C/2024/3381

31.5.2024

Opinion of the European Economic and Social Committee

Proposal for a regulation of the European Parliament and of the Council 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

(COM(2023)779 final - 2023/0453 (COD))

and

Proposal for a regulation of the European Parliament and of the Council amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals

(COM(2023)783 final - 2023/0455 (COD))

and

Proposal for a directive of the European Parliament and of the Council amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency

(COM(2023)781 final - 2023/0454 (COD))

(C/2024/3381)

Rapporteur: **John COMER**

Referrals	European Parliament, 29.2.2024 Council, 16.2.2024
Legal basis	Articles 43, 114, 168 (4c), 192(1) and 304 of the Treaty on the Functioning of the European Union
Section responsible	Section for Agriculture, Rural Development and the Environment
Adopted in section	26.2.2024
Adopted at plenary	20.3.2024
Plenary session No	586
Outcome of vote (for/against/abstentions)	214/0/2

1. Conclusions and recommendations

1.1. The European Economic and Social Committee (EESC) welcomes the 'one substance, one assessment' (OSOA) package, which is intended to 'ensure the efficient delivery of coherent hazard and risk assessments of chemicals where those assessments are required by Union legal acts, to achieve a high level of protection of human health and 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.' ([1])

([1]) COM(2023) 779 final, Article 1, paragraph 1.

1.2. The EESC welcomes the one-stop-shop platform bringing together data on chemicals obtained from different sources, which will be under the control of the European Chemicals Agency (ECHA).

1.3. The ECHA will take over tasks that have so far been carried out by the Commission, supported by ad hoc committees and external consultants. The failure to publish the new regulation on reorganising the ECHA means that it is not possible to make a full assessment of the role of the ECHA in the OSOA system. This role is critical for the OSOA approach to functioning successfully.

1.4. The ECHA may commission scientific studies, on its own initiative or at the Commission's request, when results cannot be obtained through existing legal provisions or processes under EU legislation. It is not clear whether business operators will be compelled to cooperate in the conducting of these scientific studies or whether they will be able to appeal against an ECHA request.

1.5. The confidential provisions in the Common Data Platform must be clearly defined so that industry operators have full confidence in the system. In this regard it is very positive that access to confidential information can be audited. In addition, greater clarity on sharing and reusing chemicals data must be provided when the Commission publishes the common data platform governance scheme.

1.6. In the case of commissioned studies, there is a lack of clarity as to how disagreements will be resolved.

1.7. The notification of studies will add to the administrative burden on businesses. It will need to be carefully monitored, depending on the governance rules applying to the ECHA.

1.8. These proposals are complex and will have an overarching impact on the regulatory framework for chemicals in the EU. The fact that no scientific work has been taken away from existing agencies has the potential to cause uncertainty as to whether the ECHA will be able to manage the system in such a way as to achieve maximum synergies and cooperation.

1.9. The new proposals must ensure the widest possible access to documents containing chemical data and it is essential that strict rules apply in this regard.

1.10. The EESC observes that the package currently falls short on ensuring that the data is reliable and fully exploits the valuable insights from independent research such as peer-reviewed academic studies, which are relevant for regulatory purposes.

1.11. A mechanism is needed that promotes the uptake of independent academic data in the early warning and action system, as well in the general context of environmental and health assessments.

1.12. In the event of failure to resolve differing scientific opinions it is essential that the precautionary principle apply in order to protect public health and the environment.

2. **Background**

2.1. In adopting the three legislative proposals, the Commission is proposing to streamline assessments of chemicals across EU legislation, strengthen the knowledge base on chemicals and ensure early detection and action on emerging chemical risks.

2.2. The Commission is proposing two regulations and a directive:

— a regulation to establish a common data platform on chemicals (COM(2023)779 final) ([2]);

— a regulation as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals (COM(2023)783 final) ([3]). This is an 'omnibus' regulation that amends four regulations;

— a directive amending the RoHS Directive in as far as it relates to the re-attribution of scientific and technical tasks to the European Chemicals Agency (ECHA) (COM(2023)781 final) ([4]).

2.3. A fitness check of the most relevant chemicals legislation (excluding REACH) assessed over forty pieces of legislation and concluded that the legislation was fit for purpose, but found significant weaknesses preventing the regulatory framework for chemicals from reaching its full potential ([5]). Failure to reform could restrict the ability to cope effectively with the risks posed by existing and new chemicals.

2.4. Depending on the legislation in question, the work on chemicals is initiated by different bodies at different points in time, using different data and carried out by different EU agencies, scientific committees, expert groups, Commission departments and contractors. This can sometimes lead to inconsistent outcomes of assessments for the same chemicals across different pieces of legislation.

