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PRECAUTIONARY IN PRINCIPLE, FLAWED IN FACT

The EEB'S appraisal of the REACH review

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EUROPE'S LARGEST NETWORK OF ENVIRONMENTAL CITIZENS ORGANISATIONS

Authors: Dolores Romano, Elise Vitali and Tatiana Santos
Project Coordinator: Tatiana Santos
Editor: Ian Carey

To contact authors email: tatiana.santos@eeb.org

European Environmental Bureau (EEB)

Boulevard de Waterloo 34 | B-1000 Brussels | Belgium
Tel.: +32 (0)2 289 1090 |**E-mail:** eeb@eeb.org

Website:
www.eeb.org

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The Commission has published recently the results of its review of the REACH Regulation. This evaluation was performed in response to the legal obligation to report periodically on the progress of the REACH Regulation. However, it was conducted under the Commission's "deregulatory" REFIT programme, which aims to removing red tape and lowering costs to industry.

In the frame of this review, the EEB published in 2017 a general assessment on the functioning of REACH 10 years after it entered into force, signalling the areas of the legal text that urgently need strengthening, and highlighting where implementation of the regulation is poor or even non-existent.[1]

We expressed our concern on the Commission's decision to carry out the REACH review as a REFIT evaluation under its Better Regulation Agenda, as this programme is focused on reducing the burdens on industry rather than reducing the burdens on health and the environment caused by chemical substances. Nevertheless, if the right approach was given to the review process, we saw it 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 has published two documents:

- A Staff Working Document (SWD) on the REACH Evaluation[2] that compiles the results of the studies and consultations carried out by the Commission to assess the overall operation on REACH as well as its contribution to meeting the World Summit Sustainability Development 2020 goals and the Sustainable Development Goals.
- A Communication[3] including the conclusions and actions resulting from this review.

We welcome the Commission's Staff Working Document on the REACH Evaluation as we believe that it is rather balanced and comprehensive and it takes on board several of the criticism that the EEB has raised regarding the implementation of REACH. Thus, the evaluation concludes that despite the heavy criticism by industry when adopted, REACH is delivering, worthwhile and becoming a global model. **The review also identifies several areas where the implementation of REACH needs to be improved such as:**

- **The generation of information on hazards, exposure and uses of substances**
- **The flow of information throughout the supply chain and to consumer, in particular on substances in articles**
- **The restriction process is not delivering as expected, ECHA Committees demands to Member States proposing restrictions need to be lowered and must diligently scrutinise industry requests for exemptions**
- **The burden of proof has not been effectively shifted to industry**
- **The precautionary principle has not been applied**

It also recognises that the EU will not meet the World Summit Sustainability Development 2020 goals.

By contrast, **the Commission's Communication fails to commit to concrete actions on the main identified hurdles to allow REACH to provide high levels of protection to human health and the environment and help to achieve the Sustainable Developments Goals (SDGs) and the EU goal of a non-toxic environment. Further, the general actions proposed are not assorted with any specific timeframe.** Following

1 http://eeb.org/wp-admin/admin-ajax.php?juwpfisadmin=false&action=wpfd&task=file.download&wpfd_category_id=31&wpfd_file_id=33787&token=809bc215387a7a876fd1b807976bc658&preview=1
2 https://ec.europa.eu/docsroom/documents/28202
3 https://ec.europa.eu/docsroom/documents/28201

its Better Regulation Agenda, proposed actions are focused on further simplifying and streamlining REACH implementation to industry, in particular by further watering down the authorisation process and, despite the conclusions and recommendations of the SWD, **lacks specific commitments to:**

- **implement the "no data, no market" principle and effectively shift the burden of proof to companies**
- **truly stimulate the substitution of toxic substances through the authorisation process**
- **improve the identification of new substances of very high concern**
- **encourage proper EU-wide enforcement of Art. 33 and make the consumer "right to know" more practicable**
- **lower the burden of required evidence for regulating substances of concern and improve the use (and misuse) of alternative test methods**
- **better address emerging issues, in particular nanomaterials, endocrine disrupters and combination effects of chemicals**
- **bring low-volume production substances and polymers into the REACH regulation**

APPRAISAL OF THE COMMISSION STAFF WORKING DOCUMENT ON THE REACH EVALUATION

We welcome the Commission's Staff Working Document on the REACH Evaluation as it acknowledges the great potential of REACH to achieve its main goal of protection of health and environment and that it is worthwhile as well as identifies the main challenges and hurdles of the current implementation of REACH. In fact, it takes on board several of the criticism that the EEB has raised regarding the implementation of REACH.

