April 24, 2024

One Substance One Assessment (OSOA)

This factsheet was developed as part of a series on evolving European Union chemical policies.

SUMMARY

- The One Substance One Assessment (OSOA) approach is a key element put forward by the Chemicals Strategy for Sustainability (CSS) to streamline chemicals legislation and assessments.

- OSOA is an approach (not legislation) meant to coordinate hazard and risk assessments of chemicals across EU Chemicals Legislation, ensure consistent outcomes for similar chemicals, and assess chemicals just once.

- The OSOA package was published by the Commission on December 7, 2023. Its implementation is supported by three leiglsative proposals: one to improve chemicals data management, one to reallocate work across EU Agencies, and one to reattribute scientific and technical tasks to the European Chemicals Agency (ECHA).

- OSOA is expected to simplify and make more consistent scientific assessment and regulatory actions on chemicals, promising expedited processes with greater transparency. This advancement has the potential to significantly impact the work of EU Agencies by increasing their effectiveness and minimising resources, as well as increasing predictability on upcoming decisions.

BACKGROUND & CONTEXT

The One Substance One Assessment (OSOA) approach is a key element of the Chemicals Strategy for Sustainability (CSS) adopted in October 2020 to better streamline European chemicals legislation and assessments. The European Commission views the fragmentation and complexity of EU chemicals legislation and assessment procedures as a weakness that prevents it from achieving its full potential. In some instances, chemicals that are not approved under one framework may still be allowed on the market under other frameworks.

OSOA is meant to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across different pieces of EU legislation, with the aim of ensuring consistent assessment outcomes for similar chemicals and helping the EU and Member States governing bodies work together to assess chemicals just once. OSOA will thus reduce the administrative burden placed on companies and support the gradual move to regulating substances by groups rather than individually. In summary, the approach aims to coordinate the hazards and risk assessment on chemicals across EU chemicals legislation. In the European Commission, DG Environment (ENV) is in the lead.

DESCRIPTION

In practical terms, OSOA is an *approach* to be applied in several legislative frameworks and is not itself a legislative proposal. The assessment by groups of substances with structural or functional similarities would be favored to avoid duplication of work, strengthen the knowledge base on chemicals and ensure early detection and action on possible risks. Under these considerations, the European

Commission published three legislative proposals on December 7, 2023 for faster, simplified, and more transparent processes.

1. **Proposal for a Regulation establishing a Common Data Platform on chemicals** – The creation of a Common Data Platform will introduce a 'one-stop shop' access to data on hazards, physico-chemical properties, emissions, uses, presence in the environment, and sustainability of substances, that have been compiled under EU legislation by the EU Agencies and Commission. The platform will provide increased transparency on data, support the reuse of chemical data and information collected for regulatory action, and requirements for studies commissioned or carried out by businesses to be notified. ECHA will be responsible for managing the platform, which will incorporate existing platforms such as the Information Platform on Chemical Monitoring (IPCHEM), Public Activities Coordination Tool (PACT), and EU Chemicals Legislation Finder (EUCLEF) and complement them with new tools and databases.

2. **Proposal for a Regulation on the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals** – Also called the 'Omnibus Regulation', it aims to strengthen cooperation and consolidate chemical related scientific and technical work across agencies. The aim is to better equip ECHA, the European Medicines Agency (EMA), and the European Food Safety Authority (EFSA) to align priority setting, timelines, processes, and methodologies used for the assessment of chemicals. As a result, knowledge gained from the assessment of chemicals used in products such as medical devices, toys, food, pesticides, and biocides under one legislation (e.g. pesticides) will be reused for another piece of legislation (e.g. biocides).

3. **Proposal for a Directive on the re-attribution of scientific and technical tasks to the European Chemicals Agency** – This proposal introduces relevant changes for businesses. It focuses on amending the RoHS (Restriction of Hazardous Substances) Directive (namely articles 5 and 6), giving ECHA the responsibility for the assessment of restricted substances under RoHS, and for reviewing and assessing exemptions. The RoHS restriction process would become similar to the REACH restriction process, and ECHA's new responsibility would allow for more transparency in the process and better involvement of stakeholders, giving industry better predictability in RoHS restrictions and exemptions processes. The directive itself does not add restrictions nor remove exemptions, but a Commission report that was published with the directive noted that exemptions have hindered efforts to substitute harmful substances in products. This might encourage stricter measures in the future. A "full" revision of RoHS is also planned by the Commission, but not before the REACH revision is in place.

