EUROPEAN ENVIRONMENTAL BUREAU

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EEB REACH REFIT POSITION PAPER

INDEX

1.- INTRODUCTION

Under Article 117 of REACH, the European Commission is obliged to report every five years about the experiences acquired with the operation of the Regulation. We understand that the final aim of this review is to improve REACH in order to achieve its goals and main principles. This is, to:

✓ Contribute to the achievement that, by 2020, chemicals are produced and used in ways that lead to the minimisation of significant adverse effects on human health and the environment, pursuant to the implementation plan adopted on 4 September 2002 at the Johannesburg World Summit on sustainable development.

✓ Contribute to the fulfilment of the Strategic Approach to International Chemical Management (SAICM) adopted on 6 February 2006 in Dubai.

✓ Ensure a high level of protection of human health and the environment, including the promotion of alternative methods for the assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.[1]

REACH intends to achieve these aims by:

- Improving the generation of information on hazards, exposure and uses of substances.
- Improving information throughout the supply chain and to consumers.
- Improving risk management measures (RMM)

[1] REACH whereas (1)

- Encouraging the replacement of substances of very high concern (SVHC)
- Placing the responsibility on industry to ensure that the substances they manufacture, place on the market or use do not adversely affect human health or the environment.

We are deeply concerned by the Commission's decision to carry out this REACH review as a REFIT evaluation under its Better Regulation Agenda. The REFIT evaluation is focused on reducing the burdens on industry rather than reducing the burdens on health and the environment caused by chemical substances. Indeed, one of the main pillars of REACH is the polluter pays principle, meaning that the companies placing chemical pollution in the environment are responsible for any costs, not society. The REFIT exercise so far mainly considers the direct costs to companies in complying with the different pieces of legislation rather than the benefits for society of well implemented health and environmental legislation. But there are tradeoffs between these two objectives. It is obvious that in most cases the best protection against chemical pollution also has the highest regulatory costs and the other way around. Who should bear the costs? If industry regulatory costs are reduced, the costs will then be borne by taxpayers or through loss in health, human lives and degraded ecosystems.

We are also concerned about the Commission's inertia in the face of a slow and ineffective implementation of REACH by the European Chemicals Agency (ECHA), as well as the backlog of actions on hazardous chemicals which it is either obliged or committed to undertake. These include those required under article 138, the amendment of the REACH annexes on nanomaterials and the moratorium on including SVHC in annex XIV, since August 2014.

Nevertheless, if the right approach is given to this process, we can see the REFIT as an opportunity to improve REACH in order to provide high levels of protection and help to achieve the Sustainable Developments Goals (SDGs) and the EU goal of a non-toxic environment. The Commission's REFIT exercise should propose new initiatives to accelerate and improve REACH and its implementation, in particular tackling the poor quality of data submitted by companies, improving the information flow in the supply chain, making risk management measures more effective, promoting substitution as a driver for sustainable chemistry and innovation, and requiring the ECHA to become more effective in achieving the objectives and principles of REACH.

This position paper intends to provide the EEB's general assessment on the functioning of REACH 10 years after it entered into force and to signal areas of the legal text that urgently need strengthening, and to highlight where implementation of the directive is poor or even non-existent.

2.- GENERAL ASSESSMENT OF REACH 10 YEARS AFTER ENTERING INTO FORCE

Europe's flagship chemicals legislation, REACH has shown to have a high potential to improve the protection of human health and the environment, but it needs to be properly implemented and to be developed further.

The corporate takeover of different processes, poor interpretation of the regulation and opposition from the Commission and several Member States have hampered the full implementation and development of REACH.

REACH: a global model

The EU is seen as a global frontrunner in regulating chemicals. The world is looking and copying the EU model. South Korea, Malaysia, Turkey and China have adopted REACH-like legislations, several third countries, such as Switzerland, Canada, Japan and New Zealand have shown a keen interest in learning from REACH and others, such as Iceland, Liechtenstein and Norway, directly apply REACH. The REACH regulation went significantly further than other legislations, introducing new groundbreaking principles such as 'no data, no market', substitution, building on the precautionary principle and placing the burden of proving the safety of chemicals on companies.

REACH is worthwhile

An Austrian Competent Authority study about the costs and benefits of REACH[2] has shown that the implementation of REACH is resulting in net benefits. REACH is efficient from an economic point of view and beneficial for the environment

[2] http://reach-hamburg.de/fileadmin/user_upload/Newsletter/CA_MS_33_2015_Austrian_study_on_effects_of_REACH.pdf

and the protection of workers. Leading chemical companies also agree that producing safer chemicals is good for business[3] and even a survey by Eurometaux[4] concluded that REACH is beneficial and revealed that 60% of companies recognise the benefits of REACH to help them to communicate to users the hazards and risks of the substances they manufacture, and to become more proactive on chemicals management.

Better knowledge on chemicals in use

The registration of chemicals under REACH, despite severe shortcomings in the process, is giving rise to better knowledge of the chemicals used in Europe. In order to comply with registration obligations, companies have gained a better understanding of the chemicals they are handling, their hazards and risks, thereby improving risk management measures and increasing substitution.

More information on chemicals, but data remains of poor quality

Thanks to the registration obligations, more information on chemicals is available on ECHA's website, throughout the supply chain and to consumers. However, the quality of the information on hazards, uses and exposure is extremely poor. Information on uses and exposure is lacking for most of the substances and hazard information is completely outdated and incomplete due to shortcomings of the legal text but mainly to lack of proper implementation by ECHA. The improvement of data quality is an issue that needs to be addressed urgently.

Consumers keep fighting to know

The right to know on substances of very high concern in consumer products is applied as the 'right to ask' or 'the fight to know' since article 33 of the Regulation has shown to be insufficient and its implementation is very poor.

"No data, no market" not in place

This main principle of REACH is not being applied as ECHA provides registration numbers, hence access to the market, to all registration dossiers by default, even to incomplete, inadequate and irrelevant dossiers.

REACH is stimulating substitution globally

The Candidate List has become a worldwide reference for substitution[5] and even industry considers that the Candidate List is the main driver for innovation.[6] The REACH authorisation process is also improving risk management in companies applying for authorisation and wider public access to information.[7]

REACH potential for enhancing substitution has not been fully developed

The Commission, some Member States and ECHA are blocking REACH's full potential to enhance substitution by:

- Granting (ECHA recommending) authorisation by default to all applications, even if alternatives are available or the socio-economic benefits to industry are not proven to outweigh the risks to society[8], undermines the authorisation process. It also hampers innovation and penalises companies that have created safer substitutes. In short, such an approach is sending a very negative signal to the market.

