



Council of the
European Union

167459/EU XXVII. GP
Eingelangt am 19/12/23

Brussels, 19 December 2023
(OR. en)

16972/23

Interinstitutional File:
2023/0454(COD)

ENV 1527
MI 1148
COMPET 1296
CHIMIE 114
ENT 281
IND 704
RECH 569
CODEC 2548

PROPOSAL

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	7 December 2023
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2023) 781 final
Subject:	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

Delegations will find attached document COM(2023) 781 final.

Encl.: COM(2023) 781 final



EUROPEAN
COMMISSION

Brussels, 7.12.2023

COM(2023) 781 final

2023/0454 (COD)

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

(Text with EEA relevance)

{SWD(2023) 850 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Reasons for and objectives of the proposal**

The European Union has developed a comprehensive regulatory framework for chemicals to ensure a high level of protection of human health and the environment from the harmful effects of chemicals, support the efficient functioning of the internal market for chemicals, and promote the competitiveness and innovation of EU industry. The framework consists of over 40 pieces of legislation addressing: (i) the production and placing on the market of chemicals and products containing chemicals; (ii) emissions of chemicals and safety of workers; (iii) consumer products; (iv) food and feed stuff; (v) and the environment.

The fitness check of the most relevant EU chemicals legislation¹ concluded that, overall, this legislation delivers the intended results and is fit for purpose. However, there are shortcomings in the consistency of safety assessments, the efficiency of the underlying technical and scientific work, and the consistency of transparency rules.

The implementation of the individual legislative instruments is supported by a large volume of technical and scientific work. Depending on the legislation in question, the work is initiated by different bodies at different points in time, using different data and carried out by certain EU agencies (the European Chemicals Agency (ECHA), the European Food Safety Authority, the European Environment Agency and the European Medicines Agency), scientific committees, expert groups, Commission departments and contractors. This sometimes leads to inconsistent outcomes of assessments for the same chemicals across different legislation. This is an inefficient use of resources and carries unnecessary costs – from operating multiple committees conducting similar assessments, to assessing the same chemical by several committees/bodies and duplicating supporting technical and scientific work with potentially diverging outcomes of the hazard or risk assessment. In addition, the assessments that are not carried out by the EU agencies are sometimes criticised by stakeholders as not being transparent and inclusive enough and not having sufficient scientific quality and robustness.

Building on the findings of the fitness check, the European Green Deal² put forward the commitment ‘to review how to use better the EU’s agencies and scientific bodies to move towards a process of ‘one substance, one assessment’ and to provide greater transparency

¹ Commission Staff Working Document Fitness Check of the most relevant chemicals legislation (excluding REACH), as well as related aspects of legislation applied to downstream industries accompanying the document: Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Findings of the Fitness Check of the most relevant chemicals legislation (excluding REACH) and identified challenges, gaps and weaknesses ([SWD\(2019\) 199](#)).

² Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions: The European Green Deal ([COM/2019/640 final](#)).

when prioritising action to deal with chemicals. The chemicals strategy for sustainability³ (hereby ‘Strategy’) developed the concept of ‘one substance, one assessment’ further and described it as an approach to improve the overall efficiency, consistency and transparency of the delivery of chemical safety assessments across legislation.

Two key measures set out in the strategy to improve the overall efficiency, consistency and transparency aim to:

- ‘rationalise the use of expertise and resources by **proposing the reattribution of technical and scientific work on chemicals performed under the relevant pieces of legislation to European agencies**’;
- ensure ‘a clear allocation of responsibilities and **good cooperation among the European agencies**’. The Council⁴ welcomed the ‘one substance, one assessment’ initiative and the European Parliament⁵ welcomed the ‘one substance, one hazard assessment’ approach.

Reallocating existing tasks and allocating new tasks to EU agencies require targeted amendments of the existing pieces of chemicals legislation. The preferred way of doing it is by introducing changes in the allocation of tasks when the individual pieces of legislation are being revised. However, a full revision of individual pieces of legislation is not always timely nor appropriate, thus amendments are necessary to adapt such pieces of legislation outside of a full revision.

This is the case for the Regulations: Regulation (EU) 2019/1021 on persistent organic pollutants (‘POPs Regulation’)⁶ and Regulation (EU) 2017/745 on medical devices⁷. The amendments of the regulations are proposed by a proposal for a Regulation (‘Omnibus Regulation’)⁸. The ECHA should be assigned to carry out scientific and technical tasks related to chemicals described in both regulations. The respective proposal also amends Regulation (EC) No 401/2009 establishing the European Environmental Agency⁹ and Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety¹⁰

³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Chemicals Strategy for Sustainability Towards a Toxic-Free Environment ([COM\(2020\) 667 final](#)).

⁴ [Council Conclusions on Sustainable Chemicals Strategy of the Union, 2021.](#)

⁵ European Parliament resolution of 10 July 2020 on the Chemicals Strategy for Sustainability (2020/2531(RSP)) ([OJ C 371, 15.9.2021, p.75](#)).

⁶ Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants ([OJ L 169 25.6.2019, p. 45](#)).

⁷ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC ([OJ L 117 5.5.2017, p. 1](#)).

