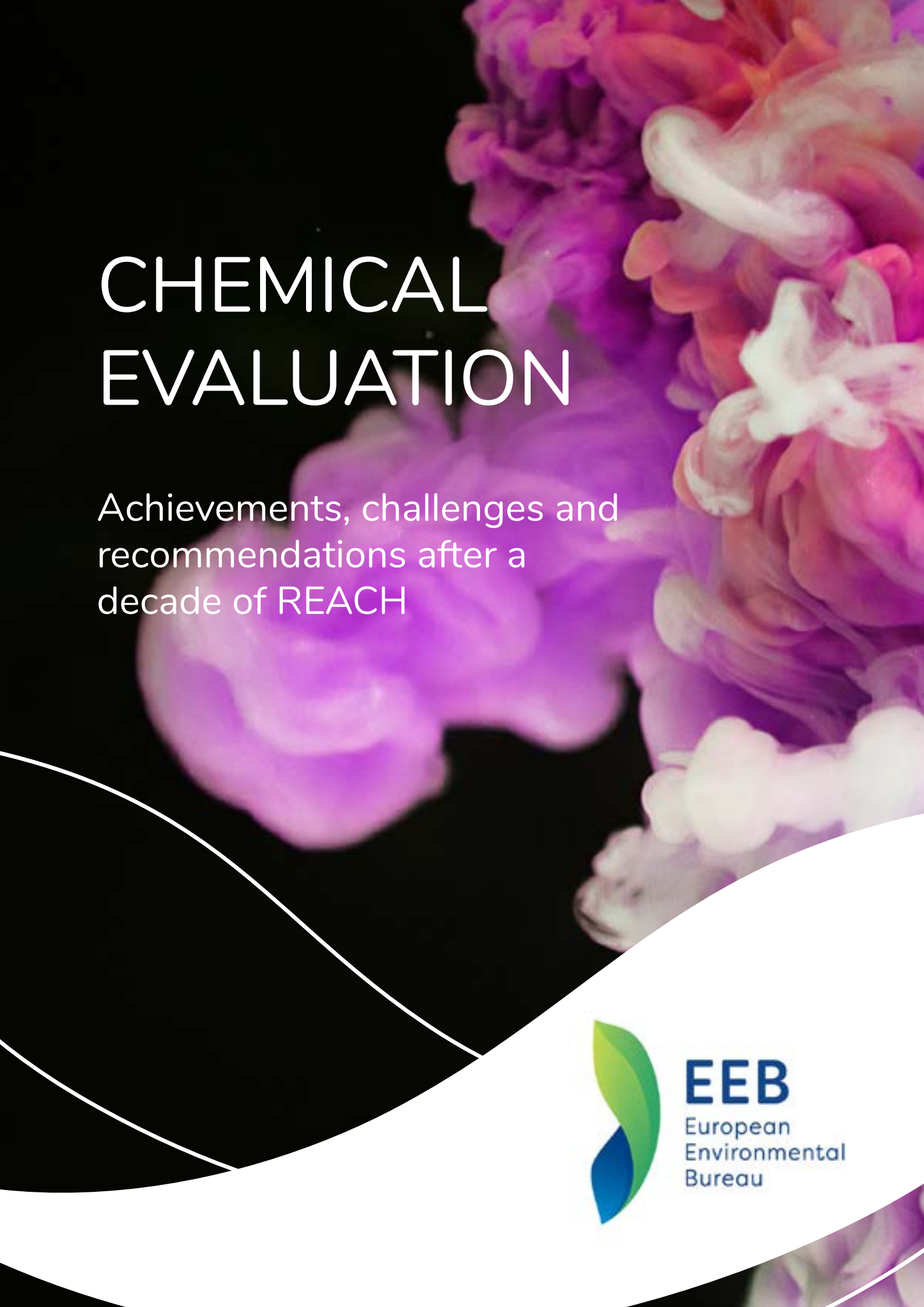

CHEMICAL EVALUATION

Achievements, challenges and recommendations after a decade of REACH

EEB
European Environmental Bureau

EUROPE'S LARGEST NETWORK OF ENVIRONMENTAL CITIZENS ORGANISATIONS

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Contents

Foreword

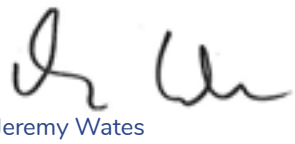
Over a decade ago, the European Union created a world-leading chemical regulation called REACH. One of its primary objectives was to overcome a state of 'paralysis by analysis' hampering regulators. REACH has made real progress in unlocking an unprecedented understanding of substances and their risks. Yet the analysis documented here reveals that progress is far slower than expected or hoped and a startling proportion of problem substances remain uncontrolled.

The numbers are a flashing warning light. Of the 94 completed and available substance evaluations filed by late 2018, nearly half of substances are known to be unsafe. Three-quarters of these have seen no meaningful regulatory action, despite potentially being present in all manner of consumer and other goods. More than a hundred substances are suspected dangerous, but their makers have failed to provide the legally required data that regulators need to act.

Chemical exposure is causing a silent pandemic of disease, according to United Nations rapporteur Baskut Tuncak. Everybody knows somebody struggling with allergies, fertility problems, cancer or other chemical exposure-related health problems. An ever increasing number of persistent and toxic substances are found in our environment and drinking water. No wonder then that polls show chemical exposure is a consistent topic of high public concern. In this year of European elections, with populism on the rise, REACH should be a flagship demonstration of how the EU can deliver on behalf of citizens, protecting their health and environment while position European industry at the forefront in the transition to a cleaner safer world. And yet it is not achieving its full potential. The numbers revealed in this report are stark. But in urging officials to raise their game, we also urge them not to get lost in the numbers. Regulators must regulate, not hesitate, snowblind in data blizzard and sealed in office siloes. They must enforce the law, sanction wrongdoers, send a signal that supports frontrunners and curbs the real-world harm being done. And they must do this with an urgency and at a pace commensurate with the suffering being caused.

Jeremy Wates
Secretary General

Jeremy Wates has served as Secretary General of the European Environmental Bureau, Europe's largest network of environmental citizens' organisations, since May 2011.



Jeremy Wates
Secretary General

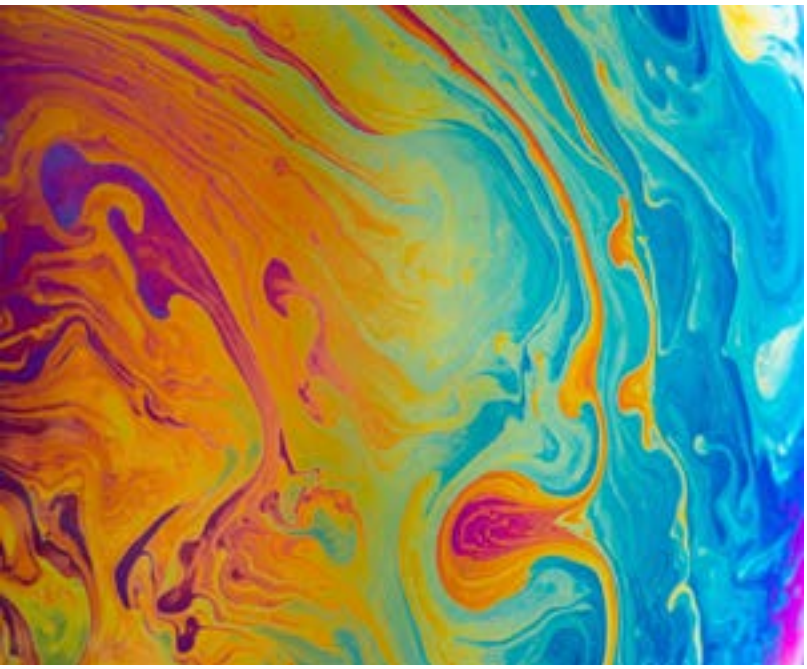
Executive summary

The REACH Registration process generated knowledge for nearly 22,000 substances in over 90,000 registration dossiers by the third registration deadline on 31 May 2018. With this impressive amount of data, REACH has the potential of becoming an advanced, global model and it has great potential in achieving its main goal of protecting human health and the environment from the exposure of chemicals.