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[3] https://www.euractiv.com/section/sustainable-dev/news/reach-chemical-law-worth-the-money-in-the-end-says-basf/
[4] https://chemicalwatch.com/21608/reach-beneficial-but-at-high-costs-says-eu-metal-industry
[5] Driving innovation. http://www.ciel.org/Publications/Innovation_Chemical_Feb2013.pdf
[6] Center for Strategy and Evaluation Services. Interim Evaluation: Impact f the REACH regulation on the innovativeness of EU chemical industry. Sevenoaks: CESS, June 2012. https://www.google.be/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=0ahUKEwji2-2t-t3RAhWL2xoKHcy1AO0QFggcMAA&url=http%3A%2F%2Fec.europa.eu%2FDocsRoom%2Fdocuments%2F11902%2Fattachments%2F1%2Ftranslations%2Fen%2Frenditions%2Fnative&usg=AFQjCNH-3-xQ_IJKNwieoGKCH8Y1IXidUQ&sig2=J2QOgcviAxGdjr6ax1l1qA&cad=rja
[7] "Lessons learnt on applications for authorisation. https://echa.europa.eu/view-article/-/journal_content/title/the-authorisation-application-process-is-working
[8] Experience in the Committee for Socio-Economic Analysis. Lessons learnt on Applications for Authorisation 10-11 February, 2015. Tomas Öberg, Chair of SEAC.

- Slowing down the inclusion of substances in the Candidate List and introducing an additional (risk-based) screening process, the Risk Management Option Analysis (RMOA), is working as a bottleneck and putting again the burden on Member States.

The substitution principle needs to be strengthened to boost a more innovative and less toxic economy in the EU. Substitution could be speeded up with a better implementation of the polluters pay principle and the application of economic incentives.

The burden of proof has not been shifted to industry

The extremely poor information provided by industry in the registration dossiers, in particular on uses and exposure, shifts the burden to Member State authorities and to ECHA Committees to complete the information needed for the development of subsequent REACH processes (e.g., candidate listing, restriction, authorisation, evaluation).

The precautionary principle is not being applied

Although REACH provisions are underpinned by the precautionary principle, the Commission and many Member States are not applying it when taking decisions on restrictions or granting authorisations. Even ECHA seems to consider that the precautionary principle doesn't apply to its activities.[9]

The whole process lacks transparency

There is a lack of transparency on enforcement activities, completeness and compliance checks of registration dossiers, substance evaluations or decisions of confidentiality claims. Transparency is one of the pillars of democracy. Without it, citizens' right to know, participation and access to justice is undermined.

REACH should be improved in order to serve a circular economy

In order to ensure the safe reuse and recycling of materials, articles and consumer products, hazardous chemicals entering the economy should be prevented and information on chemicals content in material cycles should be available throughout the supply chain, to consumers and to waste management companies. Restriction and authorisation processes need to be speeded up and no exemptions, derogations or transitional periods to restrictions or authorisations should be given for recycled materials.

3.- WHAT NEEDS TO IMPROVE

3.1. Generation of information on hazards, exposure and uses of substances

Quality and transparency of information generated

Following the REACH "no data, no market" principle, a chemical is only allowed on the market once manufacturers and importers register the substance and prove it is safe by submitting specific information. The competent authorities will only be able to regulate chemicals effectively when they have a clear picture of what is on the market – and this can only be established through information provided by companies. This information would also better inform citizens about the chemicals to which they are exposed. Registration dossiers are, therefore, the pillar of REACH and this is why it is so crucial that the information provided is accurate, adequate, reliable, relevant and trustworthy.

However, despite the fact REACH has generated massive amounts of information on chemicals in use through the registration process, the quality of the data is so poor that it doesn't allow adequate risk management measures to be properly and effectively adopted. Moreover, most of the documents from the 2010 and 2013 REACH registration have never been updated.[10]

[9] Letter from ECHA Director Geert Dancet to Jeremy Wates, EEB Secretary General; 21.12.2016.

[10] Report on the Operation of REACH and CLP 2016, ECHA: https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf

According to ECHA, 69% of the registration dossiers are not even in compliance with the regulation. The main problems are with the identification of the substance and the waivers or justifications given for not submitting studies or parts of the safety report. This is fundamental information to ensure substance safety.[11]

In order to help companies to improve the quality of the registration dossiers, ECHA, since 2009, has launched a very varied bunch of soft measures, such as quality observation letters, informal contact with companies, targeted letter campaigns, lists of substances that are likely to face compliance checks, REACH guidance updates, more streamlined and concise advice and statements of non-compliance (SONCs).

Nevertheless, despite the Agency's efforts, compliance has not improved at all. The percentage of non-compliant dossiers has remained well over 50% for the last five years. Moreover, the German Federal Institute for Risk Assessment (BfR) released a study in 2015 on data availability in REACH registrations that showed only one dossier, out of 1,814, was compliant with standard information for all endpoints.[12]

It is evident that the soft measures applied by ECHA are highly ineffective. Not only is there a lack of incentives to ensure compliance, but there are too many encouraging the opposite. Some examples of incentives for non compliance are the lack of regulatory action and the low chance that a dossier will be evaluated – under REACH, ECHA has to examine at least 5% of registration dossiers for the first two deadlines, but ECHA only (partially) checks the minimum required by REACH. **It is time to move on from soft measures, guidance and advice, and get serious about enforcing compliance.**

The compliance checks process is the most important measure to improve the quality of dossiers, but ECHA is seen as very weak by most registrant companies, which are doing nothing to improve their dossiers. **A more ambitious approach by the agency, that gives fewer carrots and more sticks to non-compliant companies in order to ensure full compliance with the legal text, should be by hook or by crook the minimum.**

We propose that ECHA:

- **does not grant registration numbers, in the first place, for empty dossiers or dossiers with inadequate information**, such as insufficient description of a substance identity. **More manually examined dossiers**, and fewer automated completeness checks that don't evaluate how adequate the information is, are needed;
- **completeness checks, performed for the whole registration dossier**, including chemical safety reports;
- excludes from the market, by **cancelling registration numbers**, those substances where safety has not been proven (for example, if the compliance check shows very bad quality dossiers or the dossier is not complete) in order to ensure a level playing field that favours companies taking REACH seriously. Although ECHA agreed it may invalidate registration numbers in well-justified cases a few years ago, revocation has only been considered in cases where registration numbers were assigned to non-existent registrants, and where they failed to pay the correct registration fee. However, there are some "good cases", such as the Board of Appeal case where an almost empty dossier was accepted by ECHA (Case 22/2013)[13];
- applies a "**naming and shaming**" mechanism, such as disseminating the names of non-compliant companies, or a traffic light system for the dossiers that pass an evaluation in the dissemination portal. These mechanisms would be a very good incentive to compliance as both market access and reputation are very important for companies. Moreover, it would ensure informed decisions by citizens, increase market pressure and protect human health and environment; and
- **increases the compliance checks rate beyond 5%** of registration dossiers.

According to ECHA, most of 2010 and 2013's REACH registration documents have never been updated.[14] We welcome the Agency's proposal to reinforce the obligation to update dossiers. In our view **dossier registrants should update their dossiers at least every five years**, in order to ensure the information provided to prove safety is up to date.