THE REACH EVALUATION CONCLUDES THAT:

REACH Delivers

"Progress has been made towards achieving the REACH objectives, as evidenced by the outcomes delivered so far. Although this progress is lagging behind the initial expectations of 2006, the progress has steadily improved and expectations recalibrated. The different building processes and actions envisaged in the intervention logic of REACH are being largely implemented, which suggests that REACH is protecting human health and the environment". (SWD, page 126)

REACH is worthwhile:

"the costs of REACH to business to meet their obligations are justified by the benefits for human health and the environment, the improvement of the management of chemical risks at workplaces, the better knowledge on chemicals and improvement of information in the supply chain and stimulating substitution of substances of very high concern." (SWD, page 123)

"the scale of potential benefit of REACH remains still, as already stated in the 2013 REACH Review, at least EUR 50 billion for human health by 2030 and EUR 50 billion for the environment by 2025." (SWD, page 72)

"Overall, the main direct costs under REACH are observed to be mainly arising from "the registration obligations and from the communication of information along the supply chain (extended Safety Data Sheets). Whilst there is some uncertainty over the costs incurred so far, the costs for the first two registration deadlines appear to be between EUR 2.3 -2.6 169 billion, in the range of the Impact Assessment." (SWD, page 80).

"While no discernible impact of REACH was identified, several companies expressed the view that REACH had made a significant contribution to the harmonisation of European

chemicals legislation / integration of the Single Market." (SWD, page 50)

REACH is becoming a global model

"For example, REACH is increasing the expertise of public authorities and industry on chemicals and it has become a benchmark for third countries in terms of chemical regulation, thus contributing to international harmonisation in the implementation of chemicals policy. REACH provides a comprehensive data generation and assessment of most chemicals, compared to non-EU regimes that focus only on new and/ or prioritised chemicals. Hence, REACH has also led to a vast publicly available database on chemicals, unique in the world." (SWD, page 127)

However, the SWD also concludes that the

REACH implementation needs to improve:

"However, the shortcomings in relation to the high level of non-compliance of the registration dossiers, the insufficient flow of information along the supply chain and the challenges associated with the evaluation, authorisation and the restriction processes are slowing down the delivery of those benefits. As stated in the legal text, REACH's provisions are underpinned by the precautionary principle, however, since the entry into force of the legislation, the risk management actions proposed by the Commission have been limited. The development and consideration of alternative methods have greatly improved during the last ten years, although at the expense of the hazard information being delivered to Member States and hence at the expense of the protection of human health and the environment." (SWD, pages 126-127)

REACH NEEDS TO IMPROVE THE GENERATION OF INFORMATION ON HAZARDS, EXPOSURE AND USES OF SUBSTANCES.

Registration is the pillar of the REACH Regulation as it is intended to provide the information on hazards, uses and exposure needed to identify and control the risks posed by chemicals to human health and the environment. It is the basis for further regulatory action and for ensuring proper information along the supply chain and to consumers. Thanks to REACH, the amount of information available to the public and downstream users has significantly increased and ECHA has been able to set up a system that has managed (until June 2018) 82,282 dossiers for 20,428 unique substances. However:

- The poor quality of the information provided by the chemical industry in the registration dossiers is hampering REACH implementation:

"Work is still needed to rectify important data gaps or inappropriate adaptations in registration dossiers for specific endpoints and for information on uses and exposure. The data gaps or data quality issues in dossiers hamper the identification of priority substances for SVHC identification or other regulatory action". (SWD, page 26)

- Registration dossiers are not being updated, showing that the 'soft' and voluntary measures applied to encourage industry to comply with their legal obligations are not working:

