

# Comments from ClientEarth to the public consultation

## Proposal for a Regulation establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals

ClientEarth welcomes the Proposal for a Regulation establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals published by the European Commission on 7 December 2023 as part of the “One Substance One Assessment” package.

In particular, we fully support the aims to, following Article 1(1) of the proposed regulation, ensure the efficient delivery of coherent hazard and risk assessments of chemicals, 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 Union’s citizens’ trust in the scientific base for the decisions taken under Union legal acts on chemicals. It is also paramount that, as Article 1(2) stipulates, the proposed regulation establishes the widest possible scientific base for the implementation and development of Union legislation and policy on chemicals.

In what follows, more detailed comments on specific aspects of the proposal are presented.

## Common data platform

### Ensure Member State involvement

According to recital 12 of the proposal, public authorities should be “encouraged to use the chemicals data and information contained in the common data platform”. Wide use of the available data indeed is needed to streamline processes and ensure efficiency gains. Besides the EU Agencies, Member State Competent Authorities (MSCA) and National Enforcement Agencies (NEA) are best placed to judge how data must be e.g. structured and presented to make sure it has an impact on the actual work. Yet, measures to encourage use of the data are missing. We are concerned that the system set-up does not sufficiently take into account actual needs of MSCA

and, notably, NEA. In particular, while a platform steering committee shall advice on the roll-out and further development of the common data platform and its governance scheme, Member States lack representation in that body. There is thus the need to ensure Member State involvement in governing bodies, such as the platform governance.

## Actively seek stakeholder involvement

Furthermore, since the “common data platform should serve the widest possible community” (recital 19) ClientEarth expects that stakeholders, notably Civil Society Organisations representing the concerns of the general public, will be proactively involved when the Commission or the steering committee creates and updates elements of the chemicals platform.

The same principles should apply when the Monitoring Framework, the Early Warning and Action System and the Observatory are further developed.

## Instil trust through access to enforcement data

An important objective of the proposed regulation is to “improve the Union’s citizens’ trust in the scientific base for the decisions taken under Union legal acts on chemicals”. Hence, given the role of enforcement with a view to improving citizens’ trust, the common data platform should provide structured access to the enforcement activities at the European and national levels and their outcomes. While the term “chemicals data” as proposed in Article 2(10) is rather inclusive, comprising both scientific facts and e.g. regulatory process-related information, it is not clear if this covers enforcement/compliance data. It should be clarified that this type of information is included.

In addition the question arises, whether there are mechanisms in place to ensure that existing enforcement data would have to be submitted to the system. REACH, for example, in Article 117(1) requires Member States to submit to the Commission a report on the operation of REACH, including a section on enforcement. This report, however, is due only every five years, and is too narrow in scope. It follows that even if Article 2(10) were to cover enforcement data and the Commission were to make that data available to ECHA as per Article 5(2) of the proposal, such data would lack comprehensiveness needed to make it a useful source and at the same time enable trust. The legislators therefore need to create an input channel for Member State to submit enforcement data. Use of this mechanism could be voluntary in nature.

## Enhance access to key risk data

Data on substances in products (mixtures and articles in terms of REACH) are covered by the term “chemicals data” as proposed in Article 2(10), and so are data on alternatives to targeted substances. However, such data are scattered across different regulatory procedures, including from different legislations (e.g. RoHS, REACH). The proposal does not provide for the structured access to these important items, thereby not allowing targeted retrieval of relevant and actionable information, across legislations and procedures (e.g. all products linked with a specific substance, alternatives discussed in relation to a specific substance or use). Hence, to better contribute to the goals to achieve a high level of protection of human health and the environment and to enable the development and use of sustainable chemicals, we suggest that distinct services – within the meaning of Article 3(5) of the proposal – are established with all available data on substances in products and available data on alternatives.