⁸ 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

⁹ Regulation (EC) No 401/2009 of the European Parliament and of the Council of 23 April 2009 on the European Environment Agency and the European Environment Information and Observation Network ([OJ L 126 21.5.2009, p. 13](#)).

¹⁰ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ([OJ L 031 1.2.2002, p. 1](#)).

to ensure good cooperation among EU agencies on all aspects involving the efficiency, consistency and transparency of chemical assessments.

This proposal focuses on amending the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment ('RoHS Directive')¹¹. This proposal follows the 'one substance, one assessment' approach and aims at a limited amendment of Directive 2011/65/EU in order to allocate the existing scientific and technical tasks to the European Chemical Agency. This proposal is therefore closely linked to the Omnibus Regulation to ensure consistency, to comply with the concept 'one substance, one assessment' and to complete the re-attribution of tasks for Directive 2011/65/EU.

The objectives of the proposal are to ensure that:

- allocation of responsibilities for performing the assessments and the underlying technical and scientific work on chemicals is clear, exploits and maximises synergies and makes the best use of available expertise and resources;
 - deliverables are of high scientific quality and the procedures are transparent and inclusive.
- **Consistency with existing policy provisions in the policy area**

As described above, this proposal is linked to the Omnibus Regulation but also to a proposal for a Regulation of the European Parliament and of the Council on chemicals data. That proposal will, among others, aim to strengthen sharing and reusing chemical data and information among EU agencies and Member State competent authorities. This will further contribute to improving the consistency, efficiency and transparency of chemical assessments across legislation.

This proposal relates to the general review of Directive 2011/65/EU under Article 24(2) of that Directive. The review, launched with the evaluation process in 2018 and concluded with the review report requested by Article 24(2), the staff working document on the evaluation¹² and this proposal, identified the need to strengthen consistency and maximise synergies between Directive 2011/65/EU and chemicals legislation, particularly in the two assessment procedures under Directive 2011/65/EU which require scientific and technical expertise in the field of chemicals.

Directive 2011/65/EU currently restricts the use of 10 substances and substance groups listed in Annex II to that Directive. Article 6(1) lays down a procedure for a periodic review of Annex II on the Commission's initiative or following the submission of a proposal by a Member State. The procedure is not described in detail in Article 6(1), it only includes how to initiate the review and the obligation to consult interested parties. In order to increase the transparency of the restriction process, there is a need to set out key steps in the process explaining how to review and amend the list of restricted substances.

The second paragraph of Article 6(1) contains criteria for the review and amendment of the list of restricted substances in Annex II. The first criterion is that amendments should be 'coherent' with other legislation related to chemicals, in particular Regulation (EC) No

¹¹ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ([OJ L 174 1.7.2011, p. 88](#)).

¹² Staff working document on the evaluation of the RoHS Directive (SWD (2023) 760)

1907/2006 ('REACH Regulation')¹³ and, inter alia, Annexes XIV and XVII to that Regulation. In order to identify substances for a potential restriction and to assess whether they meet the criteria under Article 6(1), the European Commission contracts external experts to gather evidence, to provide expertise and, finally, to prepare a dossier about the substance.

Article 4(6) of the Directive allows time-limited and application-specific exemptions for technical applications listed in Annexes III and IV, to which the substance restrictions do not apply. The industry can submit applications for time-limited exemptions. Annex III exemptions can apply to all categories of electrical and electronic equipment, while Annex IV lists applications specific to medical devices and monitoring and control instruments. Article 5(1) defines the process and criteria whereby the European Commission adds, amends or deletes materials and components of electrical and electronic equipment for specific applications in Annexes III and IV. The first criterion for an inclusion of materials and components of electrical and electronic equipment in the lists in Annexes III and IV is that their inclusion does not weaken the environmental and health protection afforded by the REACH Regulation. When assessing whether to add, amend or delete exemptions, the Commission requests external experts to evaluate exemption requests from industry and to assess if any of the criteria in Article 5(1)(a) is met.

The condition to be consistent with decisions and practice under the REACH Regulation shows that both procedures require close coordination with the REACH Regulation. In addition, there can be single cases in which interfaces with other legislation are relevant, e.g. the POPs Regulation, which may restrict substances covered by the RoHS Directive in articles. By allocating the existing scientific and technical assessment procedures to the European Chemical Agency, the consistency between existing policy provisions is expected to increase.

The REACH Regulation has two assessment processes resembling the two processes under the RoHS Directive: The authorisation process under title VII and the restriction process under title VIII of the REACH Regulation. While there are important differences due to the different nature and motivation of the legislation, these processes can be compared to and correspond in the broadest sense to, respectively, the substance restriction process and the exemption process under the RoHS Directive. By streamlining the substance restriction and exemption process under the RoHS Directive with the restriction and authorisation process under the REACH Regulation, authorities and stakeholders can benefit of aligned procedures based on methodologies established under REACH and managed by the ECHA. To improve the scientific robustness of assessments, the scientific committees in the ECHA should be involved for the exemption and substance restriction process, similar to the REACH processes.