"... only 25% of dossier owners conduct a regular routine review of their REACH data and 50% of updates were requested by ECHA. ECHA concluded in 2016 that stronger incentives may be needed for companies to stimulate updates of registration dossiers, especially on the use, exposure and tonnage information. The only incentive working in practice might be enforcement actions by the Member State Competent Authorities on dossiers which updates are overdue." (SWD, page 26)

- REACH is not generating new information on hazardous properties as expected:

Evaluation of substances needs to be improved and speeded up in order to generate new information:

"Fewer substance evaluations have taken place than predicted, with 82 decisions by ECHA on substance evaluation adopted so far. This falls far short of expectations of 448 substances evaluated by 2016. If more substances would be evaluated by the Member States, this would benefit the implementation of the integrated regulatory strategy conducted by ECHA." (SWD, page 31)

"Dossier and substance evaluation processes are working but need to be improved so that they can deliver faster and better, and do not represent the bottleneck in the 'pipeline' of the integrated regulatory strategy. Over half of the

registration dossiers have been found non-compliant, suggesting that industries have to generate further information." (SWD, page 31)

"Evaluation decisions are an important driver to generate new information; also in the recent decision of the European Ombudsman concerning the delay by the European Commission in processing files on reproductive toxicity of chemicals, the lack of incentives for registrants to spontaneously update their registration files despite their obligation is, together with the enforcement difficulties, have been identified as the main cause of the delay to generate new information." (SWD, page 32)

Less substances of very high concern (SVHC) than expected have been identified:

"In spite of these positive trends, REACH has not yet produced the amount of new information on chemicals that was expected when REACH was adopted, in particular concerning the long term endpoints. … This means that less new hazard information than expected has been generated to enable identification of substances of very high concern" (SWD, page 42).

There is a need to better identify endocrine disruptors:

"However, the tests required still do not include the endpoints relevant for endocrine disrupting properties or they are only optional. This suggests that a better integration is needed of the latest developments on test methods and screening strategies to better identify endocrine disrupting properties." (SWD, page 114)

There is a need to better address emerging issues:

"REACH is addressing emerging issues by increasing knowledge and addressing current gaps. Nonetheless, some challenges have been identified, generating relevant and specific information for nanoforms of substances, ensuring the identification of endocrine disrupting properties and addressing the combination effects of chemicals. Efforts are still needed to reflect on ways to integrate scientific developments into REACH so that it further addresses those emerging issues. With regards to the issue of nanomaterials, the ongoing revision of the REACH annexes should lead to a proportionate response to clarify the registration requirements for nanomaterials." (SWD, page 117)

Avoidance of animal testing is hindering the identification of new SVHC:

"This confirms that many registrants seriously implement the legal requirements to propose testing on animals only as a last resort. However, the adaptations used by registrants have often been found to be insufficiently justified, especially when the conclusion is the absence of a given hazard and in case of non-compliance, further testing is requested. ECHA has recently increased efforts to provide improved information and guidance to registrants, in order to improve the quality of adaptations. Consequently, less vertebrate animals than initially predicted have been used for testing, but on the other hand, hazard information has not been generated to the extent predicted." (SWD, page 28)

"Overall, effort has gone into the development and promotion of alternative methods. This is reducing the need for animal testing, but this may have been at the expense of delivering (hazard) information as for high-tier endpoints, alternative methods are not yet available and registrants have applied data waivers, adaptations or submitted testing proposals." (SWD, page 49)

"REACH has also promoted alternative methods for testing though the legislative requirements to only test on animals as a last resort has been implemented at the expense of hazard information relevant for the protection of human health and the environment." (SWD, page 126)

THERE IS A NEED TO IMPROVE THE FLOW OF INFORMATION THROUGHOUT THE SUPPLY CHAIN AND TO CONSUMERS, IN PARTICULAR ON SUBSTANCES IN ARTICLES

"The obligations to communicate the presence of SVHCs in articles allows operators along the supply chain to implement appropriate risk management measures as well as enabling operators and consumers to make informed purchasing decisions. This is happening, as information flows improve, but slower than foreseen reflecting perhaps the costs of managing the information flows and the need to learn from experience." (SWD(2018) 58 fin, p. 30)

