Action 2: Increase predictability for regulatory risk management

The Issue?

The current system for regulating chemicals is overly complex, not always transparent, slow, unpredictable, and resource intensive. Although REACH streamlined and consolidated legal requirements on chemicals back in 2006, chemicals are still subject to more than 40 different pieces of EU legislation, with a few more added recently[1]. Rresponsibilities for chemicals are divided across multiple authorities, European Commission directorates, and agencies.

Each of these legislations have their own specific processes leading to decisions on what and how to regulate. The vast majority of the final rules are set via implementing legislations (a mix of implementing acts, delegated acts, and measures via regulatory procedure with scrutiny). As a result, the regulatory system is a maze of rules. Once a chemical enters into the maze, it becomes impossible to predict if, when and how it will be regulated (Annex I).

In 2016, ECHA launched its Integrated Regulatory Strategy (IRS) seeking to identify substances or groups of substances that could potentially raise a concern. In some cases, a voluntary upfront analysis of regulatory options, like the Regulatory Management Option Analysis (RMOA), is performed by certain Member States. However, this process is fragmented and inconsistently applied, leading to several challenges, including:

- REACH regulatory actions are often applied as the go-to process by competent authorities, while other legislative tools may be more suitable.
- The effectiveness of the regulatory action is typically assessed once the regulatory process has been initiated by the authorities, i.e. authorisation or restriction, leading to suboptimal outcomes, inefficient use of resources, and delayed decision-making.[2]
- There is no firm commitment to adhere to the selected risk management route in the RMOA, creating a risk of contradictory and overlapping regulations.

In addition, the process does not systematically and transparently take industry's input into consideration overlooking sector specificities.

The Solution?

Towards a more transparent and centralised system for regulatory risk management analysis

Industries, authorities and society share a need for a system which uses resources efficiently, is transparent and can – more effectively – identify the "high risk substances and uses", allowing to choose and practically implement the best and targeted solution to manage risks to human health and the environment. This can be achieved via REACH or other regulatory risk management frameworks

[1] Ecodesign for Sustainable Products Regulation, Packaging and Packaging Waste legislation, Batteries Regulation.

[2] The case of cobalt salts is an example of delays in decision-making and attempts to retroactively fix the issue: in 2011, 5 cobalt salts were recommended to be included in Annex XIV (authorisation); in 2017, the European Commission requested ECHA to prepare a restriction proposal instead of the authorisation route; at the end in 2021, the European Commission decided to set an Occupational Exposure Limit (OEL) under the Carcinogens, Mutagens and Reprotoxins Directive (Directive 2004/37/EC) which still has to be adopted.

for example, Industrial Emissions Directive, product specific legislation, occupational health and safety legislation.

The choice of the most appropriate risk management framework requires a better understanding of the concern by an upfront analysis of available data on hazardous chemicals resulting in:

- identification of high-risk uses of substances, based on more realistic use and exposure information, and
- a joint regulatory risk management action rolling workplan for identified priority chemicals and uses for which risk-mitigating action is agreed to be taken either under REACH or other regulatory tools.

REACH can provide the framework to do the assessment and provide for the process for the identification of the appropriate risk management actions.

Figure 2 gives a simplified schematic overview of the proposed process for regulatory risk management action identification.

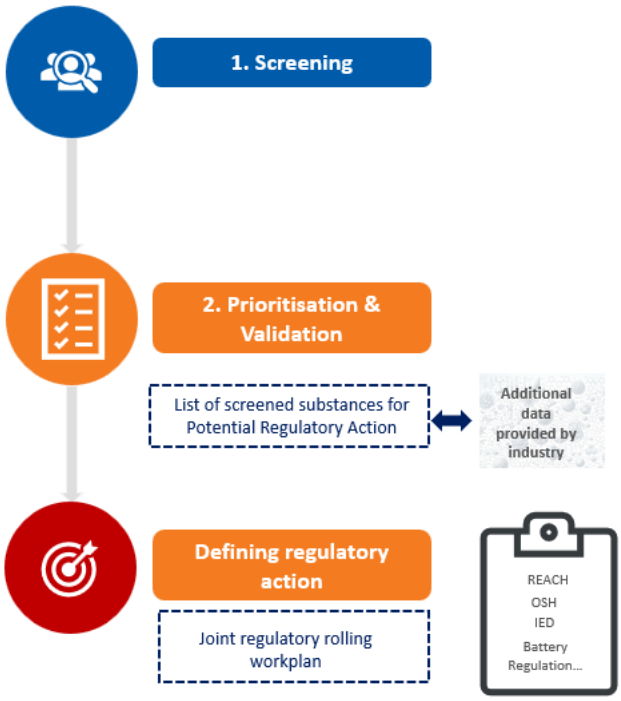

Figure 2. Schematic and simplified overview of the proposed process for regulatory risk management action identification

A joint regulatory risk management action rolling workplan would benefit all, providing transparency in the process of identifying regulatory risk management actions, allowing to focus resources where needed the most and building trust with all stakeholders that chemicals are properly managed.

