10 REACH Tests for ECHA

Performance assessment on implementation of REACH Regulation in 2020

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Introduction

This is an assessment of the European Chemicals Agency (ECHA) by the European Environmental Bureau (EEB), the largest network of environmental citizens' organisations in Europe.
Our mandate encompasses all environment-related issues, a broad agenda comprising 'traditional' environmental issues as well as sectoral and horizontal policies with a direct or potential environmental impact, sustainable development and participatory democracy. The Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation n° 1907/2006 is the EU flagship regulation on chemicals. It is based on key EU democratic and environmental principles that need to be implemented in order to ensure that human health and the environment are protected against the risks posed by hazardous chemicals. The ECHA is responsible for the management and the technical, scientific and administrative aspects of REACH. We appreciate that ECHA cannot make decisions on its own. Nonetheless, the agency can still have considerable impact and influence on chemicals control in Europe, for example through the priority and profile it gives to specific chemicals and through the way in which it chairs discussions and develops opinions. This test aims to measure progress on and improve the implementation of REACH by enhancing ECHA's adherence to REACH's underlying principles, such as the precautionary principle, the allocation of the burden of proof on industry that substances do not adversely affect health or the environment, upholding the 'no data, no market' rule, substitution to safer substance or technology and transparency. Our assessment is based on the ECHA 10 Tests we presented to ECHA in March 2020. The EEB challenged ECHA with the following ten activities to be performed in 2020. We consider the delivery of these activities as indicators of ECHA's commitment towards implementing REACH's underlying democratic and environmental principles. Success depends on many factors, often highly affected by external events and Commission priorities. Our assessment therefore focuses both on effort and result. During this process, the EEB has opened a cooperative dialogue with ECHA to discuss its performance. We would like to acknowledge and express our appreciation to the agency for its openness to a frank and open exchange of views during the exercise.

10 REACH tests for ECHA

'Good on improving transparency, but disappointing on application of the precautionary principle and very poor on socio-economic assessments'

ECHA has made good progress to improve the transparency of the decision making processes of its committees and to improve the transparency and user friendliness of its online database on registered substances containing hazard, exposure and regulatory information of chemicals.

ECHA assessments of socio-economic impacts remain the chief hurdle to progress. ECHA should make efforts to improve, for example, how it estimates benefits to society of banning hazardous chemicals, how it assesses safer alternatives and the ability of the market to adapt to changes and innovation. ECHA should stop supporting unjustified exemptions to restrictions of chemicals and taking industry arguments on the need to continue using these chemicals at face-value, undermining the protection of human health and the environment for the benefit of commercial interests.

We regret that the application of the precautionary principle is not a priority for the agency. This principle is a crucial instrument for EU institutions to protect health and the environment from exposure to harmful substances. The agency should improve its committee members' understanding of their role in the implementation of the precautionary principle. ECHA should also prioritize its activities to support the substitution of hazardous chemicals.

Ten REACH Tests	Effort	Outcome
INCREASE TRANSPARENCY AND IMPROVE DISSEMINATION		
1. Ensure transparency of ECHA committees.		
2. Ensure the transparency and user-friendliness of ECHA databases.		
APPLY THE PRECAUTIONARY PRINCIPLE		
3. Develop guidance and organise a workshop.		
ALLOCATE BURDEN OF PROOF TO INDUSTRY		
4. Commission an independent evaluation of ECHA's socio-economic assessment methodology.		
5. Develop guidance on the minimum information requirements needed to justify granting derogations to restrictions.		
6. Final opinions of ECHA committees on restrictions transparently highlight the changes to the dossier submitter's original proposal and their justification.		
ENHANCE SUBSTITUTION		
7. Co-organise two supply-chain workshops per year on alternatives to Annex XIV or candidate list substances.		
8. ECHA committees opinion templates for applications for authorisation include the possibility to recommend not granting an authorisation.		
9. ECHA requires systematic proof from the applicant that it contacted existing alternative providers and reports from the discussion on the feasibility of the alternatives.		
10. Stop granting derogations for use of substances of concern in recycled materials without having assessed the whole lifecycle of materials such as plastic, including the post-recycling phase.		