REACH consists of four processes: Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). In this report the achievements of the REACH Evaluation process are reviewed. The two steps of Evaluation under REACH are Dossier evaluation and Substance evaluation. Dossier evaluation is performed by the European Chemicals Agency (ECHA), while Substance evaluation is executed by the Member States.

Dossier evaluation checks whether the information provided by industry in the registration dossiers is compliant with the legal information required by REACH. ECHA performed Dossier evaluations on over 2,000 dossiers covering 700 substances. Dossier evaluation revealed that 70% of the dossiers is not compliant with the legal information requirements of REACH.

The aim of Substance evaluation is to clarify whether a substance is of concern for human health or the environment and if so, recommend risk management measures to properly address these concerns. In this report the results obtained under Substance evaluation are analysed and factors contributing to the slow pace of evaluation are discussed together with recommendations to improve evaluation under REACH.



Under REACH, 352 substances were prioritised for Substance evaluation in CoRAP (Community Rolling Action Plan) by the end of 2018. 94 Substance evaluations were completed by the end of 2018. Member States concluded that **for almost half of the substances with completed Substance evaluation the use today on the EU market is not safe for EU citizens and/or the environment. Risk management has been initiated for only twelve substances to control the risks as follow-up of the Substance evaluation programme since the entry into force of REACH. For 74% of substances (34 out of 46), concerns were demonstrated, but no actual regulatory follow-up has been initiated to control the risks. These substances are allowed on the EU market today, while it is known that their use is not safe for EU citizens and/or the environment.**

In addition, Member States concluded that **64% of the substances under evaluation (126 out of 196) lacked the information to demonstrate the safety of the chemicals marketed in Europe**. Further information was required from industry before the concerns could be clarified, extending the evaluation procedure to an average estimated 7 - 9 years, during which exposure of people and environment continues.

The results achieved by Evaluation under REACH demonstrate the need to speed-up evaluation and make the process more effective. Suggestions for improvement are included in this report. Registration dossiers do not comply with the information required by law and do not contain sufficient information to ensure a safe use for EU citizens and the environment. This shifts back the burden of proof to authorities and it delays the implementation of risk management measures (restriction, authorisation and classification & labelling). **The results also demonstrate the need to improve the interface between Evaluation and follow-up risk management. If a concern is identified, risk management** should be initiated without delay.

The results obtained under Evaluation after 10 years of REACH demonstrate the need to streamline and simplify the Evaluation process.

Introduction

REACH aimed to shift the responsibility of ensuring that chemicals placed on the EU market do not adversely affect human health or the environment, making industry rather than the authorities responsible for assessing the risks and hazards of substances. ECHA together with member state authorities would check whether industry implemented this new responsibility properly and if not, authorities would propose measures quickly and efficiently to manage potential risks appropriately.

The REACH Registration process generated knowledge for nearly 22,000 substances in over 90,000 registration dossiers by the third registration deadline on 31 May 2018[1]. The REACH database now contains information on all chemicals on the EU market > 1tpa. With this impressive amount of data, REACH has the opportunity of becoming an advanced, global model and it has great potential in achieving its main goal of protecting human health and the environment.

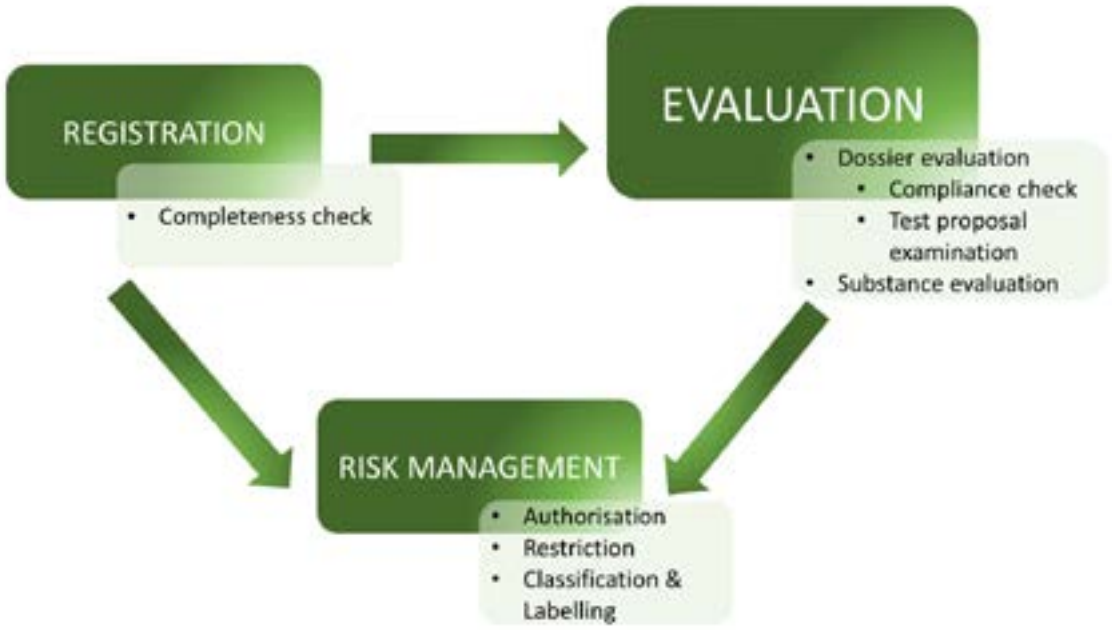
The Registration process is the pillar of the REACH regulation as it aims to generate the information needed through the supply chain to ensure safe use of the substances and the information that should prompt regulation if dangerous chemicals are identified under REACH, such as authorisation, restriction or the need for a mandatory, harmonised classification and labelling at EU level.

However, the second REACH Review[2] concluded that compliance of the data was not at the expected level: “Issues have been identified in particular in relation to the quality of dossiers,” and recognised that the Evaluation process under REACH is not working as efficiently as expected. ECHA found through the process of dossier evaluation that 70% of the checked dossiers were not in compliance with REACH information requirements[3].