It aligns with the objectives of the EU political guidelines in terms of reducing unnecessary administrative burdens while serving the protection of human health and the environment.

For the industry, the joint regulatory risk management rolling workplan would bring clarity on where to invest and prioritise resources. It would also facilitate discussion on strategic applications of chemicals and the most effective regulatory approach.

Steps in the new approach to identify the most appropriate regulatory risk management action:

1) **Screening of substances for potential regulatory action (ECHA and Member States)**

The starting point would be ECHA's current assessment of the needs for regulatory action (ARN) on a group of substances under the umbrella of its Integrated Regulatory Strategy (IRS).

Building on the data generated via REACH registration[3] including exposure information, ECHA has identified today around 700 substances[4] that could be targeted for further regulatory action. This list generated by ECHA could be complemented with substances where Member States have identified a potential need for regulatory follow-up.

This list would serve as the starting point for selecting substances as a second step and their uses for further targeted investigation, as described in the next step. This overview would be available on the ECHA website, as the ARN results are also published there.

2) **Prioritisation, validation (ECHA and Member States) – List of Screened Substances for Potential Regulatory Action**

The next step would be to prioritise from the list resulting from the first screening step, those chemicals, and their uses for which regulatory action should be further explored. This prioritisation should consider hazard properties, likelihood and level of exposure, risks, the regulatory risk management already in place and workability for authorities and industry to address first what matters the most. Prioritised substances would then be included in a List of Screened Substances for Potential Regulatory Action, which would comprise of a limited number of substances that is regularly updated.

ECHA would consult its Member States Committee (MSC) before publishing the List of Screened Substances for Potential Regulatory Action.

Inclusion of substances in the List of Screened Substances for Potential Regulatory Action would trigger a new opportunity for all relevant industry actors, like manufacturers, importers, distributors and downstream users, to provide targeted and granular data[5]. Notifications should be manageable, proportionate and standardised.

Collected information and data would be used to refine and validate the findings of the screening action (step 1) and decide on the most appropriate regulatory risk management action in the next step.

After the assessment, the substances would be removed from the list of screened substances for Potential Regulatory Action and a new set of substances would be published to collect additional data.

[3] In the future, Common Data Platform under OSOA could be used as a "one-stop-shop" for all data generated under REACH and other legislation.

[4] ECHA workshop on Integrated Regulatory Strategy 6 March 2024 (https://echa.europa.eu/-/irs-06/03/2024). For another 700 substances, additional data is being generated on hazard properties. Depending on the generated data, the number might go up to approximately 1400 substances.

[5] Information on uses, exposure, emissions data, information on potential alternatives, waste management practices etc. to complement refine and validate the information that is included in the registration dossiers at the time of the screening.

3) **Defining action (European Commission, ECHA, and Member States) – resulting in a joint regulatory risk management action rolling workplan**

The last step would be to define the type of regulatory action(s) using the full EU regulatory toolbox, including both REACH and non-REACH legislation[6].

In the spirit of "One Substance, One Assessment" (OSOA), all relevant regulatory actions should be explored and coordinated, avoiding duplications (see Cefic views on OSOA). For one substance and its uses, multiple potential regulatory actions may be identified under REACH and/or other regulatory frameworks depending on the identified targeted regulatory needs (example of a case study in figure 3).

The final result would be a joint regulatory risk management action rolling workplan outlining:

- the substance(s) (including their proper identification)
- the identified use(s) that need to be addressed
- the concern(s) that need to be addressed
- the proposed regulatory risk management action
- indicative timeline and
- the responsible authority for the preparation of the dossier.

The list should be targeted and manageable. It would be updated every *X* years. ECHA Member States Committee would be consulted and would eventually adopt the final workplan for the regulatory process under their remits, with an indicative timeline and responsible authority.

If, based on all collected data, there is no need for regulatory action, the decision would be implemented and transparently made available on a website. The substance/use would be removed from the list.

Only those substances and uses listed in the joint regulatory risk management rolling workplan could be proposed for inclusion in Annex XIV (authorisation) or Annex XVII (restriction) if they are deemed the most effective options to control risks.

