Council of the European Union

Brussels, 19 December 2023
(OR. en)

16973/23

Interinstitutional File:
2023/0455(COD)

ENV 1528
CHIMIE 115
FOOD 103
SAN 757
AGRI 839
MI 1149
RECH 570
COMPET 1297
CODEC 2549

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) 783 final
Subject:	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

Delegations will find attached document COM(2023) 783 final.

Encl.: COM(2023) 783 final

EUROPEAN
COMMISSION

Brussels, 7.12.2023
COM(2023) 783 final

2023/0455 (COD)

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

(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 and to support the efficient functioning of the internal market for chemicals while also promoting 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 (iii) workers; (iv) consumer products; (v) food and feed stuff; (vi) and the environment.

The fitness check of the most relevant EU chemicals legislation[1] concluded that, overall, this framework of Union acts 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 different EU agencies (the European Chemicals Agency ('ECHA'), the European Food Safety Authority ('EFSA'), the European Environment Agency ('EEA') and the European Medicines Agency ('EMA')), scientific committees, expert groups, Commission departments and contractors.

This sometimes leads to inconsistent outcomes of assessments for the same chemicals across different legislation. This situation also implies an inefficient use of resources and carries unnecessary costs – from operating multiple committees conducting similar assessments, assessing the same chemical by several committees or bodies, to duplicating supporting technical and scientific work with potentially diverging hazard or risk assessment outcomes. In addition, the assessments that are not carried out by the EU agencies are sometimes perceived by stakeholders as not being transparent and inclusive enough or as not being of sufficient scientific quality and robustness.

Building on the findings of the fitness check, the Commission committed in the European Green Deal[2] to present a Chemicals Strategy for Sustainability[3] ('the Strategy'). As part of this work, it committed to start using the '**one substance – one assessment'** approach to

---

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 The European Green Deal. COM (2019) 640 final.

3 The Chemicals Strategy for Sustainability COM (2020) 667 final.

improve the efficiency, effectiveness, coherence and transparency of issuing safety assessments of chemicals across different pieces of EU legislation.

Overall, the one substance, one assessment approach focuses on the main factors influencing the efficiency, effectiveness, coherence and transparency of safety assessments. It covers:

- *Initiation of chemicals safety assessments.* This means synchronising and coordinating the initiation or triggering of assessments and assessing groups of substances instead of assessing substances individually, to the extent possible.

- *Attribution of tasks.* This involves a clear allocation of responsibilities to bodies performing assessments, making good use of available expertise and resources, as well as ensuring the good cooperation between the parties involved.

- *Information.* Ensuring that information is easily findable, accessible, interoperable, secure, of high quality and shared and reused to ensure that assessors have access to all available data without technical or administrative burden.

- *Methodologies.* The methods used for the assessments are coherent and, to the extent possible, harmonised.

- *Transparency.* Ensuring a high level of transparency in performing assessments, as well as in the underlying scientific data and information on chemicals.

Two key actions set out in the Strategy to improve the overall efficiency, effectiveness, coherence and transparency are 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, including work of the Scientific Committee on Health, Environmental and Emerging Risks and Scientific Committee on Consumer Safety';

- ensure 'a clear attribution of responsibilities and **good cooperation among the European agencies**'.

The Council[4] welcomed the 'one substance, one assessment' initiative and the European Parliament[5] welcomed the 'one substance, one hazard assessment' approach.

The EU Action Plan 'Towards Zero Pollution for Air, Water and Soil'[6] further contributed to this effort through commitments to consolidate the roles of the European Environment Agency and the Commission's Joint Research Centre in close collaboration with the European Chemicals Agency, the European Food Safety Agency, the European Maritime Safety Agency and other relevant agencies as the EU's Knowledge Centres of Excellence for Zero Pollution Monitoring and Outlook Framework.

---

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 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions 'Pathway to a Healthy Planet for All - EU Action Plan: 'Towards Zero Pollution for Air, Water and Soil' (COM(2021) 400 final).

Re-attributing existing tasks and attributing new tasks to EU agencies require targeted amendments of the existing pieces of chemicals legislation. The preferred technique is to attribute tasks by making amendments when the individual Union acts are revised for other purposes, such as meeting other objectives of the Strategy. Therefore, where possible, relevant changes have already been proposed or will be proposed as part of the revisions of individual pieces of legislation or as part of new legislation as detailed in the section below.

This proposal focuses on amending those pieces of legislation that are not currently being revised. It proposes targeted amendments to attribute tasks in Regulation (EU) 2019/1021 on persistent organic pollutants[7], and Regulation (EU) 2017/745 on medical devices[8]. The proposal also amends Regulation (EC) No 401/2009 establishing the European Environmental Agency[9] and Regulation (EC) No 178/2002 laying down the general principles and requirements of food law and establishing the European Food Safety Authority[10]. These amendments will ensure good cooperation among EU agencies on all aspects involving the consistency and efficiency of chemical assessments. These include the development of methodologies, data exchanges and reconciling divergence in scientific output.

The objectives of the proposal are to ensure that:

- the allocation of responsibilities for performing the assessments and the underlying technical and scientific work on chemicals is clear, exploits and maximises synergies and makes best use of available expertise and resources in EU agencies;
- the deliverables are of high scientific quality and the procedures are transparent and inclusive;
- there is good cooperation and coordination among players on all aspects underling the assessment of chemicals, including methodology development and data exchange.

- **Consistency with existing policy provisions in the policy area**

The proposal complements and is consistent with the re-attribution of tasks on chemicals to EU agencies already proposed, that are under development as part of the revisions of individual pieces of legislation, or that are envisaged as part of new legislation.

Attribution or re-attribution of tasks to EU agencies has been already proposed as part of:

---

7 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).

8 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).

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).

- Directive (EU) 2020/2184 of the European Parliament and of the Council on the quality of water intended for human consumption[11];

- Regulation (EU) 2022/2371 of the European Parliament and of the Council on serious cross-border threats to health[12];

- Proposal for a Regulation of the European Parliament and of the Council concerning batteries and waste batteries[13];

- Proposal for a Regulation of the European Parliament and of the Council on reporting of environmental data from industrial installations and establishing an Industrial Emissions Portal[14];

- Proposal for a Directive of the European Parliament and of the Council amending Directive 2010/75/EU on industrial emissions (industrial pollution prevention and control)[15];

- Proposal for a Directive of the European Parliament and of the Council amending Directive 2000/60/EC establishing a framework for Community action in the field of water policy, Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and Directive 2008/105/EC on environmental quality standards in the field of water policy[16];

- Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures[17];

- Proposal for a Regulation of the European Parliament and of the Council on packaging and packaging waste[18];

- Proposal for a Directive of the European Parliament and of the Council amending Directive 2000/53/EC on end-of-life vehicles[19];

- Proposal for a Regulation of the European Parliament and of the Council on the safety of toys[20];

- Commission Implementing Decision (EU) 2022/1979 on establishing the form and databases for communicating the information referred to in Articles 18(1) and 21(3) of Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances[21].

---

11 OJ L 435 23.12.2020, p. 1.
12 OJ L 314 6.12.2022, p. 26.
13 COM(2020) 798 final.
14 COM(2022) 157 final.
15 COM(2022) 156 final/3
16 COM(2022) 540 final.
17 COM(2022) 748 final.
18 COM(2022) 677 final.
19 COM/2023/451 final.
20 COM(2023) 462 final.
21 OJ L 272 20.10.2022, p. 14.

Attributing or re-attributing tasks to EU agencies are being considered as part of the following proposals in preparation:

- Proposal for a Regulation of the European Parliament and the Council on the European Chemicals Agency[22];
- Proposal for a Regulation of the European Parliament and the Council amending Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals[23];
- Proposal for a Regulation of the European Parliament and the Council amending Regulation (EC) No 1223/2009 on cosmetic products[24].

The proposed provisions on the development of methodologies and cooperation among EU agencies complements the proposal for a Regulation of the European Parliament and the Council[25] amending Regulation (EC) No 726/2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency, which contains similar provisions.

This proposal relates to the proposal being prepared for a Regulation of the European Parliament and the Council on the ECHA, which may contain similar provisions on methodologies and cooperation among EU agencies applicable to ECHA. In addition, the ECHA proposal will consider restructuring the agency's scientific committees to better manage the increased workload arising from the tasks re-attributed by means of this proposal and of those listed above.

This proposal is closely linked to, and part of the same 'one substance, one assessment' legislative package, as the proposal for a Directive of the European Parliament and the Council amending Directive 2011/65/EU[26] as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency, specifically amending Articles 5 and 6 of that Directive. Those amendments refer to the attribution of 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, in line with existing procedures laid out in Regulation (EC) No 1907/2006[27] ('the REACH Regulation').

---

22 European Chemicals Agency – proposal for a basic regulation (europa.eu)

23 Chemicals legislation – revision of REACH Regulation to help achieve a toxic-free environment (europa.eu)

24 EU chemicals strategy for sustainability – Cosmetic Products Regulation (revision) (europa.eu)

25 COM/2023/193 final.

26 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).

27 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).

This proposal also relates to other 'one substance, one assessment' actions announced in the chemicals strategy for sustainability – in particular to the proposal for a Regulation of the European Parliament and 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[28]. That proposal aims, among others, to encourage the sharing and re-using of chemicals 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. It will also attribute several new tasks to EU agencies in the sharing and generation of data, as well as in data and information management.

- **Consistency with other EU policies**

Attributing and re-attributing scientific and technical tasks in the assessment of chemicals to EU agencies is consistent with the objectives of the Better Regulation agenda. EU agencies benefit from robust scientific expertise and transparent and inclusive processes, which effectively support policymaking. Consolidating the work in the EU agencies and thus lowering the number of bodies involved contributes to simplifying and standardising procedures and reducing administrative burdens.

The proposal also contributes to the objectives of the EU's data and digital policies by promoting the interoperability and machine-readability of chemical data held by EU agencies.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

The legal basis for this proposal is Articles 43, 114, 207, 168(4)(c) and 192(1) of the Treaty on the Functioning of the European Union. The proposal is an 'omnibus' regulation that amends four regulations, each having their own legal bases. Regulation (EC) No 178/2002 is based on Article 43, 114, 207 and 168(4)(c), Regulation (EU) 2019/1021 is based on 192(1) TFEU, Regulation (EU) 2017/745 is based on Article 114 and Article 168(4)(c) TFEU, while Regulation 401/2009 is based on Article 192(1) TFEU.

It is therefore appropriate to base this Regulation on all legal bases of the individual acts being amended.

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

The initiative will revise and amend existing EU legal instruments in a targeted manner. The revisions target the attribution 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

[28] Proposal for a Regulation of the European Parliament and 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)

bodies regulated at the EU level, the objective can only be achieved at EU level, respecting thus the subsidiarity principle.

- **Proportionality**

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

The accompanying staff working document[29] assesses the administrative impact of the proposed revisions taking into account the re-attribution of other tasks to EU agencies in other legislative proposals.

The scientific and technical tasks attributed to ECHA in this proposal are existing tasks that are similar to tasks that the agency already carries out under other pieces of legislation. The slight increase in administrative costs is proportionate to the added value of the re-attribution of tasks. The added value stems from the improved quality and scientific robustness of the assessments, the 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 choices for the benefit of the public, industry and the environment. The envisaged amendments will also reduce administrative burden at EU and national levels due to more streamlined scientific work and the avoidance of duplication.

- **Choice of the instrument**

The desired changes require targeted amendments of specific provisions related to roles and tasks of Agencies in scientific assessments. This requires amendment by means of a directly applicable Omnibus regulation of four regulations.

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

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

The fitness check of the most relevant chemicals legislation (assessing over 40 pieces of legislation) was carried out in 2019[30]. It concluded that overall, the legislation delivers the intended results and is fit for purpose. However, several significant weaknesses prevent the legislation from reaching its full potential. Across the framework, it identified shortcomings

[29] 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)

[30] 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 (COM/2019/264 final).

in the consistency of safety assessments, the efficiency of the underlying technical and scientific work, and the consistency of transparency rules. These shortcomings can lead to inconsistent safety assessments, slow procedures, inefficient use of resources, unnecessary burdens, a (perceived) lack of transparency, and an impact on the quality of scientific advice.

The fitness check also showed that there are significant opportunities for streamlining the technical and scientific work through EU agencies. 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). It would also simplify the current set-up, improve the quality of assessments, and ensure predictability for stakeholders and the public.

This proposal directly addresses the problems and opportunities identified in the fitness check.

