

## REACH Evaluation Joint Action Plan

### Ensuring compliance of REACH registrations

#### 1. Why This Action Plan?

The 'R' in REACH<sup>1</sup> ('Registration') sets out legal obligations on industry to demonstrate that the substances they manufacture or import are used safely. Industry thereby must meet tonnage dependent minimum information requirements on the hazards of their substances, and also inform on their volumes, uses and exposure.

The 'E' in REACH ('Evaluation') provides that ECHA and the Member States can evaluate the information submitted by companies. Under dossier evaluation, ECHA, in cooperation with the Member States, checks if industry meets their registration obligations. If the information submitted is insufficient, industry is required to fill the gap. Under substance evaluation, Member States evaluate substances to clarify a potential concern. Industry may be required to submit further information or perform a test if additional information is needed going beyond the standard information requirements. Therefore, both dossier and substance evaluation contribute to the generation of relevant data which can then be used to identify if risk management measures by industry or at EU level are necessary.

ECHA must check the compliance of at least 5% of all registration dossiers within each of the tonnage bands. When REACH was adopted, this percentage together with Member State penalties and enforcement actions was considered sufficient to achieve industry's compliance.

The European Commission concluded in its second report on the operation of REACH<sup>2</sup> that REACH was fully operational and delivering results towards its objectives. Despite steady progress, there are however key issues that hamper progress, notably the non-compliance of registration dossiers. This is in line with ECHA's findings<sup>3</sup> through the ten years of performing compliance checks. The German Federal Institute for Risk Assessment (BfR) and the German Environment Agency (UBA)<sup>4,5</sup> came up with similar findings in other reports and, in 2018, their study concluded that, out of a set of 3 800 dossiers of substances registered over 1000 tonnes per year, only one third met the information requirements, whereas one third likely did not. The situation for another third was unclear.

These findings are of substantial concern despite ECHA already exceeding the 5% compliance check target in the higher volume registrations. The explanations are multiple. Compared to the expectations 15 years ago, industry submitted substantially more adaptations covering data gaps and substantially fewer testing proposals, at least in part due to the fact that the provisions to reduce animal testing were strengthened during the adoption of REACH. These adaptations are very often lacking solid scientific justification and have made the assessment of the information more complex and time consuming. In addition, incentives are lacking for companies to update their dossiers and rectify data gaps or inappropriate adaptations to

<sup>1</sup> Regulation (EC) No 1907/2006 concerning the Registration, Evaluation and Authorisation of Chemicals (REACH). OJ L 396, 30.12.2006, p. 1. Corrected version in OJ L 136, 29.5.2007, p. 3.

<sup>2</sup> Commission communication on the REACH review: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2018:116:FIN>

<sup>3</sup> ECHA's annual evaluation reports and reports on the operation of the REACH regulation: <https://echa.europa.eu/overall-progress-in-evaluation>

<sup>4</sup> <https://www.bfr.bund.de/cm/349/reach-compliance-workshop-at-the-bfr.pdf>

<sup>5</sup> <https://www.bfr.bund.de/cm/349/data-quality-of-environmental-endpoints-in-registrations.pdf>

testing<sup>6</sup>. Irrespective of the explanations, the consequences of non-compliance in the registrant's dossier are clear: first, the registrant and accordingly any of his downstream users cannot implement the necessary risk management measures nor provide adequate safety advice in the supply chain. Therefore, workers, EU citizens and the environment are not fully benefiting from the protection REACH offers. Additionally, industry is not getting a fully functioning internal market, with a level playing field, nor all the competitiveness and innovation benefits that new information and enhanced knowledge could bring. Finally, this hampers the functioning of other REACH and CLP processes and the implementation of other EU chemicals legislation, which depends on REACH for information.

Therefore, the evaluation process, and in particular the compliance check, contributes to an important extent to the generation of relevant data on chemicals and to instil confidence of the general public in industry taking responsibility to ensure the safety of their chemicals.

This Joint Action Plan is ECHA's and the Commission's answer to address the lack of compliance of the information in the registration dossiers. It brings a more comprehensive approach to reap the human health, environmental and economic benefits of REACH. It also requires commitment from authorities to make the process more efficient and industry to review their dossiers and generate further information as needed.

The action plan is in line with ECHA's new strategic plan 2019-2023<sup>7</sup> which places data generation and identification and regulation of substances of concern at the core of ECHA's work in the next years. But, it offers a new and more ambitious approach to identify substances that deserve to be regulated and to obtain compliance within a timeline of nine years.

