogations after the restriction has entered into force.

Recommendation

- **Avoid any doubt on what is covered** by the restriction. The main scope, regarding the substances included, e.g. “PFHxA, its salts and related substances”, and uses, should be sufficiently defined and clear.

Challenge

The EU States have the right - and one could even argue the obligation⁵⁰ - to propose very broad restrictions when justified. It is good practice to anticipate the critiques that will inevitably arise by giving explicit and detailed reasoning as to why they are needed.

The more substances and uses are in scope, the greater the impacts on the respective industries. How to justify the proportionality of such measures, especially when a grave risk exists but is not well characterised, is politically sensitive. In this case, the need to take action requires authorities to clearly explain why the risk is unacceptable, looking at identified political and societal objectives, such as the need to anticipate the risk of irreversible pollution or to protect a vulnerable part of the population.

Lesson learned

Lesson 7: Make explicit why a broad restriction is the most proportionate option.

In previous broad restrictions, various arguments have been brought forward to justify the unacceptability of a risk.

Establishing the seriousness and irreversibility of the potential damage to health or the environment, as Germany and ECHA did in their respective dossiers,⁵¹ is key to demonstrate that

⁵⁰ In its report on the duty to prevent exposure, the Special Rapporteur on human rights and hazardous substances and wastes (toxics) explains the State's duty to prevent exposure to toxics. See here: OHCHR | Report on duty to prevent exposure.

⁵¹ Annex XV Report for PFHxA, p. 77; Annex XV Report for intentionally added microplastics, p. 132.

the risk is unacceptable, hence the restriction is the most appropriate regulatory option. Moreover, it is important to report on the societal benefits of the restriction, for example by explaining how it will encourage the development of existing alternatives, or how it responds to a societal imperative recognised at the political level.⁵² Both Germany and ECHA used a qualitative argument to show that the restriction was the most cost-effective option, looking at the objective of pollution reduction. ECHA argued that the restriction would significantly reduce (i.e. by 85%-95%) environmental pollution of microplastic emissions from intentional uses each year.⁵³ Both dossiers also mentioned the possibility to set up transitional arrangements, to offset the impact of the restrictions on companies who need time for product reformulation.⁵⁴

These practices have helped justify the appropriateness of the inclusive scope, and therefore the proportionality of the restriction.

Recommendation

- **Emphasise the seriousness (e.g. irreversibility) of the potential harm.** If particularly vulnerable parts of the environment or the population are likely to be affected, use it as a further argument to justify taking action.
- **If you cannot quantify the benefits of the restriction, provide a qualitative assessment, looking at broad political objectives.** E.g. in the context of the European Green Deal, or legal provisions pointing to a societal willingness to pay for the restriction.
- When it is justified and in the absence of available alternatives, mention the possibility to set up **transitional periods** for the industry affected.
- Based on your assessment of the seriousness of the potential risk, **explicitly refer to the prevention principle** enshrined in the EU Treaties⁵⁵ to highlight to the Commission the need to take action, even if it entails immediate costs for society. Member States should also feel comfortable **referring to the precautionary principle**, which requires policy makers to take action to protect the environment and human health when a grave risk cannot be ruled out,

⁵² Annex XV report for PFHxA, p. 76.

⁵³ Annex XV Report for intentionally-added microplastics, p. 129.

⁵⁴ Annex XV Report for PFHxA, p. 79, Annex Report for intentionally-added microplastics, p. 95.

⁵⁵ Article 191 TFEU.

even in the face of uncertainty.⁵⁶ It is important to note that public authorities even have a human rights obligation to protect from exposure.⁵⁷

What is an acceptable derogation?

Challenge

Because broad scopes are all encompassing and politically sensitive, they may require the inclusion of exceptions - transition periods, derogations. The difficulty is to ensure that the exceptions are sufficiently precise to avoid unforeseen or important uses to unduly escape the ban because they are too broad, leave too much to interpretation or are unjustified.

Lesson 8: Set time-limited and precisely defined exceptions

REACH's main objective is the protection of health and the environment,⁵⁸ which REACH restrictions must meet by ending unacceptable risk. Exceptions may be allowed only when they do not undermine this goal.