- **Stakeholder consultations**

A **call for evidence** for the initiative on making the best use of EU agencies to streamline scientific assessments was published on the Commission 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. Most submissions were received from business associations and companies (around 70% of submissions), followed by submissions from EU citizens (11%), non-governmental organisations (6%), public authorities (6%), others (5%) and academic/research institutions (1.5%).

Generally, there was a large support of the initiative among the respondents for the 'one substance, one assessment' approach, as well as for the specific initiative on the reattribution of tasks. 67% of respondents expressed their explicit support, 23% did not express explicitly their opinion but provided relevant advices on how to develop the one substance, one assessment approach. About 10% expressed doubts about usefulness of the initiative or opposition to the initiative.

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

An extensive discussion on re-attribution of tasks to EU agencies was held with representatives of Member States and EU agencies at the **meetings of the Expert Group on One Substance, One Assessment**[31] 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 from the consultations

The feedback regarding the re-attribution of tasks to the EU agencies received from the call for evidence and from Member States and EU agencies during meetings of the Expert Group on One Substance, One Assessment can be grouped in 6 areas:

Level of centralisation

[31] Register of Commission expert groups and other similar entities (europa.eu).

Stakeholders and Member States suggested that re-attribution of work should not result in one agency being responsible for the risk evaluations of all chemicals. The regulations must clearly set out the responsibilities of each agency.

This suggestion is reflected in the proposal. The proposal does not reallocate tasks between EU agencies. The proposal aims to only re-attribute those tasks carried out by bodies other than EU agencies.

Expertise

Stakeholders suggested that re-attributing tasks should be done based on the existing expertise in the agencies to ensure that the agency receiving the task benefits from the necessary expertise. It should be ensured that valuable expertise acquired by existing bodies is preserved. Expertise in risk assessments under the different regulations should stay with those agencies currently responsible for them. Each agency is best positioned to lead and carry out specific assessments because of their extensive experience in product-specific matters, e.g. EFSA for food use, EMA for medicines use.

These suggestions are reflected in the proposal. The criteria used to decide which EU agency should carry out a certain task includes similarity with existing expertise and how the task fits with an agency's core focus and mandate. The initiative and the proposal do not change the conditions for using data in the regulatory processes and maintains the 'specialisation' of the agencies.

Resources

Member States insisted that the new tasks for the agencies must be accompanied by the required resources. Re-attributing work should not lead to an agency or committee being unable to manage the workload and jeopardising the quality of the work.

This suggestion is reflected in the proposal. The proposal is accompanied by a detailed assessment of the EU agencies' resource and capacity needs. The proposals for re-attributing tasks (made as part of the revisions of individual pieces of legislation or as part of this omnibus proposal) are accompanied with proposals of financial and human resources to ensure that adequate resources are available taking into account synergies and economies of scale.

Organisation of scientific committees

Member States indicated that the agencies' committees, especially those of ECHA, might need reorganising such as to deal with the increased workload, especially insofar as the committee for risk assessment (RAC) of ECHA has already now a high workload. Instead of creating new scientific panels or committees, the agencies should preferably reinforce and reuse the existing panels, committees, and expert/working groups. In any event, safety assessments should be performed by an independent panel, independent committee or expert group that is independent.

This suggestion is partly reflected in the proposal. The resources provided for this proposal will also be beneficial for the involved scientific committees. The structure of ECHA committees will be addressed as part of the Proposal for Regulation of the European

Parliament and the Council on the European Chemicals Agency[32], which is under preparation. All agencies' scientific committees are independent and this is not changed.

Tasks to re-attribute

Some stakeholders and Member States suggested that the ECHA should be involved in hazard assessments as part of the assessment of food contact materials, and EFSA should be involved in risk assessments. The agencies should be included in evaluating cosmetic ingredients, deriving environmental quality standards under the Water Framework Directive and in opinions on chemical substances in products (i.e., in toys).

This comment is reflected in the proposal. All the suggested legislation and tasks were considered for re-attribution, and the proposals have been either made or are in preparation.

Assessment of potential impacts on business operators

A few respondents from stakeholders suggested to carry out an impact assessment on the one substance, one assessment initiative to ensure that possible impacts on businesses are considered sufficiently and that businesses are involved in developing the initiative.

This suggestion is reflected in the proposal. Although no formal impact assessment was carried out, the impacts were assessed where relevant and possible in the accompanying staff working document[33], with particular focus on the impacts on EU agencies' resources. The proposed measures will not imply costs to businesses or have significant economic impact at EU scale.

- **Collection and use of expertise**

The Commission considered input provided by the EU agencies concerned when it assessed which tasks are worth re-attributing to EU agencies, how they should be attributed, as well as potential effects on those agencies.

- **Impact assessment**

The fitness check of all chemical legislation (excluding REACH) assessed most of the challenges and risks addressed through this initiative and concluded that there are significant opportunities for streamlining the technical and scientific work through EU agencies. Moreover, there is little discretion of the policy choice as 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 EU Agencies. Therefore, no formal impact assessment was carried out. The impacts were nevertheless assessed where relevant and possible in the accompanying staff working document[34].

Overall, this proposal is expected to improve the efficiency, effectiveness, coherence and transparency of EU processes for chemical assessments for the benefit of all stakeholders. Citizens and the environment will benefit from better protection from dangerous chemicals as a result of more efficient and effective assessment processes. Companies will benefit from

32 European Chemicals Agency – proposal for a basic regulation (europa.eu)
33 SWD (2023) 850
34 SWD (2023) 850

more harmonised and transparent processes across legislation, from a reduced number of bodies involved in safety and risk assessments, as well as from strengthened certainty regarding the validity of assessments. Finally, the national and EU authorities will benefit from improved efficiency of delivery of assessments and improved public trust and acceptance of regulatory decisions.

- **Improved scientific consistency and coherence of assessments** – The reduced number of actors involved in the scientific and technical work, as well as an increased cooperation and obligation to solve divergent opinions among agencies leads to improved coherence and scientific consistency - both across the various Union acts, and across the assessment processes laid out therein. The consolidation of work allows to better align priority setting, timelines, processes, and methodologies used for the assessments. It facilitates re-use of assessment insights developed under one Union act on chemicals in the assessment process of another.

- **Improved robustness of assessment, trust and acceptance of regulatory decisions** – The involvement of the EU agencies and their committees in the scientific and technical work on chemicals adds more scientific expertise, ensures high quality of scientific advice and leads to improved robustness of assessments and thus their acceptance.

- **Strengthen independence of the scientific advice** – Moving scientific and technical work on chemicals from the Commission, ad hoc committees or consultants to EU agencies and their committees reinforces the independence of the scientific advice and the separation between science and policy or between risk assessment and management. Agencies are independent and their committees work under stricter conflict of interest avoidance rules, improving guarantees of independent scientific advice to the Commission.

- **Improved transparency** – The involvement of the EU agencies in scientific and technical work will ensure transparency to the process in terms of overall process transparency.

- **Improved efficiency of delivery of assessments** – Centralising assessment work in the EU agencies will allow the re-use of capabilities, the re-use of knowledge and experience, and the re-use of IT tools and support services.

While the proposed measures will not imply costs to businesses or have significant economic impact at EU scale, the initiative will have a major impact on the EU agencies' resource and capacity needs. This impact was assessed in detail quantitatively in cooperation with the agencies concerned. The re-attribution of tasks made as part of the individual pieces of legislation were assessed as part of their respective impact assessments. For the re-attribution of tasks made as part of this proposal for an omnibus regulation amending four pieces of legislation, as well as the accompanying proposal for a Directive amending the RoHS directive, the assessment is presented in the staff working document[35] accompanying this proposal. That document summarises the impact of all re-attributed tasks and assesses their cumulative impact on the EU agencies.

- **Regulatory fitness and simplification**

[35] SWD (2023) 850

The proposed re-attribution of tasks to EU agencies and the provisions requiring cooperation among EU agencies will improve the coherence, efficiency, effectiveness and transparency of the legal framework on chemicals as a whole, and especially of the chemical assessments.

Re-attributing tasks to EU agencies will enable efficient use of resources as a result of:

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

The proposed re-attribution of tasks and obligations on agencies to cooperate on the development of methodologies will generate added value in terms of improving scientific consistency across the chemicals legislation and the scientific quality and robustness of assessments. In addition, re-attributing tasks will significantly improve the transparency and inclusiveness of the processes. It will also guarantee the independence of the processes and ensure a separation between risk assessment and risk management.

The proposed provisions requiring cooperation among agencies on exchanging data and setting formats and controlled vocabularies will promote interoperability of data and facilitate digitalisation. This is also important in achieving the objective of removing technical barriers to sharing data strived for in 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.

The proposal has an overall positive impact on companies, including on small and medium-sized companies and micro-enterprises. Centralising the scientific and technical work in the EU agencies will reduce the number of committees, expert groups or assessors the companies need to interact with in case of a regulatory action on a chemical. Furthermore, assessment and consultation procedures as well as IT tools used for the submission of data and information across legislation will be more standardised across legislation, thus easier to manage and follow. Strengthening the coherence of assessments across legislation and reducing the potential for divergent scientific outcomes across legislation will reduce the uncertainty for companies stemming from potential divergent scientific outcomes across legislation.

- **Fundamental rights**

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

4. BUDGETARY IMPLICATIONS

The annexed financial statement relates to the **one substance, one assessment package**, which includes:

- the current proposal,

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

- the 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.

The financial statement also covers the financial implications for the European Chemicals Agency and the European Environment Agency of the proposals already adopted by the Commission which have not been reflected in the accompanying legislative financial statements, namely:

- Proposal for a Regulation of the European Parliament and of the Council on packaging and packaging waste[36],

- Proposal for a Directive of the European Parliament and of the Council amending directive 2008/98/EC on waste[37], and

- Proposal for a Regulation on Circularity requirements for vehicle design and on management of end-of-life vehicles[38].

The financial statement shows the budgetary implications and the human resources required in the Commission, ECHA, EEA, EFSA and EMA. These impacts reflect both changes in the allocation of responsibilities across the agencies and the allocation of new tasks that the agencies will carry out. The main impacts are:

- For ECHA, an increase of the EU contribution by EUR 24,2 million for the period 2025-2027, and additional 17 TAs and 13 CAs;

- For EEA, an increase of the EU contribution by EUR 4,5 million for the period 2025-2027 and additional 4 TAs and 2 CAs;

- For EFSA, additional 2 CAs without an increase of the EU contribution;

- Contribution/service level agreements with EFSA an EMA for an estimated amount of EUR 4,4 million for the period 2025-2027 to cover 3 CAs per year for EFSA, 3 CAs per year for EMA and operational budget.

The detailed explanation of the financial needs of the proposals is provided in the financial statement and in the respective proposals.

5. OTHER ELEMENTS

36 COM (2022) 677 final.
37 COM (2023) 420 final.
38 COM (2023) 451 final.

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

The efficiency in performing the attributed tasks in the EU agencies will be monitored as part of the regular evaluation of the agencies' performance. In addition, implementation will be evaluated and reported on as part of the review or reporting obligations of each piece of legislation.

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

Article 1 amends Regulation (EC) No 178/2002 (General Food Law Regulation)[39]. It includes provisions enabling EFSA to better cooperate and coordinate with ECHA, EMA and EEA. This cooperation would lead to more consistent scientific assessments of chemicals and encourage the agencies to develop consistent scientific opinions and methodologies, taking into account specific sectoral characteristics. The provisions on data and information exchange would bring the EU a step closer to the one substance, one assessment goals. These provisions make greater interoperability possible and scientific processes more robust.

Article 2 amends Regulation (EC) No 401/2009 (the EEA Founding Regulation)[40]. It includes streamlining obligations on the EEA to promote and coordinate the development of assessment methodologies and places the cooperation obligation laid out under Article 1 for EFSA, also on the EEA.

Article 3 amends Annex I of Regulation (EU) 2017/745 (the Medical Devices Regulation)[41] to task ECHA with updating existing guidelines on conducting the risk-benefit assessment of the presence of phthalates in medical devices. The agency will also develop guidelines for other substances, which are classified as either carcinogenic, mutagenic or toxic to reproduction, of category 1A or 1B or have endocrine disrupting properties for human health of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 (the CLP Regulation)[42].

Article 4 amends Regulation (EU) No 2019/1021 by giving the Commission the possibility to request ECHA to develop a report analysing the human health, environmental, social, and economic impact of introducing or modifying concentration limit values specified in Annexes IV and V to Regulation (EU) No 2019/1021 (POPs Regulation)[43]. Together with the newly introduced requirement for an opinion of the agency's Committee for Socio-Economic Analysis on the report and on the proposed concentration limit values therein, this report will

---

39 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 31, 1.2.2002, p. 1).