- **Consistency with other Union policies**

Allocating and reallocating scientific and technical tasks in the assessment of chemicals to ECHA is consistent with the objectives of the Better Regulation agenda. EU agencies benefit from robust scientific expertise and transparent and inclusive processes, which help ensure the

¹³ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ([OJ L 396, 30.12.2006, p.1](#)).

support to policymaking. Consolidating the EU agencies' work and thus lowering the number of bodies involved contributes to simplifying and standardising procedures and reducing administrative burden.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The legal basis for this proposal is Article 114 of the Treaty on the Functioning of the European Union. The proposal is a directive that amends an existing directive the legal basis of which is Article 114. Therefore, it is appropriate to base this Directive on the same Article.

- **Subsidiarity (for non-exclusive competence)**

The initiative will amend Directive 2011/65/EU in a targeted manner.

The amendment is strictly limited to the allocation of tasks for conducting scientific and technical work at EU level, which is necessary for the operation of those instruments. Given that the Member States are not in a position to ensure the re-attribution of tasks to the EU Agencies, which are EU bodies regulated at the EU level, the objective can only be achieved at EU level, thus respecting the subsidiarity principle.

The two procedures described under Article 5 and Article 6 are applicable at the EU level. National provisions should not deviate from these Articles set in Directive 2011/65/EU.

Under the exemption procedure of Article 5, economic operators can initiate the process by submitting an application. In the context of the procedure for the review of substances to amend the list of restricted substances pursuant to Article 6, Member States or the Commission can initiate the process. All parties involved in the process can consult the provisions of Directive 2011/65/EU for the sake of legal certainty.

- **Proportionality**

The initiative does not go beyond what is necessary to achieve the desired objectives.

The review of Directive 2011/65/EU concluded that a full revision of that Directive was not appropriate nor timely¹⁴ but the procedures for substance restrictions laid down in Articles 5 and 6 of the Directive leave room for improvement which can be addressed by a targeted amendment of the procedural steps under the concept of 'one substance, one assessment'. Therefore, only Articles 5 and 6 are subject to revision. The proposed amendments are kept to a minimum and do not affect the substantive requirements that form the basis for the adoption of substance restrictions or corresponding exemptions.

- **Choice of the instrument**

The desired changes require targeted amendments of specific provisions related to roles and tasks of Agencies in scientific assessments under Directive 2011/65/EU.

¹⁴ Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the review of the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment

In accordance with the principle of the "parallélisme des formes", a Directive is to be amended by a Directive, for reasons of legal certainty, clarity and transparency. It was therefore not appropriate to include this proposal in the Omnibus Regulation. Instead, while being closely linked to the Omnibus Regulation, a limited number of selected provisions of Directive 2011/65/EU is amended by this separate Directive.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

Article 24(2) of Directive 2011/65/EU requires the Commission to carry out a general review of the Directive. The general review of Directive 2011/65/EU concluded that the Directive is a well-functioning instrument. The Directive has helped to reduce hazardous substances in electrical and electronic equipment in the EU and to protect human health and the environment at different stages of the value chain.

Nevertheless, the general review identified procedural shortcomings in the processes for deciding on exemptions and updating substance restrictions under Directive 2011/65/EU concluding that these processes are to some extent lacking transparency and efficiency and can be improved in terms of scientific robustness. Some methodological and procedural differences were also identified between preparatory work for the substance restriction under the RoHS Directive, on the one hand, and for the substance restrictions and authorisations under the REACH Regulation on the other. Lacking coordination, possible repetitive or overlapping assessments, and increasing risk that provisions are misunderstood were the main identified shortcomings. These shortcomings can lead to inconsistent chemical assessments, slow procedures, inefficient use of resources, unnecessary burdens, a (perceived) lack of transparency, and an impact on the quality of scientific advice. The review has shown that allocating the two processes under the remit of the ECHA can address those problems and take advantage of opportunities. It would simplify the current set-up, improve the quality of assessments, and ensure predictability for stakeholders and the public.

In addition, the fitness check of the most relevant chemicals legislation (assessing over 40 pieces of legislation, except the REACH Regulation) was carried out in 2019. The fitness check showed that there are significant opportunities for streamlining EU agencies' technical and scientific work. This would improve the efficiency of chemicals legislation (e.g. avoiding duplication of efforts and making the best use of available expertise in EU agencies) and make it more consistent (e.g. reducing the risk of different outcomes of hazard or risk assessments at EU level).

- **Stakeholder consultations**

During the evaluation of that Directive, the Commission published an evaluation roadmap for the RoHS Directive in 2018, which was open for public feedback from 14 September 2018 to 12 October 2018 and received 20 responses. Stakeholders were invited to participate in the [open public consultation](#) (OPC) organised by the Commission for 12 weeks until 6 December 2019. In total, 163 responses were collected. In parallel to the OPC, an in-depth survey (questionnaire) was shared with Member State authorities involved in implementing the RoHS Directive. A total of 20 responses were received. Between October 2019 and March 2020, three focus group meetings were organised covering the following topics: (i) for Member States authorities regarding assessment of implementation and enforcement of the

Directive, (ii) for NGOs regarding effectiveness and efficiency – environmental and health aspects, (iii) for business associations regarding effectiveness and efficiency – costs and benefits aspects, and (iv) for external and internal coherence. 15 in-depth interviews with targeted stakeholders (e.g. manufacturers, distributors, NGOs) were held, partly as follow-up to stakeholder input provided via the OPC. A virtual workshop joined by around 125 individuals was held in March 2020 to present the preliminary findings of the study and provide stakeholders with another opportunity to give input.

