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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the European Chemicals Agency and amending Regulations (EC) No 1907/2006, (EU) No 528/2012, (EU) No 649/2012 and (EU) 2019/1021

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1 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, to support the efficient functioning of the internal market for chemicals, and to promote the competitiveness and innovation of EU industry. The framework consists of over 40 pieces of legislation addressing: (i) the production and placing on the market of chemicals and products containing chemicals; (ii) emissions of chemicals and the safety of workers; (iii) consumer products; (iv) food and animal feed; (v) the environment.

The fitness check of the most relevant EU chemicals legislation[1] concluded that, overall, this legislation delivers the intended results and is fit for purpose. However, there are shortcomings in the consistency of safety assessments, the efficiency of the underlying technical and scientific work, and the consistency of transparency rules.

The chemicals strategy for sustainability[2] (CSS), adopted on 14 October 2020, is part of the EU's zero pollution ambition and a key commitment of the European Green Deal[3].

The CSS outlines a number of measures to improve the effectiveness, efficiency and consistency of safety assessments through the 'One Substance, One Assessment' approach. **This includes a proposal 'to strengthen the governance of the European Chemicals Agency (ECHA) and increase the sustainability of its financing model**' considering: (i) the reduced and unpredictable fee income following the last regulatory registration deadline in 2018 under the REACH Regulation[4]; and (ii) **the existing and planned reassignment of new scientific and technical work to EU agencies, including ECHA[5].**

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

2 Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the regions, Chemicals Strategy for Sustainability (COM(2020) 667 final).

3 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).

4 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 (OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

5 Commission proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals (COM(2023) 783 final 2023/0455 (COD)) and Commission proposal for a Directive of the European Parliament and of the Council amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (COM(2023) 781

The European Chemicals Agency ('the Agency' or 'ECHA') was established on 1 June 2007 under the REACH Regulation. Its remit is managing the registration process, to play a key role in ensuring consistency of evaluation, providing criteria to guide Member States'' selection of substances for evaluation and taking decisions that require further information on substances under evaluation. ECHA's tasks under REACH also include providing independent opinions during the authorisation and restriction procedures which are taken into account for drafting and adopting EU measures.

ECHA has under REACH also decision-making powers which allows it to adopt individual decisions on technical matters, under clearly and precisely defined conditions. The range of powers given to ECHA is strictly limited and is in line with the principles of the EU legal order, which imposes constraints on the scope of the powers that can be given to Agencies[6].

Since the Agency was founded, its tasks have expanded to other pieces of EU legislation (see Annex 1 to this Explanatory Memorandum), to include additional scientific, technical, and administrative tasks, *i.e.* to:

- manage and carry out technical, scientific, and administrative tasks under the Classification, Labelling and Packaging (CLP) Regulation[7], adopted in 2008;
- manage and carry out technical, scientific, and administrative tasks of the Biocidal Products Regulation (BPR)[8], adopted in 2012;
- manage and carry out technical, scientific, and administrative tasks related to the export and import of hazardous chemicals under the Prior Informed Consent (PIC) Regulation[9], adopted in 2012;
- develop and manage a database with the information provided by suppliers on the presence of Substances of Very High Concern in articles following an amendment to the Waste Framework Directive (WFD)[10], adopted in 2018;
- provide scientific and technical support to the Commission and the Member States in fulfilling their obligations under the Persistent Organic Pollutants (POP) Regulation[11], adopted in 2019;

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final 2023/0454 (COD)) and Commission proposal for a Regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals (COM(2023) 779 final 2023/0453 (COD)).

6 Communication from the Commission, The operating framework for the European Regulatory Agencies (COM(2002)718 final), p. 8; Communication from the Commission and the European Parliament and the Council, European agencies – The way forward (COM(2008)135 final), p. 5.

7 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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj)

8 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj).

9 Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (recast) (OJ L 201, 27.7.2012, p. 60, ELI: http://data.europa.eu/eli/reg/2012/649/oj).

10 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p.3, ELI: http://data.europa.eu/eli/dir/2008/98/oj).