40 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).

41 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).

42 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).

43 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).

provide the necessary expert support for the Commission to develop the required proposal to introduce or amend the concentration limits in those Annexes.

Considering the highly technical nature of the amendments, this provision also introduces the adoption of amendments to Annexes IV and V by means of a delegated act. To promote the development of a comprehensive chemical exposure and toxicity knowledge base, as well as streamline data flows in line with the one substance, one assessment policy target, the provision also diverts data flows on the presence of persistent organic pollutant substances in the environment to EEA, which is the agency responsible for collecting occurrence data on chemicals in the environment.

2023/0455 (COD)

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

(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 Articles 43, 114, 168(4)(c), 192(1) and 207 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 Committee,

Having regard to the opinion of the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The European Green Deal[1] sets a high ambition for enabling the transition towards a toxic-free environment and zero pollution. The Chemicals Strategy for Sustainability[2] ('the Strategy') is a crucial delivery of the zero-pollution ambition and introduces the 'one substance, one assessment' approach, which aims to improve the efficiency, effectiveness, coherence, and transparency of safety assessments of chemicals across Union legislation.

(2) In order to achieve this objective, a part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be

[1] 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.

[2] 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

consolidated in the relevant Union agencies, while obligations on Union agencies to cooperate for the development of assessment methodologies and exchange of data and information should be introduced. This would simplify the current set-up, improve quality and coherence of safety assessments across Union legislation and ensure more efficient use of existing resources.

(3) The reattribution of certain existing scientific and technical tasks to the European Chemicals Agency, as well as the attribution of new tasks, were proposed as part of ongoing revisions of Union acts. This horizontal proposal aims to provide for further attribution of tasks in respect of those Union acts which are not in the process of being revised and is necessary in order to ensure that the European Chemicals Agency is involved in tasks pertaining to its expertise and developed capacities on chemicals. This is in line with the 'one substance, one assessment' aim to ensure that technical and scientific work is performed by the appropriate Union agency, benefiting from demonstrated experience and established tools in its field. The proposal for a Regulation is accompanied by a proposal for a Directive for the amendment of Directive 2011/65/EU of the European Parliament and of the Council[3], aiming to achieve the same objectives.

(4) As part of the coordinated consolidation and attribution of tasks under the 'one substance, one assessment' approach, provisions to allocate a mandate to the European Medicines Agency to develop and cooperate on the development of assessment methodologies, standard formats and controlled vocabularies and exchange of data and information on chemicals have been introduced in Article 138(1), subparagraphs (zd) and (ze), as well as new procedures for ensuring the coherence between scientific opinions in Article 139 of the proposal for a Regulation amending Union pharmaceutical legislation. [4]

(5) To ensure the coherence of methodologies for assessments related to chemicals at Union level, all relevant Union agencies should have an equal mandate to develop such methodologies in the areas falling within their respective missions and should be subject to the same obligations to cooperate amongst each other to develop such methodologies.

(6) To ensure the coherence and efficiency of assessments related to chemicals across Union legislation, it is also important to enable data interoperability and easy exchange of data between the relevant Union agencies, as well as to encourage cooperation on the development of standard formats and controlled vocabularies. Thus, to facilitate data exchange between agencies, any new data formats defined by the European Food Safety Authority or by the European Environmental Agency should be set in cooperation with other relevant Union agencies working on chemicals. To this end, relevant provisions should be introduced in Regulation (EC) No 401/2009

---

[3] 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.

[4] Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006, COM(2023) 193 final. [*OJ:Please insert correct reference once the Regulation is adopted]*.

of the European Parliament and of the Council and, in Regulation (EC) No 178/2002 of the European Parliament and of the Council, existing provisions should be strengthened and, where relevant, new ones be introduced. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation.

(7) To promote the coherence and efficiency of assessments related to chemicals across Union legislation, steps should be taken by the relevant Union agencies to avoid divergent scientific opinions. Existing cases of divergent opinions have lead to increased uncertainty for operators, as well as to declined public trust in the scientific robustness and coherence of scientific decision making. Proposals to address and strengthen procedures for resolving divergence of scientific opinions concerning the European Medicines Agency with other scientific bodies is proposed as part of the revision of Union pharmaceutical legislation. Similar provisions should also be considered to be proposed for a strengthened mandate of the European Chemicals Agency in its founding regulation, whilst such provisions are not relevant and applicable to the European Environmental Agency, since this agency does not issue scientific opinions on individual chemicals such as to be part in divergent outcomes.

(8) Correspondingly, this Regulation aims to address the eventual divergence between scientific opinions of the European Food Safety Authority and those of other Union agencies. Regulation (EC) No 178/2002 of the European Parliament and Council already contains provisions establishing a procedure to solve divergent scientific opinions. Those resolution procedures should be reinforced, in that the European Food Safety Authority and the other dissenting agency should be bound to make their best effort to resolve the divergence on general scientific issues, and only when they are not able to resolve the divergence, should they refer to risk managers.

(9) In the more specific case of scientific divergence pertaining to the hazard identification of chemical substances, a new procedure enabling the resolution of the divergence should be established. This procedure should enable the Commission to request the European Chemicals Agency, as the Union agency most equipped with expertise and capacity in hazard assessment, as well as long-standing experience with the harmonised classification and labelling process, to develop a proposal for harmonised classification and labelling, in accordance the Regulation (EC) No 1272/2008 of the European Parliament and Council, moving closer to the 'one substance, one assessment' vision as regards uniformity of hazard assessments of chemicals across the Union. This possibility should be reflected in the relevant provision providing for the resolution of diverging scientific opinions laid down in Regulation (EC) No 178/2002**.**

(10) To comply with the obligation laid down in Section 10.4.3 of Annex I to Regulation (EU) 2017/745 of the European Parliament and of the Council[5], the Commission has provided the Scientific Committee on Health, Environmental and Emerging Risks ('SCHEER') with a mandate to prepare guidelines on the benefit-risk assessment of the presence of phthalates which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting

[5] 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).

properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council[6]. The SCHEER issued those guidelines in 2019 and the Commission has issued a mandate to the SCHEER to perform a first update of those guidelines.

(11) To comply with the obligation laid out in Section 10.4.4. of Annex I to Regulation (EU) 2017/745, the Commission should mandate the relevant scientific committee to prepare guidelines for substances other than phthalates and which are classified as either carcinogenic, mutagenic or toxic to reproduction category 1A or 1B, or which have endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

(12) The European Chemicals Agency already provides scientific advice on chemical substances, including on phthalates, endocrine disruptors and carcinogens, mutagens and reproductive toxicants under Regulation (EC) No 1907/2006. Several key capacities of the agency can be reused, including hazard, risk, exposure and socio-economic assessment capacities, the Committee opinion development and IT capabilities for stakeholder consultation and dissemination. To enable timely future updates on the presence of phthalates and to ensure that the appropriate Union agency develops new guidelines on other substances on the basis of the latest scientific evidence, these tasks should be attributed to the European Chemicals Agency.

(13) Taking account of the new hazard classes and criteria for classification, labelling and packaging of substances introduced by Commission Delegated Regulation (EU) 2023/707 of 19 December 2022[7], reference to endocrine disruptors for human health, of Category 1, should be specified in 10.4.1., point (b) of Annex I of Regulation (EU) 2017/745 in light of the relevance of that hazard class to the type of substances in medical devices.

(14) To make best use of the European Chemicals Agency's knowledge and expertise gained through its involvement in the nomination and assessment processes under the Stockholm Convention on Persistent Organic Pollutants, the European Chemicals Agency should, upon request, assist the Commission in complying with its obligation to amend Annexes IV and V to Regulation (EU) 2019/1021[8]. Where the opinion of the Committee for Socio-Economic analysis is required, and in order to allow for the necessary capacity and resources for the effective functioning of that committee, Member States should be given the opportunity to cover for the specific expertise

---

6 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. 1–849).

7 Commission Delegated Regulation (EU) 2023/707 of 19 December 2022 amending Regulation (EC) No 1272/2008 as regards hazard classes and criteria for the classification, labelling and packaging of substances and mixtures (OJ L 93, 31.3.2023, p. 7–39).

8 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).

required for the effective performance of the task by nominating experts. In order to ensure that the Committee for Socio-Economic analysis benefits from sufficient resources, when the committee appoints one of their members as a rapporteur, that person, or his employer should be remunerated.

(15) In order to amend certain non-essential elements of Regulation (EU) 2019/1021 of the European Parliament and of the Council, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of amending Annexes IV and V in order to adapt them to the changes to the list of substances set out in the Annexes to the Stockholm Convention or the Protocol or adapt them to scientific and technical progress.

(16) As part of their reporting obligations under the Regulation (EU) 2019/1021 of the European Parliament and of the Council, Member States must report to the European Chemicals Agency information on the presence of substances listed in Part A of Annex III in the environment. The use of the Information Platform for Chemical Monitoring ('IPCHEM') is encouraged as a means for Member States to comply with their obligations to report that chemical occurrence data and to simplify and reduce their reporting obligations. Where Member States make data available through IPCHEM, they no longer need to report it to the European Chemicals Agency, as the agency may retrieve it from the platform.

(17) The revision of the Directive (EU) 2020/2184 of the European Parliament and of the Council[9] requires Member States to share with European Environmental Agency all chemical occurrence or monitoring data in water. Additionally, the monitoring data on the presence of POPs in air are already being reported by Member States to the EEA as part of the Union air quality legislation. The proposal for a Regulation of the European Parliament and 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[10] will require all chemical occurrence data to be held by the EEA. As a result, chemical occurrence data provided to and held in IPCHEM by the Commission will thus be collected and held by the EEA, instead of by the Commission. Therefore, it is necessary to simplify the reporting obligations for Member States to ensure that, where Member States have already submitted that information to the EEA as part of fulfilling obligations required by the provisions of other pieces of Union environmental legislation, Member States should be considered to have fulfilled their reporting obligations under Regulation (EU) 2019/1021.

(18) Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 should therefore be amended accordingly,

---

9 Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast), (OJ L 435, 23.12.2020, p. 1–62).

10 [*OJ Please insert reference once proposal is adopted*]

HAVE ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 178/2002

Regulation (EC) No 178/2002 is amended as follows:

(1) in Article 23, the following point (m) is added:

'(m) to cooperate with the competent bodies in the Member States that carry out similar tasks to those of the Authority and to cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Medicines Agency, and the European Environment Agency on the provision of relevant scientific opinions, on the exchange of data and information, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.';

(2) Article 30 is replaced by the following:

'Article 30

Diverging scientific opinions

1. The Authority shall take the necessary and appropriate measures to monitor and identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks.

2. Where the Authority identifies a potential source of divergence, it shall contact the body concerned in order to ensure that all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues.

   The Authority and the body concerned shall cooperate to resolve the divergence**.** If the Authority and the body concerned are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues and identify the relevant uncertainties in the data and be made publicly available.

   Where the body concerned is a Union agency or a scientific committee, the Authority shall present the joint report to the Commission.

3. Where relevant, and where the divergence concerns conflicting scientific opinions of the Authority and another Union body or agency on whether a substance fulfils the criteria laid out in Annex I of Regulation (EC) No 1272/2008 of the European

Parliament and of the Council[11], the Commission may request the European Chemicals Agency to prepare a proposal for harmonised classification and labelling of substances and, where appropriate, specific concentration limits, M-factors or acute toxicity estimates, or a proposal for revision thereof following the procedure laid out in Article 37 of Regulation (EC) No 1272/2008. The Authority and the Union body or agency concerned shall co-operate with the European Chemicals Agency in developing that proposal.'.

Article 2

Amendments to Regulation (EC) No 401/2009

Regulation (EC) No 401/2009 is amended as follows:

(1) in Article 2, the following point (p) is added:

'(p) to develop assessment methodologies related to chemicals in the fields falling within its mission.';

(2) in Article 15, the following paragraph 5 is added:

'5. The Agency shall cooperate with other scientific bodies established under Union law, notably the European Chemicals Agency, the European Food Safety Authority, and the European Medicines Agency, on the exchange of data and information on chemicals, including the possible establishment of related data formats and controlled vocabularies to facilitate such an exchange, and on the development of scientific methodologies for the assessment of chemicals.'.