As follow-up of the second REACH Review a lot of discussion was triggered on the process of dossier evaluation and how to improve compliance of dossiers. However, discussion on Substance evaluation remained lacking. The aim of Substance evaluation is to clarify suspected concerns of a given substance. In this report, the EEB analysed the results obtained so far under Substance evaluation. For how many substances sufficient information was available in the dossiers to assess their safety? What was the number of substances for which further data generation was needed? For how many substances risks were not adequately controlled? To what extent were the identified risks followed-up by regulatory risk management measures to reduce them?

First, a short explanation of the main processes relating to Evaluation in REACH is provided, followed by an analysis of the achievements under REACH Evaluation, with focus on the EEB analysis of the results achieved under Substance evaluation. Finally, the bottlenecks and challenges of the Evaluation process are discussed together with recommendations for improvement.

THE EVALUATION PROCESS UNDER REACH



Completeness check

The completeness check is part of the Registration process. It is performed by ECHA on all dossiers upon submission and takes place before assigning a registration number. The completeness check does not assess the quality or suitability of the data but ensures that all required elements are formally present in the registration dossier. The “No data, no market” principle should apply: if a dossier is found incomplete, no registration number should be assigned. Completeness check is not formally part of the Evaluation process under REACH and should not be confused with the compliance check.

Dossier evaluation

ECHA performs Dossier Evaluation (DEv), which can be either a Compliance Check of the dossier or a Testing Proposal Examination.

Compliance Check (CCh): ECHA verifies whether the registration dossiers submitted by industry comply with the standard information required by law under REACH, including the Chemical Safety Assessment (CSA), Chemical Safety Report (CSR) and proposed risk management measures by the registrant. Compliance checks are undertaken on a sample of the dossiers submitted at each tonnage level. At least 5% of the dossiers at each tonnage level should be checked for compliance by law. ECHA decides in consultation with the Member State Committee (MSC) if and what further information is required from the registrant to make the dossier compliant.

Testing Proposal Examination (TPE): The registrant submits a testing proposal detailing the tests that are required according to Annexes IX and X of REACH (for substances > 100 t/a). ECHA decides in cooperation with the MSC whether these tests are necessary and under which conditions.

Substance evaluation

Substance Evaluation (SEv) is the in-depth evaluation of substance concerns by national Member State Competent Authorities (MSCA). The in-depth evaluation is performed on substances that have been prioritised because of suspected concerns for human health or the environment. Prioritised substances are listed in the Community Rolling Action Plan (CoRAP). The draft CoRAP is proposed by ECHA and the final CoRAP is adopted on the basis of the opinion of the MSC (Member State Committee). Substance evaluation may conclude that further information is required to clarify the suspected concerns, before a final conclusion can be reached. Once the Substance evaluation is concluded, MSCA considers how the information can be used for the purpose of risk management measures such as authorisation, restriction or classification & labelling.

Evaluation is crucial. Risk management -classification and labelling, restrictions and authorisations- all start with reliable data.

Achievements and challenges a decade into REACH

Completeness check

Achievements

Completeness check is not part of the Evaluation process under REACH but is performed upon registration. Completeness check is addressed in this report because it may have an impact on the adequacy of the dossiers and because completeness check and compliance check are sometimes confused in the discussions about REACH.

The completeness check was performed on ALL dossiers submitted in the Registration process of REACH as legally required by REACH (Article 20.2). After the last registration deadline on 31 May 2018, ECHA performed an enhanced completeness check on all dossiers within 3 months after the deadline.

Challenges

Three percent of the dossiers registered in 2018 were found incomplete by ECHA and were not assigned immediately a registration number - part of these registrations are still pending, awaiting further information.

An extensive evaluation of data availability on high production volume chemicals (HPVC) by the German Federal Institute for Risk Assessment (BfR) and the German Environment Agency (UBA)[45], suggests that dossiers with incomplete data are still allowed on the market as they were given a registration number by ECHA. Reasons for non-compliance listed in the BfR study include missing data, information not documented, not available or not provided; wordings suggesting that these dossiers should not have passed the completeness check.

Granting registration numbers, even when dossiers were not complete is contrary to REACH provisions (Article 20.3), hinders the ability of the authorities to regulate chemicals and essentially moves the burden of proof back towards authorities[6]. The automated completeness checks performed before 2016 failed to identify dossiers that were de facto incomplete in certain areas. The automated completeness check was improved, and the manual completeness check implemented in 2016. Given the lack of updates of dossiers[7] and the findings of the BfR and UBA evaluation, it can be assumed that substances that should not have been granted a registration number due to incomplete data are still on the market today.

Recommendations

Apply the 'No data, no market' principle. EEB proposes that ECHA retrospectively subjects to the enhanced completeness check all substances that were not subjected to this enhanced check before (i.e. dossiers not updated since implementation of the enhanced completeness check). Registration numbers should be revoked if dossiers are still incomplete in order to ensure a level playing field and to favour companies taking REACH seriously.

Require mandatory periodic updates. REACH Article 22 requires mandatory updates of registration dossiers when new data becomes available. Lack of updates cause a waste of time and resources for ECHA and member states when preparing draft decisions based on outdated information. 75% of the dossiers have never been updated by the dossier owners since the initial registration, while other registrants implemented the practice of annual dossier updates. Annual updates should become the standard for all dossiers at tonnages > 100 t/a and should be the aim of the implementing act planned by the Commission.

Improve transparency (1). Information on substances that did not pass the completeness check is not made public, neither is information on companies for which market access was not granted and the reasons behind. Completeness check decisions can therefore not be challenged undermining the access to justice of citizens.[8]

Improve transparency (2). Information on dossier updates is not easily accessible to the public. Only the latest update date can be found at ECHA's website, with no information about the different respective updates and the nature of these. We recommend ECHA to publish the date for each dossier update and which data have been updated. The information on the registrants that annually update dossiers and registrants that never updated their dossiers should also be listed and easily searchable.

Compliance check

Achievements

ECHA met the minimum legal requirement of compliance checks of 5% of the registration dossiers > 1000 t/a. It performed dossier evaluation on around 2,000 dossiers covering 700 substances by the end of 2018. The results presented in this section are based on ECHA's 10th Evaluation Progress Report detailing the achievements made in the first ten years of REACH[9].

In the first 10 years after entry into force of REACH, ECHA compliance checked 7% (1,350) of the dossiers registered before the 2010 deadline and 4% (430) of the dossiers registered before the 2013 deadline. A total of 1,952 compliance checks were performed in the first 10 years of Evaluation under REACH, 70% of which were found non-compliant, leading to a Decision requesting further information from the Registrants. The total number of requests resulting from compliance checks amounted 2,582 by the end of 2017. The majority of information requests related to human health toxicity (37%), ecotoxicity and environmental fate (26%), substance identification (16%), and chemical safety report (14%).

Around 85% of the end-points that were originally non-compliant, were concluded to be compliant after follow-up evaluation. ECHA sent a Statement of non-compliance (SONC) to the member state competent authority (MSCA) and National Enforcement Authority (NEA) of the registrants' country for enforcement action in the remaining cases. 76 unresolved SONCs were reported by the end of 2017.

Status of dossiers after follow-up evaluation	Percentage of dossiers
Compliant	85%
Not compliant	14%
2nd compliance check	1%

Table 1: Follow-up conclusions of dossier Evaluation after requested information has been submitted. Figures are based on ECHA's Progress Report on Evaluation, 2017

Challenges

The 2nd Review on the operation of the REACH Regulation published by the Commission in 2018 [10], concluded that achievement of the objectives of REACH have been hindered due to the high level of non-compliance of the registration dossiers.