Lesson learned

The European Commission has been sanctioned in the past for granting unjustified exemptions to the restriction of hazardous chemicals.⁵⁹ Therefore, before proposing easing restrictions for some uses, authorities must make sure it is necessary and legitimate in the light of the goal pursued. In particular, they must only consider longer transition when:

- The functional use of the substance is critical for the end-use;
- There is no alternative immediately available to that substance; and
- The risk is minimised, so that the exception does not undermine the purpose of the overall restriction.

⁵⁶ See joined cases T-125/96 Boehringer Ingelheim Vetmedica and C.H. Boehringer Sohn v. Council and T-152/96 Boehringer Ingelheim Vetmedica and C.H. Boehringer Sohn v. Commission, Para.73.

⁵⁷ See Report of Special Rapporteur on human rights and hazardous substances and wastes on the duty to prevent exposure (Op. Cit. p. 10).

⁵⁸ The Court held on several occasions that when interpreting a provision of EU law, it is necessary to consider not only its wording, but also the context in which it occurs and the objectives pursued by the rules of which it is part: Case C-156/98 Germany v Commission Para. 50, and Case C-306/05 SGAE Para. 34.

⁵⁹ Joined cases C-14/06 and C-295/06 EP v. Commission regarding Directive 2002/95, Para. 52.

In line with the duty to state reasons,⁶⁰ authorities must always justify why an exception to the main regime is warranted in a clear and unequivocal manner. That means they must bring verifiable evidence that will back up their conclusion.

The restriction dossier for microplastics included significant exemptions to the scope of the restriction, e.g. for nanoplastics, solubles or biodegradable polymers, as well as derogations to the main ban, notably for granules in sport pitches. The problem is that the ECHA proposal did not sufficiently prove that the proposed derogations were indispensable. It is unclear, for example, why microplastics that are added to menstrual products and nappies, should benefit from an exemption.⁶¹

Germany also proposed derogations for uses even when the substances are not critical to the end-use or when alternatives had been proven to be available, e.g. for certain types of personal protective equipment or fire-fighting foams.⁶² A broad derogation for 'medical uses' as a whole was proposed, without much of a rationale.

Recommendation

- **Ensure that the scope of any derogation, transition or exception is sufficiently precise, well-defined and future-proof.** Setting an exception in an imprecise way is dangerous because it might lead companies to eventually interpret what uses can fall under the exception in their favour.
- **Explain why it is legitimate and necessary to include this exception.** Bring verifiable and reliable evidence to support it. If you decide to set broad derogations, make sure it does not undermine the overall objective of the restriction, i.e. minimising the impact of a chemical on health or the environment. This also means assuring that the quantities and emissions associated with them are known - a precondition to accept the derogations.
- **Do not grant an exception when the use is not critical or essential.**
- **Avoid free-way exemptions that may undermine the effectiveness of the restriction.** Any exemption should ensure that companies that continue using the hazardous chemicals implement risk management measures, monitor and report to authorities uses and emissions, and label any article containing the chemicals.

⁶⁰ Case C-265/97 P VBA v Florimex and Others, Para. 93; see also Case T-13/99 Pfizer Para. 510.

⁶¹ See for more information Rethink Plastic Alliance, "Phasing out the use of Microplastics" report (2021). [Phasing out the use of microplastics \(eeb.org\)](#).

⁶² Annex XV Report for PFHxA, p. 54: "At the Stakeholder Workshop on firefighting foam (24.09.2019, Helsinki) several experts confirmed that alternatives are available for critical applications, like for example for aviation. The Dossier Submitter is aware of two EU members, where the defence sector shifted to FFF: Denmark and Norway (IPEN 2018). The Dossier Submitter was informed by the fire-fighting services of the Royal Danish Airforce that alternatives were available to them on short notice and that extinguishing of JP-8 fuel (which is used by defence sector) is possible."

Lesson 9: Be aware of the documents guiding the Committees'

3. How to effectively defend your proposal

Challenge

The restriction dossier is not the only source of information ECHA relies upon to deliver its opinion. A plethora of working documents⁶³ and external contributions inform the work of the Committees throughout the restriction process. This can render the opinion process confusing and opaque for the dossier submitter.