- provide assessments of substances for materials in contact with drinking water under the recast of the Drinking Water Directive (DWD)[12], adopted in 2020;
- establish a new monitoring and reporting framework on the use of chemicals as part of the 8th Environment Action Programme published in 2021[13];
- carry out a public health risk assessment in case of a serious cross-border threat to health of chemical or environmental origin which falls under its tasks and support the European Centre for Disease Prevention and Control (ECDC) in assessing public health emergency preparedness as regards preparedness for chemical threats under the Regulation on serious cross-border threats to health[14], adopted in 2022;
- prepare, at the request of the Commission, a restriction dossier for substances in batteries under the Batteries and Waste Batteries Regulation[15], adopted in 2023;
- support the Commission in the review of the best available techniques reference documents (BREF) under the Industrial Emissions Directive[16], revised in 2024;
- carry out assessments underpinning restrictions of substances in packaging and assist the Commission in preparing a report on substances of concern contained in packaging or used in its manufacturing under the Packaging and Packaging and Waste Regulation[17], adopted in 2024;
- provide support to the Commission, under a grant agreement, for the implementation of the instrument for pre-accession (IPA) for EU candidate countries and potential candidates.

The Agency also signed ad hoc agreements with the Commission to undertake technical and scientific tasks. These include the implementation of the European Union Observatory for

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11 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, ELI: http://data.europa.eu/eli/reg/2019/1021/oj).

12 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, ELI: http://data.europa.eu/eli/dir/2020/2184/oj).

13 Decision (EU) 2022/591 of the European Parliament and of the Council of 6 April 2022 on a General Union Environment Action Programme to 2030 (OJ L 114, 12.4.2022, p.22, ELI: http://data.europa.eu/eli/dec/2022/591/oj).

14 Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU, PE/40/2022/REV/1 (OJ L 314, 6.12.2022, p.26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).

15 Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p.1, ELI: http://data.europa.eu/eli/reg/2023/1542/oj).

16 Directive (EU) 2024/1785 of the European Parliament and of the Council of 24 April 2024 amending Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions (integrated pollution prevention and control) and Council Directive 1999/31/EC on the landfill of waste (OJ L, 2024/1785, 15.7.2024, ELI: http://data.europa.eu/eli/dir/2024/1785/oj).

17 Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC (OJ L 2025/40, 22.1.2025, ELI: http://data.europa.eu/eli/reg/2025/40/oj).

Nanomaterials (EUON)[18], the EU chemical legislation finder (EUCLEF) and the provision of opinions by the Committee for Risk Assessment on occupational exposure limits (OELs)[19].

The Agency also took on the role of reviewing regulatory relevance of in a 'Horizon Europe' research project programme as well as to participate in the *European Partnership for the Assessment of Risks from Chemicals (PARC).*

As part of the implementation of the CSS and the 'One Substance, One Assessment' approach, additional tasks have been proposed for attribution to ECHA, either by targeted amendments of existing relevant chemicals legislation which is already being revised or under the recent proposals for the re-attribution of tasks to agencies[20]. The pieces of legislation concerned and the additional tasks for the Agency proposed under each revision are listed in Annex 1 to this Explanatory Memorandum.

The aim of this proposal for a self-standing regulation on the European Chemicals Agency is to provide the Agency with an autonomous legal framework, to enhance its governance, enabling it to carry out the tasks allotted to it in current legislation and allowing its tasks to evolve to accommodate the new tasks envisioned by already adopted or planned Commission proposals. It should also ensure that the Agency can react effectively to new challenges and provide better support to the Commission, Member States and duty holders.

It should also be noted that the Agency was founded in 2007, before the European Parliament, the Council of the EU and the European Commission endorsed the Common Approach on decentralised EU agencies[21]. The proposal ensures that the principles of the Common Approach are fully taken into account for the planning of the Agency's activities, the financial rules, fraud prevention, the management of conflict of interest, the independence of scientific committees and the Board of Appeal, the supervisory role of the Management Board, the periodic evaluations of the Agency's performance and their follow-up, delimiting the roles of the Agency in international relations, the headquarters agreement, etc.

The main changes from the current framework are explained below:

- ***ECHA's Committee for Risk Assessment and the Committee for Socio-economic Analysis***

The Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) are scientific committees within the ECHA that play critical roles under the EU's chemical regulation framework, particularly the REACH Regulation. RAC is responsible for evaluating the risks to human health and the environment associated with chemicals. It

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18 Commission Delegation Agreement on European Union Observatory for Nanomaterials and the European union Chemical Legislation Finder of 6 December 2016, https://ec.europa.eu/docsroom/documents/20432

19 Commission Decision of 3 March 2014 on setting up a Scientific Committee on Occupational Exposure Limits for Chemical Agents and repealing Decision 95/320/EC (OJ L 62, 04/03/2014, p. 18–22, ELI: http://data.europa.eu/eli/dec/2014/113(1)/oj)

20 Commission proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals (COM(2023) 783 final 2023/0455 (COD)) and Commission proposal for a Directive of the European Parliament and of the Council amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (COM(2023) 781 final 2023/0454 (COD)).