Non-compliance of dossiers was also addressed in the evaluation of all HPVC dossiers by the German Federal Institute for Risk Assessment (BfR) and the German Environment Agency (UBA), revealing that even for high-volume chemicals (> 1000 t/a) only 31% of the (eco)toxicological endpoints were clearly compliant with the legal requirements under REACH. One third (32%) of these endpoints was found in non-compliance, lacking basic safety information on the most concerning health and environmental properties (cancer, neurotoxicity, mutagenicity, bioaccumulation and/or hazards to developing children or human fertility), whereas 37% of the endpoints contained complex information, requiring further scrutiny. It was even suggested that only one dossier was found compliant in all endpoints. For 100-1000 t/a substances the following figures were found: 44% compliant, 19% non-compliant and 37% complex cases. It was concluded that many high tonnage dossiers urgently need improvement[11].

ECHA reported that non-compliance is for a large part due to inadequate adaptations of the standard information requirements and poorly justified data waiving statements[12]. According to ECHA, around 75% of registrations contain read-across instead of reliable experimental data. As a consequence, newly generated data on developmental studies, toxicity for reproduction, genetic toxicity, repeated dose toxicity or toxicokinetics is scarce since REACH entered into force. This is fundamental information to ensure substance safety.

ECHA launched a varied set of 'soft measures' since 2009, such as (targeted) letter campaigns to registrants, quality observation letters, informal contact with companies, lists of substances that are likely to face compliance checks, and REACH guidance updates. Although, "soft measures" triggered dossier updates, their effects are not sufficient as shown in table 2 below. The percentage of non-compliant dossiers remained well over 50% over the years.

A general lack of incentives exists to ensure compliance, while there are too many encouraging the opposite. Some examples of incentives for non-compliance are the low chance that a dossier will be evaluated, the lengthiness of the process, the lack of transparency and the lack of regulatory action or softness of enforcement (if any). Enforcement, transparency and market access are the best incentives to improve compliance.

Year	2009	2010	2011	2012	2013	2014	2015	2016	2017
Number of CCh	14	70	239	146	1130	283	183	184	222
% Non Compliant	50%	64%	92%	61%	61%	82%	91%	91%	68%

Table 2: Percentage of non-compliant dossiers identified in compliance checks based on ECHA's Evaluation Progress Reports 2008-2017.

Recommendations

Improve transparency on registration dossiers (1). Increase transparency about non-compliance to the public in order to inform which dossiers are not reliable and for which dossiers safety is not proven. Disseminating the names of compliant and non-compliant companies, or a traffic light system for the dossiers that pass an evaluation in the dissemination portal are good incentives to encourage compliance as both market access and reputation are important for companies[13].

Improve transparency on dossier decisions (2). Preparatory documents related to decision making are confidential and, even after the decision has been taken, essential parts of the decision may be censored (including the company name).

Increase the compliance check rate beyond 5%. The low level of non-compliance requires an increased rate of compliance checks beyond the 5% minimum. ECHA should specify numbers and dates for achieving certain percentages of compliance checked dossiers, such as the date by which all high-volume chemicals will be checked for compliance.

Publish information on the level of compliance in random checks. ECHA indicates that the figure of 70% non-compliance is not representative, because compliance check is targeted on dossiers suspected to be non-compliant. However, the BfR/UBA project on REACH compliance showed for ALL high production volume chemicals (>1,000 t/a) that only 30% of the endpoints were clearly in compliance with REACH legal information requirements. Information on the level of compliance found in random checks should be disseminated.

Implement compliance checks for the newly submitted low-tonnage registrations. Meeting the 5% compliance check rate for the newly submitted dossiers means > 1,750 compliance checks to be performed. By what date will this legally required minimum be achieved? Consider how to assess the safety of the lower volume chemicals with limited available data. Shift from compliance check to Substance evaluation may be needed.

Extend compliance checks, increase the number of compliance checks of chemical safety assessments and chemical safety reports.

Set information requirements for low tonnage substances and polymers. Evidence suggests that further assessment of the affordability of registration requirements for low tonnage substances and registration of certain polymers is warranted.

Address the misuse of data waiving and non-animal test methods. Incorrect data waiving is the main reason for non-compliance of most of the registration dossiers. ECHA and enforcement authorities should be stricter when allowing these chemicals in the market. Ensure that protection of test animals is not achieved at the expense of protection of human health and the environment as acknowledged by the Commission in the second REACH review staff working document.

Improve enforcement. National enforcement is needed to elicit updates and improve industries' overall compliance with their legal obligations. Enforcement measures and sanctions should be harmonised across the EU member states and EEA countries in order to establish a level playing field. The Forum REACH-EN-FORCE reports 1, 2 and 3 show that 'soft' prescribed measures (mainly verbal and written advice) undertaken as a result of non-compliance are predominant[14 15 16], REACH article 126 says that "the penalties provided for MUST be effective, proportionate and dissuasive." It is time to move on from soft measures, guidance and advice, and get serious about enforcing compliance. 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 the minimum.

Accelerate regulatory risk management action. Initiate regulatory actions (restriction, authorisation or harmonised C&L) without delay on substances with non-compliant dossiers, if risks to workers, consumers or the environment are not controlled.

Non-compliance hampers and delays implementation of REACH follow-up processes. Compliance, high-quality data and dossier updates are essential for effective REACH implementation. Industry must comply with information requirements and keep dossiers up-to-date.

Substance evaluation

Achievements

Under REACH, 352 Substances are scheduled for Substance evaluation in the Community Rolling Action Plan (CoRAP) because of suspected concerns by the end of 2018. Member States have worked on 265 of them. The status and outcome of these Substance evaluations is detailed in figure 2. The numbers were derived from the ECHA website by the end of 2018[17].