Lesson learned

The ECHA guidance informing the restriction process provides a set of guiding principles to be applied by dossier submitters, but also by the Committees. For example, it lays down practical rules to deal with uncertainties in socio-economic analysis, rules that were not consistently applied by the SEAC Committee in its assessment of the derogations to the ban of PFHxA. The more familiar authorities are with the content of the guidance, the more comfortable they can be referring to it and reminding the Committees of their obligations each time it is necessary and relevant.

Another important lesson from the PFHxA, microplastics and substances in baby diapers restrictions is the influence of the contributions of external stakeholders on the Committees' opinion-making. This can be during the public consultations and calls for evidence or specific ad-hoc meetings organised by ECHA. Many of the derogations that were introduced by the Committees during the PFHxA opinion development were proposed by industry stakeholders through the various consultations.⁶⁴ Being aware of these contributions is key to defending the dossier and reacting to potentially unjustified amendment proposals, such as derogations.

⁶³ All the relevant documentation with related links is listed on the ECHA website: [How to prepare an Annex XV report - ECHA \(europa.eu\)](#).

⁶⁴ For instance, industry stakeholders requested during the consultation that the manufacture of concentrated firefighting foam mixtures be included in the derogation for firefighting foam concentrates (comments 3031, 3102, 3146). See for other derogations: SEAC Draft Opinion on Annex XV Report for PFHxA.

Lesson 10: Voice your position during Committee meetings

Recommendation

- It is good to **be familiar with the main documents that guide the Committees' work**. The broad Guidance for the preparation of an Annex XV dossier for restrictions⁶⁵ and the Guidance on SEA in restriction⁶⁶ are particularly important.
- **Ask ECHA to send, as soon as the public consultation is over, a summary of the contributions and questions**. Be sure to prepare a reaction to the input that may discredit or weaken your dossier's main assumptions or conclusions. You may need to provide additional information - be prepared for this.

Challenge

It can be discouraging to stand up in a committee of EU experts, to which representatives of multiple interest groups who are eager to push for their position take part. Being familiar with the Committees' working rules and functioning is also a challenge but it is nevertheless necessary for effectively influencing the discussions. Detailed discussions on restrictions are increasingly happening in restrained settings (RAC restriction working group, SEAC ad hoc meetings), the functioning of which remains to be defined. In particular, the role and rights of the dossier submitter in those groups is unclear.

Member States should recall that they have the right to defend their dossier during the Committee and smaller group sessions, and the potential impact of exercising that right should not be underestimated. They also have a right to ensure that the procedure and allocation of powers are complied with.

Lesson learned

In the context of the microplastics file, ECHA took a proactive role as a dossier submitter by actively participating in the Committees' discussions and organising information sessions for the members ahead of the plenary (e.g. concerning biodegradability tests). Many experts attended, which helped trigger RAC's supportive opinion. In comparison, Germany was much less involved in the defence of the PFHxA dossier, which undeniably allowed the ECHA Committees a broad level of discretion in interpreting the data. It also gave industry stakeholders a large window of

⁶⁵ RDDS - Batch Process 0.9 (europa.eu).

⁶⁶ RDDS - Batch Process 0.9 (europa.eu).

opportunity to actively defend the need for more derogations, without sufficient evidence to justify it.

The representatives of national authorities should not hesitate to make their voices heard, especially when confronted with procedural breaches which are likely to significantly affect the quality of the Committees' opinion. For both the PFHxA and microplastics restrictions, derogations were added after the public consultation, based on vague data submitted by some of the stakeholders, or without a clear assessment by both the Committees.⁶⁷ In the context of the microplastics restriction, a derogation for carbon-free polymers was added by SEAC without first being reviewed by RAC, which is clearly in breach of REACH.⁶⁸

Lesson 11: Make sure the restriction is legally sound

Recommendation

- Be sure to **understand how ECHA Committees and their respective working groups work before the process starts**. Notably, ask the RAC and SEAC chairs to see and review the conclusions of the restriction working group or any ad-hoc group before they go to the plenary.
- **Don't hesitate to oppose unjustified derogations and irregularities in the process** directly at the meeting or after, by reaching out directly to the chairs or the ECHA secretariat. If necessary, you could get legal assistance to make sure your concern is founded.
- **Reach out to independent experts** who can attend and intervene during the ECHA Committee meetings by your side. A commanding speaker from the States services, assisted by independent experts who can scientifically support your conclusions, are uniquely placed to clarify parts of the dossier and refute late or abusive requests from the industry.

