Cefic views on the Open Data Platform

In the Communication on a Chemical Strategy for Sustainability (CSS), the Commission announces its intention to put in place a 'One substance, One assessment' approach destined inter alia to **improve the interoperability and accessibility of chemical data**.

To achieve this, one of the proposals of the Commission is to **"*develop a common open data platform on chemicals to facilitate the sharing, access and re-use of information on chemicals coming from all sources*".**

Cefic welcomes the concept of a common platform as one key technical enabler of the 'One substance, One assessment' approach: authorities need to have access to a common dataset to fulfill their mandate under applicable legislation and avoid divergent regulatory opinions on the hazards and intrinsic properties of chemicals. However, we have several questions and concerns as to how the platform would operate, the scope of information to be made publicly accessible and how the legal rights attached to that information will be respected.

A common platform to technically enable the 'One substance, One assessment' approach

A fit-for-purpose 'One substance, One assessment' approach should lead to:

- increased **efficiency** and **predictability**: today the chemicals management activities are seldom aligned when it comes to data management and risk assessment, sometimes leading to duplication of efforts;
- Enhanced **consistency** of assessments and their outcomes, carried out on the same dataset;
- Improved **robustness** of assessments;
- Involvement of the right **expertise** at the right place at the right time;
- Provision of **tailored assessments for specific legislations/uses** if relevant.

Moving towards this objective requires action at multiple levels, including:

- Upfront close coordination of assessments across different DG's, Scientific committees and Agencies at European level;
- **Data exchange across Committees and Agencies**;
- Application of **One hazard assessment**;
- **Centralising exposure assessment tools and methodology on a common platform;**
- Securing tailored risk management;
- Increasing **transparency on the decisions and processes**;

Currently, scientific advice and risk assessment are provided to the Commission by different agencies and scientific committees. Their areas of intervention and their competencies are determined in the relevant pieces of legislation.

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In most cases, the delineation of areas of competencies is clear. For instance, for cosmetics, ECHA is doing the environmental risk assessment and human health for workers while the Scientific Committee on Consumer Safety (SCCS) is in charge of assessing risks for human health, building on the data generated under REACH and CLP (though not exclusively). In some other cases, there is a potential overlap (e.g. toys, detergents or other consumer goods, nanomaterials, food contact materials, workers' protection).

There are valid reasons why different agencies/committees have been created over time, depending on the objectives of the Regulation that establishes the mandate of a given agency/committee and on the type of expertise needed. Without coordination of different processes and assessment bodies, there is a risk of inefficient use of resources, duplication of assessments and even diverging opinions,[1] which is confusing to industry and the general public.

Situations that lead to divergent regulatory opinions on the hazards and intrinsic properties of chemicals need to be avoided as it creates uncertainty as well as inconsistency and undermines investments in safe and sustainable chemicals.

The Open Data Platform could provide a technical solution to enable a fit for purpose 'One Substance, One Assessment', by ensuring that:

1. **authorities** (i) have **access to a common dataset on hazard and use**, ensuring consistency of assessments and their outcome; (ii) share a common set of exposure assessment tools and methodology and (iii) **coordinate the analysis of risk management options**, leading to only **one risk assessment per specific use across EU legislation** valuing existing expertise;

2. **stakeholders** can **better anticipate** which substance/use will be assessed and/or regulated (e.g. extended Public Activities Coordination Tool-PACT including other processes under different legislative frameworks outside the scope of ECHA). The decision not to classify and/or regulate a substance if the classification criteria are not met should also be communicated.

Open questions and reservations

However, the Open Data Platform concept and feasibility study currently underway trigger many questions:

- **Purpose**. In addition to the identified need to ensure more consistent risk assessments based on existing safety data, what are the other specific purposes of the platform?

  Could the platform facilitate data-sharing for the purpose of third country registration (e.g. South Korea, Taiwan, Turkey) by facilitating contacts with data owners of studies submitted under EU chemical legislation? How would this be tracked?
- **Governance and maintenance**. Who will upload and maintain safety data on the Open Data Platform and ensure that data remains updated, sound and scientifically valid? The Stakeholder Briefing presented by the Commission consultant state that information is to be automatically transformed, integrated, harmonized and matched: how does the Commission intend to ensure data quality? How will data owners be involved in the process?
- **Quality control**. The February Stakeholder Briefing circulated by the Commission's consultant refers to the uploading of research from academia. As data is intended to enable prioritization of

[1] This was recognised by the European Commission in the Fitness Check of Chemicals legislation (excluding REACH) in June 2019.

substances for regulatory purposes, how will the Commission ensure reliability and quality control of the studies/information? Who will decide on relevance and quality/reliability of uploaded information for a given regulatory purpose?

- **Public access and third-party use**. Which information would be published on the platform (full study report, study summaries, ...)? Would the Open Data Platform replace the ECHA dissemination portal/the newly created OpenEFSA portal[2]? How will the Commission ensure that IP protected data and confidential information are not subject to unauthorized or unfair commercial use? How will the platform ensure that data protection periods/data exclusivity rules are respected?