## 2. The Objectives of the Action Plan

*By 2023 for all registrations in the tonnage bands over 100 tonnes/year and by 2027 also for the tonnage bands 1-100 tonnes/year, ECHA will have screened<sup>8</sup> all registration dossiers submitted by the 2018 deadline, independent of their tonnage band and performed a compliance check for all substances where data gaps prevent from concluding whether there is a concern or the substance is of low priority for further regulatory action.*

ECHA estimates that 20% of all registration dossiers in each tonnage band will be checked for compliance. Overall this corresponds to 30% of all registered substances.

There will continue to be newly registered substances, new manufacturers or importers of already registered substances and updates to existing registrations. The screening will be periodically repeated to take the new information into account and identify and plan further action as needed. This also means that dossier and substance evaluation will carry on beyond 2027.

In order to achieve these objectives, additional human resources must be (re)allocated to significantly increase the efforts on compliance check. ECHA and the Commission assume that Member States, the Commission as well as ECHA will not receive additional resources, but do expect a constant resourcing at least up to 2027. The increase in resources must therefore

<sup>6</sup> See the European Ombudsman decision OI/2/2016/RH.

<sup>7</sup> ECHA's Strategic Plan 2019-2023: [https://echa.europa.eu/documents/10162/26075800/echa\\_strategic\\_plan\\_2019-2023\\_en.pdf/3457ccff-7240-2c1f-3a15-fa6e5e65ac56](https://echa.europa.eu/documents/10162/26075800/echa_strategic_plan_2019-2023_en.pdf/3457ccff-7240-2c1f-3a15-fa6e5e65ac56)

<sup>8</sup> See Section 3.1

come from re-prioritising within the overall resources available for REACH and CLP. Considering the increased workload stemming from the implementation of the actions as result of the second REACH review, efforts are needed for creating efficiencies under all other REACH and CLP processes.

The implementation of the plan requires a reduction in bureaucracy in the decision making, an increase in enforcement efforts, interaction with industry associations to ensure registrants step up their compliance efforts, and the establishment of a transparent and publically available monitoring system of the progress made.

### 3. The Action Plan

Compliance check is embedded in ECHA's Integrated Regulatory Strategy<sup>9</sup> that supports authorities to use the most appropriate combination of REACH and CLP processes to address substances of concern as effectively as possible.

#### 3.1. Address all substances

In 2018, ECHA developed an approach<sup>10</sup> in order to decide how all registered substances need to be addressed and accelerate the work.

All dossiers are screened using IT-based algorithms in order to group<sup>11</sup> all registered substances according to their structural similarity and other available information such as category information provided by the registrants in their dossiers.

Each individual group of substances is then subject to further manual assessment to identify whether the substances are:

- **Of priority for regulatory risk management**

These are substances with an identified concern. There is sufficient information to initiate either:

- hazard identification (Harmonised Classification and Labelling or identification as Substances of Very High Concern for PBT and/or ED properties); or
- a restriction or authorisation process under REACH or further regulatory risk management measures under other EU legislation.

- **Currently of low priority for further regulatory action**

These are substances which are already subject to sufficient regulatory requirements including existing risk management measures that are deemed sufficient, or for which available data is sufficient to conclude that they are of low concern at present. For those of low concern, the priority will be reconsidered when/if new information related to hazard or use is submitted.

<sup>9</sup> Integrated Regulatory strategy, General report 2018, page 9:

[https://echa.europa.eu/documents/10162/21877836/general\\_report\\_18\\_en.pdf/4b442bd7-5b03-e2ce-ed3d3ac1b785861c](https://echa.europa.eu/documents/10162/21877836/general_report_18_en.pdf/4b442bd7-5b03-e2ce-ed3d3ac1b785861c)

<sup>10</sup> Mapping the chemical universe to address substances of concern, Integrated Regulatory Strategy Annual Report 2019, April 2019. [https://echa.europa.eu/documents/10162/27467748/irs\\_annual\\_report\\_2018\\_en.pdf/69988046-25cc-b39e-9d43-6bbd4c164425](https://echa.europa.eu/documents/10162/27467748/irs_annual_report_2018_en.pdf/69988046-25cc-b39e-9d43-6bbd4c164425)

<sup>11</sup> This approach does not correspond to the specific 'grouping of substances and read-across approach' as laid out in section 1.5 of Annex XI to REACH.

