



Downstream Users of Chemicals Co-ordination group

## **DUCC's response to public consultation on the OSOA package ("One Substance, One Assessment")**

### **Proposal for a Regulation on establishing a Common Data Platform on Chemicals**

The Downstream User of Chemicals Coordination Group (DUCC), representing 11 European associations whose member companies use chemicals to formulate mixtures, provides the following response to the OSOA public consultation.

DUCC supports the main objective of the **OSOA approach**<sup>1</sup> under the Chemicals Strategy for Sustainability (CSS) to improve the efficiency, effectiveness, coherence, and transparency of issuing safety assessments of chemicals across different pieces of EU legislation. Nevertheless, we share some considerations on the legislative proposal regarding the **establishment of a Common Data Platform on Chemicals (CDPC)**. The proposal aims to ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by EU legal acts, to achieve a high level of protection of human health and the environment, to enable the development and use of sustainable chemicals, to ensure the proper functioning of the single market for chemicals, and to improve the EU citizens' trust in the scientific base for the decisions taken under EU legal acts on chemicals.

DUCC welcomes the objectives of building a CDPC and driving a better chemical assessment coherence across EU legislations and considers that this will foster scientific progress and increase the availability of New Approach Methods data around chemical safety, as well as help in gaining and disseminating knowledge on chemical safety assessment. This new system might also contribute to reducing animal testing as the proposal concerns all sectors. In addition, collecting all available information in one place could make safety assessments more robust and faster, and consequently reinforcing citizens' trust in the chemical safety evaluation and in decision-making process for chemicals. To ensure proportionality and

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<sup>1</sup> The **OSOA approach** focuses on the main factors influencing the efficiency, effectiveness, coherence and transparency of **safety assessments**. It covers: **1) Initiation of chemicals safety assessments**. This means synchronising and coordinating the initiation or triggering of assessments and assessing groups of substances instead of assessing substances individually, to the extent possible. **2) Attribution of tasks**. This involves a clear allocation of responsibilities to bodies performing assessments, making good use of available expertise and resources, as well as ensuring the good cooperation between the parties involved. **3) Information**. Ensuring that information on chemicals is easily findable, accessible, interoperable, secure, of high quality, and can be shared and reused to ensure that assessors have access to all available data without technical or administrative burden. **4) Methodologies**. The methods used for the assessments are coherent and, to the extent possible, harmonised. **5) Transparency**. Ensuring a high level of transparency in performing assessments, as well as in the underlying scientific data and information on chemicals.



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reduce administrative burden mostly for SMEs, any potential duplication of information across various platforms should be avoided.

Nevertheless, DUCC highlights some elements of the proposal, as follows:

- Scope and definitions.

DUCC considers that chemicals data in the scope are only those that must be submitted within the context of a safety assessment. DUCC underlines that some definitions should be further clarified, such as “environmental sustainability related data”. An exhaustive list of type of data expected to fall in this definition would be helpful. In addition, definition of “chemical data” should be further clarified. Also, a clarification is needed on the powers given to the Commission to add new categories of data types through delegated acts. The difference between “duty holder” and “business operator” is not clear and a clarification would be welcomed. Furthermore, a definition of “study” should also be included.

- Study notifications.

In line with the understanding on the scope, only studies generated as part of the regulatory obligation within a safety evaluation will have to be notified. Additionally, studies to be notified should be limited to those relevant for hazards/risk identification. DUCC recommends defining an exhaustive list of studies that would need to be notified, including for which hazard endpoint of interest. Clear acceptability standards and criteria for the studies should be also indicated.

- Confidentiality, access, and use of data.

DUCC supports the protection of confidential information under the originator principle as foreseen in the proposal. DUCC understands that the current rules and practices as regards confidential information submitted in the context of a safety assessment would be kept. Therefore, the public will have access to chemicals data contained in the CDPC, when such information has been already disclosed in accordance with EU acts under which the data was submitted. DUCC underlines that to continue fostering innovation, a particular attention should be given by ECHA to the protection of proprietary data in the CPDC, especially as some data will be made publicly available.

- Data standardization.

DUCC highlights the importance to ensure that data standardization (format and vocabularies) do not create unnecessary burdens for the economic operators (industry) and is relevant to sectoral specific legislation.



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## About DUCC

DUCC is a joint platform of **11 European associations** whose member companies use chemicals to **formulate mixtures** (as finished or intermediary products) for professional and industrial users, as well as for consumers.

DUCC focuses on the downstream users' needs, rights, duties and specificities under **REACH** and **CLP**.

DUCC's membership represents several important industry sectors, ranging from cosmetics and detergents to aerosols, paints, inks, toners, pressroom chemicals, adhesives and sealants, construction chemicals, fragrances, disinfectants, lubricants, crop protection, and chemical distributors industries. Altogether, their membership comprises more than **9.000 companies** across the respective sectors in Europe, **the vast majority being SMEs**. The calculated turnover of these companies is more than 215 billion euros in Europe.

**For more information on DUCC:** [www.ducc.eu](http://www.ducc.eu)

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DUCC's public ID number in the **Transparency Register of the European Commission** is: **70941697936-72**