Legend

Good 

Mixed

Poor 

Increase transparency and improve dissemination

1. *Ensure transparency of ECHA committee meetings*

The verdict

Effort:  Outcome: 

Transparency of decision-making is essential to guarantee public access to information and public participation in decision making, legal principles guaranteed by the Aarhus Regulation n° 1367/2006. Accountability, public awareness and support for the decisions taken cannot be ensured if ECHA committee documents are not accessible in a timely manner to observers, including civil society. The tests proposed under this section aim to effectively guarantee transparency to ensure the implementation of these principles.

Ensure all documents subject to discussion at all ECHA committee meetings are available to participating stakeholders at least one week in advance.

The verdict

Effort:  Outcome: 

ECHA has improved its procedures and during 2020 documents have, in general, been shared in advance of discussions, although for some meetings, crucial documents were not made available. For example, committee members and stakeholders did not have advanced access to the documents for the discussion at SEAC's June 2020 meeting on how this committee should assess, under the REACH authorisation process, the suitability of alternatives that are generally available.

Allow civil society stakeholders access to advanced information, participation and reporting of any workshops or training sessions organised for ECHA committee members as well as industry-ECHA dialogues.

The verdict

Effort:  Outcome: 

During 2020, no workshops were organised by ECHA for committee members. ECHA has continued to organise bilateral discussions with industry, for example on grouping of polymers for registration. In addition, ECHA has expressed the position that some meetings, such as member state workshops, should remain closed to stakeholders. Although stakeholders can contribute to these processes via public consultations and observe the decision-making process in the committees, the EEB believes this practice is insufficient since, in our view, by not granting the same level of knowledge to all actors, ECHA hampers the public participation in the decision making process. Nevertheless, the EEB and ECHA agree that the Covid-19 constraints offer opportunities to facilitate virtual meetings and to institutionalise a process that would guarantee a more balanced representation of civil society organisations, for instance.

Ensure advanced access to documents subject to written procedures, so far accessible by members of the Member State Committee only.

The verdict

Effort:  Outcome: 

Observers do not have access to documents that are processed by written procedure in advance of MSC meetings. By contrast, the Commission's CARACAL guarantees more transparency. Although ECHA improved the briefings to stakeholders on closed processes, meetings behind closed doors do not enable accountability on voting positions. The EEB believes this practice is intransparent.

2. Ensure the transparency and user-friendliness of ECHA databases

The EEB believes that publicly accessible online tools improve public access to information and public participation in decision making, accountability and public awareness. ECHA databases are useful tools, particularly for downstream users of chemicals and civil society, to improve access to health and environmental information. The tests of this section aim at improving the accessibility and completeness of the information related to ECHA's online database on registered substances.

Include a clear and short explanation note in the front page of ECHA's registered substances database explaining that the data is provided by industry, not by ECHA or any scientific body or public authority. Make clear that the industry is responsible for the reliability of the data.

The verdict

Effort:  Outcome: 

The front page of the registration section now clarifies that the information is provided by industry.

Develop a proposal on how to ensure ECHA's registered substances database better reflects the results of dossier and substance evaluation with regard to the compliance and evaluation status of the dossiers. For example, dossier has been checked for compliance [X,Y,Z endpoints]; dossier has been found incompliant and when this is the case, reasons/concerns found and follow-up actions mandated, etc.

The verdict

Effort:  Outcome: 

ECHA's goals for continual improvement in transparency for 2021-2022 include the improvement of navigation between different parts of this database, as well as clearer indication and granularity of the dossier/substance evaluation status. ECHA told the EEB that

improvements are in progress.

Initiate a two-year stepwise approach to improve transparency of ECHA dossier evaluation status pages and substance evaluation - CoRAP pages as suggested in EEB's Substance Evaluation report (2019). For example: Specify whether "Follow-up" means follow-up evaluation by ECHA or follow-up by a national enforcement authority; Add explanatory notes on the different categories under "status" for substance evaluation (as already included on dossier evaluation); Add outcome of substance evaluation (further risk management needed or not); State explicitly if dossier was found non-compliant and on what grounds; stop redacting the names of the companies ECHA finds in non-compliance with registration obligations; Add outcome of Board of Appeal decisions, as well as the follow up delivered or intended by ECHA.