- **Of priority for data generation**

For the substances which the assessment could not already fit into one of the two pools above, a substance could still be of concern due to its hazardous properties, potential for exposure or data gaps preventing from concluding on the need for regulatory risk management action or low priority. These substances are prime candidates for compliance check and/or substance evaluation. The information generated and/or submitted by the registrants further to the evaluation decision will be assessed to allocate the substances in any other of the two pools above.

The approach has been validated and is already in use for substances registered over 100 tonnes. It will be adapted in the next two years as needed for substances registered in the two lowest tonnage bands, 1-10 tonnes and 10-100 tonnes.

By 2027, the aim is to have checked all registration dossiers, allocated all registered substances in the pools above and requested information where needed.

This action plan focuses on how ECHA and the Commission will step up their efforts to address the substances which are of priority for data generation, via compliance check or substance evaluation. The plan also relies on the Member States that play an integral role in all evaluation and enforcement processes.

The substances concerned by the Action Plan are the 16 500 substances registered in full<sup>12</sup> in 66 000 dossiers as of end 2018.

However, the EU chemicals market is dynamic and this number will grow over time. Based on trends observed so far, it is estimated that over 3 000 new substances will have been registered by 2027. In addition, ECHA receives every year about 2 500 new dossiers for already registered substances and 15 000 dossier updates. Main reasons for updates are triggered by new information on intrinsic properties or uses, outcomes of evaluation decisions or revised information requirements (e.g. for nanomaterials). Therefore, all actions described below have a first deadline, but should be understood as a periodic activity to take new information into account and keep the conclusions up-to date.

35-40% of substances registered above 100 tonnes, and a lower share of 20% for substances registered in the 10 – 100 and 1 - 10 tonnage bands are expected to be of priority for data generation. This directly corresponds to the 20% of registration dossiers in each tonnage band that are projected to be checked for compliance by 2027.

**Action 1:** By mid-2019, the Commission will propose an amendment of Article 41(5) of REACH to raise the 5% minimum target in Article 41(5) to 20% of dossiers selected for compliance checking.

**Action 2:** By end of 2020, ECHA will have concluded for all substances registered above 100 tonnes/y if they are i) of priority for regulatory risk management, ii) currently of low priority for further regulatory action, or iii) need more data for a judgement to be made. Substances under iii) are candidates for further compliance check and/or substance evaluation. These conclusions will be made publicly available and will be accompanied by clear communication to all stakeholders involved.

<sup>12</sup> Substances registered with intermediate uses only are not considered.

**Action 3:** By end of 2021, ECHA will have developed an approach that will allow drawing similar conclusions for substances registered in lower tonnage bands.

**Action 4:** By 2023 for all registrations in the tonnage bands over 100 tonnes/year and by 2027 also for the tonnage bands 1-100 tonnes/year, ECHA will have concluded for each of the registered substances submitted by the 2018 deadline if it is a priority for regulatory risk management, of low priority for further regulatory action, or have requested information under compliance check where needed.

### 3.2. Improve clarity of certain legal provisions

ECHA has built up experience in applying the REACH legal provisions concerning compliance of registration dossiers. This experience comes from prospective registrants' enquiries to the helpdesk and in drafting, obtaining agreement on and checking compliance with evaluation decisions. A common and clear interpretation of the legal provisions is key in helping industry get clarity on which information must be submitted, in reducing the need for discussions and thereby supporting an efficient implementation of REACH. Based on ECHA's experience, the Commission will attempt to clarify where necessary the provisions and propose changes through an implementing regulation if needed.

**Action 5:** By end of 2019, the Commission will assess the need, and if necessary make a proposal, to amend the Annexes VI to X of REACH to provide greater clarity to the information requirements set out therein.

**Action 6:** By end of 2019, on the basis of the experience gained by ECHA, the Commission will assess the need, and if necessary make a proposal, to amend Annex XI to ensure that adaptations to standard information requirements are properly justified.

**Action 7:** By end of 2019, the Commission will assess the need of a possible implementing regulation that would efficiently put into effect the REACH evaluation decision making process.

### 3.3. Accelerate the compliance check decision making

Based on the experience gained in drafting compliance check decisions and defending these decisions towards the Board of Appeal and the Court of Justice, the text of the decisions will be improved to be clearer, more concise and easier to defend and enforce.