"Efficient functioning of supply chain communication is necessary for economicoperators to implement appropriate risk management measures and to make

informed purchasing decisions as well as for the ability of suppliers to respond to consumer requests." (SWD, page 30)"The appropriateness of information for risk management passed along the supply chain could be further improved (i.e. SDS), especially among SMEs, as indicated by the relatively high level non-compliance (52%) related to the communication of information in the supply chain that has been observed through enforcement actions (more information in annex 4 paragraph 9.1.1). Information received with extended SDS in some cases leads to improvement of risk management measures. However, limited awareness may result in risk reduction measures not being applied by downstream users." (SWD, page 43)

"The communication requirement in Article 33 has triggered the development and potential use of information management tools by companies promoted by EU-projects or activities of some Member States. However, it remains difficult for actors in the supply chain to retrieve, verify and communicate information on SVHCs in articles. The transfer of information to the consumer greatly depends on a well-functioning communication in the supply chain as well as on the awareness and understanding of consumers about their «right to know». (SWD, page 30)

"Better tracking of chemicals of concern in products would facilitate recycling and improve the uptake of secondary raw materials, as part of the Circular Economy. However, this would require transfer of information on the chemical content of end-of-life articles to the waste management sector." (SWD, page 30)

THE RESTRICTION PROCESS IS NOT DELIVERING AS EXPECTED, ECHA DEMANDS TO MEMBER STATES NEED TO BE LOWERED AND MUST DILIGENTLY SCRUTINISE INDUSTRY REQUESTS FOR EXEMPTIONS

"Overall, the number of restrictions initiated per year is about the same as in the final years of the pre-REACH system. This falls far short of expectations at the time of adoption of REACH of 11 restrictions per annum." (SWD, page 35)

"A barrier to effectiveness is that it is difficult for Member States to find and invest resources in the preparation of Annex XV dossiers, which are demanding in terms of their technical/ economic content. One Member State estimated the costs of preparing a proposal for restrictions under REACH to be between EUR 0.5 -1 million. Other barriers include high demands by the ECHA Committees during their opinion-making process." (SWD, page 35)

"RAC and SEAC should diligently scrutinise the information submitted in the dossier and via the public consultation, including in particular requests for exemptions. Finally, the Commission services intend to provide guidance to RAC and SEAC as to how to adopt opinions when, despite all efforts, information is lacking." (SWD, page 132)

THE BURDEN OF PROOF HAS NOT BEEN EFFECTIVELY SHIFTED TO INDUSTRY

"However, the identified non-compliance of registration dossiers shows that although the burden of proof is on industry, the information provided is often not sufficient for authorities to identify and prioritise the need for action. In addition to the actions envisaged in REACH, ECHA and Member States invest resources to get the additional information from other sources, causing delays and returning to the 'pre-REACH' system where the full burden of proof was on authorities." (SWD, page 42)

THE PRECAUTIONARY PRINCIPLE HAS NOT BEEN APPLIED

"Since the entry into force of REACH, the Commission has not proposed measures where action was based on the precautionary principle as ECHA opinions have not triggered such principle. In most cases, the ECHA and its Committees did not assess the scientific uncertainties to enable the Commission to consider possible action based on the Precautionary Principle." (SWD, page 45)

THE EU WILL NOT MEET THE WORLD SUMMIT SUSTAINABILITY DEVELOPMENT 2020 GOALS

"REACH contributes to meeting the WSSD 2020 goal to achieve the environmentally sound management of chemicals also beyond the EU borders. Indeed, there has been considerable progress since the first goal was adopted in 2002. Notably, many of the targets set out by the ICCM in 2006 have been met or are on track to be met by 2020. However, a number of actions needed to meet the WSSD 2020 goals have not or only partially been carried out such as: information gaps identified in the registration dossiers; better targeting consumers or civil society at large; enhanced delivery of risk management measures. This contributes to the conclusion that it is not likely that the EU will meet the 2020 goal as set out

in 2002 and hence also not the one of 2017." (SWD, 67)