The verdict

Effort:  Outcome: 

Improvements have been made to dossier evaluation status, for example by including status of cases in front of the Board of Appeal. But these improvements are not yet included on the webpage on substance evaluation (see the CoRAP webpage). The publication of the dissemination roadmap by ECHA should further address these demands.

Publish tonnage bands for all substances for each company.

The verdict

Effort:  Outcome: 

ECHA promised to consider this issue as part of the implementation of the future Dissemination Roadmap, but without a clear commitment to transparency that should have been given for this information required by civil society and investors alike for too long.

Initiate the process to publish all exposure scenarios by 2021.

The verdict

Effort:  Outcome: 

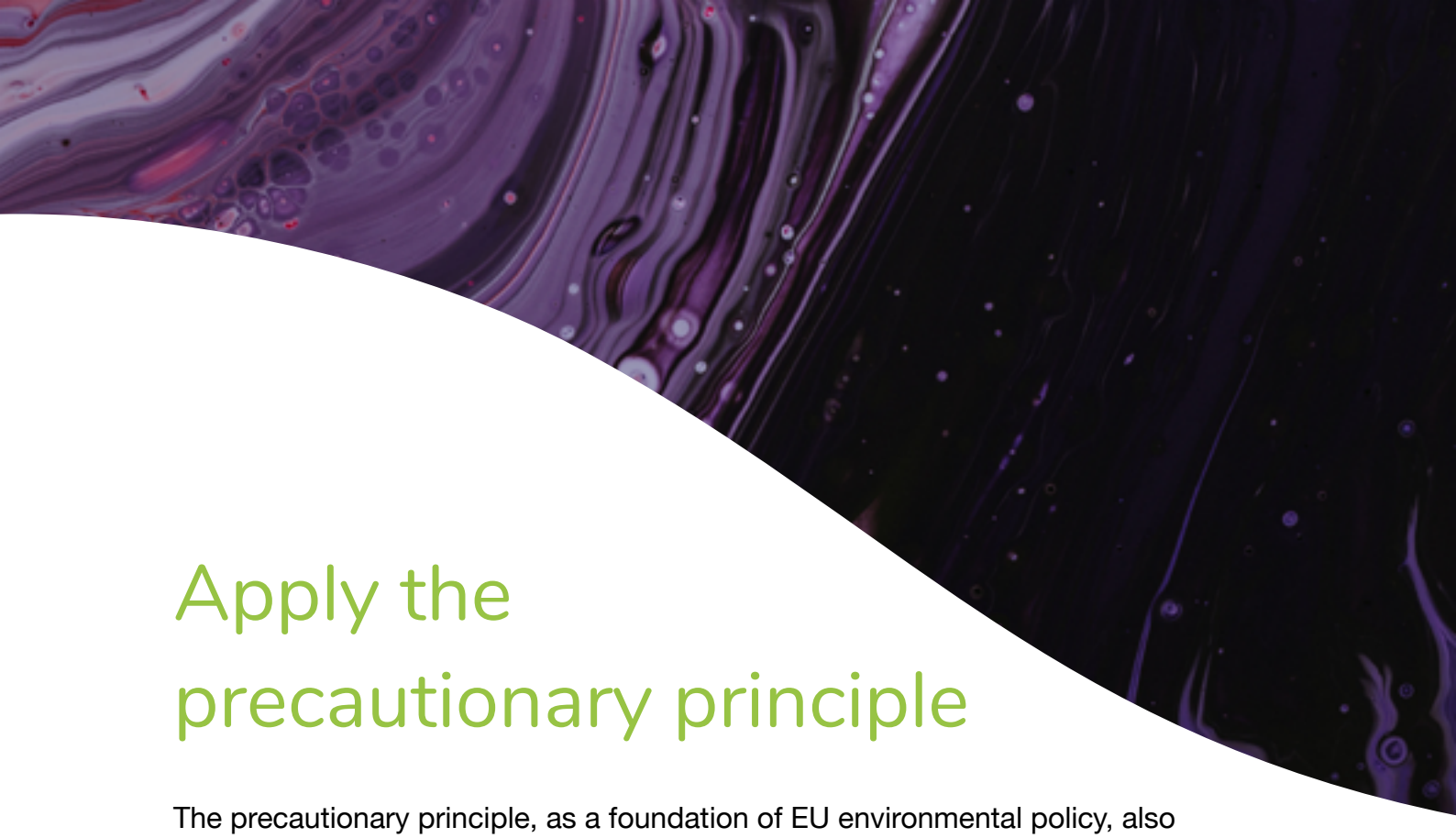
ECHA has started to work on the issue. Exposure scenarios are part of the Chemical Safety Report, which have been provided in different formats and pose technical problems for their publication.