Challenge

A broad scope multiplies the number of actors and sectors that will mobilise against the disruption of business as usual. From this mobilisation comes a heavier political pressure, and higher risk of

⁶⁷ For example, SEAC considered that the PFHxA related substances on face shields used in medical settings may merit the same considerations as personal protective equipment and, hence, be derogated. However, the RCOM compilation provides no hints to the existence of a request for this derogation. It is difficult to understand on what basis SEAC considered this application for a derogation, as no analysis of alternatives has been conducted.

⁶⁸ See Final RAC-SEAC Opinion on the microplastics restriction, p. 101. The risks associated with carbon-free polymers had not been assessed by RAC before the derogation was introduced by SEAC in its final draft opinion on the microplastics restriction.

legal challenge down the line. In practice, the review of the Court - checking only manifest errors - limits the judicial risk of a challenge. However, a rigorous legal approach and attention to the enforceability of the restriction help avoid some political debates.

Lesson learned

It is essential to secure, as much as possible, the legal basis on which the restriction is based. Good lessons can be learned from the PFHxA and microplastics restrictions in that respect: the dossier submitters used a flexible case-by-case approach to risk assessment, based on paragraph 0.10 of REACH Annex I. That is particularly appropriate in cases where the hazard properties of the restricted substance are complex and in many instances uncertain, so that conventional threshold-based risk assessment cannot be carried out. Both dossiers provided a detailed explanation of the reasons for choosing this flexible legal approach.⁶⁹

The Forum may also be called upon to give an advice on specific enforcement issues related to the restriction proposal during the opinion making process.⁷⁰ That request for advice is not systematic, but when it is requested, it is taken very seriously by the ECHA committees, as the opinion of SEAC on the microplastics' restriction shows. It is possible to anticipate possible enforcement problems, by being in touch with enforcement authorities early on but also by asking for the Forum's help during the preparation of the dossier.⁷¹

Recommendation

- **Involve legal experts throughout the restriction process**, including early on before drafting and submitting your proposal. Legal experts can help authorities make sure their assessment follows the rules of the most recent case-law. Although EU judges aim to exercise limited judicial review on a risk assessment, in practice they do not hesitate to look into the details of the supporting evidence.⁷²
- **Ask for enforcement authorities or the Forum's support** during the preparation of your dossier, to address potential enforceability questions later on.

⁶⁹ Annex XV Report for intentionally-added microplastics, p. 70.

⁷⁰ Based on Article 77(4)(h) of REACH.

⁷¹ In line with the Forum guide on enforcement for dossier submitters, see p. 4.

⁷² See analysis of the scientific evidence by the Court in Case T-636/17.

- **Make sure your dossier is litigation proof** by relying on creative legal approaches that would make it difficult for industry to challenge the restriction in court.

Challenge

Doing a great job as a dossier submitter might not be enough to secure the adoption of a restriction. The assessment of its credibility and necessity by other actors in the following stages of the process matter. The problem is that both ECHA and the Commission might not be prepared to handle broad restrictions, in particular considering the many associated uncertainties. Therefore, changes are needed from ECHA and the Commission for broad restrictions to succeed.

Lesson 12: Secure political support early on

Lesson learned

First, ECHA is reluctant to endorse a precautionary approach to risk-assessment. The opinion of RAC on ANSES' dossier regarding single-use diapers, or the SEAC conclusions on the PFHxA restriction show that the Committees are not always adequately equipped to process uncertainties inherent to restriction proposals.

Second, the Commission tends to heavily rely on the opinions of RAC and SEAC when drafting its proposals. So even the most well-prepared restriction dossier might not convince the Commission that the risk is unacceptable, especially if ECHA issued negative opinions, or raised uncertainties regarding the risk or the socio-economic impacts of the restriction.

Recommendation

- **Defend your proposal at the ECHA committee level, but also ask your Ministry to support the restriction at a more political level.** The Commission set important objectives for itself - in particular in the context of the Chemicals Strategy for Sustainability - so it is expected to act upon those. National authorities therefore have the legitimacy and power to call upon the Commission to address chemicals of concern, even when ECHA is reluctant to support regulatory action.