These proposals will additionally:

- Establish a comprehensive system for gathering human biomonitoring data within the EU, providing policymakers with crucial insights into chemical levels present in individuals, whether in blood or breast milk. This initiative will facilitate more accurate estimations of EU citizens' exposure to chemicals.

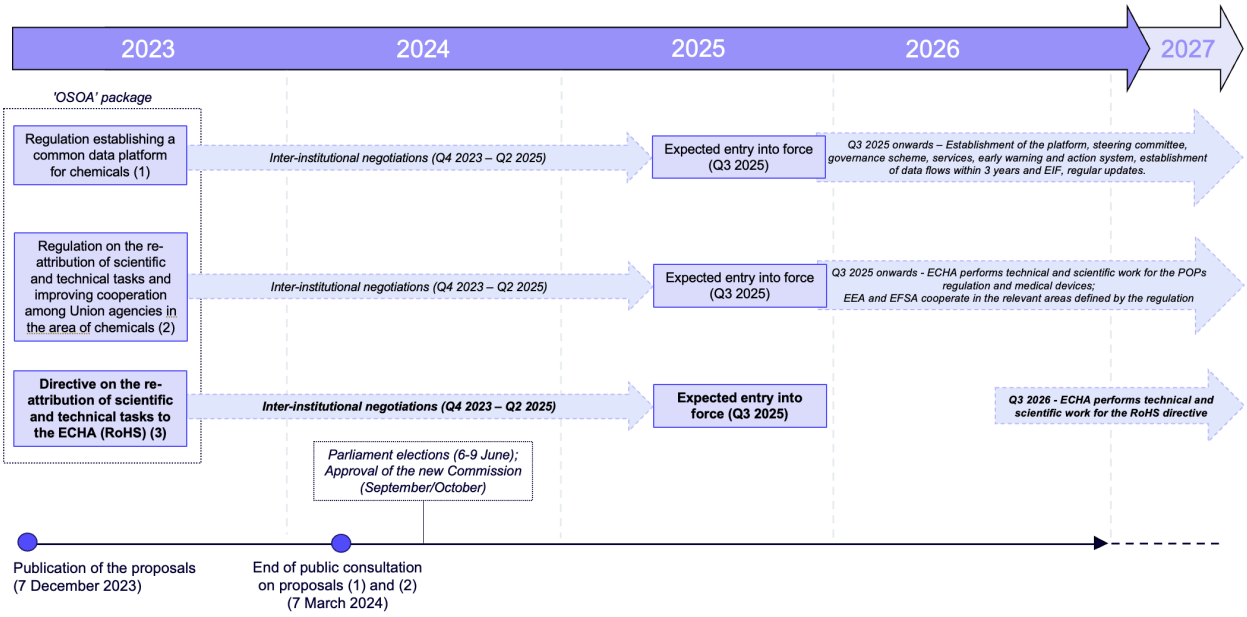
- Implement a monitoring and forecasting framework aimed at early identification of chemical risks, such as potential hazards from substances like PFAS, in order to prevent widespread contamination. This framework will enable swift regulatory responses and ongoing monitoring of the effects of regulatory interventions on chemicals. It will encompass an early warning and action system alongside a set of indicators, among other components.

- Grant ECHA the authority to generate necessary data as required.

- Ensure the transparency of scientific studies concerning chemicals, including those commissioned by companies.

CURRENT STATUS

The three proposals are currently being examined by the European Parliament and the Council under the Ordinary Legislative Procedure. The Committee on the Environment, Public Health and Food Safety (ENVI) of the European Parliament has already appointed a rapporteur and discussed the package with the Commission on March 19, 2024. Further analysis of the package will be conducted by the ENVI committee in the upcoming term, after the Parliamentary elections scheduled for June.



IMPLICATIONS

OSOA will have a significant impact on all sectoral chemicals legislation and the work other Agencies are undertaking in the assessment of chemicals. The OSOA approach can help avoid inconsistencies in regulatory action conducted under different pieces of chemical legislation and avoid duplication of work, while increasing consistency in the evaluation of chemicals across agencies. It will also speed up approval or bans of chemicals and reduce costs for regulators and industry thanks to more streamlined and coherent processes.

The OSOA approach was welcomed by EU agencies and industrial sectors when announced, arguing it would increase the efficiency and predictability of chemicals management.

For factsheets and more information on European Chemicals Policies, please visit www.sustainablechemistrycatalyst.org/eu-chemical-policy.

AUTHORS

This factsheet was developed through a collaboration between:

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