During the work on identifying policy options and assessing their impacts, the Commission asked for feedback within the call for evidence from 14 February to 14 March 2022. The [open public consultation](#) took place from 10 March to 16 June 2022. Within this consultation, stakeholders were asked to what extent they agree that it would be beneficial to introduce a mandate in the directive for the European Chemicals Agency to evaluate requests for new, renewed or for a deletion of exemptions from Annexes III and IV. There were dissenting opinions by stakeholders about the Agency's benefits: 40% disagreed and 35% agreed. Another question was addressed to the technical assessment of substances for the restriction of hazardous substances in Annex II. Here, most stakeholders (38%) agreed that it would be beneficial to introduce a mandate in the Directive for the European Chemicals Agency.

The Member States' **Expert Group for RoHS 2** (Directive 2011/65/EU) **adaptation and enforcement**¹⁵ was consulted on 26 October 2022 and on 5 June 2023 about the planned reattribution of the technical assessment of exemption requests and of potential substance restrictions to the European Chemicals Agency. The experts welcomed making provisions more streamlined and efficient in different pieces of legislation related to chemicals. The need to equip the Agency with sufficient resources and to consider product and waste aspects were highlighted.

A **call for evidence** for the initiative on making the best use of EU agencies to streamline scientific assessments was published on the Commission's [Have your say](#) website on 15 March 2022. The public and stakeholders were invited to provide feedback up until 12 April 2022. In total, 65 submissions were received. Generally, there was a large support for the 'one-substance, one-assessment' approach as a whole, as well as for the specific initiative on the reattribution of tasks. As regards the call for evidence, 67% of respondents expressed their explicit support, 23% did not express explicitly their opinion but provided relevant advice on how to develop the 'one substance, one assessment' approach. About 10% expressed doubts about the usefulness of the initiative or opposition to the initiative.

Stakeholders were also informed and consulted on the reattribution of tasks to EU agencies during the Information Session on One Substance, One Assessment with Stakeholders held on 1 June 2022. 800 participants followed this online event.

An extensive discussion on reallocating tasks to EU agencies was held with representatives of Member States and EU agencies at the second meeting of the **Expert Group on One Substance, One Assessment**¹⁶ on 2-3 June 2022 and on 30 March 2023. Representatives of Member States and EU Agencies participating in the expert group meetings were supportive to the initiative as well, providing concrete suggestions on the reattributions.

Main input received on reallocating tasks to the EU agencies and how this is taken into account in the proposal

¹⁵ E02810 - [Register of Commission expert groups and other similar entities \(europa.eu\)](#).

¹⁶ E03792 - [Register of Commission expert groups and other similar entities \(europa.eu\)](#).

Expertise:

Stakeholders highlighted the need to acquire further expertise in the field of electronic and electrical equipment and the end-of-life fate of such equipment for the ECHA. The Agency would be specialised in assessments related to chemicals but evaluating a whole life cycle of electrical equipment would require further knowledge. The Commission agrees that the ECHA services and their committees require additional expertise in these fields, in particular for the exemption procedure. Nevertheless, the Agency has already experience assessing the risk of chemicals in articles and considering the end-of-life stage of articles. The ECHA could consult external experts for specific electrical and electronic equipment and complicated cases. More information on these areas is gathered and knowledge is accumulated over time. In addition, there are services working on these areas who can support the ECHA, if necessary. This cooperation among services, here EU Agencies, will be strengthen with the Omnibus Regulation.

Several stakeholders agree to the allocation of tasks to the ECHA and its committees to increase coherence with the ‘one-substance, one assessment’ principle. Other stakeholders questioned the allocation to the ECHA as it is primarily intended for chemicals. The Commission sees strong links between the substance restrictions and the exemption process to established procedures under the REACH Regulation. This is also in line with stakeholder feedback stressing the need to better align the authorisation and restriction process for substances under REACH to the exemption process under the RoHS Directive. The Commission understands that the ECHA is the most appropriate EU Agency to deal with such chemical related tasks.

Resources:

Stakeholders insisted that the new task to the ECHA must be accompanied by the required resources. Reallocating work should not lead to an agency or committee being unable to manage the workload and jeopardising the quality of the work.

The Omnibus Regulation is accompanied with a detailed assessment of the EU agencies’ resource and capacity needs to ensure adequate resources taking into account synergies and economies of scale.

Scientific committees:

It is proposed to involve the Committee for Risk Assessment and the the Committee for Socio-Economic Analysis, set up pursuant to Article 76(1), point (c) and point (d), of Regulation (EC) No 1907/2006, for the exemption procedure as well as for the substance review. Stakeholders indicated that the agencies might need to be reorganised to deal with the increased workload. ECHA’s Committee for Risk Assessment already has a high workload. The Commission is aware about the increasing workload and sufficient resources are essential to meet the expectations. The provided resources will also benefit the involved scientific committees. For the proposed exemption process, the Committee for Risk Assessment will only be involved under certain conditions in order to limit it to the necessary.

The structure of ECHA committees will be addressed as part of the proposal for ECHA’s basic act, which is in preparation. All agencies’ scientific committees are independent.