2.5. To anticipate the harm caused by harmful chemicals, or by any emerging chemical risks or unforeseen consequences, requires having information on early warning signals.

2.6. It is essential to assess the environmental and health impact of chemicals across their entire life cycle in order to safeguard natural resources, ecosystems and people, as well as to evaluate the impact on climate change. The objective must be to produce chemicals that are safe and sustainable.

2.7. Building on the findings of the fitness check, the Commission committed in the Green Deal to presenting a Chemicals Strategy for Sustainability ([6]). Part of this entails the commitment to start using the 'one substance, one assessment' approach, with the intention of making the assessment of chemicals across EU legislation more efficient. This approach should strengthen the knowledge base on chemicals and make every effort to ensure the early detection of, and swift action on, emerging chemical risks.

2.8. The OSOA approach must focus on the following key areas:

— as far as is possible, synchronising and coordinating the triggering of assessments, and assessing groups of substances instead of assessing substances individually;

— clearly allocating responsibilities to bodies performing assessments, making best use of the expertise and resources available and ensuring good cooperation between the parties involved;

— ensuring assessors have access to all available data without any technical or administrative burdens. Information on chemicals must be easily findable, interoperable, secure, reliable and of high quality;

([2]) COM(2023) 779 final.
([3]) COM(2023) 783 final.
([4]) COM(2023) 781 final.
([5]) Fitness Check, European Commission.
([6]) COM(2020) 667 final.

— making sure methods used for assessment are coherent and harmonised to the greatest extent possible; and

— ensuring a high level of transparency in performing assessments, as well as in the underlying scientific data and information on chemicals.

2.9. In the Chemicals Strategy it was announced that the Commission would develop criteria for chemicals that were safe and sustainable by design, requiring a comprehensive assessment of both safety and sustainability throughout the life cycle of chemicals.

2.10. These proposals would also set up the systematic collection of human biomonitoring data generated in the EU, in order to inform policy-makers about the level of chemicals found in the European population (e.g. blood or breast milk).

2.11. A monitoring and outlook framework is to be established to enable early detection of chemical risks to prevent widespread chemical pollution and to enable a fast regulatory response.

2.12. The EU action plan Towards Zero Pollution for Air, Water and Soil ([7]) contributed to the objectives of the Chemicals Strategy by committing to the development of an integrated zero pollution monitoring and outlook framework.

2.13. Regulation (COM(2023)779 final) aims to collate the relevant information on the safety and sustainability of chemicals and early warning signals for chemical risks as a start to using the 'one substance, one assessment' approach, in order to:

— develop a common data platform bringing together chemicals data from multiple sources, including environmental sustainability-related data;

— ensure such information is secure, reliable, of high quality, findable, accessible, interoperable and reusable;

— allow the testing and monitoring of substances to be commissioned as part of the regulatory framework when further information is considered necessary;

— keep records of studies commissioned or carried out by businesses in a chemicals regulatory context and set up an early warning system for emerging chemical risks; and

— establish a monitoring and outlook framework for chemicals.

2.14. The common data platform will centralise and consolidate data on chemicals at EU level in one centrally accessible IT infrastructure.

2.15. The common data platform will subsume existing platforms and will expand their scope to almost all EU chemicals legislation and complement them with new tools and databases. Member States' competent authorities, EU agencies and the European Commission will have access to all the data on the common data platform. Data deemed to be publicly available will be accessible to the public.

2.16. Regulation (COM(2023)783 final) is an 'omnibus' regulation in that it amends several acts such as general food legislation, the persistent organic pollutants (POPs) regulation, the medical devices regulation and the European environmental agency founding regulation.

2.17. There are two key actions in the proposed regulation (COM(2023)783 final):

— re-allocating existing tasks and allocating new tasks to EU agencies, which will require targeted amendments to existing pieces of chemicals legislation, other than the chemicals legislation that is currently being revised;

— ensuring the clear allocation of responsibilities and good cooperation among the European agencies involved.

([7]) COM(2021) 400 final.

2.18. The main objectives of the proposal are to:

— ensure that the allocation of responsibilities for performing the assessments and underlying technical and scientific work on chemicals is clear, that it exploits and maximises synergies and that it makes best use of the expertise and resources available in EU agencies;

— ensure that the results are of high scientific quality and reliable, and that the procedures are transparent and inclusive;

— ensure that there is co-operation and coordination among players in all aspects underlying the assessment of chemicals, including methodology development and data exchange.

2.19. This proposal relates to a Commission proposal on the ECHA, which will consider restructuring the agency's scientific committees to better manage the increased workload arising from the tasks re-allocated under this proposal.