Article 3

Amendments to Regulation (EU) 2017/745

Annex I to Regulation (EU) 2017/745 is amended as follows:

(1) in Section 10.4.1, point (b) is replaced by the following:

'(b) substances which are identified as endocrine disruptors for human health, of Category 1, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council[12] and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health and which are

[11] 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 – 1355.

[12] 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).

identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council or substances having endocrine disrupting properties relevant to human health identified in accordance with Regulation (EU) No 528/2012.'

(2) in Section 10.4.2, point (d) is replaced by the following:

'(d) where applicable and available, the latest relevant guidelines in accordance with Sections 10.4.3. and 10.4.4.';

(3) Section 10.4.3 is replaced by the following:

'10.4.3. **Guidelines on phthalates**

When deemed appropriate based on the latest scientific evidence, but at least every 5 years, the Commission shall request the European Chemicals Agency (ECHA) to update guidelines on the benefit-risk assessment of the presence of phthalates which belong to either of the groups of substances referred to in Section 10.4.1., points (a) and (b). The benefit-risk assessment shall consider the intended purpose and context of the use of the device, as well as any available alternative substances and alternative materials, designs or medical treatments

When appropriate or when requested by the Commission, ECHA shall consult the Committee for Risk Assessment and the Committee for Socio-economic Analysis.';

(4) Section 10.4.4 is replaced by the following:

'10.4.4. **Guidelines on other CMR and endocrine-disrupting substances**

The Commission shall request ECHA to prepare guidelines as referred to in Section 10.4.3. and following the process described therein also for other substances referred to in Section 10.4.1., points (a) and (b), where appropriate.'.

Article 4

Amendments to Regulation (EU) 2019/1021

Regulation (EU) 2019/1021 is amended as follows:

(1) Article 8(1) is amended as follows:

(a) the following point (i) is added:

'(i) upon request from the Commission, and within 12 months from that request, draw up and provide a report on the human health, environmental and socio-economic impacts of introducing or modifying concentration limit values specified in Annex IV or V.'

(2) Article 8(1a) is added:

‘1a. The report referred to in Article 8(1), point (i), shall contain the following information:

(a) as appropriate, information on human health and environmental impacts of waste consisting of, containing or contaminated with POPs, including impacts on waste management;

(b) information on concentrations and mass flows of POPs in relevant waste streams and on waste treatment and treatment capacities;

(c) an analysis of the impacts of the different concentration limit values considered;

(d) a duly motivated proposal for concentration limit values to be introduced in Annex IV and, as appropriate, in Annex V.

The Agency shall, as soon as it receives the request referred to in the first subparagraph, point (i), publish on its website a notice that a report on a possible amendment of Annex IV or V will be prepared inviting all interested parties, including waste operators and users of recycled materials, to submit comments within 8 weeks. The Agency shall publish those comments on its website.

At the latest 9 months following the submission of that report, the Committee for Socio-economic Analysis of the Agency, set up pursuant to Article 76(1), point (d), of Regulation (EC) No 1907/2006 shall adopt an opinion on the report and on the concentration limit values proposed therein. For the purpose of adopting an opinion on the report, Article 87 of Regulation (EC) No 1907/2006 shall apply mutatis mutandis.

The Agency shall submit the report and the opinion of the Committee for the Socio-economic Analysis on the concentration limit values to the Commission without delay.’;

(3) in Article 13, paragraph 2 is replaced by the following:

‘2. Where a Member State shares the information referred to in paragraph 1, point (e), with the European Environmental Agency, that Member State shall indicate that in the report and the Member State shall be considered to have fulfilled its reporting obligations under that point.

Where the information referred to in paragraph 1, point (e), is contained in the report of a Member State provided to the Agency, the Agency shall transmit the information to the European Environmental Agency for compiling, storing and sharing that information’;

(4) in Article 15, paragraph 2 is replaced by the following:

‘2. The Commission is empowered to adopt delegated acts in accordance with Article 18, to amend Annexes IV and V to adapt them to the changes to the list of substances set out in the Annexes to the Convention or the Protocol or to adapt them to scientific and technical progress.’

(5) Article 18 is amended as follows:

(a) The first sentence of paragraph 2 is replaced by the following:

‘2. The power to adopt delegated acts referred to in Articles 4(3), 10(2) and 15 shall be conferred on the Commission for a period of five years from 15 July 2019.’.

(b) The first sentence of paragraph 3 is replaced by the following:

‘3. The delegation of power referred to in Articles 4(3), 10(2) and 15 may be revoked at any time by the European Parliament or by the Council.’.

(c) Paragraph 6 is replaced by the following:

‘6. A delegated act adopted pursuant to Articles 4(3), 10(2) and 15 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object.’.

Article 6

Entry into force

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

This financial legislative statement covers the impact of the following proposals:

One substance, one assessment package:

- 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

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

- 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

Proposals already adopted by the Commission and attributting new tasks to the European Chemicals Agency or the European Environment Agency, for which the corresponding resources for the agencies have not been reflected in the accompanying legislative financial statements:

- Proposal for a **Regulation** of the European Parliament and of the Council on packaging and packaging waste replacing and repealing Directive 1994/62/EC of the European (COM (2022) 677 final)

- Proposal for a **Directive** of the European Parliament and of the Council amending Directive 2008/98/EC on waste (COM (2023) 420 final)

- Proposal for a **Regulation** of the European Parliament and of the Council on circularity requirements for vehicle design and on management of end-of-life vehicles, amending Regulations (EU) 2018/858 and 2019/1020 and repealing Directives 2000/53/EC and 2005/64/EC (COM(2023) 451 final).

1.2. Policy area(s) concerned

09 – Environment & Climate Change

1.3. The proposal/initiative relates to:

☒ a new action

☒ **a new action following a pilot project/preparatory action**[56]

☒ **the extension of an existing action**

☐ **a merger or redirection of one or more actions towards another/a new action**

1.4. Objective(s)

1.4.1. General objective(s)

The overall aim of the one substance, one assessment approach and of the three underlying proposals is to improve the coherence, efficiency, effectiveness and transparency of safety assessments across EU chemicals legislation and thus to contribute to a well-functioning single market for chemicals and a high level of protection of human health and the environment from chemicals.

Regarding the general objectives of the proposals for a regulation on Packaging and Packaging Waste (COM (2022) 677 final), for a directive amending waste framework directive (COM (2023) 420 final) and for a regulation on Circularity requirements for vehicle design and on management of end-of-life vehicles (COM (2023) 451 final), please, refer to the legislative financial statements attached to the proposals.

1.4.2. Specific objective(s)

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 reattribution of scientific and technical tasks and improving cooperation among the Union agencies in the area of chemicals:

1. ensure that the attribution of responsibilities for performing the assessments and the underlying technical and scientific work on chemicals is clear, that it exploits and maximises synergies and that it makes the best use of available expertise and resources;

2. ensure that the output of scientific and technical tasks is of high scientific quality and that the procedures are transparent and inclusive;

3. achieve a good cooperation among all players on all aspects relating to the assessment of chemicals (such as methodology development and exchange of data);

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

[56] As referred to in Article 58(2)(a) or (b) of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (Financial Regulation). OJ L 193 30.7.2018, p. 1 – 222.

1. ensure that the attribution of responsibilities for performing the assessments and the underlying technical and scientific work on chemicals is clear, that it exploits and maximises synergies and that it makes the best use of available expertise and resources;

2. ensure that the output of scientific and technical tasks is of high scientific quality and that the procedures are transparent and inclusive;

3. ensure that procedures are more aligned with methodologies under other chemicals legislation, leading to increased consistency between existing policy provisions

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:

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

2. ensure that information contained in the common data platform is secure, of high quality, findable, accessible, interoperable and re-usable;

3. enable the commissioning of testing and monitoring of substances as part of the regulatory framework when further information is considered necessary;

4. 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;

5. establish a monitoring and outlook framework for chemicals.

Regarding the specific objectives of the proposals for a **regulation on Packaging and Packaging Waste** (COM (2022) 677 final)**,** for a **directive amending waste framework directive** (COM (2023) 420 final) and for a **regulation on Circularity requirements for vehicle design and on management of end-of-life vehicles** (COM (2023) 451 final), please, refer to the legislative financial statements attached to the proposals.

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

The expected results and impacts of the proposals for a Regulation of the European Parliament and the Council amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 as regards the reattribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals, the proposal for a Directive of the European Parliament and the Council amending Directive 2011/65/EU as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency and the proposal for a Regulation of the European Parliament and 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 are improved effectiveness, efficiency, coherence and tranparency of assessment of chemicals across legislation. In more concrete terms this include the following:

Improved scientific consistency and coherence of assessments - Involving less actors in the scientific and technical work and centralising the work in the agencies and requiring them to cooperate and resolve divergent opinions will lead to improved coherence and scientific consistency among the assessments carried out under different pieces of legislation. The consolidation of work allows to better align priority setting, timelines, processes and methodologies used for the assessments. It facilitates the reuse of assessment insights developed under one piece of legislation in the assessment under another piece of legislation. Centralising data on chemicals in the EU agencies and being able to use it creates a common knowledge base on which the assessments are based and thus further promotes coherence of assessments.

Improved robustness of assessment, trust and acceptance of regulatory decisions - Involvement of the EU agencies and their committees in the scientific and technical work on chemicals adds more scientific expertise, ensures high quality of scientific advice and leads to improved robustness of assessments and thus their acceptance. Centralising data on chemicals in the EU agencies and being able to re-use them will increase the knowledge base, improve the robustness of the scientific advice provided and increase the acceptance of conclusions and regulatory decisions. Knowing through the notifications of studies that all studies have been considered in the assessment further strengthens the trust of citizens in regulatory decisions.

Strengthened independence of the scientific advice - Moving scientific and technical work on chemicals from Commission services, ad hoc committees or consultants to EU agencies and their committees reinforces the separation between science and policy or between risk assessment and management. Agencies and their committees work under stricter conflict of interest avoidance rules, improving guarantees of independent scientific advice to the Commission.

Improved transparency - Involvement of the EU agencies in scientific and technical work will ensure transparency to the process in terms of overall process transparency; publication of regulatory intentions of EU authorities and application submission intentions via PACT improves predictability for all stakeholders; making all data and information available at one point increases the transparency.

Improved compliance - Compiling information on legal provisions for chemicals and on their regulatory reference values from all legal frameworks at one place and making it easily accessible facilitate comprehensive understanding of legal frames to which specific substance adheres to and improves implementation of law and the compliance.

Improved efficiency of delivery of assessments – centralising assessment work in the EU agencies will allow reuse of capabilities, reuse of knowledge and experience, balancing the workload and reuse of IT tools and support services. Making data accessible at one place and making them re-usable will decrease the administrative burden for the authorities when preparing assessments of chemicals.

Improved findability, interoperability, accessibility and re-use of data - this will be achieved by making the data available at one place, by removingtechnical barriers to share the data and by adopting and promoting the use of standard formats and controlled vocabularies.

Having necessary data for performing assessments by establishing data generation mechanism allowing to commission studies when there is no other legal provisions to obtain them.

Shorten reaction time between early signals of risks and regulatory measuers to mitigate the risks and thus improved protection of human health and the environment via the establishement of the early warning and action system.

For the expected results and impacts of the proposals for a regulation on Packaging and Packaging Waste (COM (2022) 677 final), for a directive amending waste framework directive (COM (2023) 420 final) and for a regulation on Circularity requirements for vehicle design and on management of end-of-life vehicles (COM (2023) 451 final), please, refer to the legislative financial statements attached to the proposals.

1.4.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

The efficiency in performing the attributed tasks to the EU agencies will be monitored as part of the regular evaluation of performance of the Agencies., In addition, implementation will be evaluated and reported on as part of the review or reporting obligations of each piece of legislation for which EU agencies provides support.

An implementation and monitoring plan for the establishment of common data platform is documented in the Project Initiation Document (referenced also in support of the assessment of impacts in the accompanying staff working document[57]). It outlines developments steps, governance setup and population of the platform by the different data providers with datasets identified for a minimum viable product. The progress through interim outputs until the 'go-live' version of the platform within 36 months after entry into force of the regulation will be closely monitored. Platform governance envisions regular reporting on its operations including the effectiveness of work on interoperability *i.e.* the ingestion of individual chemical datasets. The common data platform itself will enable monitoring of associated activities such as the early warning system and the application of a data generation mechanism. The same applies to chemical indicators that are expected to contribute to the 8th Environmental Action Plan monitoring framework[58].

[57] Commission staff working document accompanying the document 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) 855).

[58] 8th Environmental Action Plan (EAP) monitoring framework. COM (2022) 357 final.

