

In support of the EU chemicals strategy for sustainability: One substance – one assessment

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In December 2019, the Commission published its European Green Deal, announcing a **chemicals strategy for sustainability**.

The Commission will look at how to simplify and strengthen the legal framework and review how to use the EU's agencies and scientific bodies better to move towards **'one substance – one assessment'**.

EFSA and ECHA have drafted a joint position paper around the idea of one substance - one assessment for chemicals. The paper provides an analysis of the current situation and proposes solutions that support simplification, cost savings and improved regulatory predictability.



Challenges identified: overlaps and inefficiencies in assessing chemicals

Currently, risk assessment and risk management of the same chemical is carried out at different times for different uses by different bodies, under different legislation, often using different data and potentially leading to seemingly different outcomes.

For example, ECHA assesses substances registered as industrial chemicals under the REACH Regulation and decides on the needed generic risk management measures to protect human health and the environment (e.g. correct labelling, further safety testing required, proposed for phase out or restricted from certain uses). EFSA assesses the safety of many of these chemicals when they are used in food packaging, containers, utensils and as other 'food contact materials', in compliance with specific EU legislation. Since chemicals are also used in e.g. cosmetics, toys and electronic devices, they may be assessed by different EU authorities at different times often even with different data and non-harmonised methodologies, often due to the diverse regulatory frameworks for their marketing and authorisation.

Examples of such materials, where the unaligned timing and data requirements of assessments may have created uncertainty for decision-makers and the public, include bisphenol A, a substance used to make plastics, resins and plastic coatings, and phthalates which soften or 'plasticise' plastics such as PVC.

Proposal: a more integrated and holistic assessment of chemicals

Scientific advice to the Commission should be consolidated by relying systematically on a **better coordinated output from independent EU agencies** (ECHA, EFSA and EMA), instead of the multiple channels in use today (consultants, Member State experts, scientific committees attached to the Commission and independent EU agencies).

We propose that “one substance – one assessment” could be built around three main principles:

- A **central coordination mechanism**, including a coordinated problem formulation phase (i.e. identifying the correct scientific question that needs to be answered) which would enhance predictability for industry. This could include a public EU coordination registry, potentially developed from ECHA’s PACT (Public Activities Coordination Tool), to increase transparency and predictability on substance-specific activities by authorities across different chemical regulatory frameworks.
- **Better coordination on or distribution between agencies of tasks** concerning the hazard, risk assessment of the uses and, as important, the cumulative risks from all uses of the same chemical.
- **Access to all available data in the same structured format** for all EU authorities. We propose to establish a fully connected and interoperable EU chemical safety platform to facilitate seamless sharing of data between authorities and provide public access to researchers, regulators, industry and citizens.