The Member States have the right to propose amendments to ECHA's draft decisions. This is a welcome quality control. However doing so triggers the need for discussion of the proposal within the Member State Committee and a further consultation of the registrant and requires additional work and time. Increased collaboration between the ECHA Secretariat, members of the Member State committee and the Member State Competent Authorities in order to agree on the path forward before decision making is expected to reduce and better focus proposals for amendments. This will help reduce the workload for the competent authorities, ECHA and the registrants, accelerate the decision making and therefore allow to obtain the requested

data faster.

Improvements achieved in the compliance check decision making will be applied to the substance evaluation decision making as appropriate, and better integration of both processes will be sought.

**Action 8:** By end of 2019, ECHA will simplify the compliance check decisions and improve the statement of reasons, to be clearer and more focused.

**Action 9:** By end of 2019, ECHA will organise workshops with Member States, also on bilateral basis, with the aim of resolving underlying differences of view. The result will be presented to ECHA's Member State Committee for endorsement. In addition, ECHA will continue, as far as possible, identify and plan discussions on more generic issues that may arise in upcoming compliance checks.

**Action 10:** By end of 2019, ECHA will make a refined proposal to CARACAL how to better integrate substance evaluation and compliance check.

### **3.4. Keeping dossiers compliant, improving follow-up and enforcement of ECHA evaluation decisions**

Member States are required to execute enforcement action if a registrant does not comply with a decision and to establish effective, proportionate and dissuasive penalties for those registrants not complying with ECHA's decisions. Member States have been enforcing ECHA's evaluation decisions and effectively ensuring that the requested information is submitted.

Requests made to registrants to submit information via compliance check decisions are mostly fulfilled. For the remaining cases, enforcement is involved. The main reasons are: non-submission of information by the deadline, submission of a non-compliant adaptation or of the test result that does not comply with the conditions set in the decision. For each of these reasons, dedicated and specific enforcement action may be needed.

As of 2019, when ECHA's decisions are sent to all member registrants, enforcement will become more complex, requiring the Member States to keep enforcement as a high priority and dedicate sufficient resources to this area of controls. Enforcement of ECHA's decisions is a critical element of the national system of controls and should be reported together with all other inspection activities. Clear national penalties or enforcement measures that prohibit marketing of substances for registrants who failed to comply with ECHA's evaluation decisions would significantly strengthen the impact of enforcement actions.



**Action 11:** By end of 2019, ECHA will ensure that any company submitting relevant new information during a restriction, an identification of substance of very high concern, an authorisation or a harmonised classification process and that has not preceded such submission with the corresponding update of the registration dossier, will be informed of its updating obligations according to Article 22 of REACH. Moreover, in such cases ECHA will inform the responsible MS(s), so enforcement action is pursued as appropriate.

**Action 12:** By end of 2019, ECHA will prepare a compilation of enforcement measures in place in each Member State to address the breach of dossier evaluation decisions and an assessment to what extent enforcement authorities in different Member States address non-compliance with ECHA's decisions through prohibition of marketing of the substance.

**Action 13:** By end of 2020, the Commission will assess the effectiveness of the enforcement measures above, including the information submitted by Member States in their Article 127 report by 1<sup>st</sup> June 2020.

**Action 14:** By mid-2020, ECHA's Forum will have established the template to test annual reporting to the ECHA's Secretariat including a summary of all enforcement actions taken by each Member State in the area of dossier compliance. The first such report should be made available by mid-2021. ECHA's Secretariat will propose to ECHA's Forum that such annual reporting is permanent and becomes integrated in the Article 127 report.

### 3.5. Industry takes on the compliance challenge

Compliance of the individual dossier is a matter of each individual registrant. However, organisation of information in joint submissions, efficiency of capturing groups of substances either through similarities in hazard or due to common uses, exposure information etc. speak for the organisation of the dossier review and update in a more systematic manner. Companies with a large portfolio or business associations are in position to launch programmes capturing many substances and update the information as necessary to identify current weaknesses, introduce new knowledge and where necessary propose optimised testing strategies. The purpose is to contribute to better planning of compliance action by ECHA and faster and more efficient fulfilment of the objectives of this action plan.

**Action 15:** By end of 2019, ECHA will have established working arrangements with major industry associations, which will be transparent and inclusive, aiming at industry committing to develop action plans for proactive and continual improvement of their registration dossiers.