Assessment by the standing expert group on one substance-one assessment is expected to continuously monitor progress on interoperability and re-use of data and utility of the common data platform and its products.

Regarding the indicators of the proposals for a regulation on Packaging and Packaging Waste (COM (2022) 677 final), for a directive amending waste framework directive (COM (2023) 420 final) and for a regulation on Circularity requirements for vehicle design and on management of end-of-life vehicles (COM (2023) 451 final), please, refer to the legislative financial statements attached to the proposals.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

One substance, one assessment package:

Q4 2023 – Q2 2025: interinstitutional negotiation of the proposals

Q3 2025: entry into force of the legal acts

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 as regards the reattribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals:

Q3 2025 onwards: ECHA performs technical and scientific work for the POPs regulation and medical devices as of entry into force of the legal act.

Q3 2025 onwards: EEA and EFSA cooperate in the relevant areas defined by the regulation as of entry into force of the legal act.

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

Q3 2026 onwards: ECHA performs technical and scientific work for the RoHS Directive as of 1 year after the entry into force of the legal act.

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:

Q3 2025 – Q2 2026: After the adoption of the legal act, the Commission shall adopt commission decisions to establish the platform steering committee, adopt the implementation plan and adopt the governance scheme for the common data platform and its services.

Q3 2025 – Q2 2028: The common data platform containing at least the minimum viable data shall be established within 3 years of the entry into force of the legal act.

Q3 2025 – Q2 2028: Six building blocks making up dedicated services are set up as part of the common data platform within 3 years of the entry into force of the legal act. These dedicated services are an information platform for chemical monitoring, a repository of reference values, a database of study notifications, a database with information on regulatory processes, a database with information on the obligations under Union acts on chemicals and a repository of standard formats and controlled vocabularies.

Q3 2025 – Q2 2031 A database on environmental sustainability related information is set up as the seventh building block making up dedicated services of the common data platform.

Q3 2025 – Q2 2028: Establishment of relevant data flows via the agencies at the latest within 3 years of the entry into force of the legal act.

Q3 2025 – Q2 2028: The Commission transfers any human biomonitoring it holds to the European Environment Agency and it shall transfer the chemicals data contained in the Information Platform for Chemical Monitoring to the relevant agencies.

Q3 2025 – Q2 2035: All relevant data are made available via the common data platform at the latest within 10 years of entry into force of the legal act.

Q3 2025 – Q4 2035: Relevant data are made available to the common data platform in IUCLID format at the latest by 2035.

Q3 2025 and onwards: Member States provide information on regulatory processes on chemicals to ECHA.

Q3 2025 and onwards: Agencies, where relevant, specify standard formats and controlled vocabularies

Q4 2025 and onwards: Framework of indicators is set up in 2025 and regularly updated.

Q3 2025 – Q2 2026: Early warning and action system is established within one year of the entry into force of the legal act.

Q3 2025 and onwards: Observatory for specific chemicals with potential contribution to emerging chemical risks is set up in 2025

Q3 2025 onwards: Data generation mechanism is established in the first year from the entry into force and is progressively expanded to full operation after two years from the entry into force.

Q3 2026 onwards: Obligation to notify studies that are not already notified under Article 32b of Regulation (EC) No 178/2002 starts applying from 1 year of entry into force of the legal act.

Proposals for a regulation on Packaging and Packaging Waste (COM (2022) 677 final), for a directive amending waste framework directive (COM (2023) 420 final) and for a regulation on Circularity requirements for vehicle design and on management of end-of-life vehicles (COM (2023) 451 final):

- see legislative financial statements attached to the proposals.

1.5.2. *Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention, which is additional to the value that would have been otherwise created by Member States alone.*

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 as regards the reattribution 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 of the Council amending Directive 2011/65/EU as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency

The legal proposals on reattribution of tasks will revise and amend in a targeted manner the existing EU legal instruments. The revisions target the (re-)attribution of tasks for performing scientific and technical work at EU level necessary for the operation of those instruments and the cooperation among the Union agencies in performing the scientific and technical work. This cannot be sufficiently achieved by the Member States alone, by reason of its scale and effects, and therefore can only be achieved at EU level.

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

The problem of chemicals data being scattered among different Union agencies, Commission services and at Member State level can only be addressed by improvements in information availability at Union level. The ultimate objective with respect to information availability and information sharing is to bring together all chemicals data in one centrally accessible location, which by definition requires action at Union level. A similar reasoning applies to the other identified objectives of this legal proposal relating to incomplete knowledge bases with corresponding obligation to notify launching of studies planned for inclusion in EU regulatory dossiers (sister provision to related obligation under general food law), data generation mechanism for the European Chemicals Agency, but also facilitate access to data generated by EU research and run dedicated services that compile specific information like reference values, collect information on environmental sustainability

and early warning signals on emerging risks, and calculate chemicals related indicators.

Proposals for a regulation on Packaging and Packaging Waste (COM (2022) 677 final), for a directive amending waste framework directive (COM (2023) 420 final) and for a regulation on Circularity requirements for vehicle design and on management of end-of-life vehicles (COM (2023) 451 final):

- see the legislative financial statements attached to the proposals.

1.5.3. Lessons learned from similar experiences in the past

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 as regards the reattribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals,

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

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:

The EU regulatory framework for hazard and risk assessment and management of chemicals is comprehensive and consists of many legislative pieces, addressing production and placing on the market of chemicals and chemical products, emissions of chemicals and safety of workers, consumer articles, food and feed stuff and the environment.

The fitness check of the most relevant chemicals legislation assessing over 40 pieces of legislation was performed in 2019[59]. It concluded that overall the EU chemicals legislation delivers results as intended and is fit-for-purpose, but a number of significant weaknesses prevent the EU chemicals legislation from living up to its full potential. It identified shortcomings across legislative pieces as regards the coherence of safety assessments, efficiency of the underlying technical and scientific work and the coherence of transparency rules. These shortcomings can lead to inconsistency and incoherence in safety assessments, slow procedures, inefficient use of resources, unnecessary burden, (perceived) lack of transparency and impacts on the quality of scientific advice.

The fitness check also showed that there are significant opportunities for streamlining the technical and scientific work through EU agencies that would make the functioning of chemicals legislation more efficient (*e.g.* avoiding duplication of

59 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. COM/2019/264 final.

efforts and making the best use of available expertise in EU agencies) and more coherent (*e.g.* reducing the risk of diverging outcomes of hazard/risk assessments at EU level). It would also simplify the current set-up, reduce the need to provide information to multiple interlocutors, improve the quality of assessments, and ensure predictability for stakeholders and the general public. In addition, it would improve scientific quality and robustness of some assessments and ensure better separation between risk assessment and risk management.

The fitness check further found that there are shortcomings in discoverability, accessibility and availability of good-quality and reliable data and in sharing and re-using of data across legislative silos. Stakeholders have complained about this in the past (e.g. regarding inefficiencies caused by double reporting, difficulties to identify and access data, inconsistencies between outcomes of safety assessments as a result of them being based on different datasets, and not considering all available data in safety assessments). There is a lack of awareness of interested parties (EU bodies, authorities, industry, NGOs) of what information is available and where and how the existing data can be used and accessed, and re-use rights are sometimes too restrictive. Unnecessary duplication of effort in data generation still occurs in some instances due to a lack of data sharing as a result of various related factors including confidentiality and intellectual property rights. A more comprehensive approach across the EU chemicals legislation, including through an open data policy and a better use of smart technologies was identified as a way to improve the overall efficiency of the EU legislative framework for chemicals and contribute to the Commission's commitment towards more transparency.

Despite the comprehensive and advanced EU regulatory framework for chemicals there is a concern that it lacks the relevant mechanisms to adequately address emerging chemical risks in a timely manner. There are numerous examples of the long timespan between a signal of a risk and the adoption of adequate measures to address that risk[60], which include the difficulty to get emerging chemical risks such as PFAS and endocrine disruptors, on the radar of policy makers and governmental risk assessors. There is also an aspect of potential contribution to emerging risk due to potential inadequacy of existing systems, its assumptions and applied methods to cope with additional uncertainties brought by innovation, as has been the case with nanomaterials. To prevent damage caused by chemicals and help steer towards their safe and sustainable use, it is thus essential to be able to identify as early as possible emerging chemical risks and potential contribution to them, and to anticipate to unforeseen consequences related to the use of chemicals and their release into the environment.

To conserve natural resources and protect ecosystems and people, within the limits of our planet, assessing the environmental impacts generated by chemicals along their entire life cycle is needed. Evaluation of several impact categories, such as climate change and resource use, requires access to robust and high-quality information and can guide the design, development and production of chemicals that provide a desirable function or service while being safe and sustainable. Moreover, the availability of sustainability information could trigger a demand for chemicals with

60 EEA: Late lessons from early warnings: the precautionary principle 1896–2000, Luxembourg: Office for Official Publications of the European Communities, 2001

lower environmental impacts, and therefore have direct benefit for health and the environment.

Proposals for a regulation on Packaging and Packaging Waste (COM (2022) 677 final), for a directive amending waste framework directive (COM (2023) 420 final) and for a regulation on Circularity requirements for vehicle design and on management of end-of-life vehicles (COM (2023) 451 final):

- see the legislative financial statements attached to the proposals.

1.5.4. Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments

The initiative falls under the umbrella of the European Green Deal. The Green Deal recognises the advantages of investing in more digital Europe and it specifically calls 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 when prioritising action to deal with chemicals.*

The initiative falls under Heading 3 (Natural Resources and the Environment), Title 9 (Environment and Climate Action) of the Multiannual Financial Framework. As detailed below, the implementation of this piece of legislation will require additional human resources and also some supporting expenditure.

The EU funding provided on research and innovation via the Horizon Europe (e.g. PARC cooperative action) will complement this initiative.

1.5.5. Assessment of the different available financing options, including scope for redeployment

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 as regards the reattribution of scientific and technical tasks and improving cooperation among Union Agencies in the area of chemicals

The legislative proposal for a regulation as regards the reattribution of tasks and improving cooperation among Union agencies in the area of chemicals will amend 2 legislative pieces (POPs Regulation and Medical devices regulation) to reattribute the assessment work under these pieces of legislation to ECHA and it will amend the regulation on the European Environment Agency and the regulation on general principles and requirements of food law and establishing the European Food Safety Authority to ensure better cooperation among agencies on methodology development and on exchange of data.

Changes to POPs regulation will reattribute the technical assistance in reviewing Annexes IV and V to ECHA and hosting the POPs monitoring data to EEA. For this work, ECHA will require in the first year 1 FTE (1 TA) and operational budget of EUR 35 000 and as of the second year 2 FTEs (2 TAs) per year and operational budget of EUR 50 000 per year. No resources are needed for EEA. The work on reviewing the Annexes IV and V is currently performed by the Commission with the

help of consultants and amounts to approximately 1.5 FTEs per year. The involvement of ECHA and its Committee for Socio-Economic Analysis is envisaged to provide a significant increase in the scientific quality, the consistency, the robustness and the level of independence of the assessments upon which the Commission develops its proposals on this matter. The hosting of chemicals monitoring data under POPs regulation is currently done by the by Commission. Transfer of this work to EEA will require no additional resources, as POPs monitoring data in waters are to be reported to EEA under the water legislation and resources for that were proposed in the recent proposal, the POPs monitoring data in air are already being reported to EEA as part of the air quality legislation and covered by resources for that activity. The increase of the contribution to ECHA will be compensated by a reduction of the LIFE budget. This will be an effective redeployment and elimination of duplicative reporting.

Changes to medical devices regulation will not require any additional resources for ECHA. The work is currently performed by the Commission supported by the SCHEER committee. The current resource use is estimated to be 0.3 FTE per year and EUR 24 000 per year. Considering that the envisaged frequency of the work is very low, the involvement of the Committees is only where necessary and the first work will likely materialise only in 2029, the work can be absorbed by ECHA without any additional resources.

Changes to the regulation on the EEA and to the regulation on the general principles and requirements of food law and establishing the European Food Safety Authority will have no resource implications. The provisions formalise the activities already performed, they prescribe the procedural steps to follow and they enable the implementation of 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. Any possible resource needs stemming from these provisions can be absorbed by the existing resources of the agencies.