Ensure that the SCIP database under development allows easy and free public access by 2021.

The verdict

Effort:  Outcome: 

ECHA has intensified efforts to raise awareness on compliance to legal requirements arising from the creation of the database. It also ensured that despite industry opposition to the database, it launched on time. The database has been running since 5 January 2021 for companies. Consumer access is being developed, but delays are expected. The EEB notes however that ECHA is committed to creating a useful tool for the public and making it publicly accessible.



Apply the precautionary principle

The precautionary principle, as a foundation of EU environmental policy, also underpins the REACH Regulation. It is a crucial instrument for EU institutions to protect health and the environment from exposure to harmful substances. The 2018 REACH REFIT Evaluation found that the principle had not been applied under REACH so far as ECHA opinions did not trigger the application of the principle. As a first step, the test in this section aimed at improving committee members' understanding of their role in the implementation of the precautionary principle beyond the development of a guideline; the organisation of an event seemed most appropriate for this purpose.

3. Develop guidance and organise a workshop for MSC, RAC and SEAC *(or each individually) on how the committees shall reflect uncertainties, time to generate missing information and with cost of inaction in their opinions. This will enable the Commission to apply the precautionary principle.*

The verdict

Effort:  Outcome: 

Following the Commission's request in the REACH REFIT Review Action 10, ECHA has improved how uncertainties are reflected in the RAC and SEAC opinions. However, ECHA has not organised a workshop or provided guidance to improve the committee's understanding of the precautionary principle and its role in its implementation (to reflect in their opinions the uncertainties, time needed to generate missing information and cost of inaction). The REACH Review should have prompted ECHA to develop ambitious proposals to implement the precautionary principle. The development of the Chemicals Strategy for Sustainability should now be the spur to meaningful progress.

Allocate the burden of proof to industry

REACH requires companies to ensure that their substances do not adversely affect health or the environment. The burden of proof is on them, at their cost. The assessment by ECHA of the socio-economic impacts of regulatory measures has suffered criticism over the past few years, as it does not systematically place the burden to prove products are safe on industry. Industry arguments are taken at face-value, harmful and long-term effects of chemicals on human health and the environment are undermined for the benefit of companies, weakly justified derogations to restrictions are granted, etc. This reverses the burden of proof to institutions, and offloads a heavy chemical burden on society and the environment as well as costing taxpayer billions in health care and environmental remediation costs. The tests proposed under this section aim to ensure that ECHA upholds allocating the burden of proof of safety to industry.

4. Commission an independent evaluation of ECHA's socio-economic assessment methodology *to address the concerns raised by the reports "Lost at SEA" by ChemSec and "Discounting Future Damage" by CHEM Trust regarding how benefits to society were underestimated, impacts on alternative providers and on innovation to safer chemicals dismissed, handling of data claimed confidential by industry, and methods for reporting on and judging scientific uncertainty, among others.*

The verdict

Effort:  Outcome: 

ECHA considers that it has already implemented the NGO recommendations as much as possible and does not see what an independent study of the SEA methodology would bring. ECHA has partially improved the assessment of costs and benefits of restrictions (e.g avoiding monetisation and aggregation of impacts where there is only partial quantification and a high level of uncertainty over some impacts). However, the main NGO criticisms remain. For example, ECHA does not include the impact on alternative providers and competitors of the outcome of the authorisation decision. In its authorisation decisions, ECHA

continues comparing imperfectly calculated aggregated health and environment costs with claimed economic benefits, resulting in very high costs for the company and low benefits for society from banning chemicals.