Principles to guide the Open Data Platform design

The Open Data Platform design should observe the following principles:

- **Clarity of purpose**. The level of access to the data should be adjusted to the specific purpose and intended use of the data set out in EU law. Whilst we see the need to facilitate data-sharing between authorities to ensure a harmonized hazard assessment of chemical substances and upfront coordination of assessments across different DG's, scientific committees and agencies at EU level, the other needs or 'use cases' identified by the consultant supporting the Commission are less clear.

- **Data ownership and control**. The party that owns the data should remain 'data owner' through the entire chain from initial creation to deletion of the data from the platform. The party that owns the data should be able to request deletion of the data in case it needs to be replaced by more relevant data. Moreover, the party that owns the data should be able to decide who can use the data for which purpose and can alter that decision at any time. Data cannot be (re)used or analyzed by any IT vendor or actor without a clear written consent of the data owner.

- **Preservation of the quality of the data**. Processing of the data entering the platform should not impede its quality. Data ownership allows for accountability of the quality of the data.

- **Preventing unauthorized use of IP-protected data**. Ensuring IP protection is key for the EU to remain competitive in the global race for technological leadership and to successfully fight counterfeiting and piracy, in line with the EU IP Action Plan and its concept of fostering IP intense industries.
  The European Commission's Proposal for a Regulation on European data governance (Data Governance Act) states that allowing re-use of data would be possible only if this complies with IP rights, and that public sector bodies must ensure that no confidential information is disclosed because of the re-use. Hence, **where data is protected by intellectual property rights and subject to restrictions of use, the platform should provide appropriate safeguards**. With the registration of chemical substances under REACH, the industry has invested into a significant body of scientific evidence and test data. Companies have acquired ownership rights which are key to valorize their investments and to contribute to GDP growth. Those ownership rights should be respected, and accordingly:

[2] See https://open.efsa.europa.eu/.

- EU and Member State authorities should not use the test data for the benefit of subsequent applicants or registrants if the latter cannot prove to be in legitimate possession of referral rights (e.g. via a letter of access). Data protection periods (also referred to as data exclusivity rules) vary according to different pieces of legislation; and
- Non-EU authorities should not use the test data available on the platform to grant market access to competing undertakings if the latter have not compensated data owners for the right to use the study for regulatory purposes in those jurisdictions.

- **Safeguarding of data confidentiality**. EU and international law recognize and protect the legitimate right of industry to confidentiality of certain information submitted to EU authorities. The REACH and biocides regulations, as well as the EFSA Transparency Regulation, have granted procedural rights to data submitters to request confidentiality protection of certain data categories prior to dissemination. Those rights have been used: confidentiality claims have already been submitted and accepted as valid in the registration process of chemicals with the ECHA. Confidential information, including commercially valuable information, trade secrets and information sensitive under competition law and the Trade Secrets Directive (EU) 2016/943, should remain confidential and be protected from disclosure to the public and third parties.

- **Liability of unlawful third-party use of data**. Data owners should have the means to defend themselves against unlawful third-party use of data disseminated on the future Open Data Platform.

Extension of the relevant transparency principles from the EU food safety sector to other pieces of chemical legislation: initial questions

The Open Data Platform is closely related to the announced **extension the principle of open data and the relevant transparency principles from the EU food safety sector to other pieces of chemical legislation**.

There are however major differences between the EU food safety rules – governed under the General Food Law Regulation (EC) No 178/2002, as amended – and chemical legislation, especially the REACH Regulation.

First, whilst most EU regulations referring to the EFSA as risk assessment agency establish **pre-market authorization procedures** (cf. food additives, food contact materials, novel foods, health claims, pesticides), the REACH regulation relies essentially on a **registration system**. Under REACH, applications for authorization are submitted only where the substance has been placed on the Annex XIV list. Hence dissemination policies do not have the exact same purpose.

Second, whilst food safety regulations require the submission of **full study reports**, the REACH Regulation requires the submission of **robust study summaries** for a more efficient assessment of the data. The robust study summaries provide sufficient information to allow ECHA to make an independent assessment of the study. ECHA may request full study reports in specific situations where there is a clear need. REACH also requires the submission of non-scientific and non-environmental information sensitive under competition law, such as tonnage information.

Finally, whilst the new Transparency and Sustainability Regulation provides for a system of **confidentiality claims system as exception to the dissemination of data** supporting a request to EFSA for scientific output, the REACH Regulation establish a **two-tier approach for the reactive and proactive disclosure of**

information. Article 118 requests ECHA to reactively disclose information upon request of third parties, but also makes clear that the information specified in Article 118(2) "shall normally be deemed to undermine the protection of commercial interests," which may prevent the disclosure of such information. In turn, Article 119(1) outlines information that the Agency must always proactively publicly disclose, while Article 119(2) lists information that the Agency must also disclose unless a request for confidentiality is justified.

This raises the question as to what are the transparency principles that are relevant to be extended from the food safety sector to the broader area of chemical legislation.

Our view is that such extension may bring benefits to all by clarifying the status of a given substance under different EU regulatory processes; but should not lead to amending existing provisions on the type of data to be submitted nor existing confidentiality provisions.

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Cefic understands that this is only the beginning of the discussion and the above input should be considered as preliminary.

Cefic is open and ready to engage with policymakers and other relevant parties on the challenges and implications of the development of an Open Data Platform on chemicals, and willing to work together to find the best way forward.

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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 16% of world chemicals production.