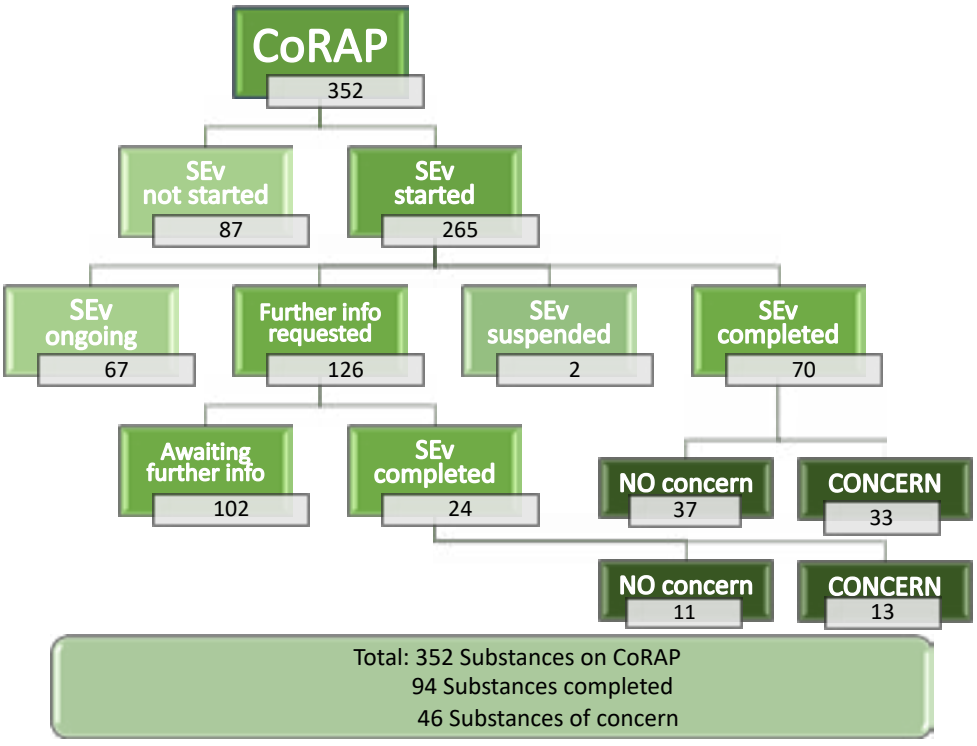


Figure 2: Number of substances processed through Substance evaluation

Conclusions

-The Community Rolling Action Plan lists 352 substances.

-Substance evaluation is ongoing or completed for 265.

-Evaluation is ongoing and awaiting decision for 67 substances.

-Evaluation was completed without need for further information for 70 substances; 33 were concluded to be of concern and 37 were not considered of concern.

-Further information was requested before a final conclusion on the need for risk management measures could be drawn for 126 substances out of 196. **The figures indicate that 64% of the substances under evaluation lacked the information that is needed to assess whether the risks are adequately controlled for public health and the environment arising from their use on the EU market.**

-38% (102) of the substances for which evaluation started are awaiting further information and follow-up evaluation.

-For 24 substances the requested information has been provided and evaluated in the follow-up evaluation; 13 were concluded to be of concern and 11 were not considered of concern.

-In total 94 Substance evaluations (70+24) have been completed and concluded under REACH by the end of 2018. **Hence, after ten years of REACH, evaluation was completed for 94 of the substances committed under CoRAP, showing the lengthiness of the process.**

-For 46 out of 94 substances, it was concluded that the risks are not adequately controlled. This means that **for almost half (49%) of the substances with completed Substance evaluation, further risk management measures are needed** to protect the citizens and the environment from the risks arising from the use of the substance in Europe.

Regulatory Follow-up to Substance Evaluation

Once the information obtained from Substance evaluation is available, the EU member state considers how to use that information for the purpose of authorisation, restriction and mandatory classification and labelling (under CLP Regulation). The recommendations made as follow-up of Substance evaluations are listed in table 3. Table 3 also indicates to what extent these recommendations have been followed-up by actual proposals to implement the risk management measures.

The conclusion that risks exist from use of the substance on the EU market was followed-up by actual proposals for risk management measures for 12 out of 46 substances with identified risks: two restrictions (one adopted and included in Annex XVII), one substance identified as Substance of Very High Concern and included in the Candidate list; and 10 proposals for C&L.

No additional intentions for the preparation of proposals were found in the Registry of intentions or PACT. This means that for 74% of the substances (34 out of 46), concerns are demonstrated, but no actual regulatory follow-up has yet been initiated to control the risks. Concerns relate to the carcinogenicity, mutagenicity, reprotoxicity, sensitising properties or endocrine effects of substances and persistent, bioaccumaltive and toxic or very persistent and very bioaccumulative substances. Exposure is likely in all cases, due to high tonnage, wide dispersive uses, consumer uses and/or exposure of the environment.

Risk management measures (RMM) have been recommended for 46 substances following Substance evaluation. The total number of recommended RMM (60) listed in table 3 exceed the number of 46 evaluated substances, because in some cases multiple measures have been proposed for the same substance (for example C&L and restriction for the same substance).

Risk Management Measure (RMM) recommended as follow-up of Substance evaluation	Number of substances for which RMM is recommended in SEv conclusion	Number of Substances for which RMM proposal is submitted to ECHA
Restriction	5	2
SVHC Identification, Candidate List and possible Authorisation	8	1
Classification & Labelling	33	10
Other EU wide measures, e.g. occupational exposure level setting	10	Not analysed
Further action to be decided	4	0

Table 3: Follow-up to Substance evaluation: Recommended and Actual submitted proposals for risk management. Figures are derived from ECHA website by end of 2018.

Challenges

Substance evaluation under REACH takes many years before a conclusion can be drawn. Substance evaluation has been completed for 94 substances by the end of 2018, which is considerably less than the 448 Substance evaluations that were expected before the onset of REACH (entailing only 21% of the forecast)[18] . Lack of information in the dossiers hampers and slows down the pace of Substance evaluation. For 64% of Substance evaluations, further information is required from industry before the safe use of the substance can be clarified. The lack of data and following requests for further information prolong the evaluation process by many years. Figure 3 presents the legal procedure of Substance evaluation as foreseen by REACH, if further data is required.

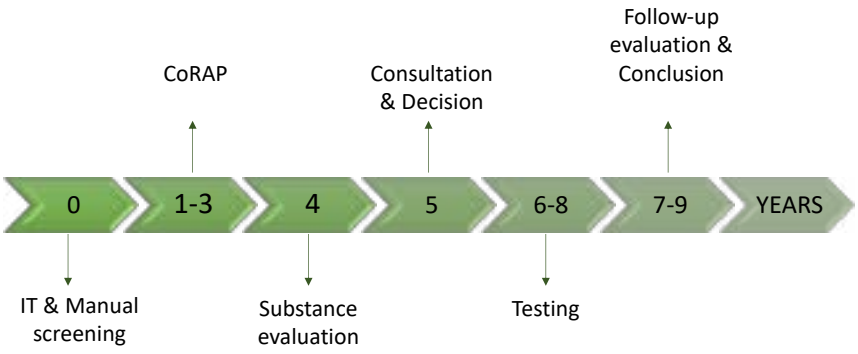


Figure 3: Substance evaluation, legal procedure in REACH.

Depending on the duration of further test requirements (usually 1-3 years), a conclusion can be drawn after 7-9 years, if the legal timeframes are respected. However, other factors may contribute to even longer duration of Substance evaluation.

Table 4 lists the number of substances in the CoRAP procedure, the number of substances for which no decision is taken (Substance evaluation is ongoing, and no decision is taken yet on the need for further information) and number of Substance evaluations completed in relation to the year of evaluation scheduled in CoRAP.

Year	2012	2013	2014	2015	2016	2017	2018
Total number of substances	36	47	51	48	39	22	21
SEv ongoing, no decision taken	0	1	10	9	11	16	21
SEv completed number and %	19 (53%)	21 (45%)	16 (31%)	14 (29%)	13 (33%)	5 (23%)	0

Table 4: Total number of substances scheduled in CoRAP for each year, Substance evaluation ongoing (no decision on further information taken) and number of Substance evaluations completed.

Substance evaluation is completed for around half of the substances listed in CoRAP 2012 and 2013. This means that it takes more than 5 years to clarify suspected concerns for around half of the substances. Table 4 demonstrates that Substance evaluation is still ongoing, and no decision has been taken for 30 substances that were scheduled for Substance evaluation in 2012 - 2016.