5. Develop guidance on the minimum information requirements needed to justify granting derogations to restrictions *and ensure that no derogation is accepted when registration dossiers are not compliant or are updated, equivalent to information required for applications for authorisation.*

The verdict

Effort:  Outcome: 

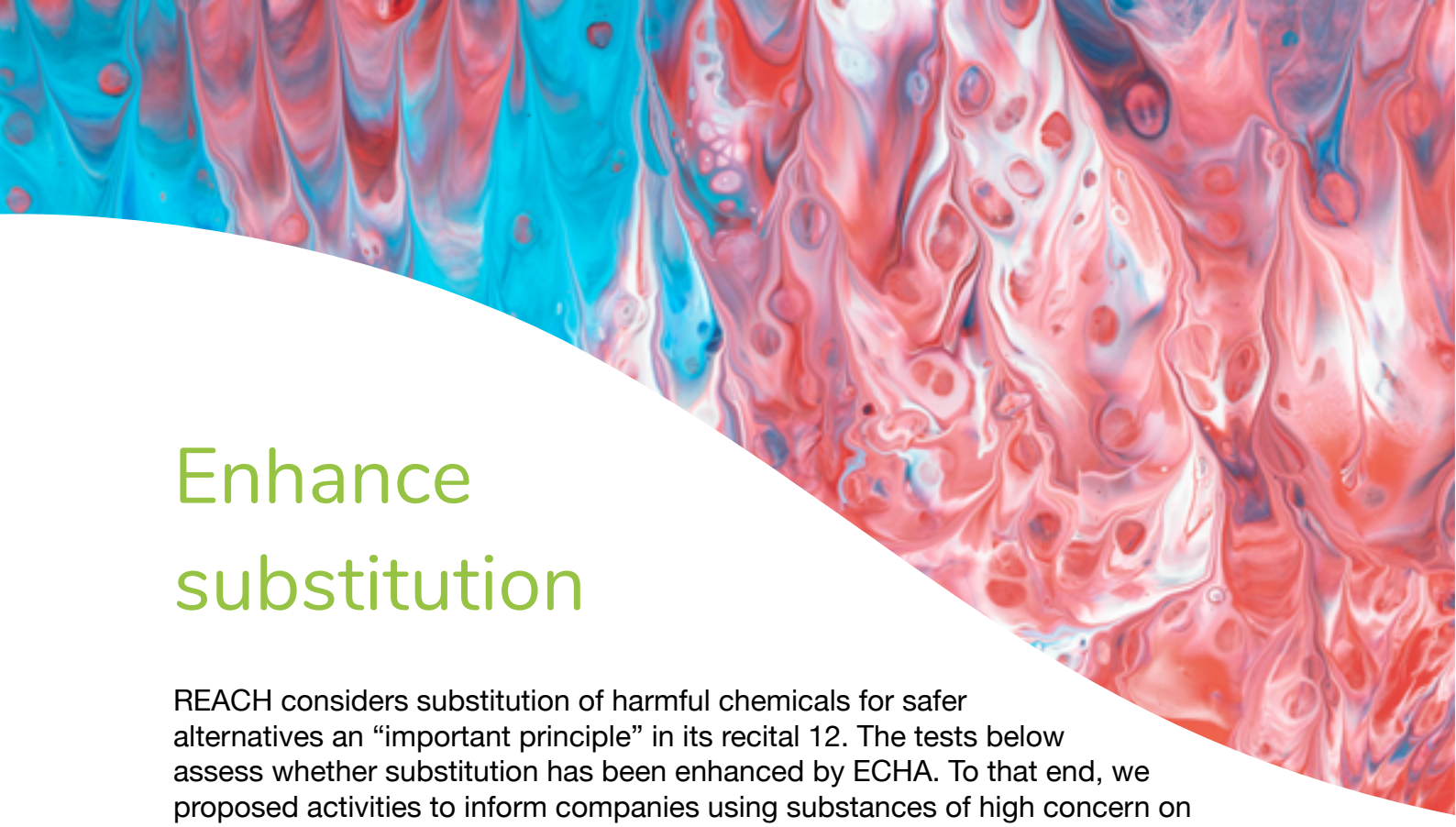
ECHA has published the minimum information that stakeholders requesting derogations should provide. Despite this, ECHA committees have continued to recommend derogations to restrictions, for example for microplastics and PFHxS, without precise, legitimate and verifiable justification as required under REACH Art. 68 and 69.