Resource needs for ECHA per legislation amended via the proposal for a Regulation amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/754 and (EU) 2019/1021 as regards the reattribution of scientific and technical tasks and improving cooperation among Union Agencies in the area of chemicals

	FTEs						Operational costs (in EUR 1 000)		
Legislation	**2025**		**2026**		**2027**		**2025**	**2026**	**2027**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**			
Proposal for a regulation on reattribution of scientific and technical work									
POPs regulation	1	0	2	0	2	0	35	50	50
Medical devices regulation	0	0	0	0	0	0	0	0	0
SUM	**1**	**0**	**2**	**0**	**2**	**0**	**35**	**50**	**50**

Current resource use for technical and scientific work to be reattributed to ECHA via the proposal for a Regulation amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/754 and (EU) 2019/1021 as regards the reattribution of scientific and technical tasks and improving cooperation among Union Agencies in the area of chemicals

POPs regulation • Technical assistance in reviewing Annexes IV and V • Hosting POPs monitoring data	Total ca. 1.5 FTEs/year: EUR 300 000 for consultants every 3 years (=1.5 FTE/year); (In addition, DG ENV ca. 0.5 FTE/year (implementing the review of Annexes IV and V) whose work will remain)
Medical devices regulation	Total ca. 0.3 FTE/year + EUR 24 000 per year: DG

• Preparation and review of the guidelines on how to perform the benefit-risk assessment of the presence of phthalates in medical devices • Preparation and review of the guidelines on how to perform the benefit-risk assessment of the presence of CMR and endocrine-disrupting substances in medical devices	SANTE SCHEER secretariat 0.3 FTE (ca. 10% of SCHEER secretariat work), EUR 24 000 per year for indemnities, travel, *e.g.* costs for members of the committee. (In addition, DG SANTE (policy unit) 0.1 FTE/year whose work will remain).
SUM	**0.3 FTEs/year of regular staff; 1.5 FTEs/year of intramurous contractors or interim staff (ca. EUR 100 000/year); Operational costs of ca. EUR 24 000/year**

In summary, in the first year, there will be a need of **1 FTE** (**1 TA**) and operational costs of **EUR 35 000** per year and as of the second year, there will be a need of **2 FTEs (2 TAs)** per year and operational budget of **EUR 50 000 per year**. All new resources are needed for ECHA. 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 **0.2 FTEs** per year and operational costs of **EUR 26 000** per year.

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

Changes to RoHS directive will reattribute the assessments underpinning restrictions of hazardous substances in electrical and electronic equipment and review of applications for exemptions from the restrictions to ECHA. For this work, ECHA will require in the first year 3 FTEs (3 TAs) and operational budget of EUR 66 000 and as of the second year 7 FTEs (4 TAs + 3 CAs) per year and operational budget of EUR 33 000 per year. The work is currently performed with the help of consultants and amounts to approximately 2.7 FTE per year. The resources currently spent are however insufficient leading to the accumulation of requests for exemptions without processing them to the legal drafting (by December 2022, over 60 exemption requests were pending) and the revision of the list of restricted substances was delayed (the review not finalised although it has started in 2018). There are also complaints about the quality and robustness of the assessments, the transparency of the process and involvement of stakeholders. The reattribution to ECHA and using its processes will address these shortcomings and will ensure alignment and coherence with other chemicals legislation. The increase of the contribution to ECHA will be compensated by a reduction of the LIFE budget. Part of these resources are currently spent on procuring the contractual support and this can be seen as effective redeployment.

Resource needs for ECHA for proposal for a Directive amending Directive 2011/65/EU as regards the reattribution of scientific and technical tasks to the European Chemicals Agency

	FTEs						Operational costs (in EUR 1 000)		
Legislation	**2025**		**2026**		**2027**		**2025**	**2026**	**2027**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**			
RoHS directive	3	0	4	3	4	3	66	33	33
SUM	**3**	**0**	**4**	**3**	**4**	**3**	**66**	**33**	**33**

Current resource use for technical and scientific work to be reattributed to ECHA via the proposal for a Directive amending Directive 2011/65/EU as regards the reattribution of scientific and technical tasks to the European Chemicals Agency

RoHS directive • Assessments underpinning restrictions of hazardous substances in electrical and electronic equipment • Review of applications for exemptions from the restrictions	Total ca. 2.74 FTEs/year: EUR 145 000 annually (on average) for outsourcing the review of exemptions (= ca. 2.2 FTEs/year) + a contract of EUR 180 000 on average each 5 years for reviewing restrictions (= 0.54 FTE/year). (In addition, DG ENV ca. 1.5 FTE/year (for overall RoHS implementation) whose work will remain)
SUM	**2.7 FTEs/year of intramurous contractors or interim staff (ca. EUR 181 000 per year);**

In summary, in the first year, there will be a need of **3 FTEs** (**3 TAs**) and operational budget of **EUR 66 000** per year and as of 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**. All new resources are needed for ECHA. 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.

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:

The proposal will establish a **Common Data Platform.** It will be established and operated by ECHA with close involvement and contribution from EEA, EFSA, EMA, EU-OSHA and the Commission. The work will include development and operation of the infrastructure and the governance and provision of data into the platform. The principal aim of new IT infrastructure operating as part of the Green Deal Data Space is to support effective and coherent chemical safety assessments. It shall provide integrated, user-differentiated and highly functional access to chemicals-related datasets owned or managed by EU agencies and provide space for the dedicated services supporting EU chemicals policy and legislative implementation.

The work will require resources for 4 agencies involved and the Commission (JRC). The resource requirement is higher for the first 3 years to set up the infrastructure and all the underlying processes to share the data and make them interoperable and in adequate formats. This will require for the first 3 years:

- for ECHA, 10 FTEs (4 TAs + 6 CAs) per year and operational budget of EUR 0 for the first year, EUR 2 226 000 for the second year and EUR 2 793 000 for the third year;

- for EEA, 3 FTEs (1 TA + 2 CAs) per year and operational budget of EUR 0 for the first year, EUR 266 000 for the second year and EUR 334 000 for the third year;

- for EFSA, 5 FTEs (5 CAs) per year and an operational budget of EUR 670 000 per year. For this purpose, a contribution/service level agreement of EUR 3 000 000 will be signed to cover the 3 FTEs (3 CAs) per year and the operational budget needed. The additional 2 FTEs (2 CAs) per year will be financed from EFSA's current budget;

- for EMA, a contribution/service level agreement of EUR 1 400 000 to cover 3 FTEs (3 CAs) per year and an operational budget of EUR 100 000 per year;

- for EU-OSHA, 0 FTEs per year and operational budget of EUR 0 per year;

- for JRC, an administrative arrangement for 3 years of EUR 540 000 to cover integration of IPCHEM in the common data platform and handing over of IPCHEM operation to ECHA.

After the initial phase of 3 years, the resource requirement is reduced to maintain the infrastructure and the underlying processes and to continue providing data. This phase will require

- for ECHA, 4 FTEs (4 TAs) per year and operational budget of EUR 600 000 per year;

- for EEA, 1 FTE (1 TA) per year and operational budget of EUR 200 000 per year;

- for EFSA, 2 FTEs (2 CAs) per year and operational budget of EUR 500 000 per year;

- for EU-OSHA, 0 FTEs per year and operational budget of EUR 0 per year;

- for EMA, 2 FTEs (2 CAs) per year and operational budget of EUR 0.

The increases of the contributions to agencies will be compensated by a reduction of the LIFE budget except for 2 FTEs (2 CAs) for EFSA which will be compensated from EFSA's current budget.

The proposal will formally establish **the Information Platform for Chemical Monitoring** (IPCHEM) and reattribute its operation to the Agencies. For this work,

- ECHA will need as of the second year 2 FTEs (1 TA + 1 CA) per year and as of the third year operational budget of EUR 180 000 per year;

- EEA will need as of the first year 1 FTE (1 TA) per year and the operational budget in the first year EUR 0, in the second year EUR 200 000, in the third year EUR 200 000 and as of the fourth year EUR 50 000 per year.

The operation of IPCHEM is currently done by the Commission and the resource use accounts for total of 4.5 FTEs/year. The operation of IPCHEM will be entrusted to ECHA which will also integrated it into the Common Data Platform. As the operation of IPCHEM will be reattributed to ECHA, the resources at the Commission's side will be saved. Hosting of data will be entrusted to the Agencies based on their mandates (ECHA will host occupational data) and EEA will host indoor air data and collect and host human biomonitoring data. The proposal will require the agencies to provide occurrence data they hold to ECHA for the integration into IPCHEM. EFSA already provides data to IPCHEM and contributes to its operation and will not require any additional resources to continue in this activity. EMA and EU-OSHA currently do not systematically collect or receive data relevant for IPCHEM and therefore will not require any additional resources. The

increase of the contribution to ECHA and EEA will be compensated by a reduction of the LIFE budget. It is therefore a partial redeployment of existing resources.

The proposal will establish a **database containing information on regulatory processes on chemicals** on the basis of existing (public) activities coordination tool ((P)ACT) and enlarging its scope to cover all relevant legislation with safety assessment processes and initiatives to promote coordination of safety assessment activities across EU legislation and provide transparency on the ongoing assessments. This work will impact ECHA, EEA, EFSA and EU-OSHA but will not require additional resources for the agencies. ECHA already operates (P)ACT for REACH, CLP and POPs processes. EFSA already operates OpenEFSA which has similar level of information as PACT for food and feed legislation. Resources for the operation and continuous provision of information are to be absorbed by the Agencies as part of the existing processes. EEA and EU-OSHA are currently not involved in any processes relevant for the database, therefore no resources are required for them. The development and coordination of the system is covered by the resources provided for the common data platform.

The proposal will establish a **repository of reference values** to promote the reuse of existing reference values and thus improve coherence of assessments and reduce repetition of deriving reference values. The proposal will impact ECHA, EEA, EFSA, EMA, EU-OSHA and the Commission. To perform the required work, ECHA will need as of the first year 1 FTE (1 TA) per year and operational budget of EUR 0 in the first year, EUR 650 000 in the second year, EUR 650 000 in the third year and as of the fourth year EUR 200 000 per year. No additional resources will be needed for EEA, EFSA, EMA, EU-OSHA or the Commission. ECHA has developed and operates the EU Chemicals Legislation Finder (EUCLEF). EUCLEF lists some regulatory reference values derived and applicable under these legislative pieces. ECHA will have to collate the 'old scientific reference values' which can be done via contracting. The new scientific reference values will be provided to the repository progressively as part of ECHA's assessment processes. ECHA will require additional resources for developing, operating and maintain the repository, being in contact with data providers. EFSA has developed and is maintaining the OpenFoodTox database that summarises the scientific reference values derived by EFSA as part of its assessment activities. EFSA will continue its activity and will provide the information to the new repository as part of its existing resources. Therefore, no additional resources are required. EMA will need to provide to the new repository on continuous basis all new predicted no effect concentrations (PNECs) derived for human and veterinary medicinal products after entry into force of this legislation. This can be done efficiently as part of EMA's future assessment activities. In addition, this can be automatized for human medicines as digitalisation of environmental risk assessment is foreseen as part of the revision of human medicinal product legislation. Therefore, no additional resources are required. EEA and EU-OSHA currently do not hold any relevant data for the repository. Therefore, no additional resources are required. The increase of the contribution to ECHA will be compensated by a reduction of the LIFE budget.

The proposal will formalise establishment and operation of a **database with information on applicable laws and legal obligations** applicable to chemicals under Union legislation to promote compliance. This work will impact ECHA but will not require additional resources under this proposal. ECHA already operates EU

chemical legislative finder (EUCLEF) as part of the contribution agreement with DG GROW. The contribution agreement amounts to ca. EUR 1.0 – 1.4 million annually. ECHA runs the service through the employment of 4 interim staff members (ca. EUR 270 000/year) and via contractors: communication activities and external helpdesk ca. EUR 60 000/year, IT costs EUR 200 000/year, data costs EUR 430 000/year. These existing resources will be used to continue operating, further developing and slightly expanding the system. The resources for major extension of the system, such as the repository of reference values, are provided under the work on repository of reference values. Although no resources are required under this proposal, the legislative proposal for a regulation on ECHA should address the fact that the operation of the EUCLEF became a structural task for ECHA and that the financing should become part of the annual contribution to ECHA.

The proposal will establish a database on **environmental sustainability related data on chemicals.** The work will impact ECHA. ECHA will be required to set up the database, operate it, establish and maintain the flows of adequate data into the database and provide interpretation of data. Other agencies (EEA, EFSA, EMA and EU-OSHA), if they host environmental sustainable data on chemicals, will provide that data to ECHA and will cooperate as necessary with ECHA on the development. To perform the work, ECHA will need as of the second year 1 FTE (1 TA) per year and operational budget of EUR 0 per year. Other agencies will not need additional resources as their task is small, currently do not actively collect any relevant data, and if they have any of such data, the amount of information held is currently very limited. The potential work on cooperation in this area can be absorbed by the agencies' current resources. The increase of the contribution to ECHA will be compensated by a reduction of the LIFE budget.