21 Joint Statement of the European Parliament, the Council of the European Union and the European Commission on decentralised agencies – Common Approach, 2012.

provides scientific opinions on the classification of hazardous substances, occupational exposure limits and other risk management measures, helping to assess whether restrictions for certain chemicals are needed to mitigate potential risks or whether some requirements for authorisations are met.

SEAC focuses on the socio-economic impact of regulatory actions proposed under REACH. Its role is to analyse the economic, social, and broader societal implications of restricting or authorising chemicals, considering factors such as costs, benefits, and possible alternatives. By providing informed opinions on the socio-economic aspects of regulatory proposals, SEAC ensures that decisions taken by the Commission are balanced and consider the potential impact on businesses, consumers and society. Together, RAC and SEAC provide scientific and socio-economic insights that support the EU's regulatory decision making on chemical safety.

Some targeted reforms are essential to enhance the capacity of RAC and SEAC. The current legal framework is not flexible enough to allow these committees to meet the future challenges, the workload and the increasing complexity of the files.

In consequence of the (re-)attribution of tasks, it is expected that **RAC** would have to deliver **80** additional **opinions** per year and **SEAC** would have to deliver **50** additional **opinions** per year as compared to today, plus **up to 5 assessments** per year to be provided upon request of the **Biocidal Products Committee**. Annex 2 of this Explanatory Memorandum provides more detailed information on the current set up of the committees and estimates the increase in their workload. To cope with this increased workload, RAC and SEAC would require some adaptations aiming to increase the number of committee members, the attractiveness of being a rapporteur and flexibility in structuring the work of the committees.

Against this background, the following targeted reforms are proposed in this proposal to allow RAC and SEAC to meet the future requirements and workloads:

- The capacity of RAC and SEAC will be enhanced by creating an obligation for Member States to nominate two members for RAC and two members for SEAC with the possibility to nominate up to two additional members for each of the two committees. Currently, the Member States are not obliged to nominate members and may nominate only two members, which has depleted the capacity of the two committees at the same time as their workload has been growing.
- Currently, the numbers of co-opted members in RAC and SEAC are limited by legislation to five members per committee. The proposal provides for more flexibility for RAC and SEAC to co-opt more members, taking into account the workload, the type of expertise needed and the availability of financial resources.
- In addition, the proposal allows RAC and SEAC to rely on the services of experts in carrying out their tasks, if such support is justified by the scientific and technical context or the level of expertise required.

Given the complex environment in which the committees will operate, the organisation of the committees and their working groups will be set out in their rules of procedure. The adoption of the rules of procedure by the Agency's Management Board will be subject to a positive vote from the Commission representatives in the Management Board.

- ***The Scientific Committee on Consumer Safety (SCCS)***

The Scientific Committee on Consumer Safety (SCCS) was established in 2015 by a Commission Decision[22]. Its mandate covers advice and opinions on health and safety risks, such as chemical, biological, mechanical, and other physical risks relating to non-food consumer products, especially cosmetic products and, exceptionally, textiles, clothing, household products and consumer services including tattooing and artificial sun tanning. In practice, SCCS worked almost exclusively on cosmetic ingredients.

SCCS plays a central role in the scientific assessment of the safety of ingredients used in cosmetic products in the implementation of Regulation (EC) No 1223/2009 on cosmetic products[23]. The most important of its tasks include carrying out of the safety assessment and providing the Commission with scientific opinions on the safety of:

- substances that are used in cosmetic products as colorants, preservatives or UV-filters. Such opinion is mandatory before the Commission can take any regulatory action (authorise the use of such substances) (Article 14 of the Cosmetic Products Regulation).
- substances classified as CMR (carcinogenic, mutagenic or toxic for reproduction) for the use in cosmetic products in case a request for derogation from the prohibition was submitted to the Commission. Positive opinion of the SCCS is a prerequisite for the derogation (Article 15 of the Cosmetic Products Regulation);
- nanomaterials where safety concerns are raised. Such opinion is mandatory before the Commission can take a regulatory action (prohibit or restrict the use of specific nanomaterials) (Article 16 of the Cosmetic Products Regulation);
- substances used in cosmetic products where concerns are raised due to potential risk to human health (Article 31 of the Cosmetic Products Regulation). Such opinion is mandatory before the Commission can take a regulatory action (prohibit or restrict the use of such substances);

SCCS also prepares the Notes of Guidance for the testing of cosmetic ingredients including nanomaterials, which include non-animal testing methodology. It provides the Commission with scientific advice, among others on emerging issues and participates in consultations on animal-free approaches.