6. Ensure final ECHA committee restriction opinions highlight any changes to the dossier submitter's original proposal and the justifications for these changes, *and ensure that they include information on the impacts to health and/or the environment of the proposed derogations, costs of inaction and justifications of the committees for supporting these derogations.*

The verdict

Effort:  Outcome: 

Committee opinions on the PFHxS and microplastic restrictions, for example, better reflect changes made to the dossier submitter's proposal. However, they still lack information on the impacts to health and the environment of the proposed derogations to these restrictions, as well as on the costs of inaction.



Enhance substitution

REACH considers substitution of harmful chemicals for safer alternatives an “important principle” in its recital 12. The tests below assess whether substitution has been enhanced by ECHA. To that end, we proposed activities to inform companies using substances of high concern on available alternatives; precise and accessible changes to templates used by ECHA for authorisation opinions; not to take the arguments of applicants on lack of alternatives at face value; and stop proposing and supporting the use of substances of concern in recycled materials.

7. Co-organise two supply chain workshops per year on alternatives to *Annex XIV or candidate list substances in order to inform potential applicants of authorisation about substitution possibilities and network with alternative providers.*

The verdict

Effort:  Outcome: 

ECHA’s effort is considered poor as it has continued to downgrade substitution as an organisational priority during 2020, citing budget constraints. The fact its sparse efforts have borne fruit, makes this de-prioritisation even more regrettable. Loss of momentum is evident from a published substitution action plan for 2020-21 that reduces to a minimum agency activities in this area. However, it continued its online training course and supported an Austrian government workshop on the issue, amounting to small overall progress.

8. Ensure that ECHA committee opinion templates *for company applications for authorisation to continue use harmful chemicals include the possibility to recommend rejecting an authorisation by including an option of zero years for the proposed review period.*

The verdict

Effort:  Outcome: 

ECHA changed its opinion template to reflect the possibility of the RAC and SEAC Committees to provide negative opinions. This is an important improvement as it shows applicants that authorisation must not be taken for granted.

9. Ensure that ECHA requires systematic proof from companies *applying for authorisation to continue using toxic chemicals that they contacted existing alternative providers, including reports from the discussion on the feasibility of the alternatives or market information from applicants. This in order not to take the arguments of applicants on lack of alternatives at face value.*

The verdict

Effort:  Outcome: 

