POSITION PAPER

AUGUST 2022

Cefic response to Call for Evidence - 'better access to chemicals data for safety assessments'

We support the re-use of chemical safety data to enable 'One Substance One Assessment' and a balanced dissemination of chemical safety information which incentivises companies to invest in safety data generation, in full trust that their data will be protected from unfair use by competing entities whilst ensuring that all essential information on the properties and health and environmental impact of their products is publicly accessible. Dissemination of robust study summaries should be preferred over full study reports.

We are however concerned about the administrative burden of new study notification requirements and do not see yet clear added value of empowering authorities to commission test data, considering existing data generation mechanisms under REACH.

I. Re-use of chemical safety data on substances

Cefic supports re-use of chemical safety data by public authorities in charge of the implementation of EU chemicals legislation, as an enabler of "One Substance-One Assessment'.

Cefic supports[i] *a 'one hazard assessment'*: it would make sense that hazard identification of chemicals is centralised up to the point of classification and labelling, which concludes that step. The next step, hazard characterisation, may be harmonised as well i.e. selection of the key studies and points of departure (POD) for risk assessment (i.e. NOAEL, NOAEC, BMDL for the relevant routes of exposures and environmental compartments).

An essential step towards consistent hazard assessments is that public authorities have access to the same chemical safety data for that purpose. This should include information generated and owned by industry, subject to the respect of data exclusivity rules and confidentiality protection accepted by the authority which first received the data ('data originator' principle – see below). Respect of ownership rights and protection from unfair use are crucially important to incentivise data generation and protect the competitiveness of our industry.

It is also important that data (re-)used by authorities is trustworthy and validated by qualified assessors. This is necessary to ensure that only reliable data is considered in further assessments[ii].

Finally, standardisation of formats could facilitate re-use. If made mandatory and based on common nomenclature, formats, vocabulary and dictionaries should be developed in consultation with stakeholders and taking account of existing initiatives like eSDSCom[iii].

European Chemical Industry Council - Cefic aisbl
Rue Belliard 40 b.15 B-1040 Brussels Belgium
Tel. +32.2.436.93.00 mail@cefic.be www.cefic.org
EU Transparency Register n° 64879142323-90

We support the 'originator' principle as a mechanism to overcome legal barriers to re-use by authorities of data generated by industry. This would ensure legal foreseeability and consistency of decisions on data treatment.

Data exclusivity: where data cannot be used for the benefit of a subsequent applicant under the legal framework under which the data was originally submitted, that rule should prevent re-use that facilitates or secures market access to another (potentially competing) company unless proof is provided that the latter has the right to refer to the data for the relevant regulatory purpose. This is likely to be more relevant where data is re-used in risk management decisions, e.g. authorisation procedures, rather than in hazard assessment opinions or decisions.

Confidentiality:

Where parts of the data were accepted as confidential under the legal framework under which the data was originally submitted, the authority re-using the data should respect that assessment in case it receives a third party access request. This would be consistent with Article 4(5) of Regulation 1049/2001, according to which Member States may request the EU Institution not to disclose a document originating from that Member State without its prior agreement.

Requests for access and confirmatory requests received by an EU Agency or Institution who has re-used data from another EU Agency or Institution should be referred to the authority who initially accepted the confidentiality claim.

Confirmatory requests should ideally be handled by a different service or unit than the one who assessed the initial request (e.g. Agency Executive Director or Board of Appeal).

II. Dissemination of chemical safety data

We advocate for a balanced approach to proactive transparency, ensuring easy and early public access to information on the properties and effects of chemicals on health, safety and the environment whilst safeguarding legitimate rights of business to protection of commercially valuable information and intellectual property rights.

Regulation 2019/1381 on transparency and sustainability of the EU risk assessment in the food chain ('EFSA Transparency Regulation') sets out the principle that all scientific data and information supporting requests for authorisations or for approvals under Union law should be made publicly available in a proactive manner – and that such dissemination is without prejudice to intellectual property rights or provisions protecting the investments made by innovators, such as data exclusivity/data protection rules.

Transposed to EU chemicals legislation, this would virtually eliminate the 'reactive' transparency route, where access requests are assessed case-by-case, and publish all scientific data on the internet, except defined categories of information where confidentiality can be requested by the applicant/registrant where proof of potential harm to a significant degree can be provided.

There are, however, some differences between EU food safety and the chemicals legislation which do not plead for a full transposition of that approach.