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[11] ECHA's Evaluation Progress Reports (2008-2015): https://echa.europa.eu/es/regulations/reach/evaluation

[12] https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_43_2015_reach_compliance_data_availibility_of_reach_registrations_0.pdf

[13] https://echa.europa.eu/documents/10162/56569ebe-dc6f-4831-aa72-6cc4819293ee

[14] https://chemicalwatch.com/48347/echa-proposes-reinforcing-obligation-to-update-dossiers

Implementation of 'no data, no market' principle

As described above, **granting registration numbers**, this is, giving market access **by default**, even when the information provided is inadequate or the substance is not even properly identified or characterised, is undermining the 'no data, no market' principle, seriously hindering the ability of the authorities to regulate chemicals and **essentially moving the burden of proof back towards the public**.[15]

Generation of information currently missing

"New" chemicals

REACH requires less information on new chemicals compared with the former EU chemicals' notification system. The notification requirements of Directive 67/548/EEC, including animal testing data for 'new substances' started at a production level of 10 kg. As for REACH, registration is required for both old and new substances only when the production or import reaches 1 tonne. Therefore, REACH generates more information for the former "existing substances" but less for 10 kg to 1 tonne "new substances". As a consequence there is less knowledge on the properties of certain substances than before REACH.

We believe that **registration should be compulsory for all chemicals produced, used or imported above 1 kg**, the information requirements and tests to substances above 10 kg should be similar to former legislation and **complete Chemical Safety Reports should be required for all SVHC**, regardless of their tonnage.

Missing hazard endpoints

According to ECHA, instead of reliable studies, around 75% of registrations contain read-across. As a consequence, newly generated data on developmental studies, toxicity for reproduction, genetic toxicity in vivo, repeated dose toxicity or toxicocinetics is scarce since REACH entered into force.[16] As said before, this is fundamental information to ensure substance safety. Given that one of the main compliance shortcomings is the poor justifications given for not submitting studies or parts of the safety report, **ECHA and enforcement authorities should be stricter when allowing these chemicals in the market**.

Furthermore, relevant toxic endpoints such as **neurodevelopmental toxicity and endocrine disruption are not adequately addressed by the information requirements laid out in the REACH Annexes**. The information obtained about the potential for neurodevelopmental toxicity is limited[17] and important gaps do not allow proper identification of endocrine disrupters as highlighted by an analysis published by the Danish Centre on Endocrine Disrupters (EDCs).[18] RIVM has also pointed out in two recent reports that the data requirements in the current legislation will not supply enough information for the identification of EDCs.[19]

A review of the legislation in order to make REACH properly address these issues is critical.

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[15] *REACH FORWARD* priorities for effective regulation. Discussion paper policy conference Brussels 1 June 2016. https://www.government.nl/ministries/ministry-of-infrastructure-and-the-environment/documents/publications/2016/06/03/discussion-paper-reach-forward

[16] ECHA's Evaluation Progress Reports (2008-2015): https://echa.europa.eu/es/regulations/reach/evaluation

[17] Developmental neurotoxicity and REACH: https://www.efsa.europa.eu/sites/default/files/5.HUUSKONEN.pdf and http://www.chemtrust.org.uk

[18] http://orbit.dtu.dk/en/publications/informationtesting-strategies-for-identification-of-substances-with-endocrine-disrupting-properties(7474cbce-908a-4e6f-ada8-b07efa5e26cd).html

[19] Endocrine disrupting chemicals within EU legal frameworks: environmental perspectives (http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2016/oktober/Endocrine_disrupting_chemicals_within_EU_legal_frameworks_environmental_perspective) and Endocrine disrupting chemicals within EU legal frameworks: human health perspective (http://www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2016/oktober/Endocrine_disrupting_chemicals_within_EU_legal_frameworks_human_health_perspective)

New non-genotoxic carcinogens

REACH is unable to identify new non-genotoxic carcinogens. As shown by a paper by Hernandez et al[20], a large proportion of human carcinogens identified by the International Agency for Research on Cancer (IARC) are non-genotoxic, however, since specific tools (like the genotoxicity assays) to identify them are not available in practice, non-genotoxic carcinogens go undetected, as even ECHA admits.[21]

Chemicals in products

REACH primarily addresses the manufacturing and use of chemical substances and mixtures (in Europe) and hardly covers chemicals in (consumer) products, particularly in imported products. The main product-related deficits of REACH are:

- Registration of substances in articles is required only if a substance is present in articles in quantities above 1 tonne per year and if the substance is intended to be released (e.g. a scented product, which is rather exceptional).
- Notification of the use of a Substance of Very High Concern (SVHC) is required only if the substance is present in articles in quantities exceeding 1 tonne per year and if the substance is present in those products above a concentration of 0.1% weight by weight (w/w), unless the manufacturer or importer can exclude exposure to humans or the environment (Article 7(2)). In fact, notifications received by ECHA are almost inexistent. Even for these few notifications, the information provided is so limited that doesn't give information on the products in the market containing SVHC.
- REACH addresses intentionally added substances and their impurities, but does not address reaction products formed in the processing of materials.
- REACH information requirements are insufficient, in particular for information on SVHC chemicals in consumer articles under article 33.

The REACH provisions can thus not ensure protection against dangerous chemicals in consumer products and cannot compensate for deficits in Products Regulation. Hence, **it is necessary to develop a new approach to address chemicals in products**.

Nanomaterials

REACH Annexes lack of specific information requirements nanomaterials. REACH does not include a definition of nanomaterials and the registration threshold of 1 tonne is too high for nanomaterials that often are used and produced in much lower amounts. REACH is therefore not fit for purpose to generate information on nanomaterials.

In 2011, the Commission rejected the idea of a nanomaterials-specific separate piece of legislation on the basis that it would be quicker to revise the REACH Annexes to adapt the regulatory framework to the specificities of nanomaterials. After five years of delay, the European Commission presented its proposed legal act to amend the REACH Annexes for substances with nanoforms at the REACH Committee meeting in February 2017. However, the proposed annex revision will not be in place in time for the last REACH registration deadline in 2018. Therefore the Commission failed to ensure that nanomaterials are properly addressed and safety demonstrated in REACH registration dossiers. In other words, the principle 'no data, no market' doesn't apply to nanomaterials.

This situation questions the validity of the Commission's claim in 2012 that "REACH sets the best possible framework for the risk management of nanomaterials". In our view, **in addition of a proper and timely amendment of the annexes, REACH should include a definition of nanomaterials and the registration threshold should be reduced in order to properly address nanomaterials**.

3.2. Information throughout the supply chain and to consumers

One of the aims of REACH is to improve the information on hazards, uses and exposure of chemicals throughout the supply chain and to consumers. To achieve this it has established information requirements downstream and upstream

[20] Mechanisms of non-genotoxic carcinogens and importance of a weight of evidence approach.

[21] Guidance on information requirements and chemical safety assessment Chapter R.7a: Endpoint specific guidance" (see R.7.7.8 Carcinogenicity, and especially Table R.7.7-6 and parts R.7.7.13.1 and .2 as well as R.7.7.13.1 Objective / General principles in pages 419-420)

the supply chain, information obligations on SVHC for consumers (article 33) and the need to notify the presence of SVHC in articles to ECHA (article 7(2)).

Industry must describe the uses of all SVHC substances, including uses in articles in the registration dossier and, if the substance is hazardous or is considered to be PBT or vPvB, information on conditions of safe use have to be included in the exposure scenarios and communicated though safety data sheets (SDS). Additionally, producers and importers of articles containing SVHC listed in the Candidate List above 0.1% should communicate this down the supply chain and to consumers (under request), and should also notify ECHA.

