April 2024

Commission proposals for 'One Substance, One Assessment'

EEB position on the proposals for the Common Data Platform on Chemicals; the Monitoring and Outlook Framework; and the Re-attribution of Tasks and Improving Cooperation among Agencies

Introduction

The European Environmental Bureau (EEB) welcomes the Commission's proposals for 'One Substance, One Assessment' (OSOA) to enhance the level of protection of the environment and human health against hazardous chemicals. The goal of the OSOA proposals is to overcome inefficiencies, inconsistencies, and slow procedures in the current system, by streamlining hazard and risk assessment of chemicals across EU legislation and improving access to information through a common open data platform on chemicals. The proposals include establishing an early warning and action system for emerging chemical risks.

This position paper combines our comments on the three OSOA proposals published by the Commission on 7 December 2023:

1) Proposal for a Common Data Platform on Chemicals (CDPC) and the Monitoring and Outlook Framework for Chemicals

2) Proposal for re-attribution of tasks and better cooperation among agencies

3) Proposal for re-attribution of tasks under the RoHS directive

We call on the European Parliament and the Council to proceed with the adoption of these proposals, securing coherent and consistent assessments, transparent access to data across EU chemicals legislation, and the implementation of an early detection and action system for emerging chemical risks.

Common Data Platform on Chemicals (CDPC) and Monitoring and Outlook Framework

The EEB supports the proposal for creating the CDPC. This platform will consolidate information on chemicals and activities of over 70 pieces of chemicals legislation into one place, aiming to serve as a one-stop-shop for chemicals information.

The CDPC will strengthen the knowledge base on chemicals and facilitate early detection and action on emerging chemical risks. Additionally, it should improve access to chemical information for authorities, citizens, and businesses. Enhanced access to data from EU chemicals legislation can expedite the identification of harmful chemicals and facilitate faster regulation of chemical risks. Herewith, we would like to provide specific comments and recommendations regarding the proposal for the CDPC and Monitoring and Outlook Framework.

- **Strengthen the early warning and action system to prompt timely follow-up responses**

We appreciate the proposed monitoring and outlook framework for chemicals, which aims to establish an EU early warning and action system for emerging chemical risks. This framework is crucial for early detection of chemical risks and prevention of future chemical pollution, particularly in light of past and present chemical pollution scandals like the PFAS incidents, which caused irreversible and widespread environmental contamination, including of drinking water sources and widespread exposure of citizens to toxic these chemicals. However, the proposal lacks plans for implementing regulatory follow-up actions, raising concerns about timely action by authorities following the identification of emerging risks.

Additionally, the limited resources allocated to the European Environment Agency (EEA) for establishing and operating the early warning and action system (only 1 full-time equivalent position), are worrisome.

To address these issues, the early warning and action system must be strengthened with a clear and mandatory mechanism for swift action by authorities upon emerging risk/early warning identification. Authorities should be required to respond to the identified emerging risks and warnings, outlining intended regulatory actions or justifying why action is not judged necessary as a minimum. Such a mechanism is essential to minimizing the gap between potential risks identification and regulatory intervention, ensuring effective risk management and protection of public health and the environment.

- **Reinforce the data generation mechanism**

The proposal for the CDPC introduces a mechanism empowering ECHA to request additional testing of chemicals when further information is deemed necessary for developing EU chemicals policy measures. This mechanism for data generation, akin to existing provisions in the general food law regulation, should enable ECHA to request both scientific and monitoring studies. While we endorse ECHA's new right of initiative, we emphasise the importance of maintaining the burden of proof on the responsible business operators in accordance with relevant EU legislation. Furthermore, expenses for monitoring and testing commissioned by ECHA should be borne by industry stakeholders in line with the polluters pay principle.

- **Incorporate information on alternatives and enforcement into the CDPC, and increase user-friendliness of the platform**

The EEB supports the proposals to establish a Common Data Platform on Chemicals, which incorporates data on chemicals from various legislations to enhance access and re-use of data, facilitating coherent hazard and risk assessments. We welcome the provisions that the platform should be able to incorporate new relevant datasets, new functionalities, and respond to developing new tools and applications. In this context, we recommend expanding the platform to include:

- Information on alternatives: providing a platform for information regarding available alternatives, encouraging alternative providers to submit product information and promoting the development and use of substances that are safe and sustainable by design.
- Information on enforcement activities: increasing transparency on enforcement output by providing a platform for information on enforcement by EU authorities.
- Increasing user-friendliness of database: making the database searchable with user-friendly search options, making search results downloadable in batches, and integrating geographic search options like currently provided in the European Pollutant Release and Transfer Register (E-PRTR) hosted by the EEA.
- Integration of information from future digital product passports.

- **Enhance uptake of academic data in environmental and health assessments and within the monitoring and outlook framework**

The CSS recognised the underutilization of academic studies in chemical assessments, despite existing legal requirements to consider academic data in the stakeholders' safety assessments. The CDPC seeks to improve the accessibility of academic data for safety assessments and ensure its suitability for regulatory use. Specifically, it proposes that researchers or research consortia funded by Union framework programmes should share human biomonitoring and environmental sustainability data with EEA or ECHA respectively, adhering to the "as open as possible, as closed as necessary principle". Furthermore, EEA is tasked to conduct targeted literature searches for the identification and evaluation of emerging chemical risks.