For those substances/uses with indicated non-REACH regulatory action, the European Commission/ECHA could use it as a guidance for action in other legislation. Both the Member States' authorities and the European Commission would need to adhere to the workplan avoiding any attempts of scattered and fragmented initiatives. The workplan and the conclusion included in it would be publicly available.

Below is an example of how this approach would look like using a case of a substance that is reprotoxic (figure 3). The substance and its uses were flagged in the screening process of the assessment of regulatory needs (step 1) and based on the prioritisation criteria listed in the List of screened substances for potential regulatory action (step 2) for instance to get more clarity on the use in consumer applications. Additional supply chain information on uses and exposure is gathered (step 2). Based on the available data and gathered data in step 2, in this case, multiple regulatory risk management actions are proposed in different frameworks. When the joint regulatory risk management rolling workplan is agreed upon, the actions are taken forward in the appropriate frameworks and processes.

[6] For instance, where exposure/emission control is in principle feasible, regulatory action under OSH legislation and IED should be considered by default. Only in cases that these default options are not considered to be sufficient to prevent unacceptable risk, complementary measures via REACH restriction could be imposed.

The status would be regularly updated, for instance on the OSOA overview website of the European Commission. For the relevant REACH processes, the overview would be maintained on the ECHA website.

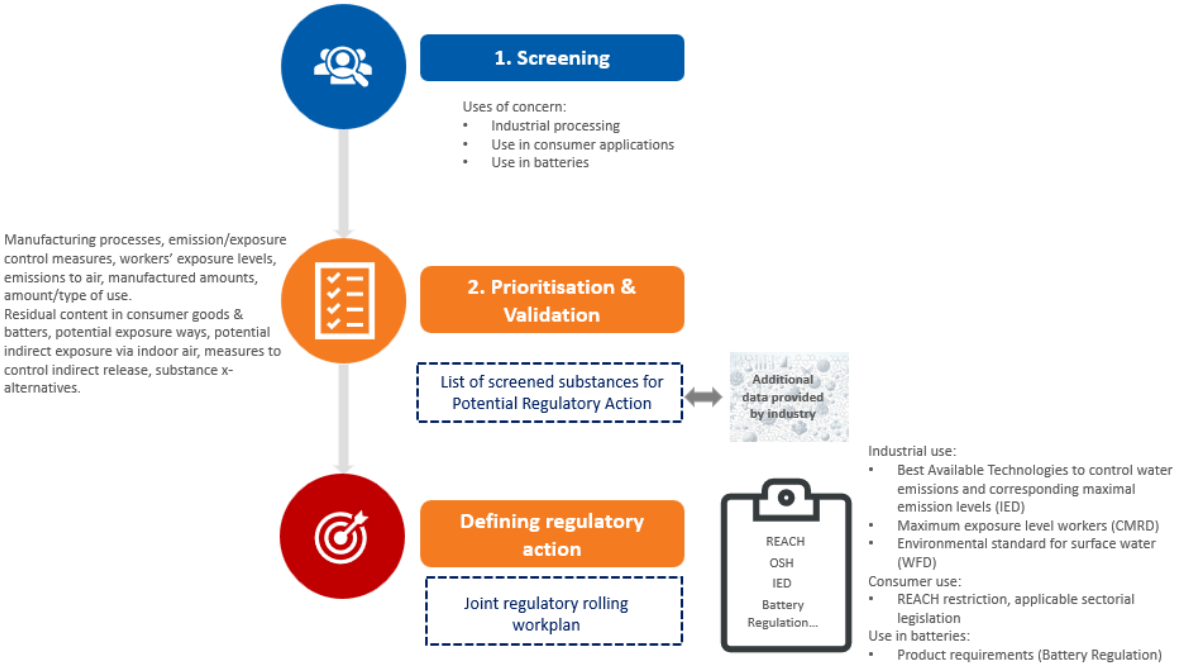

Figure 3. Example of applying the new approach on a substance that is harmonised classified as reprotoxic

Note:

The current restriction and authorisation process would need to align with this new process, especially for the role of the Candidate List for Substances of Very High Concern and their listing in Annex XIV for authorisation:

- The process to prioritise substances for authorisation would be decoupled from the Candidate List, as this new approach would be used to prioritise substances for regulatory risk management action.
- The Candidate List would be continued for the communication obligations on the presence of identified SVHC >0.1% in the article.

For more information on Cefic views to improve the authorisation and restriction processes please refer to the factsheet "Action 3: Improving Authorisation and Restriction processes".

Annex 1 – Regulatory risk management options at the EU level