First, under chemicals legislation, authorisation or approval procedures are not the main regulatory process under which safety data is submitted. There is a diversity of procedures whereby chemical safety data is being submitted to authorities (cf. registration, evaluations, restrictions, calls for data under the cosmetics regulation).

Second, due to the diversity of procedures for submitting safety data, existing chemical legislation do not always provide for clear rules to protect the investment of data owners. Whilst REACH foresees a data exclusivity rule in relation to information submitted in the registration process, there is no clear rule for data submitted in the context of other REACH procedures. In those cases, publication could give rise to free riding and unfair competition.

Thirdly, chemical legislation requires the submission of economic data in addition to chemical safety data, e.g. specific projected volumes/tonnages or commercial relations, which go to the heart of business strategies and are potentially sensitive under competition law. Such categories of information should not be subject to disclosure, and the legislative presumption of confidential treatment should remain in REACH.

Finally, the ECHA factsheets on access to documents over the past years indicate a reasonable number of requests for access to documents being filed (98 in 2019 as opposed toto 61 in 2021), which is about half of the requests received by EFSA in the past (319 in 2016, 245 in 2017)[iv].

> The profile of applicants is also very different: while industry and law firms remain the most frequent applicants for access to documents held by the ECHA (54% of all requests in 2021, 61 % in 2020), this was not the case for EFSA (roughly 30% of requests in 2017 came from industry and law firms, while close to 40% came from NGOs and citizens), suggesting that proactive disclosure could favour commercial interests rather than the general interest of the public.

We support ECHA's approach to dissemination of information on chemicals, retrieving chemical safety information on substances from industry submissions and organising it in a structured way for publication on the public portal. Dissemination of robust study summaries should be preferred over full study reports.

> REACH mandates the publication of study summaries and robust study summaries. ECHA disseminates this information with the disclaimer warning third parties about the need to confer with data owners for further use of the data. This approach could be extended to other areas of chemicals legislation, as dissemination of study summaries provides useful and essential chemical safety information and entails less risks of misuse and misappropriation than the dissemination of full study reports. In addition, dissemination in a harmonized format is beneficial for capturing the essentials of the study including information on the test item used and assessment of the validity of the study.

As regards confidentiality claims allowing to exempt certain information from proactive disclosure, we caution against extending the system of article 39 of Regulation 2019/1381 to chemicals legislation as such.

> First, because the threshold for an applicant to obtain confidential treatment of information submitted to EFSA under Regulation 2019/1381 is significantly higher than the threshold applying to EU authorities for refusing access to documents or information that it holds, including third party documents. Today, it is unclear whether applicants stand a real chance to obtain confidential treatment at all under the EFSA Transparency Regulation.
>
> Second, because the implementation of these new rules, and this new legal test for confidentiality claims, have not yet been reviewed after adoption as the first review is planned for 2026.

Preliminary results presented at the EFSA management board in June 2022, one year after the entry into application of the EFSA Transparency Regulation, indicate a loss in efficiency of risk assessment procedures: the ratio of timely adoption of EFSA scientific outputs for regulated products in 2022 dropped. In 2022, only 63%[v,vi]of those scientific outputs were finalized within the deadline (EFSA's target is 90%). In 2019, before the entry into application of the transparency Regulation, EFSA scored 82,8% on the same index[vii]. These figures highlight the increased burden for EFSA arising from the provisions of the new Regulation. Extending the EFSA transparency principles to other pieces of legislation on chemicals is likely to add significant burden on applicants and EU agencies, which is contrary to the overall objectives of this initiative.

III. Notification of studies by operators and laboratories

In principle, we agree to a notification system for studies. However, attention should be paid to (i) limit the administrative burden; and (ii) protect sensitive company data from disclosure.

An obligation to report all studies at an early stage in the process, even before an application is submitted, would involve a great deal of effort for companies and laboratories and would lead to significantly more bureaucracy. Special consideration should be given to the well-defined integration of notification and dossier processes to limit administrative overhead.

There is also a risk that research results and business strategies of companies will be disclosed. In a notification process confidentiality of company data, especially R&D data, must always be ensured.

Moreover, test strategies and study design are usually modified as new products are developed. Reports might have to be updated continuously, which would mean an additional burden. In addition, only EU laboratories would be affected by the reporting obligation for laboratories. This could affect competitiveness compared to non-EU laboratories.