The proposal will establish **data generation mechanism** to allow ECHA and the Commission to commission studies supporting the implementation of Union chemicals legislation within ECHA's mandate or contributing to the development of Union chemicals policy. The studies can be commissioned only when results cannot be obtained through existing legal provisions and they shall not have predominant research and development objective. The mechanism will allow ECHA and the Commission to generate data where needed and cannot be obtained otherwise. ECHA's involvement is necessary as commissioning of such studies requires technical expertise. To perform the work, ECHA will require in the first year 1 FTE (1 TA) and operational budget of EUR 0, in the second year 2 FTEs (1 TA and 1 CA) and operational budget of EUR 1 000 000, in the third year 2 FTEs (1 TA and 1 CA) and operational budget of EUR 3 000 000 and as of the fourth year 2 FTEs (1 TA and 1 CA) per year and operational budget of EUR 5 000 000 per year. No current process exists, but there is a complementary process operated by EFSA for the food sector (4 FTEs/year, EUR 15 000 000/year). This will continue to be operated next to the new one and the two Agencies (ECHA and EFSA) are required to cooperate when commissioning such studies and develop a joint plan. The increase of the contribution to ECHA will be compensated by a reduction of the LIFE budget.

The proposal will expand the **obligation to notify studies** before they start from food sector to all chemical sector. The work will require additional resource for ECHA. ECHA will need as of the first year 3 FTEs (1 TA and 2 CAs) per year and operational budget in the first year of EUR 0, in the second year EUR 1 200 000, in the third year EUR 400 000 and as of the fourth year EUR 200 000 per year. ECHA

will be required to develop the database, operate it, facilitate and check compliance with the provisions and provide feedback to the duty holders. EFSA already operates a database of notification of studies to serve the obligation under the food sector legislation. The resource use amounts to 2 FTEs/year and EUR 400 000/year. EFSA and ECHA will be required to ensure compatibility of the systems. No additional resources are needed for this for EFSA. The increased contribution to ECHA will be compensated by a reduction of the LIFE budget.

The proposal will formalise the operation of the **indicators framework for chemicals** and will establish an **early warning and action system for chemicals.** The work will require additional resources for EEA. EEA will need as of the first year 1 FTE (1 TA) per year and operational budget for the first year of EUR 0, for the second year EUR 300 000 and as of the third year EUR 150 000 per year. EEA and ECHA already jointly develop the indicators framework for chemicals as part of the commitment under the 8th Environment Action Programme. As the resources for indicator framework (2 FTEs per year for ECHA, 1 FTE per year for EEA) were already attribution as part of the 8th EAP, no additional resources are needed for this work. The establishment of the early warning and action system is a new, non-existing task that aims to significantly shorten the regulatory response to identified risks. The EEA will be tasked to collect early warning signals from other agencies, Member State and by its own activity and compile annually a report for discussion and decision on the follow up with Member States authorities. The increased contribution to EEA will be compensated by a reduction of the LIFE budget. Other contributing agencies (ECHA, EFSA, EMA and EU-OSHA) will absorb the costs as part of exiting activities. In case of ECHA, the resources attribution for the indicator framework will be partly used to support the EEA by generating relevant early warning signals. The increased contribution to EEA will be compensated by a reduction of the LIFE budget.

The proposal will establish an **observatory for specific chemicals with potential contribution to emerging chemical risks.** This will de facto formalise the operation of existing EU Observatory for nanomaterials and extend its scope to specific chemicals considered to benefit from additional scrutiny and reliable information on their properties, safety aspects, uses and market presence. This work will impact ECHA but will not require additional resources under this proposal. ECHA operates the EU Observatory for nanomaterials as part of a contribution agreement with DG GROW. The resource use amounts to approximately EUR 700 000 per year including the 3 FTEs (3 CA). These existing resources will be used to continue operating, further developing and slightly expanding the system. The legislative proposal in preparation for a regulation on ECHA will address the fact that the operation of the EUCLEF became a structural task for ECHA and that the financing should become part of the annual contribution to ECHA.

Resource needs per activity for 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

	FTEs						Operational costs (in EUR 1 000)		
Activity	**2025**		**2026**		**2027**		**2025**	**2026**	**2027**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**			
Common data platform	5	16	5	16	5	16	950	3 442	4 077
Information Platform for Chemical Monitoring (IPCHEM)	1	0	2	1	2	1	0	200	380

Information on regulatory processes on chemicals	0	0	0	0	0	0	0	0	0
Repository of reference values	1	0	1	0	1	0	0	650	650
Information on the obligations under Union acts on chemicals	0	0	0	0	0	0	0	0	0
Environmental sustainability related data on chemicals	0	0	1	0	1	0	0	0	0
Data generation mechanism	1	0	1	1	1	1	0	1 000	3 000
Mechanism for notification of studies and database for study notifications	1	2	1	2	1	2	0	1 200	400
Early warning and action system for emerging chemical risks and framework of indicators	1	0	1	0	1	0	0	300	150
Observatory for specific chemicals with potential contribution to emerging chemical risks	0	0	0	0	0	0	0	0	0
SUM	**10**	**18**	**12**	**20**	**12**	**20**	**950**	**6 792**	**8 657**

Resource needs per agency/service for 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

	FTEs						Operational costs (in EUR 1 000)		
	2025		2026		2027		2025	2026	2027
Agency / Service	**TA**	**CA**	**TA**	**CA**	**TA**	**CA**			
ECHA	7	8	9	10	9	10	0	5 076	7 023
EEA	3	2	3	2	3	2	0	766	684
EFSA	0	5	0	5	0	5	670	670	670
EMA	0	3	0	3	0	3	100	100	100
EU OSHA	0	0	0	0	0	0	0	0	0
JRC	0	0	0	0	0	0	180	180	180
SUM	**10**	**18**	**12**	**20**	**12**	**20**	**950**	**6 792**	**8 657**

Current resource use for technical and scientific work to be reattributed to Agencies as part of 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	
IPCHEM	Total 4.5 FTEs/year: DG JRC staff 2.5 FTEs/year + IT experts intramurous 2 FTEs/year (EUR 130 000 per year).
Information on regulatory processes on chemicals	ECHA already operates (P)ACT for REACH, CLP and POPs processes. EFSA already operates OpenEFSA which has a similar level of information as PACT. Resources for the operation and continuous provision of information are to be absorbed by the Agencies.
Information on the obligations under Union acts on chemicals	ECHA already operates EUCLEF and this is financed through the contribution agreement between DG GROW and ECHA. No additional resources needed but the formalisation of the resource allocation should be done by the proposal for regulation on ECHA.
Observatory for specific chemicals with potential contribution to emerging chemical risks	ECHA already operates the EU Observatory on Nanomaterials and this is financed via the contribution agreement between DG GROW and ECHA. No additional resources needed but the formalisation of the resource allocation should be done by the proposal for a regulation on ECHA.
SUM	**2.5 FTEs/year of regular staff; 2 FTEs/year of intramurous contractors or interim staff (ca. EUR 130 000/year)**

In summary, the legislative proposal on chemicals data consists of 10 distinct activities that will have an impact on resource needs of ECHA, EEA, EFSA, EMA and the Commission. The first three years there will be a need of up to **32 FTEs (12 TA + 20 CA) per year** and an operational budget of up to **EUR 8 657 000 per year**. In the fourth year and beyond, there will be a need of **20 FTEs (12 TA and 8 CA)** per year and an operational budget of **EUR 7 080 000** per year. It must be noted that some activities included in the calculation above already exists and are financed as part of existing core ECHA and EFSA work (such as (P)ACT), through the contribution agreements between GROW and ECHA (EUCLEF and EU Observatory for nanomaterials) or from JRC core activities (IPCHEM). Resources for the operation of (P)ACT and OpenEFSA portal that should feed into the extended version of (P)ACT will be used to absorb the expansion of the (P)ACT for other pieces of legislation, including the merge of OpenEFSA into (P)ACT. Resources for the operation of EUCLEF and EUON will be used to continue operation, development and slight expansion of the systems, while the fact that that the operation of the EUCLEF and EUON became a structural task for ECHA and that there is a need to ensure that the financing should be part of the annual contribution to ECHA will be addressed in the proposal for a regulation on ECHA. Therefore for this part of work no additional resources are required under this proposal. The resources currently used for the operation of IPCHEM consists of 2.5 FTEs/year of regular staff, 2 FTEs of intramurous contractors (EUR 130 000 per year). As this task will be reattributed, the current resources used for this task will not be needed by the Commission. Therefore, the **total net increase in the resources from 2028 and beyond as compared to today** will be **15.5 FTEs** per year and operational budget of **EUR 7 080 000** per year.

Proposal for a Regulation on packaging and packaging waste (COM (2022) 677 final):

In theory, national legislations in Member States could have been established. However, there would have been to guarantee of consistent application across the EU and would inevitably contribute to further fragmentation of the internal market.

Tasks related to development of legislation at the EU level cannot be externalised.

The proposal attributes the task to ECHA to perform a scoping study on chemical in packaging that would be candidates for restriction. This is a new process that will require **1 FTE (1 TA) per year for 3 years** in ECHA. The increased contribution to ECHA will be compensated by a reduction of the LIFE budget.

Resource needs for ECHA for proposal for a Regulation on packaging and packaging waste (COM (2022) 677 final)									
	FTEs						**Operational costs (in EUR 1 000)**		
Legislation	**2025**		**2026**		**2027**		**2025**	**2026**	**2027**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**			
Packaging and packaging waste	1	0	1	0	1	0	0	0	0
SUM	**1**	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**0**

Proposal for a directive amending waste framework directive (COM (2023) 420 final):

The proposal lays down changes in the reporting requirements of Member States with regard to the re-use of products data flow to the European Environmental Agency. The enhanced reporting requirements will require **1 FTE (1 TA)** per year in EEA. The increased contribution to EEA will be compensated by a reduction of the LIFE budget.

Resource needs for EEA for proposal for a Directive amending waste framework directive (COM (2023) 420 final)									
	FTEs						**Operational costs (in EUR 1 000)**		
Legislation	**2025**		**2026**		**2027**		**2025**	**2026**	**2027**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**			
Waste framework directive	1	0	1	0	1	0	0	0	0
SUM	**1**	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**0**

Proposal for a Regulation on circularity requirements for vehicle design and on management of end-of-life vehicles (COM (2023) 451 final):

ECHA support is required for improving the risk assessment of the remaining hazardous substance exemptions, in particular for reviewing the scope extension and potential wider coverage of substances of concern (**1 FTE (1 TA)** per year for ECHA). The increased contribution to ECHA will be compensated by a reduction of the LIFE budget.

Resource needs for ECHA for proposal for a Regulation on circularity requirements for vehicle design and on management of end-of-life vehicles (COM (2023) 451 final)									
	FTEs						**Operational costs (in EUR 1 000)**		
Legislation	**2025**		**2026**		**2027**		**2025**	**2026**	**2027**
	TA	**CA**	**TA**	**CA**	**TA**	**CA**			
End-of-life vehicles regulation	1	0	1	0	1	0	0	0	0
SUM	**1**	**0**	**1**	**0**	**1**	**0**	**0**	**0**	**0**

1.6. Duration and financial impact of the proposal/initiative

☐ **limited duration**

– ☐ in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ Financial impact from YYYY to YYYY for commitment appropriations and from YYYY to YYYY for payment appropriations.

☒ **unlimited duration**

– Implementation with a start-up period from 2025 to 2028,

– followed by full-scale operation.

1.7. Method(s) of budget implementation planned[61]

☒ **Direct management** by the Commission

– ☒ by its departments, including by its staff in the Union delegations;

– ☐ by the executive agencies

☐ **Shared management** with the Member States

☒ **Indirect management** by entrusting budget implementation tasks to:

– ☐ third countries or the bodies they have designated;

– ☐ international organisations and their agencies (to be specified);

– ☐ the EIB and the European Investment Fund;

– ☒ bodies referred to in Articles 70 and 71 of the Financial Regulation;

– ☐ public law bodies;

– ☐ bodies governed by private law with a public service mission to the extent that they are provided with adequate financial guarantees;

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that are provided with adequate financial guarantees;

– ☐ bodies or persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

– *If more than one management mode is indicated, please provide details in the 'Comments' section.*

[61] Details of budget implementation methods and references to the Financial Regulation may be found on the BUDGpedia site: https://myintracomm.ec.europa.eu/corp/budget/financial-rules/budget-implementation/Pages/implementation-methods.aspx

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

This Legislative Financial Statement includes an increase of the contribution to the ECHA and the EEA, and contribution/service level agreements with the EFSA and the EMA.