ECHA has made substantial progress in informing downstream users and consumers on the hazards of individual substances though the publication of infocards.[22] However as the information provided by registrants on uses and exposure is extremely poor, it is hindering the quality of the information provided to downstream users.

Also the accuracy and quality of safety data sheets, the main source of information on chemical risks for workers and SMEs, is very poor, as shown by the results from the second Enforcement Forum project regarding obligations of downstream formulators of mixtures: "SDSs with deficient information were reported for more than half of the companies checked (52%, n=1112). Quality problems were observed in the companies of all size categories at very similar rates".[23]

This long standing situation of bad quality SDS could be easily improved by establishing a European database of electronic SDS managed by ECHA. This database (if linked with ECHA's information on classification and labelling) would help formulators, in particular SMEs, to prepare their SDS and would guarantee the access of downstream SMEs, workers and consumers to SDS.

Regarding the fulfilment of article 33 obligations, ECHA's Report on the Operation of REACH and CLP 2016[24] states that: "the number of notifications received so far has also therefore remained (very) limited. By the end of 2015, 359 notifications of the presence of Candidate List substances in articles for a total of 38 Candidate List substances had been submitted to ECHA. While it is difficult to estimate how many notifications there should be, the low figure is likely to illustrate a low level of compliance". Evidence on industry's lack of compliance and even lack of awareness on their obligations to report on SVHC in articles has also been shown in a study for DG Environment that intended to compile information on CMR[25] 1A/1B substances used in construction products.[26]

The obligation under article 33 to inform consumers is not working well, as NGOs already forecasted during the writing of the REACH Regulation. On request by consumers, suppliers of articles should inform them if an SVHC is contained and how the article can be safely used. However, from the consumer's perspective the provision is of no use as the supplier may answer within 45 days, the information the company is legally obliged to provide is only the name of the substance and, in case no SVHC is contained, does not have to provide an answer at all. Therefore, the information is not available to consumers on the spot to influence the purchasing decisions and they cannot distinguish between noncompliant suppliers and suppliers not answering because the article does not include an SVHC. Moreover, only a minority of extremely well informed consumers are aware of and make use of this right.

In order to improve consumers' protection, or at least allow them the right to decide on the items they purchase, **REACH Regulation's article 33 should be modified in order to make the labelling of SVHC in articles mandatory**.

Furthermore, as ECHA's Report on the Operation of REACH and CLP 2016[27], states "there are currently no mechanisms to collect and generate information on substances in imported articles other than for substances on the Candidate List. This makes it difficult to identify substances of potential concern in imported articles and to initiate action in a proactive manner. This is particularly challenging for substances not registered in the EU".

This lack of information on chemicals present in articles and products hinders the capacity to reuse or recycle them into new products once their life has ended or even to adequately manage them as waste, and compromises the goals of the

[22] https://echa.europa.eu/documents/10162/22177693/what_is_an_infocard_en.pdf/4960b3a4-a84f-461d-926c-b4a683b2f98f
[23] https://echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf/6ae12cf0-a24d-4263-a30f-3dabf9928aed
[24] https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf
[25] Carcinogenic, mutagenic, reprotoxicant
[26] https://chemicalwatch.com/51104/commission-study-shows-low-industry-response-to-article-33-requests
[27] https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2016_en.pdf

EU to advance towards a circular economy. **The REACH Regulation should be revised in order to include the obligation on manufacturers and importers to report information on full chemical content when placing articles and products on the EU market. A comprehensive, harmonised information system should be developed in order to facilitate this information throughout the supply chain**.

In addition, we believe that **registration information needs to be improved with more urgency in the short term. Electronic SDS and a European database of SDS could be a good and easy solution to improve the quality of SDS**.

Article 33, as it reads now in the legal text, is not protecting consumers or providing information downstream. We believe it **should be amended to ensure that consumers and downstream users are informed on the substances with SVHC properties in all articles and final products. Some options to ensure the effective application of the right to know would be through labelling and/ or mobile applications**.

In our view, **mandatory information on the full chemical content of articles and products** not only would allow traceability along the supply chain but also help to avoid delayed and outdated information on hazardous substances that create the legacy problem in the circular economy. It would be therefore worth **exploring how an EU harmonised information system could be connected with both the SDS database and the implementation of the consumers' right to know in REACH article 33**.

3.3. Identification, phase out and substitution of substances of concern

Authorisation

Authorisation is a novel regulatory process established by REACH in order to hasten the substitution of SVHC with safer alternatives while ensuring innovation and competitiveness. The EEB report "A Roadmap to revitalise REACH"[28] concludes that although authorisation is a very 'young' process, we can already identify many positive impacts: the Candidate List is an important driver to encourage companies to replace SVHC with safer alternatives; applications for authorisation have not been submitted by the "sunset date" for half of the substances included in Annex XIV, meaning that they are no longer on the market in the EU (unless introduced through imported articles); public consultations are showing the technical and economic feasibility of safer alternatives in the supply chain; substitution plans are foreseen for several uses, which will result in the use of safer alternatives; and the risk management of chemicals is improving as a result of the application process, as companies attempt to prove adequate control of the risks from SVHC.

However, the slow pace of identification of SVHC and the decision by the Commission and ECHA to grant (or recommend) all applications for authorisation by default, even when safer alternatives are known to be available or when the analysis of alternatives is inadequate, undermines the substitution and authorisation processes, supports a "business-as-usual" approach by which authorisations become permits to pollute, and creates an economic disadvantage for companies that have invested in safer alternatives.

As foreseen in the legal text, all substances identified as meeting the criteria for authorisation should be included in a Candidate List for eventual inclusion in the authorisation procedure. {Recital 77, article 59}. Although the EU White Paper[29] estimated that 1,400 substances had hazardous properties giving rise to very high concern and should therefore be progressively phased out and substituted with safer alternatives via authorisation, only 173 substances have been included in the Candidate List to date. For the most part, the speed of substances placed on the list has been very slow. At this pace, it would take over a hundred years to have all SVHC in the candidate list. **The process for including substances of very high concern in the Candidate List should be swift, but the process has been made over-costly and over-burdensome for Member States through the introduction of the RMOA**. By front-loading the process with demands for use and exposure information that legally belongs only to the prioritisation step, the RMOA process is dissuading Member States from preparing dossiers.

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[28] http://www.eeb.org/index.cfm/library/a-roadmap-to-revitalise-reach/

[29] Commission of the European Communities. White Paper Strategy for a future Chemicals Policy. COM(2001) 88 final. Brussels, 27.2.2001. *http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0088:FIN:EN:PDF*

In order to help to the identification of SVHC, in particular PBT and ED substances, ECHA has set expert groups. However, after a few year of work, these groups did not manage to overcome the 'paralysis by analysis' and the information generated in REACH is so poor that identification of SVHC is scarce. An example is the ECHA's expert group on PBT substances that has been unable to identify more than five PBT/vPvB substances out of 121 substances discussed. In 92 cases, further information was needed.[30] Meanwhile industry has identified 56 substances as been PBTs/vPvB in their registration dossiers.[31]

Also **ECHA's risk assessment and socio economic analysis committees (RAC and SEAC) need to improve their assessments**. In particular, SEAC's narrow interpretation of technical and economic feasibility means that alternatives appear as unsuitable, even if they are available and similar companies use them. Indeed **SEAC lacks of criteria and tools to evaluate the feasibility of alternatives**. Furthermore, **SEAC's methodology for socio-economic assessment systematically overestimates the benefits for applicants and underestimates the costs for society as a whole** for the continued uses of the SVHC. **RAC should take all available science into account** when delivering its opinion, including low dose effects of certain chemicals and the combined exposure to several SVHC in the same use.