Postponement of the year of evaluation in CoRAP contributes to even longer procedures than shown in table 4. The scheduled year of evaluation in CoRAP was postponed for around half of the substances listed in CoRAP over the last two years (51 substances postponed in 2017, for unknown reasons probably pending compliance check, 50 substances postponed in 2018). Certain substances reside on CoRAP for many years, before the Substance evaluation is finally started. An example is triphenyl phosphate suspected of having endocrine effects. It is an organic flame retardant used in consumer products and detected at high levels in household dust. The substance was originally scheduled for evaluation in 2013 in CoRAP. After postponement of the year of evaluation in CoRAP for four years in a row, evaluation was finally started in 2017 (and counted for 2017 in table 4).

Ironically, since implementation of the Integrated Regulatory Strategy in 2015, that aimed to speed up the evaluation process, the length of the evaluation process has become even longer, mainly because Substance evaluation awaits the outcome of the compliance check. This is often indicated as the reason for postponing the year of evaluation on CoRAP. While this might take away the reason for Substance evaluation in certain cases, it unacceptably prolongs the Substance evaluation in others.

Overall, it takes 7-9 years or more before a suspected concern is clarified if further information is required. This timeframe for clarifying the risks and deciding which regulatory measures to adopt is clearly too long for chemicals that are suspected to be of concern. Then, the development of risk management measures such as restriction or authorisation still has to start, which may take another 5-7 years until implementation. This means that it may take 12 to 16 years to regulate chemicals of concern. Meanwhile people and the environment are unnecessary exposed. Lengthy evaluation procedures lead to delays in the development of risk management measures and put at risk the European citizens and the environment.

Recommendations

Accelerate evaluation (1): Avoid delays in CoRAP. Half of scheduled Substance evaluations in CoRAP were postponed over the last years. Consider how to implement an integrated approach to accelerate evaluation. Consider how approach proposed by ECHA can be developed into an efficient approach integrating compliance check and substance evaluation within legal prerequisites.

Accelerate evaluation (2): Respect legal timeframes stipulated by REACH. Ensure that preparation of draft decision or conclusion of evaluation is completed within 12 months of publication of CoRAP as stipulated in article 46.1 of REACH. Start follow-up evaluation if requested information is not provided by legal deadline and ensure that follow-up evaluation is completed within 12 months as required by REACH article 46.3.

Accelerate evaluation (3): Avoid delays in reaching conclusions due to requests for further testing. Ensure that all available information is used. It is important to use all weight of evidence and apply the precautionary principle. In cases of very high level of concern, restriction should follow immediately instead of substance evaluation.

Accelerate evaluation (4): Optimise interplay between Expert groups and MSC. Organise a workshop for MSC and EGs to align principles and optimise use of expertise in Expert Groups on PBT and Endocrine Effects to accelerate decisions.

Implement review of final conclusions of evaluation. Currently no review of the follow-up conclusion by the evaluating MSCA is foreseen for MSC. The final decision whether the substance is of concern is the sole responsibility of the evaluating MSCA. Implement consultation for MSC on the final conclusion of Substance evaluation by default.

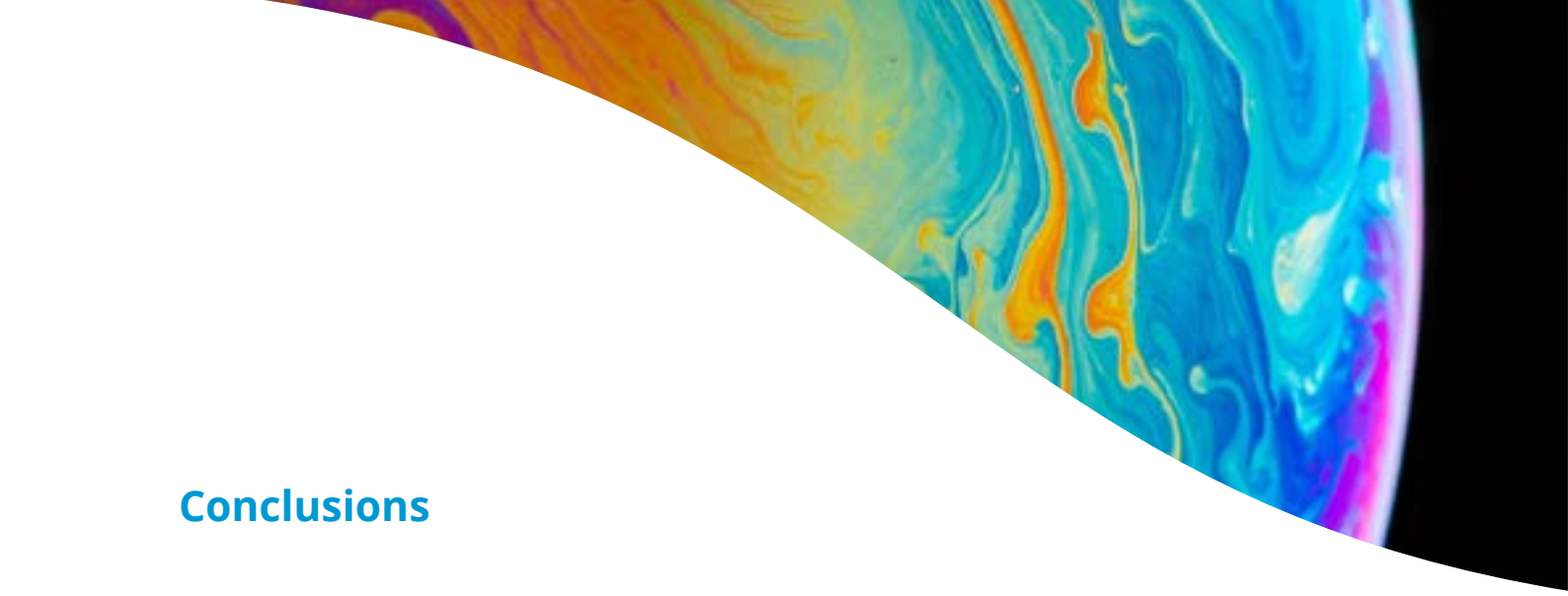
Improve transparency of decision-making: Hardly any access is granted to preparatory documents for Substance evaluation. Given the complexity of the cases and of the decisions, it would be very difficult to challenge a Substance evaluation decision.

Improve transparency of conclusion of Substance evaluation: The lack of transparency impedes the public to knowing what substances are not proven to be safe, what are their concerns, and which are the companies illegally marketing those.

Accelerate regulatory risk management action if concern is confirmed in Substance evaluation. Currently there is a general lack of risk management measures initiated as follow-up of Substance evaluation. Ensure that risk management proposals are prepared without delay if concern is confirmed. MSCA to prepare Annex XV restriction dossier if MS considers that risks to human health or the environment are not adequately controlled (art. 69(4)).

Improve enforcement. The achievement of the REACH objectives to protect human health and the environment is undermined and slowed down due to the high level of non-compliance and low level of Substance evaluations. Harmonised enforcement actions across EU member states are urgently needed.