EEB's APPRAISAL OF THE COMMISSION COMMUNICATION ON THE REACH EVALUATION

The EEB welcomes the actions proposed by the Commission Communication to improve the implementation of REACH, in particular, the measures to:

- Improve evaluation procedure
- Improve the communication throughout the supply chain by improving the workability and quality of the extended Safety Data Sheets and by tracking substances of concern in the supply chain.
- Promote substitution of SVHC
- Improving the restriction procedure and frame the application of the precautionary principle.
- Enhance enforcement
- Support compliance by SMEs
- Guarantee ECHA's mission and independence

However, the Communication lacks action or is procrastinating action on key issues that hinder the capacity of REACH to effectively protect people and the environment from the risks posed by hazardous chemicals:

NO ACTION TO IMPLEMENT THE "NO DATA, NO MARKET" PRINCIPLE AND EFFECTIVELY SHIFT THE BURDEN OF PROOF TO COMPANIES

No action points are proposed by the Commission to improve the compliance and the quality of the information of the registration dossiers. Despite the recognition that this is the main hurdle to the effective implementation of REACH since REACH registration dossiers should be used for regulatory processes, the Commission procrastinates actions and decides to continue collaborating with industry to try to identify proposals for improvement. No legislative work or mandatory actions are proposed. No actions are included to truly incentivise and improve the quality of the registration dossiers. No action point on implementing act requiring mandatory updates of registration dossiers with precise deadlines is included. Without these actions the burden will continue relying on Member State authorities and ECHA Committees to complete the information needed for the development of subsequent REACH processes (e.g., candidate listing, restriction, authorisation, evaluation).

NO ACTION TO TRULY STIMULATE THE SUBSTITUTION OF TOXIC SUBSTANCES THOUGH THE AUTHORISATION PROCESS

Although we welcome the activities proposed by the Commission to promote capacity building, collaborative networks and R&D investments, no actions are considered to enhance the substitution of toxic substances though the authorisation process, which has been identified as the main driver for substitution:

- **No actions are considered for simplifying and speeding up the inclusion of SVHC in the candidate list.** From the 900 substances originally considered for screening through the RMOA process, conclusions have been finalised for 67 and only 36 substances have been added to the list between 2013 and 2017. However, the Commission, instead of recognising that the RMOA process is creating a bottleneck for the inclusion of SVHC in the candidate list, it concludes that the SVHC Roadmap is proving an effective tool and work at this stage is progressing as expected in terms of effectiveness. (SWD, 46)

- **No actions are considered to improve ECHA Committees' opinion making process regarding authorisation.** In particular, regarding the need to improve the analyses of alternatives and the socio-economic assessment process.

- **No actions are considered to avoid that authorisation is granted 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, undermining the authorisation process. It also hampers innovation and penalises companies that have created safer substitutes.

The EEB disagrees with the actions put in place, and further proposed by the Commission, under its deregulatory agenda, to reduce the costs for applying for authorisation (costs for applications halved since 2013) and simplifying the process as it provide incentives to continue using SVHCs instead of substituting.

NO ACTION TO ENCOURAGE PROPER EU-WIDE ENFORCEMENT OF ART. 33 AND MAKE THE CONSUMER "RIGHT TO KNOW" MORE PRACTICABLE

"REACH enables citizens to ask companies whether the articles they supply contain SVHCs, but this provision has had limited use (i.a. in terms of the response timeline of 45 days). Where it is used, companies struggle with its implementation." (COM(2018) 116 fin, p. 4)

Although we appreciate Action 4: Tracking substances of concern in the supply chain, as identified by the Review in COM(2018) 116 fin, which was already taken on board by the revised Waste Framework Directive, the Commission's communication lacks of concrete proposals to encourage proper EU-wide enforcement of article 33 and make the consumer "right to know" more practicable by for example labelling, development of mobile applications and/ or set up a reliable communication standard.