The Commission should focus on achieving substitution, the main goal of the authorisation process, as well as on improving **its implementation as a whole by making it more efficient**. Instead of favouring certain sectors, namely those that lobby hardest, and making it easier and cheaper for companies producing and using obsolete substances of very high concern to get authorisations, **improvements should be targeted at fulfilling the goals set by REACH: making it simpler for Member States to nominate substances for the SVHC Candidate List; getting all SVHC recommended by ECHA in Annex XIV; and delivering more rigorous decisions on applications for authorisation**.

Our detailed recommendations to improve the authorisation process are included in the report "**A Roadmap to Revitalise REACH**"[15]. These are five key recommendations:

- **The Commission and Member States in the REACH Committee should follow the legal text** and **grant authorisations only when an applicant has demonstrated that**:

1.a. ***The risks are adequately controlled***: This has not been the case for broad scope applications, covering hundreds of workplaces and hundreds of different working conditions. These applications provide very general descriptions of uses that are not documented by corresponding exposure and alternatives assessments. As a result, it is not possible to understand the risks from the continued use of the substance or the availability of alternatives for all the uses.

In addition, as the aim of authorisation is to progressively replace SVHC by suitable alternative substances and technologies, we propose that **article 60.2 should be amended to state that 'an authorisation shall be granted if there are no suitable alternative substances or technologies and if the risk to human health or the environment ... is adequately controlled…**'.

or that:

1.b. ***Alternatives are not available***. This has not been the case for many granted applications such as the use of DEHP in recycled PVC, the use of lead chromate in paints, the use of HBCDD in PS insulation boards, etc., where third parties demonstrated the availability of alternatives for the uses applied for.

And

2. ***The benefits for applicants outweigh costs for society***. SEAC's methodology for socio-economic assessment, which is accepted by the Commission, overestimates the benefits for applicants, underestimates the costs for society as a whole for the continued uses of the SVHC, and does not take into account the impact on other economic actors, such as companies that have or use alternatives.

[30] Review of the number of substance evaluations by ECHA PBT expert group and their results (as of October 2016)

[31] https://echa.europa.eu/information-on-chemicals/registered-substances?p_p_id=dissregisteredsubstances_WAR_dissregsubsportlet&p_p_lifecycle=1&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=1&p_p_col_count=2&_dissregisteredsubstances_WAR_diss

- Improve the analysis of alternatives

SEAC's narrow interpretation of technical and economic feasibility leads to the opinion that no alternatives are ever suitable for the applicants. This Committee, and afterwards the Commission, is following the applicant's view exclusively, focusing only on the availability of alternatives for the substance's function and are not considering the alternatives for all the uses covered by the application, including downstream uses (E.g. HBCDD, DEHP, lead chromates). **The scope of the application should be clearly defined, including the description of the technical function of the SVHC, its end uses and service life applications**.

Criteria are needed for defining the uses covered by the application, the technical feasibility and the economic feasibility of alternatives. SEAC and the Commission are following the applicant's view and mainly considering only the feasibility of a drop in the use of the chemical, and not considering the feasibility of other alternatives for downstream users.

In our view, **technical feasibility is demonstrated by the availability of alternatives in the market for the uses covered by the application. Alternatives should include substances, materials, processes and design/organisation measures.**

For assessing the economic feasibility, SEAC and the Commission should follow, at least, ECHA's Guidance on the preparation of application for authorisation.[32] This agrees that an alternative is feasible "*if the net present values of the revenues of the applicant minus costs is positive*", hence if the company still generates gross profits when using the alternative. Again, **all companies covered by the application should be considered and also the feasibility for similar companies operating in the EU market**.

The evaluation on whether the alternatives are feasible could be supported by the employment of consultants by ECHA to investigate the issue.

- Improve the socio-economic assessment

SEAC should be basing its opinions and the Commission its decisions on the benefits for society rather than the benefit to the individual applicant. A better balance and a bigger picture is needed that better considers health and environmental costs and the costs for alternatives producers and users, as the report from Chemsec "The bigger picture" highlights.[33]

To clarify this, we propose that **the words "for the applicant" are removed from article 60.5.b**[34] which requires the Commission to consider the technical and economic feasibility for the individual application when granting an authorisation.

- Improve ECHA's conformity check for applications for authorisation

All applications are deemed in conformity by default even if they do not conform with the information requirements. **ECHA's consideration of the conformity check as a bureaucratic step or a completeness check shifts the burden of proof and information provision on the committees instead of on the applicants**. This is one of the main failures of the implementation of the authorisation process. ClientEarth has made a legal in-depth analysis of this situation and a proposal to improve the conformity check that should be considered[35].

- Extend authorisation to SVHCs in imported articles

To make REACH more efficient **the authorisation process should be extended to cover imported articles**. A comprehensive analysis carried out on behalf of the German Environment Agency identified several regulatory options

[32] https://echa.europa.eu/documents/10162/13637/authorisation_application_en.pdf
[33] http://chemsec.org/wp-content/uploads/2016/03/The_bigger_picture_160217_print.pdf
[34] *the technical and economic feasibility of alternatives for the applicant*
[35] Client Earth (2016) Bringing conformity checks on authorisations into conformity

that could achieve the objectives of REACH for articles containing SVHC as well as improve information and communication on articles containing SVHC.[36]

Restriction

The implementation of REACH has had a negative impact on the restriction process. REACH produces fewer restrictions and they are less efficient as they have a lower scope than the restrictions achieved by the former system (Directive 76/779/EEC). As shown by a thesis study,[37] under the old system 52 new restrictions were decided in the period 1976 – 2006, with an average 1.7 new restrictions per year, while REACH has "produced" 1.2 new restrictions per year.

One of the reasons for the lower number of restriction proposals is that the ECHA Committees have increased the information obligations for Member States to demonstrate the need for a restriction (contravening the precautionary principle!!), and increasing therefore the time, resources, and in consequence, the costs for preparing a restriction proposal.

There is a substantial difference between the level of evidence required by ECHA from restriction dossier submitters to demonstrate risk, or appropriateness of risk management options (RMO), compared to the level of evidence required from industry applying for authorisation.

A survey performed by ECHA, showed that almost 80% of (Member State) dossier submitters of restriction proposals believed the committees made unreasonable requests for additional information.[38] Moreover, Member States attending 'the REACH Forward' conference conduced: "The perception was that the current procedures to adopt an authorisation obligation or a restriction can be slow. As such, **actions to simplify, clarify and speed up procedures**, while maintaining proper assessment of risk management options, would be welcomed. In particular, **reduction of the costs of compiling restriction proposals** (in addition to recent improvements) **could enable an increase in restrictions**".[39]

The scope of restriction proposals is now narrower. As shown by the thesis study by Marc Brandt, most restriction decisions under Directive 76/779/EEC were broad or very broad while most of the restriction proposals by REACH are very narrow or narrow. As a consequence, REACH restrictions do not provide more protection compared with 76/779/EEC.