Thus, any notification effort should be limited and a process more streamlined and fit for purpose than e.g., the EFSA approach is required. Whereas notification of vertebrate animal testing for regulatory purpose might be acceptable, this should not apply to other testing and no link should be established between such notifications and any authorization of the respective substance later-on. In cases where prior approval of a testing approach by authorities is required the testing proposal should be recognized as notification.

IV. Commissioning of studies by EU authorities

Cefic fully supports the 'no data, no market' principle underpinning the REACH Regulation. It is for industry to prove that substances can be safely manufactured and placed on the market. Any empowerment to authorities to commission studies should only be complementary, in exceptional and justified situations where existing regulatory mechanisms cannot be used to fill the data gap and require adequate funding from the EU budget.

REACH substance evaluation provisions already empower competent authorities to request additional information from registrants, beyond standard information requirements. At this stage, it remains unclear how an additional empowerment would add value or streamline the data generation process and where the funding would come from.

While under REACH Dossier Evaluation, ECHA cross-checks if standard information requirements are available in the dossier or in a testing proposal, under the Substance Evaluation procedure authorities can request additional data from registrants beyond what is required under standard information requirements for the registration of the substance. Any empowerment to authorities to commission studies should only be complementary, in exceptional and justified situations where existing regulatory mechanisms cannot be used to fill the data gap and require adequate funding from the EU budget. Data going beyond the scope of Substance Evaluation would be of no relevant and proportionate added value for risk assessment and respective risk management, except if done for scientific research.

When performing testing under REACH, the first step is to suitably identify or generate a sample to be tested. Detailed information on its composition using appropriate analytical techniques is required to demonstrate that what is to be tested is reflective of the substance that is on the market. The second step is the evaluation and selection of a test facility that can handle the test substance, has the proper experience in performing the required test methods with the given substance class and is able to interpret the results in combination with the substance specification.

Any third party or authority who intends to test substances for the purposes of REACH has to ensure the same level of scrutiny in determining the substance to be tested such as that studies conducted to investigate the hazardous properties give results that are representative of the substance that is supplied. Without such scrutiny and detail, it may not be possible to confirm that the tested substance results are relevant and representative; in such case, test results would be either of very limited value or even confusing if they contradict information that is already available via a suitable test result.

When commissioning testing, authorities are likely to face the same hurdles than companies[viii] and it is unclear at this stage how this would made the process more efficient and effective. Legal rights related to data use will also need to be clarified and a formal and transparent process including an obligation to justify added value of studies to be commissioned should be in place for generating additional studies. Cefic provided further insights on this topic in its response to CARACAL.[ix]

For more information please contact:
Liesbeth Timmermans, Director Legal Affairs (lti@cefic.be)
Dunja Drmač, Manager Chemicals Legislation (REACH) (ddr@cefic.be)

About Cefic
Cefic, the European Chemical Industry Council, founded in 1972, is the voice of large, medium and small chemical companies across Europe, which provide 1.2 million jobs and account for 15% of world chemicals production.

[i] Cefic position paper on One Substance One Assessment: https://cefic.org/app/uploads/2021/06/Cefic-view-on-One-Substance-One-Assessment-OSOA.pdf

[ii] Scientific data usually comes with applicability constraints stemming from either the source or the methodology used for their generation. The data specific validity area must be part of the package shared and its consideration must be compulsory for any secondary use of the data.

[iii] https://www.esdscom.eu/

[iv] Factsheets - ECHA (europa.eu) and presentation by D. Detken given in June 2018 on Requests for public access to documents at the 5th Roundtable with Industry Associations, https://www.efsa.europa.eu/sites/default/files/event/180613-p07.pdf

[v] C14. EFSA performance report - note - 8. mb220629-i4.pdf (europa.eu)

[vi] PowerPoint Presentation (europa.eu)

[vii] EFSA Consolidated Annual Activity Report 2021 (europa.eu)

[viii] For instance, timelines for approval (animal studies), adequate justification for animal testing, lab capacity, writing and sending requests for proposals (RFP), working with other MSCAs, assessing GLP of other labs, obtaining test material, getting approval by the Member States Committee.

[ix] Cefic response to the reform of REACH Evaluation process: https://circabc.europa.eu/ui/group/a0b483a2-4c05-4058-addf-2a4de71b9a98/library/37c702d4-c487-4406-9045-2e87e42601be/details