In addition to these measures, we propose strengthening regulatory requirements and enforcement when it comes to (academic) data uptake in chemical safety assessments, alongside the establishment of tools and practices to improve the availability and accessibility of academic data relevant for regulatory purposes. These measures should be implemented not only within the early warnings and action system but also in the broader context of environmental and health assessments. The inclusion of academic data should not be limited to human biomonitoring and environmental sustainability data but include any exposure and safety data on chemicals.

- **Expand the integration of medicinal products data in the CDPC**

The Commission proposes including only a specific subset of data concerning medicinal products and medicinal active substances. For medicinal active substances, only data on relevant substances needs to be included, where relevant active substances refer to substances that are not only covered by medicines legislation, but also have a relevance for other chemical legislation or environmental or health properties. We are concerned about these limitations and recommend to extent the selection of pharmaceutical data to be incorporated into the CDPC. This expansion should encompass all human health and environmental data, retrospective data, and pharmaceuticals with PMT/vPvM properties, in addition to those with PBT/vPvB properties. This would enhance the comprehensiveness of (monitoring) data on persistent pharmaceuticals, which have the potential to cause widespread and long-lasting pollution in the environment and of drinking water sources.

- **Increase access to information: transparency and confidentiality**

The CDPC aims to facilitate access and re-use of information collected under various EU legislations. It is clear that the current Commission proposal protects the confidentiality of data via the originator principle and provides specific use conditions for authorities and the public, ensuring the preservation of confidentiality policies granted under the original legislation.

However, this results in a variety of confidentiality regimes under various chemicals legislation, hampering the objective of increasing transparency. Increased transparency and access to data are paramount to facilitate scrutiny by third parties of data and decision making. Ultimately, this can help bolstering public confidence in the assessments.

Therefore, we propose transitioning towards harmonised transparency rules across legislation in the future. This transition could start by extending the transparency principles from the food safety sector to other pieces of legislation. In any case, authorities should have access to all the chemicals data contained in the CDPC, including claimed confidential data. As a minimum, information on chemical properties and effects on human health and the environment should always be made publicly available.

- **Encourage the assessment of groups of substances**

The CSS promised that the OSOA approach would facilitate "the gradual move away from assessing and regulating substance-by-substance to regulating them by groups" and promoting coordinated actions by prioritising assessments of groups of substances with structural or functional similarities. Therefore, we suggest reviewing the OSOA proposals to incorporate references to "groups of substances" where appropriate. For example, Article 44.1 could be revised to read “The ECHA shall

establish, operate and maintain an observatory for specific chemicals *or groups of chemicals* that the Commission considers as requiring additional scrutiny" and article 44.2: " the Commission shall adopt and publish a list of the selected chemicals *or groups of chemicals* by means of an implementing decision."

Re-attribution of Tasks and Improving Cooperation among Agencies, including reallocation of tasks under the RoHS directive

The proposals for reallocating tasks and improving cooperation among EU agencies in the field of chemicals aim to streamline chemical assessments across EU chemicals legislation and ensure coherence and transparency. Additionally, they include proposals to strengthen cooperation among the four EU agencies active in this field (ECHA, EFSA, EMA and EEA), including the coordination of priority setting and assessment processes, as well as harmonising assessment methodologies.

Below are specific comments regarding this proposal.

- **Re-attribution of tasks to ECHA**

The Commission proposes re-attribution of tasks to ECHA through targeted revisions of the medical devices' Regulation, the POPs Regulation, and the RoHS Directive.

The revision of the RoHS Directive aims to align RoHS more closely with REACH procedures, particularly regarding restriction and review of applications for exemptions. This alignment aims to streamline regulatory risk management across RoHS and REACH. However, the proposal ignores serious flaws identified in these REACH processes, which have triggered the need for revision of REACH to address these concerns. Therefore, we are concerned about the potential burden placed on the regulatory process under RoHS and the interference with the delayed revision of REACH. It is important to note that incorporating these REACH Restriction and Authorisation procedures into RoHS should not hinder their future revision within the context of the REACH reform. Therefore, we recommend inclusion of a clause in the RoHS Directive that ensures its future alignment with revisions in REACH.

- **Improving cooperation among agencies and solving divergent opinions**

The assessment of the same chemical under different legislation and by different agencies has sometimes resulted in inconsistent outcomes. The Commission's proposal outlines how to enhance the cooperation among agencies, ensuring coherence and consistency across assessments, through targeted revision of the general food law Regulation. It includes a mechanism to encourage agencies to resolve divergences in opinion, by preparing a joint report for consideration by the Commission if disagreements persist.

We stress the importance of prioritising the highest level of health and environmental protection in cases of divergent opinions. Therefore, we recommend incorporating a provision to ensure that the most protective opinion prevails in such instances, safeguarding health and environmental standards.

- **Ensure sufficient resources for ECHA and its committees**

The OSOA package proposes reallocating tasks between agencies and the Commission, with ECHA taking responsibilities previously handled by the Commission and supporting committees and external consultants. The expanded scope of ECHA's tasks requires a new basic regulation to establish its re-organisation and sustainable funding. Despite the Commission's commitment in the CSS to propose strengthening ECHA's governance and financing model, this proposal is still awaited. Therefore, we urge the Commission to promptly publish the basic regulation proposal for ECHA to enable the successful implementation of the OSOA proposals and ensuring ECHA's ability to cope with new and existing tasks within the legal deadlines.

In addition, further consideration is required regarding the organisational and budgetary implications of the new tasks assigned to ECHA's committees. It is crucial for the member state authorities to ensure sufficient resources for the successful implementation of the new tasks assigned to RAC and SEAC.