Tasks to reallocate:

Stakeholders suggested that the ECHA should be involved in hazard assessments of the chemicals and external consultants can remain to provide technical expertise. This approach is not supported by the Commission as it could complicate the practical work and risk divergent conclusions. One central body to manage and assess exemption requests or to develop and assess restriction dossiers is needed on the working level to avoid inefficiencies. Depending on the case, the responsible agency can request external experts to provide further expertise.

According to stakeholders there are benefits in applying well-established methodologies developed under REACH in the procedures under the RoHS Directive. The Commission agrees in general that there is potential to align methodologies and to use best-practices in similar procedures to maximise the consistency and efficiency of the processes. That is why, the two procedures were aligned with the REACH procedures for granting authorisations and restricting substances, wherever possible. For the substance restriction process, this approach is in line with existing procedures under the REACH Regulation and the Regulation (EU) 2023/1542¹⁷.

- **Collection and use of expertise**

The Commission took into account input provided by the ECHA when it assessed which tasks are worth (re)allocating to the ECHA, how they should be allocated and what effect it will have on them.

- **Impact assessment**

Although (re)allocating scientific and technical work to the ECHA will improve the efficiency, consistency, quality and transparency of EU processes for the benefit of Member State authorities, stakeholders and the public, it will have no significant economic, social or environment impact on EU scale. The use of synergy effects and the application of established methods can be beneficial for the parties involved, as they increase the transparency and clarity of the processes.

There is also little discretion of the policy choice. In order to achieve objectives of the initiative, the consolidation of the technical and scientific work on chemicals at the EU level is possible only in the ECHA. Therefore, no formal impact assessment was carried out.

However, the ‘one substance, one assessment’ package will have a major impact on the EU agencies’ resource and capacity needs. This impact was assessed in detail in cooperation with the agencies concerned. The reallocation of tasks made as part of the individual pieces of legislation were assessed as part of the respective impact assessments. For the reallocation of tasks made as part of the Omnibus Regulation amending four pieces of legislation, the assessment is presented in the staff working document¹⁸ to that proposal. That document

¹⁷ Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p. 1–117).

¹⁸ Commission staff working document accompanying the documents 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 and Proposal for a Directive of the European Parliament and 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 (SWD (2023) 850)

summarises the impact of all reallocated tasks and assesses their cumulative impact on the EU agencies.

The fitness check of all chemical legislation except REACH also served as an evidence base for the proposal. The fitness check concluded on the risks of duplication of efforts, inefficient use of resources or divergent outcomes of the assessments stemming from the use of contractors, Commission services and ad hoc expert groups in performing scientific and technical work next to the similar work performed by the EU Agencies. The fitness check also concluded that there are significant opportunities for streamlining the technical and scientific work through EU agencies.

Concerning the specific transfer of tasks under the RoHS Directive to the ECHA, a support study¹⁹ was concluded within the work of identifying policy options and assessing their impacts. However, a full impact assessment was not seen as appropriate and only preliminary results were concluded. As a preliminary impact, it was found that the process can be more efficient and stakeholder can benefit of existing assessment and consultation structures (e.g., websites, databases).

Aligning restriction mechanisms of the RoHS Directive with the REACH mechanism described in Articles 69-73 of this Regulation, was also discussed in the same support study. Resources have to be allocated to the ECHA to ensure a high-quality assessment. The industry might benefit from more consistent and transparent consultation steps in the process. Administrative changes at Member State level may be necessary to adopt to the procedural changes and communication with ECHA.

Transferring the whole exemption process and/or the substance review process to the REACH Regulation was seen as not appropriate and timely.

- **Regulatory fitness and simplification**

The proposed reallocation of tasks to the ECHA will improve the coherence and efficiency of the legal framework on chemicals as a whole.

Reallocating tasks to EU agencies will create synergies as a result of:

- reusing existing expertise on hazard, risk, exposure and socio-economic assessments, development of committee opinions, stakeholder consultation;
- reusing existing hazard and risk data;
- the economies of scale from reusing scientific support services and IT tools.

The proposed reallocation of tasks will generate added value in terms of improving scientific consistency with other legislation and the scientific quality and robustness of assessments. In addition, reallocating tasks will significantly improve the transparency and inclusiveness of the processes. It will also guarantee the independence of the processes.

The proposal has no impact on small and medium-sized companies or micro-enterprises.

¹⁹ [Study to support the assessment of impacts associated with the general review of Directive 2011/65/EU \(RoHS Directive\).](#)

- **Fundamental rights**

The proposal has no implications for the protection of fundamental rights.

4. BUDGETARY IMPLICATIONS

The budgetary implications and the human and administrative resources are described and assessed within the Annex to the Omnibus Regulation amending several regulations under the ‘one substance, one assessment’ package.

The scientific and technical tasks allocated to ECHA in this proposal are existing tasks that are currently executed by the European Commission by contracting external experts. The allocation of tasks under this proposal will be provided with sufficient resources described and assessed in the staff working document²⁰ accompanying the proposal for a Regulation amending several regulations on the reattribution of technical and scientific tasks to EU Agencies. Aligning the procedures of these scientific and technical tasks with existing and comparable procedures under the REACH Regulation and placing their execution under the remit of the ECHA will result in an added value of improved quality and scientific robustness of the assessments, strengthened transparency and inclusiveness of the procedures, and improved consistency with assessments conducted under other pieces of legislation. In the long term, the improved consistency of EU scientific assessments will lead to better, more informed, and more efficient policy options for the benefit of the public, the industry, and the environment.