The Commission will be overall accountable for implementing the proposed Regulation as well as for reporting to the European Parliament and the Council on implementation and compliance. The agencies will report on the implementation of their contributions and of the related actions in their annual activity reports.

2.2. Management and control system(s)

2.2.1. Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

This Legislative Financial Statement includes an increase of the contribution to the ECHA and the EEA, and contribution/service level agreements with the EFSA and the EMA.

DG Environment, in the context of its supervision of decentralised entities, and the agencies will apply its respective control strategies to this expenditure.

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

While the Commission will be overall accountable for implementing the proposed Regulation as well as for reporting to the European Parliament and the Council on the implementation and compliance, the additional resources put at the disposal of the agencies will be covered by their internal control and risk management systems that are aligned with the relevant international standards. DG Environment will apply the controls related to its supervision of decentralised agencies. No specific risks are identified in relation with the implementation of the additional budget to be provided to the agencies.

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio of "control costs ÷ value of the related funds managed"), and assessment of the expected levels of risk of error (at payment & at closure)

The risk of error at payment and at closure is expected to remain under 2%. The agencies are full responsibility over the implementation of their budget, while DG Environment is responsible for the regular payment of the contributions.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures, e.g. from the Anti-Fraud Strategy.

In addition to the controls stemming from the control strategie listed above, the action is subject to scrutiny of the Internal Audit Service, in its capacity of internal auditor of the Commission and of the decentralised agencies, and of the European Court of Auditors, in its capacity of external auditor of the EU Institutions.

The Commission maintains robust antifraud strategy, the CAFS, that is currently under revision. DG Environment complements this by a local antifraud strategy that covers the activities falling under its remit.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[62]	from EFTA countries [63]	from candidate countries and potential candidates [64]	fromother third countries	other assigned revenue
3	09.0202 – LIFE Circular Economy and Quality of Life	Diff	YES	YES	NO	NO
3	09.10.01 European Chemicals Agency – environmental directives and international conventions	Diff	YES	NO	NO	NO
3	09.10.02 European Environment Agency (ENV)	Diff	YES	YES	YES	NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

N/A

62 Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.
63 EFTA: European Free Trade Association.
64 Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated financial impact of the proposal on appropriations

3.2.1. Summary of estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ☒ The proposal/initiative requires the use of operational appropriations, as explained below:

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	**Heading 3 (Natural resources and environment)**

Agency: ECHA – Environmental Directives			**2024**	**2025**	**2026**	**2027**	**TOTAL**
Title 1: Staff expenditure	Commitments	(1a)	0	1,765	4,991	5,091	**11,848**
	Payments	(2a)	0	1,765	4,991	5,091	**11,848**
Title 2: Infrastructure	Commitments	(1b)					
	Payments	(2b)					
Title 3: Operational expenditure	Commitments	(1c)	0	0,101	5,159	7,106	**12,366**
	Payments	(2c)	0	0,101	5,159	7,106	**12,366**
TOTAL appropriations for agency ECHA	Commitments	=1a + 1b + 1c	0	1,866	10,150	12,197	**24,214**
	Payments	=2a + 2b + 2c	0	1,866	10,150	12,197	**24,214**

The details of the tasks to be performed by ECHA are specified in the staff working document[65] accompanying this legal proposal, in particular in the Annexes III and IV. The above increase of the contribution to ECHA will be offset from the LIFE Programme (budget line: 09.02.02).

[65] SWD (2023) 850

Agency: EEA			2024	2025	2026	2027	TOTAL
Title 1: Staff expenditure	Commitments	(1a)	0	0,595	1,214	1,238	**3,046**
	Payments	(2a)	0	0,595	1,214	1,238	**3,046**
Title 2: Infrastructure	Commitments	(1b)					
	Payments	(2b)					
Title 3: Operational expenditure	Commitments	(1c)	0	0	0,766	0,684	**1,450**
	Payments	(2c)	0	0	0,766	0,684	**1,450**
TOTAL appropriations for agency EEA	Commitments	=1a + 1b + 1c	0	0,595	1,980	1,922	**4,496**
	Payments	=2a + 2b + 2c	0	0,595	1,980	1,922	**4,496**

The details of the tasks to be performed by EEA are specified in the staff working document[66] accompanying this legal proposal, in particular in the Annexes III and IV. The above increase of the contribution to the EEA will be offset from the LIFE Programme (budget line: 09.02.02).

DG: ENV	Budget line: 09.02.02		2024	2025	2026	2027	TOTAL
Contribution/Service level agreement with EFSA	Commitments	(1a)	-	1,000	1,000	1,000	**3,000**
	Payments	(2a)	-	1,000	1,000	1,000	**3,000**
Contribution/Service level agreement with EMA	Commitments	(1b)	-	0,467	0.467	0.467	**1,400**
	Payments	(2b)	-	0,467	0.467	0.467	**1,400**
Administrative arrangements with JRC	Commitments	(1b)	-	0,180	0,180	0,180	**0,540**

[66] SWD (2023) 850

	Payments	(2b)	-	0,180	0,180	0,180	**0,540**
○ TOTAL operational appropriations	Commitments	(4)	-	1,580	1,580	1,580	**4,740**
	Payments	(5)	-	1,580	1,580	1,580	**4,740**
○ TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)					
TOTAL appropriations for DG ENV	Commitments	=4+ 6	-	1,647	1,647	1,647	**4,940**
	Payments	=5+ 6	-	1,647	1,647	1,647	**4,940**

The need for additional resources for EFSA is estimated at 3 contract agents and EUR 2 million of operational expenditure. The need for additional resources for EMA is estimated at 3 contract agents and EUR 0,3 million of operational expenditure. For 2025-2027, these costs will be covered through a contribution/service level agreement between the agencies and DG ENV. Without prejudice to the future MFF agreement, the costs from 2028 on should be covered by the EU subsidies to these agencies.

In addition, the need for additional resources for JRC is estimated at EUR 0,540 million of operational expenditure, to be channelled through an administrative agreement.

			2024	**2025**	**2026**	**2027**	**TOTAL**
○ TOTAL operational appropriations (all operational headings)	Commitments	(4)					
	Payments	(5)					
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes (all operational headings)		(6)					
TOTAL appropriations under HEADINGS 1 to 6 of the multiannual financial framework (Reference amount)	Commitments	=4+ 6	0	4,108	13,777	15,766	**33,650**
	Payments	=5+ 6	0	4,108	13,777	15,766	**33,650**

Heading of multiannual financial framework	**7**	'Administrative expenditure'

This section should be filled in using the 'budget data of an administrative nature' to be firstly introduced in the Annex to the Legislative Financial Statement (Annex 5 to the Commission decision on the internal rules for the implementation of the Commission section of the general budget of the European Union), which is uploaded to DECIDE for interservice consultation purposes.

EUR million (to three decimal places)

		Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			**TOTAL**
DG: <…….>									
○ Human resources									
○ Other administrative expenditure									
TOTAL DG <…….>	Appropriations								

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)								

EUR million (to three decimal places)

		2024	**2025**	**2026**	**2027**	**TOTAL**
TOTAL appropriations under HEADINGS 1 to 7 of the multiannual financial framework	Commitments	0	4,108	13,777	15,766	**33,650**
	Payments	0	4,108	13,777	15,766	**33,650**

3.2.2. Estimated output funded with operational appropriations

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇩			Year **N**		Year **N+1**		Year **N+2**		Year **N+3**		Enter as many years as necessary to show the duration of the impact (see point 1.6)						**TOTAL**	
	OUTPUTS																	
	Type[67]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1[68]…																		
- Output																		
- Output																		
- Output																		
Subtotal for specific objective No 1																		
SPECIFIC OBJECTIVE No 2 ...																		
- Output																		
Subtotal for specific objective No 2																		
TOTALS																		

[67] Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

[68] As described in point 1.4.2. 'Specific objective(s)…'

3.2.3. Estimated impact on ECHA, EEA, EFSA and EMA human resources and administrative appropriations

3.2.3.1. Estimated requirements on ECHA's human resources

– ☐ The proposal/initiative does not require the use of human resources.

– ☒ The proposal/initiative requires the use of human resources, as explained below:

EUR million (to three decimal places)

Where applicable, amounts reflect the sum of the Union contribution to the agency and other revenue of the agency (fees and charges).

	2023	**2024**	**2025**	**2026**	**2027**	**TOTAL**
Temporary agents (AD Grades)	-	-	1,330	3,548	3,619	8,496
Temporary agents (AST grades)	-	-	-	-	-	-
Contract staff	-	-	0,436	1,444	1,473	3,352
Seconded National Experts	-	-	-	-	-	-
TOTAL	-	-	1,765	4,991	5,091	11,848

Staff requirements (FTE):

	2023	**2024**	**2025**	**2026**	**2027**	**TOTAL**
Temporary agents (AD Grades)	-	-	13	17	17	
Temporary agents (AST grades)	-	-	-	-	-	
Contract staff	-	-	8	13	13	
Seconded National Experts	-	-	-	-	-	
TOTAL	-	-	21	30	30	

3.2.3.2. Estimated requirements on EEA's human resources

– ☐ The proposal/initiative does not require the use of human resources.

– ☒ The proposal/initiative requires the use of human resources, as explained below:

EUR million (to three decimal places)

Where applicable, amounts reflect the sum of the Union contribution to the agency and other revenue of the agency (fees and charges).

	2023	**2024**	**2025**	**2026**	**2027**	**TOTAL**
Temporary agents (AD Grades)	-	-	0,470	0,959	0,978	2,406
Temporary agents (AST grades)	-	-	-	-	-	-
Contract staff	-	-	0,125	0,255	0,260	0,640
Seconded National Experts	-	-	-	-	-	
TOTAL			0,595	1,214	1,238	3,046

Staff requirements (FTE):

	2023	**2024**	**2025**	**2026**	**2027**	**TOTAL**
Temporary agents (AD Grades)	-	-	4	4	4	
Temporary agents (AST grades)	-	-	-	-	-	
Contract staff	-	-	2	2	2	
Seconded National Experts	-	-	-	-	-	
TOTAL			6	6	6	

3.2.3.3. Estimated requirements on EMA's human resources

– ☐ The proposal/initiative does not require the use of human resources.

– ☒ The proposal/initiative requires the use of human resources, as explained below:

Staff requirements (FTE):

	2025	**2026**	**2027**

Temporary agents (AD Grades)	-		
Temporary agents (AST grades)	-	-	-
Contract staff	3	3	3
Seconded National Experts	-	-	-
TOTAL	3	3	3

3.2.3.4. Estimated requirements on EFSA's human resources

– ☐ The proposal/initiative does not require the use of human resources.

– ☒ The proposal/initiative requires the use of human resources, as explained below:

Staff requirements (FTE):

	2025	**2026**	**2027**
Temporary agents (AD Grades)	-		
Temporary agents (AST grades)	-	-	-
Contract staff	5	5	5
Seconded National Experts	-	-	-
TOTAL	5	5	5

3.2.4. Compatibility with the current multiannual financial framework

The proposal/initiative:

– ☒ can be fully financed through redeployment within the relevant heading of the Multiannual Financial Framework (MFF).

The increases of the agencies subsidies will be offset from the LIFE programme except 2 FTEs (2 CAs) for EFSA which will be financed from EFSA's current budget as detailed above.

– ☐ requires use of the unallocated margin under the relevant heading of the MFF and/or use of the special instruments as defined in the MFF Regulation.

– ☐ requires a revision of the MFF.

3.2.5. Third-party contributions

The proposal/initiative:

– ☒ does not provide for co-financing by third parties

– ☐ provides for the co-financing by third parties estimated below:

Appropriations in EUR million (to three decimal places)

	Year **N**[69]	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations co-financed								

69 Year N is the year in which implementation of the proposal/initiative starts. Please replace "N" by the expected first year of implementation (for instance: 2021). The same for the following years.

3.3. Estimated impact on revenue

– ☒ The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

– ☐ on own resources

– ☐ on other revenue

– please indicate, if the revenue is assigned to expenditure lines ☐

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[70]						
		Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
Article …….								

For assigned revenue, specify the budget expenditure line(s) affected.

Other remarks (e.g. method/formula used for calculating the impact on revenue or any other information).

[70] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20 % for collection costs.