Once a restriction proposal (RP) has been submitted, it is reviewed by ECHA's RAC and SEAC committees. In recent restrictions, it is very common for the committees to substantially change the scope almost always leading to a much narrower scope than originally proposed. These changes may occur in several ways: by the addition of derogations; 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. This was the case with the restriction proposal for the flame retardant DecaBDE. Exemptions for auto spare parts and aviation claimed by industry were not critically evaluated by the ECHA Committees although alternatives are already available.[40] Recently the restriction of PFOA was approved by the REACH Committee. However, the exemptions and higher concentration levels included by the ECHA Committees, changing the original proposal from Norway and Germany, rendered the approved proposal meaningless as it would no longer reduce global consumption and emissions of PFOA. The ECHA Committees increased the allowable limits to concentrations that are 10 times higher than those proposed by the dossier submitter, with no process, no justification and without any data to back up the new numbers.[41]

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[36] Enhancement of the REACH requirements for substances in articles. https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_41_2015_enhancement_of_the_reach_requirements_for_imported_articles_0.pdf

[37] It's Not All About the Money. Why the Current Practice of Socio- Economic Analysis Used in Restriction Proposals Under the EU REACH Regulation Is Not Delivering. Marc Brandt. 2015

[38] Results of ECHA's survey on restrictions efficiency. ECHA's Presentation "Restriction efficiency task force: state of play"

[39] Policy conference "REACH Forward" (Brussels, 1 June 2016) - Information from the Presidency. http://data.consilium.europa.eu/doc/document/ST-10098-2016-INIT/en/pdf

[40] http://www.eeb.org/index.cfm/library/letter-to-reach-committee-concerning-decabde/

[41] http://www.eeb.org/?LinkServID=598FA7B1-5056-B741-DBC54EDBDF2CF0D7&showMeta=0&aa

On the contrary, the ECHA Secretariat has systematically refused any change in the scope proposed by NGOs to increase the protection of people and the environment. 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 proposed to widen the scope to include BPS, arguing that it did not fall under the responsibility of the Committee.

A clear mandate, instructions and guidance should be given to ECHA about the role of the Committees to change the scope, and the evidence needed to do so.

Other challenges that need to be addressed in order to improve the restriction process include:

- **RAC needs to incorporate modern science in its opinion making process**

RAC's assessments are mostly based on principles of traditional toxicology. Scientific knowledge generated over the last 20 years, for example on endocrine disruption, cocktail effects, low dose effects or non monotonic dose response curves are dismissed by RAC.

Clear examples can be found, for example, in RAC opinions on the restriction of BPA in thermal paper[42] and on the restriction of PFOA[43]. In this last case, the dossier submitter included cholesterolemia, adverse mammary gland effects and effects on birth weight and cholesterolemia due to low dose exposure in the human health risk characterisation. However, due to the low dose at which these effects were found, RAC considered the dose response relation to be uncertain and did not use these effects and doses for the risk characterisation, which led to a much higher starting point for deriving non effect levels, and therefore reduced the potential protection of the population and the environment.

- **Corporate studies should not be prioritised over independent academic evidence**

ECHA's lack of Systematic Review Criteria for literature selection means that RAC prioritises corporate over independent academic studies, dismissing most of the scientific evidence provided by public authorities submitting a restriction proposal. This is done by privileging studies that comply with Good Laboratory Practice (GLP), although this is not a measure of quality, good study design, execution or interpretation of a study.[44]

It is ironic that the scientific evidence generated over the last 20 years in Europe thanks to the public scientific funding schemes is disregarded in its regulatory processes!

- **To improve the socio-economic analysis process**

Restriction proposals need to demonstrate that the risk management measure proposed is the most appropriate. SEAC's evaluation almost always addresses only the costs and benefits of the selected RMO. This goes against its own guidance, which says that cost/benefit is only one aspect to consider. Its opinion on BPA restriction is a clear example.[45] Cost-benefit was the only one aspect of "appropriateness" considered, neglecting other aspects such as equity, affordability, and practicality, which is especially important when dealing with the avoidance of diseases of high societal importance such as breast cancer.

Substitution

The substitution principle needs to be strengthened to boost a more innovative and less toxic economy in the EU. A recent report published by ECHA[46], shows that key to this is **enhanced collaboration between all stakeholders and, in particular, between agencies, Member States, the Commission and ECHA, and between the Commission's**

[42] http://www.eeb.org/index.cfm/library/eeb-opinion-on-the-proposed-restriction-of-bisphenol-bpa/
[43] http://www.eeb.org/?LinkServID=598FA7B1-5056-B741-DBC54EDBDF2CF0D7&showMeta=0&aa
[44] Myers et al. (2009) Good Laboratory Practices: Myers et al. Respond. Environ Health Perspect; 117(11): A483–A484. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2801173/
[45] http://www.eeb.org/index.cfm/library/eeb-opinion-on-the-proposed-restriction-of-bisphenol-bpa/
[46] Improving the Identification, Evaluation, Adoption and Development of Safer Alternatives: Needs and Opportunities to Enhance Substitution Efforts within the Context of REACH. Joel Tickner and Molly Jacobs. University of Massachusetts Lowell, Lowell Center for Sustainable Production. https://echa.europa.eu/documents/10162/13630/substitution_capacity_lcsp_en.pdf/2b7489e1-6d96-4f65-8467-72974b032d7b

different directorates (DGs). **ECHA would be the best facilitator between these different actors as it already plays a similar role for the helpdesks and enforcement authorities**.

These bodies need help with capacity building and to manage information and training needs. **This could be provided via a centralised EU substitution centre or national helpdesks providing companies support for substitution and disseminating information and successful case stories could be the way forward**.

Substitution could also be speeded up with a better implementation of the polluters pay principle and the application of **economic incentives** that penalise laggards while rewarding frontrunners.

A good model is the Toxics Use Reduction Act[47] from Massachusetts, US which obliges users of hazardous chemicals to pay a fee which is used by authorities to help reduce the use of hazardous chemicals. Meanwhile, the Toxics Use Reduction Institute (TURI) helps companies to substitute and has successfully reduced the emissions of hazardous substances to the environment and the generation of hazardous waste while supporting local companies. **An EU TURI model would the best way to boost substitution in Europe**.

REACH should deal with groups of chemicals

There is a need to move away from dealing with chemicals on the market, one by one.

One by one risk control is highly inefficient and regulators are always lagging behind new chemicals in the market since to regulate a single chemical can take several years, even decades.

REACH should be developed to allow assessment and facilitate management of the risks of groups of chemicals, such as halogenated organic substances.

Moreover, **the effects of combinations of chemicals should be tackled under REACH**. The fact that these substances are used together in various combinations and replace each other in many types of articles further suggests combined management of the group of substances. Industry should have to take account of combination effects of their chemicals. Additionally, to regulate groups of chemicals would avoid regrettable substitutions.