## Bring access to information in line with EU “Aarhus” rules

Considering the proposed regulation’s objectives, the widest possible access to documents containing chemicals data is paramount, and so is legal clarity as to the scope of access rights. In this regard, the proposed exemption from access to data relating to the authorities’ internal working or decision making pursuant to Article 3(4) raises

severe concerns. Union legislation (Regulation No 1049/2001 and Regulation 1367/2006) already governs access to this type of documents; however, the proposed wording of Article 3(4) is too expansive (i.e. potentially creating limiting effect) and thus inconsistent with existing laws. This provision must therefore be deleted from the proposal.

## Data generation mechanism must not impose costs on society

ClientEarth supports the introduction of a data generation mechanism that gives ECHA appropriate discretion in decisions to commission scientific studies. As explained in the [working document accompanying the legislative proposal](#), this mechanism is needed "to cater for the situation where it is not legally possible to request data from industry or where there is an explicit reason why data should be generated by a non-industrial stakeholder" (p. 60). However, the root cause of such a need will always be products and processes from industry. ClientEarth therefore calls on legislators to harmonise the mechanism with the polluter pays principle, one of the cornerstones of EU environmental policy. As [European Court of Auditors](#) also emphasises, the EU budget should not be used to finance measures which, according to the polluter-pays principle, should be borne by the polluters. A financing model is therefore needed to ensure that industry bears the costs of all commissioned studies.

## Early Warning and Action System

### Lack of ambition

The proposed Early Warning and Action System is an important step in the right direction, aiming to avoid future cases of ignorance and negligence towards (supposedly) "new" chemical phenomena that cause or may potentially cause harm to human and animal life as well as the environment. We note however that, compared to the options assessed in the [pilot study done by contractors](#), the Commission decided to only implement the bare minimum. ClientEarth therefore requests the legislators to step up their commitments, i.a. by implementing the elements suggested below.

### Lack of accountability

The proposal does foresee the compilation and assessment of emerging risk signals, which are then presented to the Commission, Agencies and Member State Authorities in the form a report, for "consideration of the need for regulatory or policy action related to the early warning signals". First of all, enforcement activities should be expressly added to the scope, since signals may indicate non-compliance of industry with existing legal obligations. Second, to instil trust in the system, presenting a report and leaving both the *if* and *how* of any follow-up activities up to the full discretion of authorities is not sufficient. Rather, we suggest the named authorities should be obliged to react upon the report, explain which measures are planned and where reaction does not appear necessary, and justify any of the decisions to ensure minimum accountability of the regulatory bodies. This information should be made public.

### Lack of use of independent science

Considering the regulation's objectives, including enhancing trust and widening the scientific base of chemical policies, the proposed mechanism does not fully exploit available scientific resources, notably the valuable insights from independent research (e.g. peer-reviewed studies from academia), or the information collected by research groups investigating cases of local pollution. In line with the [CSS commitment](#) to "establish tools and practices to ensure that relevant academic data is easily and readily accessible for safety assessments and is suitable for regulatory purposes" (p.17), and taking into account the EEA's limited resources (see below) to do literature research under the proposed Article 19(2)(d), we suggest establishing a mechanism for third parties to input data

that meet certain criteria (e.g. relevant for regulatory purposes) to support EEA with the identification of emerging risk signals. To this end, one may refer to available concepts discussed in literature.

## Lack of resources

According to the financial statement accompanying the OSOA package, EEA will receive additional human resources equivalent to 1 FTE to set up the Early Warning and Action System and subsequently fulfil the various tasks. In ClientEarth's view, this resource allocation by no means reflects the systemic importance of the mechanism nor the demanding work requested from EEA linked to that. We therefore request the legislators to re-calculate and equip the agency with the appropriate means to make sure the mechanism does not remain purely symbolic but achieves real impact to protect human and animal health as well as the environment.

## Overall lack of clarity and monitoring

The proposed provisions lack clarity, e.g. when it comes to the role of other EU agencies who "shall identify and gather relevant available data on early warning signals from the field falling within their mandate". A Commission implementing act could further specify and flesh-out the provisions.

Furthermore, periodic reviews should, in addition, assess the effectiveness of the system and make sure the system is future proof, using state-of-the-art means to collect and assess relevant data.

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