Part of the resources used for the assessments under the RoHS Directive are currently spent on procuring the necessary contractual support and amounts approximately 2.8 FTE per year.

The future resources are calculated for evaluating and managing restriction dossiers, and the evaluation of exemption requests, both including issuing opinions by the relevant scientific committees. In addition, the ECHA provides horizontal support, and develop and modify existing IT tools. Scientific and technical support from ECHA for the tasks to be reattributed under this proposal will require 3 FTEs (3 TAs) and an operational budget of EUR 66 000 in the first year. In the second year, there will be a need of 7 FTEs (4 TAs + 3 CAs) per year and operational budget of EUR 33 000 per year. Considering the resources currently used for the tasks to be reattributed, there will be a total net increase in the resources from 2026 and beyond as compared to today of 4.3 FTEs per year and EUR 33 000 per year.

When issuing an opinion, the scientific committees should appoint one of their members as a rapporteur. The person concerned, or his employer, should be remunerated in accordance with Article 87 of the Regulation (EC) No 1907/2006. The use of experts for the scientific committees to cover specific expertise by these tasks shall take place in accordance with Article 87 of the Regulation (EC) No 1907/2006. These measures should ensure that the committees can be provided with sufficient resources. However, the reattribution of tasks under this proposal will not affect the organisational conditions within the Agency.

²⁰

Commission staff working document accompanying the documents 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 and Proposal for a Directive of the European Parliament and 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 (SWD (2023) 850)

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The roll-out of the reattribution of the tasks under Article 5 and Article 6 of Directive 2011/65/EU to the ECHA requires a sufficient transitional period to allow organisational steps and resource allocations. A transitional period of 12 months is seen as sufficient.

The efficiency in performing the allocated tasks in the EU agencies will be monitored as part of the regular evaluation of the agencies' performance, once the relevant provisions are in place in the agencies' founding regulations.

- **Explanatory documents (for directives)**

Due to the limited implications for Member States and the low complexity of this proposal, an explanatory document pursuant the Joint Political Declaration of 28 September 2011²¹ is not considered necessary.

- **Detailed explanation of the specific provisions of the proposal**

Article 1 of the proposed regulation aims at amending Articles 5 and 6 of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment²². The amendments allocate a role and specific tasks to ECHA and its scientific committees in the processes for substance restrictions and assessing exemption requests corresponding to the restrictions.

That amendment should ensure alignment with existing procedures under the Regulation (EC) No 1907/2006²³. Those procedures will be adapted where relevant to the specific characteristics of electrical and electronic equipment and the regulatory system of Directive 2011/65/EU.

²¹ OJ C 369, 17.12.2011, p. 14.

²² Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment ([OJ L 174, 1.7.2011, p. 88](#)).

²³ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ([OJ L 396, 30.12.2006, p.1](#)).

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) The Commission has, in its Communication ‘European Green Deal’², set an objective that chemical safety assessments should move towards a process of ‘one-substance, one-assessment’, calling for more transparent and simpler risk assessment processes in order to reduce the burden on all stakeholders, accelerate decision-making, as well as to increase consistency and predictability of scientific decisions and opinions. The Commission, in its Communication on Chemicals Strategy for Sustainability³ concludes that, in order to achieve that objective, part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be reattributed to the most suitable Union agencies. This would simplify the current

¹ OJ C [...], [...], p. [...].

² Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal ([COM \(2019\) 640 final of 11 December 2019](#)).

³ Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, Chemicals Strategy for Sustainability Towards a Toxic-Free Environment ([COM \(2020\) 667 final of 14 October 2020](#)).

set-up, improve quality and coherence of safety assessments across Union legislation, and ensure more efficient use of existing resources.

- (2) The reattribution of certain scientific and technical tasks to the European Chemicals Agency is necessary in order to align processes and levels of scientific scrutiny and digitalisation with current standards and processes of the European Chemicals Agency. This is also necessary in order to ensure a consistent standard of scientific quality, transparency, data searchability and interoperability, in line with the ‘one-substance, one-assessment’ ambition.
- (3) Directive 2011/65/EU of the European Parliament and of the Council⁴ contains two procedures related to the assessment of chemicals: the evaluation of economic operators’ applications for granting, renewing or revoking an exemption from the substance restrictions pursuant to Article 5 of that Directive and the review of substances to be added to the list of restricted substances pursuant to Article 6 of that Directive. There is a need to increase transparency by setting detailed procedural steps for the process to review substances for a potential inclusion in the list of restricted substances.
- (4) Data and information held by the European Chemicals Agency in the context of regulatory processes under Titles VII and VIII of Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁵ can be usefully deployed for the assessment of potential substance restrictions and for assessing applications for exemption under Directive 2011/65/EU. Established structures and procedures can help to build on the existing knowledge base, maximise synergies, and make the best use of available expertise and resources.
- (5) To ensure consistency between the evaluation of economic operators’ applications for granting, renewing or revoking an exemption pursuant to Article 5 of the Directive 2011/65/EU, as well as to make the best use of existing chemicals-related expertise, the technical evaluation to assess the justification of such exemption requests should be carried out by the European Chemicals Agency and its committees in close coordination with the Commission.
- (6) To ensure that the restriction process referred to Article 6 in Directive 2011/65/EU is consistent with the restriction processes under other legislation related to chemicals, in particular with the substance restriction process laid down in Articles 69 to 73 of Regulation (EC) No 1907/2006, it is necessary to amend Directive 2011/65/EU to formally task the European Chemicals Agency with a role in the restriction process. In the light of experience obtained when carrying out substance reviews, it is essential for the quality of the related technical assessment, and for enabling synergies, to make use of information and tools being used in the context of assessments for chemical restrictions under Regulation (EC) No 1907/2006.