3.4. Shifting responsibility and burden of proof to industry

REACH aims to shift the responsibility of ensuring that chemicals placed on the EU market do not adversely affect human health or the environment (article 1.3), making industry rather than the authorities responsible for assessing the risks and hazards of substances. However, despite these legal obligations, the burden of proof still rests with the authorities.

The extremely poor information provided by industry, in particular on uses and exposure, in the registration dossiers shifts the burden to Member State authorities and to the ECHA Committees to complete the information needed for the development of subsequent REACH processes (e.g., candidate listing, restriction, authorisation, evaluation).

As signalled by the REACH Forward conference discussion paper[15] "Decision making under REACH is often hampered by deficiencies in the registration dossiers. This essentially moves back the burden of proof towards the public authorities and challenges them to find the balance between a precautionary approach on the one hand and refraining from measures that could be disproportionate on the other. This becomes apparent in different REACH processes." The Risk Management Option Analysis (RMOA) is an excellent example. This screening process is not from the REACH legal text, but a subsequent procedural development. By front-loading the process with demands for use and exposure information, the RMOA process is dissuading Member States from preparing dossiers. The whole screening exercise is behind schedule; its objective is to screen 440 substances by 2020, around 55 substances per year. So far, it has been completed for only 32 substances.[48]

[47] http://www.turi.org/Our_Work/Chemicals_Policy/The_Toxic_Substances_Control_Act_TSCA
[48] https://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact

Another good example of placing the burden of proof on public authorities is the substantial work load involved in preparing restrictions due to challenging information demands from ECHA. This is ironic given that REACH was designed to overcome 'paralysis by analysis' and ensure action was taken when there was any doubt about demonstrations of safety from industry.

The consideration by the ECHA Committees of deficient and incomplete authorisation applications as being in conformity obliges them to either make an opinion based on insufficient information or actively investigate the missing information themselves. This puts the burden on the Commission and the Member States to take a decision on the application based on insufficient data.

Furthermore, the granting of broad scope applications for authorisation, which cover dozens of uses and hundreds (even thousands) of companies, places a huge burden on the national enforcement authorities.

When considering the burden of REACH through this REFIT exercise, it would be useful to have an assessment of the costs to public authorities because of industry's lack of compliance with its information duties under REACH.

3.5. Application of the Precautionary Principle

Article 1.3 of the legal text clearly states that REACH provisions are underpinned by the precautionary principle. However, REACH implementation has clearly disregarded the precautionary approach.

ECHA should be guided by the precautionary principle when assessing evidence about hazards and the risks of restriction proposals, substance evaluations, authorisation applications or harmonised classifications. On the contrary, the actual practice of ECHA is to request undeniable evidence on hazards as a pre-requisite to recommend action. Examples of this are RAC's refusal to consider scientific evidence on the immunotoxicity of PFOA, breast cancer, metabolic and immunotoxic effects of BPA, or endocrine effects of phthalates, among others. Instead of applying the precautionary approach, the Committee establishes thresholds based on the highest values, giving preference to data from industry-funded studies.

We would therefore like to invite ECHA to discuss which measures (including grouping, extended scope of restrictions, etc) could be taken to make the processes more effective in ensuring a high level of protection of environment and health. Of particular interest to us would be to see an in-depth discussion on how the Agency can better contribute to the application of the precautionary principle in the decision making on individual chemicals. This requires a comprehensive description of all potentially adverse effects as well as highlighting the extent of the scientific uncertainty.

3.6. Enforcement

Good enforcement is essential for a 'high level' of protection. Without enforcement, REACH becomes a voluntary agreement. Enforcement measures and sanctions should also be harmonised across the EU Member States and EEA countries in order to establish a level playing field.

However, as a study on the issue by Milieu[49] shows, the level of penalties and the methods of enforcement vary quite a lot from one country to another. The Nordic Countries base their enforcement on coercive measures, while other countries enforce their legislation through administrative and criminal law or through administrative law only. Most importantly, there is a **substantial lack of consistency as to the level of penalty from one country to another**.

Transparency is also key. It is not clear to stakeholders what concrete measures are taken against non compliant companies and which are non compliant companies or non compliant products. **Naming and shaming** mechanisms would be a very good incentive to encourage compliance as both market access and reputation are very important for

[49] Report on penalties applicable for infringement of the provisions of the REACH Regulation in the Member States. http://ec.europa.eu/environment/chemicals/reach/pdf/report_reach_penalties.pdf

companies. Moreover, it would ensure informed decisions by citizens, increase market pressure and protect human health and the environment.

On the other hand, ECHA and National Enforcement Authorities prioritise 'soft measures' instead of sanctions or other hard measures. The Forum REACH-EN-FORCE reports 1, 2 and 3 show the 'soft' prescribed measures undertaken as a result of non-compliance are predominant:

REACH-EN-FORCE 1: The prescribed measures undertaken as a result of non-compliance were: administrative order (169), letter of appeal (96), fines (12), blame and shame (3), criminal complaint (3) and others (121).[50]

REACH-EN-FORCE 2: In reaction to contraventions, inspectors imposed various measures, but in most cases it was verbal or written advice that was given (43% and 51% of cases respectively). (See Figure 8 of the report).[51]

REACH-EN-FORCE 3: As acknowledged by the report "a high percentage of corrective measures taken to correct non compliant companies took the form of written and verbal advice... Altogether, the percentage of applied sanctions against an offender in the form of a fine or criminal complaint is low… Different approaches may exist in any one Member State. It seems that in terms of sanctioning missing substance registrations, rather soft measures are taken by NEAs in cases where companies do not comply with registration obligations".[52]

A more ambitious approach by Enforcement Authorities, that gives fewer carrots and more sticks to non-compliant companies in order to ensure full compliance with the legal text, should be by hook or by crook the minimum.

Finally, **the principle of dissuasiveness should be respected**, adapting the amount of the fine to the particularities of the REACH system of tonnage. When the tonnage is higher, in most countries, the level of fine incurred is not high enough to match the high costs of compliance.

3.7. Scope

The scope of the REACH Regulation has been shown to be insufficient to protect human health and the environment from the risks posed by hazardous chemicals.

It is estimated that around 20,000 chemical substances are handled in low volumes (between 1 and 10 tonnes per year). For the vast majority of these substances, the requirements for information in registration in REACH are entirely inadequate to allow hazard and risk assessment. **Information requirements should** therefore **be extended to low volume chemicals. This is particularly important for nanomaterials and CMR substances**.

Ten years after REACH came into force the industry maintains tight secrecy on the nanomaterials they manufacture and use. There are around 2,500 consumer products containing nanomaterials in the European market.

Although the Commission claimed in 2014 that 62% of nanomaterial substances were already covered by REACH registration dossiers and 90% of substances were expected to have REACH registration dossier by 2018, today only 21 nanomaterials had been registered as such in the REACH system. Yet in 2017, the French national register alone identified about 320 nano-substances. Only four of these 320 substances have been registered under REACH (as nanomaterials). Since two-thirds of the declarations in France are under the one tonne threshold, they would never be registered under the current REACH system as it is. It is clear that without low volume registration requirements, the situation will continue close to spinning out of control.