Regulatory risk management measures have been initiated for 12 substances as follow-up of the Substance evaluation programme since the entry into force of REACH (one restriction, one SVHC identification, 10 proposals for C&L). Concerns are demonstrated for 34 substances, but no proposals for risk management have yet been submitted to ECHA by the end of 2018. Clarification of suspected concerns of substances on the EU market takes many years. Increased resources are needed for ECHA and MSCA to speed-up evaluation and to accelerate regulatory follow-up if concern is confirmed through Substance evaluation.



Conclusions

The implementation of REACH is well underway. However, reaching its full potential of protecting human health and the environment from the exposure to dangerous chemicals is severely hampered by (1) the lack of compliance of registration dossiers, (2) lengthy evaluation procedures and low output of Substance evaluations, and (3) lack of regulatory follow-up actions when concerns are identified.

(1) 70% of the dossiers provided by chemical registrants is not compliant with the legal requirements, (2) suspected concerns remain unclarified for many years, while exposure of EU citizens and the environment continues and (3) three quarters of the substances found to pose a serious risk to human health or environment have seen no regulatory action for the time being.

A proper discussion at political level is needed on how to (1) truly allocate the burden of proof on industry and (2) improve the burdensome and lengthy evaluation procedures and (3) ensure strong and proper enforcement, to speed-up the evaluation work and thereby improving the implementation of risk management measures that are urgently needed.

A deciding factor in whether public bodies are able to protect European citizens and the environment from dangerous chemical exposure is whether or not proper resources are allocated to substance evaluation. Today, this is not the case.

End notes

1 Registration, ECHA https://echa.europa.eu/registration-statistics-infograph

2 REACH Review 2018, Commission Staff Working Document accompanying the COM (2018) 116 Communication on Commission General Report on the operation of REACH and review of certain elements – Conclusions and Actions https://ec.europa.eu/docsroom/documents/28202

3 ECHA's Progress Report 2017. Evaluation under REACH: 10 years of experience. Available at: https://publications.europa.eu/en/publication-detail/-/publication/06ab3ae9-4f46-11e8-be1d-01aa75ed71a1/language-en

4 REACH compliance: Data availability of REACH registrations Part 1: screening of chemicals > 1000 tpa (2015); https://www.umweltbundesamt.de/publikationen/reach-compliance-data-availability-of-reach

5 REACH compliance: Data availability in REACH registrations Part 2: evaluation of data waiving and adaptations for chemicals > 1000 tpa (2018); https://www.umweltbundesamt.de/publikationen/reach-compliance-data-availability-in-reach

6 REACH FORWARD priorities for effective regulation. Discussion paper policy conference Brussels 1 June 2016. https://www.government.nl/documents/publications/2016/06/03/discussion-paper-reach-forward

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

8 10 years in: time for ECHA to disseminate strategic information to empower third parties; Clientearth 2017 https://www.documents.clientearth.org/wp-content/uploads/library/2017-12-18-10-years-in-time-for-echa-to-disseminate-strategic-information-to-empower-third-parties-ce-en.pdf

9 Evaluation under REACH, Progress Report 2017, DOI: 10.2823/76886, ECHA https://echa.europa.eu/documents/10162/13628/evaluation_under_reach_progress_en.pdf/24c24728-2543-640c-204e-c61c36401048

10 REACH Review 2018, Commission Staff Working Document accompanying the COM (2018) 116 Communication on Commission General Report on the operation of REACH and review of certain elements – Conclusions and Actions https://ec.europa.eu/docsroom/documents/28202

11 REACH compliance: Data availability in REACH registrations Part 2: evaluation of data waiving and adaptations for chemicals > 1000 tpa; https://www.umweltbundesamt.de/publikationen/reach-compliance-data-availability-in-reach

12 ECHA's Evaluation Progress Reports (2008-2017): https://echa.europa.eu/es/regulations/reach/evaluation

13 10 years in: time for ECHA to disseminate strategic information to empower third parties; Clientearth 2017 https://www.documents.clientearth.org/wp-content/uploads/library/2017-12-18-10-years-in-time-for-echa-to-disseminate-strategic-information-to-empower-third-parties-ce-en.pdf

14 Forum Reach-en-Force-1 Project Report https://echa.europa.eu/documents/10162/13585/ref-1_project_report_conclusions_en.pdf/346ccbf3-3152-48d8-99c7-533ec5fd80c5

15 Forum Reach-en-Force 2 Project Report https://echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf

16 Forum Reach-en-Force 3 – Phase 1 Project Report https://www.echa.europa.eu/documents/10162/13577/forum_report_ref3_en.pdf

17 Substance evaluation – CoRAP https://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

18 REACH Review 2018, Commission Staff Working Document accompanying the COM (2018) 116 Communication on Commission General Report on the operation of REACH and review of certain elements – Conclusions and Actions https://ec.europa.eu/docsroom/documents/28202

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Annex 1

Case studies

Bisphenol A
Bisphenol A is added to plastic goods made from PVC and polycarbonate. It can be found in a wide array of consumer products such as food packaging and plastic bottles, tableware, toys, and sport equipments. BPA in food contact materials can migrate into food resulting in human exposure. BPA is detected in the urine and blood of almost all humans. Exposure to low doses of BPA is associated with miscarriages, decreased birth weight, male infertility, breast and prostate cancer, altered immune system activity, obesity, cognitive and behavioural development disorders in young children. Evaluation of Bisphenol A under REACH resulted in the official conclusion that the substance has endocrine disrupting effects on human health and the environment, this after decades of discussion among authorities. The decision will lead to strong regulatory action in the future. However, today BPA is still found in many day-to-day consumer products leading to continuous exposure of citizens including vulnerable groups like newborn babies.

Annual production: Over 1,000,000 tonnes
Substance evaluation - CoRAP
ECHA brief profile, including information on producers and uses
Date added to CoRAP: 2012
Date file was concluded: 2017
Status by winter 2018: Substance evaluation complete. Risk management measures started.

Triphenyl phosphate (TPP)
TPP belongs to the group of organophosphate flame retardants used in furniture, curtains and electronic equipment. TPP is a potential endocrine disruptor and therefore prioritised for substance evaluation. TPP is reported at high concentrations in indoor dust from UK cars, classrooms, living rooms and offices (Brommer and Harrad, 2015). TPP is an example of how long it can take to clarify the suspected concerns. It was first prioritised for evaluation in 2013 because of concerns about its endocrine disrupting effects. The start year of evaluation was postponed in CoRAP for four consecutive years (2013 -> 2014 -> 2015 -> 2016 -> 2017). Concerns about its endocrine effects are still not clarified today and regulatory action not taken, while exposure continues.

Annual production: 100 - 1000 tonnes
Substance evaluation: CoRAP
ECHA brief profile, including information on producers and uses
First date added to CoRAP: 2013
Status by winter 2018: Incomplete

Titanium dioxide
Titanium dioxide is a suspected carcinogen and mutagen (altering DNA). The substance was originally scheduled for substance evaluation in 2013 to clarify the properties of concern of titanium dioxide (including the nano form). The ECHA database does not contain public registered data indicating whether or in which chemical products the substance might be used. However it is known that the substance is used in a wide range of products that can be used by consumers (including sensitive populations), for example paints, varnishes, inks, coatings, plastics, rubbers, papers, plasters, adhesives, coated fabrics and textiles, glassware, ceramics, electronic components, floor coverings, roofing granules, food additives (E 171), pharmaceuticals, cosmetics, dental impressions, etc.