⁴ Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment – [OJ L 174 1.7.2011, p 88](#).

⁵ Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC - [OJ L 396 30.12.2006, p. 1](#).

- (7) The two procedures described under Article 5 and Article 6 are applicable at the EU level. National provisions should not deviate from these Articles set in Directive 2011/65/EU.
- (8) For amending procedural provisions under Directive 2011/65/EU, a transitional period of 12 months is necessary to allow for appropriate resource and task allocation for the European Chemicals Agency. That timeframe is considered sufficient to allow potential applicants or Member States to adjust to the modified procedural steps under that Directive.
- (9) Directive 2011/65/EU should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Amendments to Directive 2011/65/EU

Directive 2011/65/EU is amended as follows:

(1) Article 5 is amended as follows:

(a) paragraphs 3 and 4 are replaced by the following:

‘3. An application for granting, renewing or revoking an exemption shall be made to the European Chemicals Agency set up pursuant to Article 75(1) of Regulation (EC) No 1907/2006 (‘the Agency’) in accordance with Annex V.

4. The Agency shall:

- (a) acknowledge receipt of an application within 15 days of its receipt, stating the date of receipt of the application;
- (b) verify that the application contains all the elements laid out in Annex V;
- (c) if necessary, request the applicant to complete the application, and provide an appropriate deadline;
- (d) make the application and any supplementary information supplied by the applicant available to Member States;
- (e) make a summary of the application and a non-confidential version of the application as submitted by the applicant, as well as the date when the application is considered complete, available to the public on the Agency’s website;
- (f) invite interested parties to submit information within 3 months of its publication on the Agency’s website.

Where the applicant does not complete the application with the missing elements identified by the Agency in compliance with Annex V within the deadline provided

in accordance with the first subparagraph, point (c), the Agency may reject such application. The Agency shall establish and communicate to the applicant without undue delay the date when the application is considered complete.

Upon receipt of an application, the Agency shall notify the Commission of the application and keep it informed of any of the procedural steps under points (b) to (f).’;

- (b) the following paragraph 4a is inserted after paragraph 4:

‘4a. The Agency shall, after verifying the completeness of the application, request the opinion of the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d) of Regulation (EC) No 1907/2006. It shall request the opinion of the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, in the case of an application for a new exemption, or where otherwise considered appropriate.

The Committee for Socio-economic Analysis and, where relevant, the Committee for Risk Assessment:

- (a) shall draw up draft opinions within 9 months of the date the application has been considered complete by the Agency under paragraph 4, point (b);
- (b) shall assess whether the criteria in Article 5(1), point (a), are met and shall provide clear guidance to the Commission on granting, renewing or revoking an exemption;
- (c) may request the applicant or third parties to submit, within a specified period, additional information;
- (d) upon adopting the draft opinions, shall communicate those draft opinions to the applicant and shall allow the applicant the opportunity to comment within 4 weeks of the communication of the draft opinions to the applicant;
- (e) shall adopt their final opinions, taking into account the comments from the applicant.

Each Committee shall take into account any information submitted by third parties in accordance with the second subparagraph, point (c).

The Agency shall send the final opinion(s) of the Committees to the Commission within 12 months from the date an application has been considered complete by the Agency.

The Agency shall identify which parts of its opinions and of any attachments thereto should be made publicly available on its website and shall make those parts publicly available on its website.

For the purpose of adopting opinions pursuant to this paragraph, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.’;

- (c) paragraph 8 is replaced by the following:

‘8. The Agency shall, in agreement with the Commission, provide a harmonised format for the applications referred to in paragraph 3 of this Article as well as comprehensive guidelines for such applications, taking into account the situation of SMEs. Any submission to the Agency shall be made using the format and the submission tools made available by the Agency.’;

- (2) in Annex V, the following paragraph is added:

‘In cases referred to in the first paragraph, point (h), the applicant shall submit a non-confidential version of the application.’.

- (3) Article 6 is amended as follows:

- (a) in paragraph 1, the first subparagraph is replaced by the following:

‘With a view to achieving the objectives set out in Article 1 and taking account of the precautionary principle, a review, based on a thorough assessment, and an amendment of the list of restricted substances in Annex II shall be considered by the Commission periodically on its own initiative or following the submission of a restriction dossier prepared by a Member State containing the information referred to in paragraph 2.’;

- (b) in paragraph 1, the fourth subparagraph is deleted.

- (c) paragraph 2 is replaced by the following:

‘2. The review and amendment of the list of restricted substances in Annex II shall be based on restriction dossiers prepared by the Agency at the request of the Commission or prepared by a Member State.