2.20. Directive (COM(2023)781 final) focuses on amending the RoHS Directive ([8]), which deals with restrictions on the use of certain hazardous substances in electrical and electronic equipment. This proposal follows on from the OSOA approach and aims at a limited amendment to the RoHS Directive in order to allocate the existing scientific and technical tasks to the ECHA. It is linked to the 'omnibus' regulation to ensure consistency.

3. **General comments**

3.1. The EESC welcomes the Commission's objective of achieving the OSOA approach.

3.2. Moving towards this objective will require action at many levels, including close coordination between different DGs and better coordination of Member States' regulatory initiatives.

3.3. If this OSOA approach is properly implemented, it should benefit EU citizens, industry and the regulatory authorities, ensuring better protection of public health and the environment, as well as promoting competition and innovation in EU industry.

3.4. With a substantial increase in the global production of chemicals expected over the next ten years, it is most important that every effort be made to introduce the OSOA approach to improve the efficiency and effectiveness of the chemicals regulatory system. Failure in this will mean that the EU will fail in its goals of zero pollution and a toxic-free environment.

3.5. The EESC welcomes the fact that the common data platform is to be designed in such a way that access to confidential information can be audited.

3.6. The proposal requires business operators and laboratories/testing facilities to notify the ECHA separately on proposed scientific studies commissioned to support an application, notification or regulatory dossier notifying, or submitted to, the Commission, EU agencies or the competent authorities of the Member State concerned. This is a new administrative requirement for business operators.

3.7. The EESC observes that the package falls short on ensuring the data is reliable and fully exploits the valuable insights from independent research (e.g. peer-reviewed academic studies), which are relevant for regulatory purposes.

3.8. Greater transparency and public access to data should help gain public confidence in the regulatory process for the assessment of chemicals.

([8]) Directive 2011/65/EU.

3.9. These proposals are complex and will have an overarching impact on the regulatory framework for chemicals in the EU.

4. **Specific comments**

4.1. The OSOA proposals seem to prioritise the hazard and risk assessment of chemicals under the overall direction of the ECHA. This means that the ECHA will take over tasks that have so far been carried out by the Commission, supported by ad hoc committees and external consultants. The failure to publish the new regulation on reorganising the ECHA means that it is not possible to make a full assessment of the role of the ECHA in the OSOA. This role is critical to the successful functioning of the OSOA approach.

4.2. The ECHA may commission scientific studies on its own initiative or at the Commission's request, when results cannot be obtained through existing legal provisions or processes under EU chemicals law. EFSA already has a similar mandate to commission scientific studies under EU food law but here this new mechanism may be used in particular to generate data on chemicals in general requiring additional scrutiny. It is not clear whether business operators will be compelled to cooperate in the conducting of these studies or whether they will be able to appeal against an ECHA request.

4.3. The objective of OSOA is to streamline studies and avoid disagreements. However, it is inevitable that disagreements on commissioned studies arise, and there is a lack of clarity as to how these disagreements will be resolved.

4.4. The proposals strengthen the obligation to solve diverging scientific opinions. Where a resolution is not possible, the matter is referred to the Commission. In the event of a divergence in hazard identification, this is to be solved via a harmonised classification developed by the ECHA.

4.5. It is vital that the confidential provisions on the common data platform be clearly defined so that industry operators have full confidence in the system. In particular, it is of paramount importance to ensure the widest possible access to documents containing chemical data, and strict rules need to apply to ensure that crucial information on chemicals is not withheld by companies.

4.6. Greater clarity on authorities sharing and reusing chemicals data should be provided when the Commission publishes the common data platform governance scheme.

4.7. It seems that no scientific work is being taken away from existing agencies, so it remains uncertain as to whether the ECHA will be able to manage the system in such a way as to achieve maximum synergies and cooperation. In the absence of a new regulation to reform the ECHA, it is difficult to assess whether the ECHA will be able to cope with all the new tasks assigned to it.

4.8. The early warning and action system needs a mechanism ensuring prompt regulatory action as soon as emerging risks are identified.

4.9. A mechanism is needed to promote the uptake of academic data in the early warning and action system, as well as in the general context of environmental and health assessments.

4.10. When it comes to reconciling divergent scientific opinions, it should be noted that certain sensitive adverse effects, such as immunotoxicity, cannot be adequately addressed by the ECHA with the Regulation on the classification, labelling and packaging of substances and mixtures ([9]). Therefore, where scientific opinions differ among agencies, the precautionary principle should apply to ensure the protection of EU citizens, including vulnerable groups and future generations.

Brussels, 20 March 2024.

The President
of the European Economic and Social Committee
Oliver RÖPKE

([9]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1.)