Furthermore, **industry should have the obligation to register all CMR category 1 substances, regardless of the tonnage band at which they are manufactured or imported**. As research by ETUC shows, there is a very high

[50] https://echa.europa.eu/documents/10162/13585/ref-1_project_report_conclusions_en.pdf/346ccbf3-3152-48d8-99c7-533ec5fd80c5
[51] https://echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf
[52] https://www.echa.europa.eu/documents/10162/13577/forum_report_ref3_en.pdf

number of substances (711) that have been notified to ECHA with a harmonised classification as CMR1 have not been registered under REACH regulation. Several of these substances have been notified by hundreds (an in several cases thousands) of companies, thereby, it appears that the use of non-registered CMR1 is much more extended in the EU than was originally expected.[53] Furthermore, a report by ECHA concluded that 40% of substances classified as CMRs were neither registered under REACH nor notified under CLP and over 4,000 CMRs notified by industry have not been registered under REACH.[54]

Registration should also be extended to polymers and waste as hazardous substances present in these materials are not adequately regulated. Hazardous chemicals present in polymers have been shown to leach from these materials (e.g. BPA from polycarbonate water pipes or packaging, styrene from polystyrene or vinyl chloride from PVC) posing a threat to consumers and the environment. When REACH was developed it was considered that requesting registration for polymers was too difficult because of the complexity of the polymer market. However, reports carried out under the request of the Commission show different feasible registration options.[55,56]

Hazardous chemicals present in waste hamper the capacity to recycle or to use articles produced with recycled materials. To be able to achieve a circular economy, waste needs to be detoxified. **The inclusion of waste under REACH information and risk management measures obligations is an important step in this direction**.[57]

The scope of REACH should also be extended to imported and exported articles. REACH is intended to regulate the risks posed by imported articles with the possibility of restricting the use of substances in articles that have not been granted an authorisation if ECHA considers that the risks are not adequately controlled (article 69.1). Again the burden of proof rests with the public authorities with imported articles containing SVHC allowed on the market while those marketed in the EU are not. In order to avoid this situation, **article 69.1 should be amended to include an immediate restriction on all articles containing the substances listed in Annex XIV after the sunset date. Another solution would be for authorisation not to exempt imported articles**.

Finally, **the EU should not have double standards when considering risks to human health and the environment inside or outside of its borders**. **REACH provisions should apply also to substances, mixtures and articles exported to third countries**. Furthermore, **the Regulation should be amended in order to specify that the risks generated in third countries should also be taken into account when assessing the risks posed by substances under the authorisation and restriction processes**. For example, when assessing the risks posed by asbestos in order to allow its use by several companies in Europe, the RAC did not consider its main risk, namely worker and environmental exposure at production sites located outside the EU.

3.8. Transparency and Access to justice

"…, it is unbelievable that the EU, US or any other country have not yet demanded full information on which of these substances are used where…. Transparency must be the way forward. I personally regard this as a human right." Professor Åke Bergman, Executive director Swetox.[58]

Transparency is one of the pillars of democracy. Without it, citizens' right to know, participation and access to justice would be undermined. Some examples of the lack of transparency of the REACH processes are:

- There is still a general lack of information on hazards, uses and exposure of chemicals throughout the supply chain and to consumers. This is particularly relevant for nanomaterials.
- The right to know about substances of very high concern is applied as the right to ask or the fight to know since implementation is very poor. The same is true for the notification of SVHCs in products.

[53] Illegal CMR at the Marketplace. ETUC (In preparation).
[54] ECHA (2015) 2014 CMR Report. Helsinki: ECHA. https://echa.europa.eu/documents/10162/13562/cmr_report_2014_en.pdf
[55] Risk & Policy Analysts Ltd (2012) Review of REACH with regards to the registration requirements on polymers, Part A: Polymers (Final report).
[56] Deloitte (2015) Technical assistance related to the review of REACH with regard to the registration requirements on polymer. Final report.
[57] http://www.eeb.org/index.cfm/library/keeping-it-clean-how-to-protect-the-circular-economy-from-hazardous-substances/
[58] Guest column – Professor Åke Bergman, Swetox, Chemical Watch, November 2016
https://chemicalwatch.com/51016/guest-column-professor-%C3%A5ke-bergman-swetox

- As stated above, the lack of transparency of enforcement activities also impedes the public's attempts to make informed choices, demand and push for safer products in the market and overall it undermines the protection of health and environment.

ECHA also lacks transparency in some of the REACH processes, such as:

Completeness checks: information is not public about which and when dossiers were checked by ECHA, the results of the completeness checks and for which companies market access was not granted. Completeness check decisions can therefore not be challenged undermining the access to justice of citizens.

Compliance checks: the same is true for the compliance checks by ECHA. There is no information on which and when dossiers have been checked for compliance by ECHA, which companies are found not to be in compliance and their location. All preparatory documents related to decisions are secret and, even after the decision has been taken, essential parts of the decision may be censured (including the company name).

Substance Evaluation: No access whatsoever is granted to any preparatory documents for substance evaluation. Given the complexity of the cases and of the decisions, it would be very difficult to challenge a substance evaluation decision within the six weeks foreseen by the Aarhus Regulation. Access to Justice is therefore limited.

ECHA's decisions to accept confidentiality claims as well as its justifications are also not made public.

The Board of Appeal (BoA) is an independent body of the European Chemicals Agency that can be used to appeal against ECHA decisions in a fast and cheap way. The BoA is really an "asset" in the institutional design of REACH and any measures to strengthen the administrative independence of the BoA would contribute to the functioning of the system.

REACH recital 106 states "*A Board of Appeal should be set up within the Agency to guarantee processing of appeals for any natural or legal person affected by decisions taken by the Agency*." However, REACH in practice only allows industry to have access to the Board of Appeal as only addressees of a decision and persons who are "*directly and individually concerned*" can be an appellant (according to REACH article 92.1).

There is also a limit to the type of decisions that can be challenged. The only decisions that can be challenged at the BoA are data sharing, substance evaluation, examination of testing proposals, compliance check of registrations/intermediates, rejections of registrations (SMEs/appropriate fee) and PPORD exemption (according to article 91.1), this is, decisions only affecting companies.

Not within the jurisdiction of the BoA are e.g.:

- ECHA's decisions to accept data confidentiality claims (and hence reject public access to certain information) in the registration dossiers.
- ECHA's decisions to accept data confidentiality (and hence reject public access to certain information) without in the applications for authorisation dossiers.
- ECHA accepting a registration as complete while ascertaining that "*all the elements required under Articles 10 and 12 or under Articles 17 or 18, as well as the registration fee referred to in Article 6(4), Article 7(1) and (5), Article 17(2) or Article 18(2), have been provided*" as foreseen in article 20(1)1 REACH.

The power to review decisions should therefore, in our view, be better balanced. Thus the scope of REACH article 91.1 should also include other decisions that have an impact on society such as the above mentioned. Moreover, since these decisions are not public, it is extremely difficult for third parties to challenge any of them and the REACH review should envisage how this might happen. The EEB hence believes that **any person affected by decisions taken by ECHA or with an interest in the result of a decision should be able to submit an appeal to the BoA**. Under the current system, only industry has direct access to the Board, with civil society organisations and Member States restricted to amicus curiae letters. Thus **the scope of REACH article 92.1 should be modified accordingly**.