In 2014, ECHA performed a compliance check of the registration for titanium dioxide and concluded on the need of further information to allow France to properly evaluate the risks. However, the companies registering TiO2 challenged ECHA's decision to avoid this information being submitted. In 2017, the board appeal annulled this decision (case number: A-011-2014) based on ECHA's request deficiencies. Nevertheless, France made a proposal in 2015, for EU harmonised classification for titanium dioxide as carcinogen (Carc. Cat 1B – H350i). This proposal covered "particles of titanium dioxide in all phases, phase combinations and morphologies". In September 2017, the RAC concluded that titanium dioxide should be classified as Carc. 2 – H351 (inhalation). Today, following unprecedented lobbying by industry, the ECHA recommendation is still questioned by the European Commission and some Member States based on economic arguments (irrelevant to classification and labelling process) and consensus has not been reached.

Six years after the evaluation process started, the recommendation to classify TiO2 as a suspected carcinogen (by inhalation) is not implemented by the EU authorities.

Annual production: Over 1,000,000 tonnes
Substance evaluation: CoRAP
ECHA brief profile, including information on producers and uses
First date added to CoRAP: 2013
Status by winter 2018: Incomplete

Annex 2

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Substances on the EU market posing a hazard or risk to human health and/or the environment

Substance	EC Number	Annual Tonnage	EU regulatory action*	ECHA's Brief Profile of Substance
Methanol	200-659-6	10 000 000 - 100 000 000	Yes	https://echa.europa.eu/brief-profile/-/briefprofile/100.000.599
Pentan-1-ol	200-752-1	100 - 1000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.000.684
Chloromethane	200-817-4	1 000 000 - 10 000 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.000.744
Ethylene oxide	200-849-9	1 000 000 - 10 000 000	Yes	https://echa.europa.eu/brief-profile/-/briefprofile/100.000.773
Bisphenol A	201-245-8	1 000 000 - 10 000 000	Yes	https://echa.europa.eu/brief-profile/-/briefprofile/100.001.133
Methyl methacrylate	201-297-1	100 000 - 1 000 000	Yes	https://echa.europa.eu/brief-profile/-/briefprofile/100.001.180
Naphtalene	202-049-5	100 - 1000		https://echa.europa.eu/brief-profile/-/briefprofile/100.001.863
3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate	202-112-7	10 - 100	Yes	https://echa.europa.eu/brief-profile/-/briefprofile/100.001.921
Butanone oxime	202-496-6	1 000 - 10 000	Yes	https://echa.europa.eu/brief-profile/-/briefprofile/100.002.270
Furfuryl alcohol	202-626-1	10 000 - 100 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.002.388
Citronellal	203-376-6	10 - 100		https://echa.europa.eu/brief-profile/-/briefprofile/100.003.070
Succinic anhydride	203-570-0	1000 - 10 000	Yes	https://echa.europa.eu/brief-profile/-/briefprofile/100.003.246
Maleic anhydride	203-571-6	100 000 - 1 000 000	Yes	https://echa.europa.eu/brief-profile/-/briefprofile/100.003.247

Resorcinol	203-585-2	1 000 - 10 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.003.260
Cyclohexanone	203-631-1	1 000 000 - 10 000 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.003.302
n-hexane	203-777-6	1 000 - 10 000	Yes	https://echa.europa.eu/brief-profile/-/briefprofile/100.003.435
1,3,5-trioxane	203-812-5	100 000 - 1 000 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.003.466
Decan-1-ol	203-956-9	10 000 - 100 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.003.597
6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol	204-327-1	1 000 - 10 000	Yes	https://echa.europa.eu/brief-profile/-/briefprofile/100.003.934
Benzophenone	204-337-6	1 000 - 10 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.003.943
Hydroquinone	204-617-8	10 000 - 100 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.004.199
Acetone oxime	204-820-1	100 - 1 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.004.383
Benzothiazole-2-thiol	205-736-8	1 000 - 10 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.005.216
Dimethyl disulphide	210-871-0	10 000 - 100 000	Yes	https://echa.europa.eu/brief-profile/-/briefprofile/100.009.883
2,4,6-tri-tert-butylphenol	211-989-5	100 - 1 000	No / Yes	https://echa.europa.eu/brief-profile/-/briefprofile/100.010.900
Dipotassium tetraborate	215-575-5	100 - 1 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.014.160
Octabenzone	217-421-2	1 000+	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.015.838
7-oxabicyclo[4.1.0]hept-3-ylmethyl 7-oxabicyclo [4.1.0]heptane-3-carboxylate	219-207-4	1 000 - 10 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.017.463
1,3,5-Tris(oxiran-2-ylmethyl)-1,3,5-triazinane-2,4,6-trione (TGIC)	219-514-3	100 - 1 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.017.741
N,N-dicyclohexylbenzothiazole-2-sulphenamide	225-625-8	1 000 - 10 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.023.296
Citral	226-394-6	10 000 - 100 000		https://echa.europa.eu/brief-profile/-/briefprofile/100.023.994
Hexyl salicylate	228-408-6	1 000 - 10 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.025.826
Silver (incl. nano form)	231-131-3	1 00 000 - 1 000 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.028.301

Beryllium	231-150-7	10 - 100	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.028.318
Sodium perchlorate	231-511-9	1 000 - 10 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.028.647
Disodium disulphite	231-673-0	1 00 000 - 1 000 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.028.794
Potassium permanganate	231-760-3	1 000 - 10 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.028.874
Ammonium perchlorate	232-235-1	1 000 - 10 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.029.305
Amylase, α-	232-565-6	1 000 - 10 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.029.592
(-)-pin-2(10)-ene	242-060-2	10 000 - 100 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.038.222
Diisotridecyl adipate	247-660-8	1 000 - 10 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.043.313
Phenol, dodecyl-, sulfurized, calcium salts	272-486-4	-	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.065.878
2-(phenylmethoxy)naphthalene	405-490-3	1000+	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.100.706
Nonylphenol, branched, ethoxylated	500-209-1	100+	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.105.700
1-(2-hydroxy-5-nonyl(branched)-phenyl)ethanone oxime	627-083-1	10+	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.155.416
Fatty acids C18 unsat, reaction products with Pentaethylene-hexamine	629-732-4	100 - 1 000	No	https://echa.europa.eu/brief-profile/-/briefprofile/100.157.862

Source: European Chemicals Agency, http://echa.europa.eu

* Regulatory action: 'Yes' means that risk management proposal is submitted to ECHA while 'No' means that no proposal is received by ECHA. It is not the responsibility of the evaluating member state to take the regulatory follow-up action. Further details on actual status of regulatory action can be found at ECHA website in the Registry of Intentions for restrictions, SVHC and CLH. Table refers to proposals as follow-up of substance evaluation.

Further details on Substance Evaluation and CoRAP can be found at ECHA website: https://echa.europa.eu/es/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table

Note that in the brief profile (link to substance information on ECHA website): up to date information on tonnage, company names, substance evaluation etc. can be found.