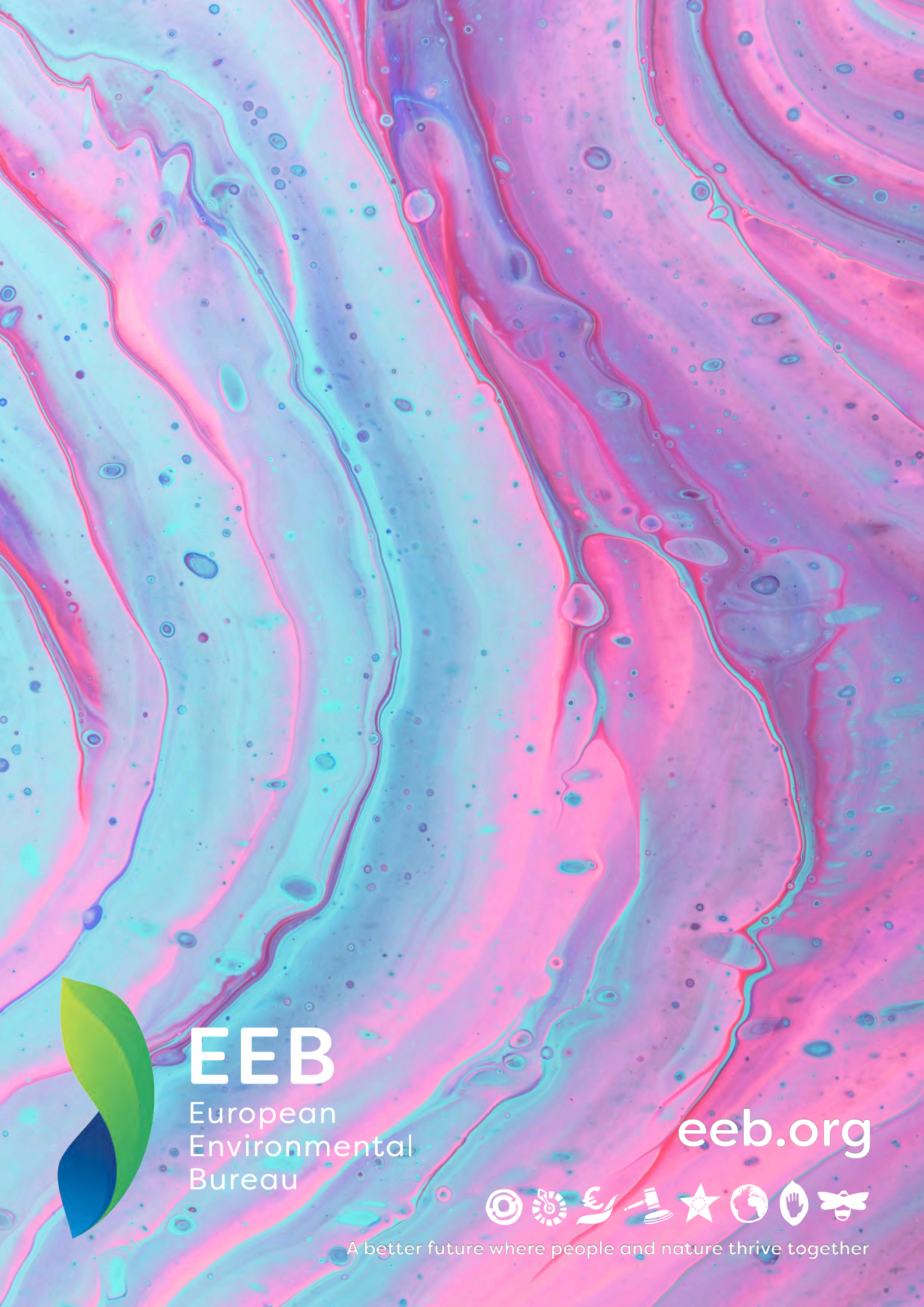
ECHA considers that they are making efforts to improve as the new application format requires companies to report if they have contacted their supply chain, including downstream users, and SEAC routinely challenges applicants about the time they need to implement alternatives. However, ECHA still does not require proof that “external” alternative providers have been consulted, as opposed to internal supply chains, and why their products are not feasible alternatives. ECHA is reluctant to change how SEAC assesses the analysis of alternatives provided by applicants, despite the fact that SEAC has concluded that criteria on how to assess the credibility of substitution plans is needed.

10. Stop proposing and supporting the use of substances of concern in recycled materials *without having assessed the whole lifecycle of materials, such as plastic, including the post-recycling phase, at least until a clear position has been adopted by the European Commission. Emissions estimates for recycling should incorporate new use phases (lifecycles) and final disposal options e.g. landfilling or incineration.*

The verdict

Effort:  Outcome: 

ECHA recognises the need for more holistic decision-making, taking into account accurate lifecycles of materials and SVHCs in recycling streams, something reflected in the EU Circular Economy Action Plan. However, ECHA, as dossier submitter, has asked for a wide derogation for the use of recycled tyre granules as infill material for sport pitches under the microplastics restriction. Also, SEAC continues to tacitly suggest derogations for recycled materials even if not considered by the dossier submitter (eg. PFHxA restriction). ECHA should adhere to the Commission position on the issue in the 2020 Chemicals Strategy for Sustainability that states that “[a]s a principle, the same limit value for hazardous substances should apply for virgin and recycled material” and that exceptional derogations could be adopted where they are limited, have no negative impact on health or the environment and where the use of recycled materials is justified, on a case by case analysis.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