NO ACTION TO LOWER THE BURDEN OF REQUIRED EVIDENCE FOR REGULATING SUBSTANCES OF CONCERN AND IMPROVE THE USE (AND MISUSE) OF ALTERNATIVE TEST METHODS

As acknowledged by the REACH review, the current use (and misuse) of animal testing is lowering data quality and impeding the generation of data needed for identifying new substances of very high concern, undermining the protection of human health and environment. The Commission lacks of any action to lower the burden of proof to identify substances of concern for regulatory purposes by invoking the precautionary principle and the relevance of in vitro testing in order not to develop the animal tests. On the other hand, the Commission should have proposed actions to achieve a better balance between protecting laboratory animals and protecting people's health as well as the environment (including wildlife) such as the development of integrated experimental designs for the assessment of multiple toxicological endpoints.

NO ACTION TO BETTER ADDRESS EMERGING ISSUES, IN PARTICULAR NANOMATERIALS, ENDOCRINE DISRUPTORS AND COMBINATION EFFECTS OF CHEMICALS

Although the SWD acknowledged the difficulties of REACH to properly address the scientific gaps as to the suitability of test methods for nanoforms, endocrine disruptors and combination effects of chemical substances, there are no actions foreseen to generate the relevant and specific information needed for ensuring the implementation of risk management measures.

NO ACTIONS TO IMPROVE THE IDENTIFICATION OF NEW SUBSTANCES OF VERY HIGH CONCERN

Despite the thorough analyses of the issue and proposals for improvement provided by the SWD no action points are considered to improve the identification of new SVHCs and SVHCs with equivalent level of concern such as improving the interplay between ECHA Member State Committee and the Expert Groups. The proposed actions to improve the evaluations are welcomed although they are clearly insufficient.

NO ACTIONS TO BRING LOW-VOLUME PRODUCTION SUBSTANCES AND POLYMERS INTO THE REACH REGULATION

REACH includes a review clause stating that the Commission shall carry out, by 1 June 2019, a review to assess whether or not to extend the application of the obligation to perform a chemical safety assessment and to document it in a chemical safety report to substances manufactured or imported in quantities of less than 10 tonnes per year. Moreover, for carcinogenic, mutagenic and reprotoxic substances (CMRs), category 1A or 1B, the review should have been carried

out by 1 June 2014. (article 138.1)

The studies[4][5][6], published from 2014 to 2017 on whether to extend the requirement for chemical safety assessments and chemical safety reports to CMR 1A/1B substances below 10 tonnes and to modify the minimum standard information requirements for substances produced at 1-10 tonnes conclude that all the options assessed offer higher levels of protection of human health and the environment than the current requirements. The cost analysis of the different options concluded that all of the options would provide an increased benefits/costs ratio and also improve cost-effectiveness compared to the current requirements for registration in 2018.

Furthermore, REACH includes a review clause stating that the Commission may present, as soon as a practicable and cost-efficient way of selecting polymers for registration can be established, a legislative proposal aiming at registering a range of selected polymers. (article 138.2)

However, no action points are included to extend the scope of REACH. The adoption of measures is procrastinated due to concerns on the burden for industry of the increased information requirements. This is a missed opportunity to meet the legal deadlines, improve REACH and avoid the costs of inaction by generating inexistent information on low tonne chemicals, including CMRs and polymers.

THERE IS NO TIMEFRAME ON THE PROPOSED ACTIONS

Although we welcome the 16 actions by the European Commission to improve REACH, we miss clear commitments and a timeframe to ensure these actions will be performed without further delay.

4 Study number ENV.A.3/SER/2013/0057r: http://ec.europa.eu/environment/chemicals/reach/pdf/1-10t%20InfReq%20Final.pdf
5 Study number 070307/2013/668917/SER/ENV.A.3: http://ec.europa.eu/environment/chemicals/reach/pdf/1-10t%20P2%201-10t.pdf
6 Study number 2015 SFRA RPA SI2.724177 low tonnes: http://rpaltd.co.uk/uploads/report_files/reach-article-138-1-10-tonnes-reviews.pdf

EEB
European
Environmental
Bureau

European Environmental Bureau

Boulevard de Waterloo 34
B-1000 Brussels, BELGIUM

Tel +32 2 289 1090

eeb@eeb.org | www.eeb.org