The Agency or a Member State shall take into account any available information and any relevant risk assessment submitted for the purposes of other Union legislation covering the life cycle of the substance used in EEE, in particular the waste phase. To this end, other bodies established under Union law and carrying out a similar task shall, on request, provide information to the Agency or Member State concerned.

The restriction dossier shall comply with the requirements set out in Part II, point 3, of Annex XV to Regulation (EC) No 1907/2006 and shall, in addition, contain the following information:

- (a) information on the use of the substance or the group of similar substances in EEE;

- (b) information on detrimental effects and exposure in particular during waste EEE management operations.’

- (4) the following Articles 6a, 6b and 6c are inserted:

‘Article 6a

Initiation of procedure for review and amendment of the list of restricted substances

1. Within 12 months of receipt of the request from the Commission referred to in Article 6(2), first subparagraph, the Agency shall prepare a restriction dossier conforming to the requirements referred to in Article 6(2), third subparagraph, and suggest restrictions in order to initiate the restriction process.
2. A Member State shall notify the Agency that it proposes to prepare a restriction dossier which conforms to the requirements referred to in Article 6(2), third subparagraph, within 12 months. If that dossier demonstrates that action on a Union-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in order to initiate the restriction process.
3. The Agency shall publish without delay the intention of the Commission or the Member State to initiate the process to review and amend the list of restricted substances in Annex II.
4. The Agency shall establish and maintain a list of substances for which a restriction dossier conforming to the requirements of Article 6(2) is planned or underway by either the Agency or a Member State for the purposes of a proposed restriction.
5. The Agency shall consult the Committee for Risk Assessment, set up pursuant to Article 76(1), point (c), of Regulation (EC) No 1907/2006, and the Committee for Socio-economic Analysis, set up pursuant to Article 76(1), point (d), of that Regulation. The Committees shall verify whether the restriction dossier submitted conforms to the requirements referred to in Article 6(2), third subparagraph.

Within 30 days of receipt of the restriction dossier, the respective Committee shall inform the Agency or the Member State proposing restrictions whether the dossier conforms to the requirements referred to in Article 6(2), third subparagraph. If the dossier does not conform to those requirements, the reasons shall be given to the Agency or the Member State in writing within 45 days of receipt of that dossier. The Agency or the Member State shall bring the dossier into conformity within 60 days of the date of receipt of the reasons from the Committees, otherwise the procedure under this Article shall be terminated.

6. Where the dossier meets the requirements referred to in Article 6(2), third subparagraph, the Agency shall make it publicly available without delay, clearly indicating the date of publication. The Agency shall invite all interested parties, including economic operators, recyclers, treatment operators, environmental organisations and employee and consumer associations to submit, individually or jointly, within 4 months from the date of the publication of the dossier, the following:

- (a) comments on dossiers and the suggested restrictions;
- (b) a socio-economic analysis including an analysis of alternatives, or information which can contribute to one of the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions.

The analysis referred to in the first subparagraph, point (b), shall conform to the requirements in Annex XVI to Regulation (EC) No 1907/2006.

Article 6b

Opinion of the Agency's Committees

1. Within 12 months from the date of publication referred to in Article 6a(6), the Committee for Risk Assessment shall adopt an opinion as to whether the restriction is appropriate in reducing the risk to human health or the environment, specifically by reference to the risks set out in Article 6(1), third subparagraph, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the restriction dossier prepared by the Agency at the request of the Commission or by the Member State, and the views of interested parties referred to in Article 6a(6), point (a).
2. Within 15 months from the date of publication referred to in Article 6a(6), the Committee for Socio-economic Analysis, shall adopt an opinion on the proposed restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. Prior to that, it shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account any existing analysis or information according to Article 6a(6), point (b).
3. The Agency shall publish the draft opinion of the Committee for Socio-economic Analysis on its website without delay and invite interested parties to provide their comments on the draft opinion no later than 60 days from its publication.
4. The Committee for Socio-economic Analysis shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set in paragraph 3. This opinion shall take into account the comments of interested parties submitted under Article 6a(6), point (a), and paragraph 3 of this Article.
5. Where the opinion of the Committee for Risk Assessment diverges significantly from the restrictions proposed, the Agency shall postpone the deadline for the opinion of the Committee responsible for Socio-economic Analysis by a maximum of 90 days.
6. For the purpose of adopting opinions pursuant to this article, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.

Article 6c

Submission of an opinion to the Commission

1. The Agency shall submit to the Commission, without delay, the opinions of the Committees for Risk Assessment and Socio-economic Analysis on the restrictions suggested pursuant to Article 6b. Where the opinions of the Committees for Risk Assessment and Socio-economic Analysis diverge significantly from the restrictions suggested by the dossier, the Agency shall submit an explanatory note to the Commission providing a detailed explanation of the reasons for such differences. If one or both of the Committees do not adopt an opinion by the deadlines set in Article 6b(1) and (2) the Agency shall inform the Commission accordingly, stating the reasons.
2. The Agency shall publish the opinions of both Committees on its website without delay.
3. The Agency shall, on request, provide the Commission or Member State with all documents and evidence submitted to or considered by it.’;

Article 2

The provisions under this Directive shall be applicable from [OJ: 12 months after the publication of this Directive].

Article 3

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President