Although the mandate of SCCS covers chemical and other types of risks of non-food consumer products, since its creation in 2015, 99% of SCCS work related to cosmetic substances. **The Cosmetic Products Regulation is the only piece of EU law which expressly lays down tasks for SCCS.** It is therefore justified that SCCS managed by ECHA continues carrying out those tasks. SCCS in ECHA will not be responsible for providing scientific opinions on risk assessment of chemicals present in other non-food consumer products, such as household products, including detergents, textiles or clothing. For such scientific opinions on risk assessment, the Commission will be able to mandate RAC in accordance with the provisions of this proposal. In addition, SCCS in ECHA will not provide

[22] Commission Decision (EU) 2024/1514 of 7 August 2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment, OJ L, 2024/1514, 31.5.2024, ELI: http://data.europa.eu/eli/dec/2024/1514/oj.

[23] Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) OJ L 342, 22.12.2009, p. 59–209, ELI: http://data.europa.eu/eli/reg/2009/1223/oj.

opinions on biological, mechanical and physical risks of non-food consumer products or services, such as tattooing[24], artificial tanning, etc.

This proposal reallocates SCCS from the Commission to ECHA, while preserving some of the working modalities of this scientific committee. With this reallocation, SCCS will be a stand-alone committee of the Agency, similar to RAC, SEAC and BPC, but having its members selected through a specific open call for the expression of interests.

Establishing SCCS in ECHA Basic Regulation aligns with the Commission's initiative outlined in the CSS (specifically 'One Substance, One Assessment') as a regulatory effort within the EU aimed at streamlining and harmonising chemical safety assessments across various sectors and agencies. In addition, such reallocation confirms the role of SCCS as a pan-EU point for reference for scientific assessments of risks linked to the use of chemicals in cosmetic products, based on new approaches to animal testing. This scientific committee will receive a comprehensive administrative support and stable financing. Moreover, it will facilitate the exchange of knowledge and experience between the relevant ECHA committees improving overall the quality of risk assessment of chemicals.

Once the ECHA Basic Regulation is adopted, the 2015 Decision will have to be amended or repealed with the entry into effect date aligned with the entry into application of the relevant provisions of the ECHA Basic Regulation.***The Forum for Exchange of Information.***

The **Forum for Exchange of Information on Enforcement** (the Forum) established under REACH will continue to carry out its current tasks and in addition those that will be entrusted to it deriving from sectoral legislation.

- ***Cooperation with other EU agencies***

The proposal further enhances the cooperation with other EU agencies, to improve coherence of scientific opinions and to avoid potential divergence of scientific opinions. In the context of the 'One Substance, One Assessment' measures announced in the CSS and proposed by the Commission to promote the coherence and efficiency of assessments related to chemicals across EU legislation, the relevant EU agencies should cooperate on the provision of relevant scientific opinions, on the development of scientific methodologies for assessment of chemicals as well on the exchange of data and information, including in the context of joint risk assessments under the Regulation on serious cross-border threats to health[25]. In addition, the relevant EU agencies should take steps =to avoid divergent scientific opinions. Past cases of divergent opinions by EU agencies have led to uncertainty for economic operators and reduced public trust in the scientific robustness and coherence of opinions which form the basis for decision making. Accordingly, measures aimed at improved cooperation of the European Medicines Agency (EMA)[26] and the European Food Safety Authority (EFSA)[27]

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[24] The Opinion on the safety of tattoos was adopted by the SCCS predecessor (the Scientific Committee on Cosmetic Products and Non-food products intended for Consumers, SCCNFP) on 17 February 2000; https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions/sccnfp_opinions_97_04/sccp_out108_en.htm.

[25] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26–63, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).

[26] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/726/oj) and 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

with other EU agencies and at resolving divergence between scientific opinions of the EMA and the EFSA with other scientific bodies have been proposed in the revision of EU pharmaceutical legislation[28] and in the proposal for the omnibus regulation on the (re-)attribution of tasks respectively[29]. Furthermore, measures aimed at improved cooperation of the European Environmental Agency (EEA)[30] with other EU agencies have been proposed in the proposal for the omnibus regulation on the (re-)attribution of tasks. In line with these developments, similar provisions are proposed for a strengthened mandate of ECHA in the current proposal.

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- ***Transfer of tasks implemented by the Agency under ad hoc agreements to the Agency's mandate***

The tasks that have been carried out so far by the Agency under ad hoc agreements to implement EUON, the EU chemical legislation finder (EUCLEF) and for the provision of opinions by the Committee for Risk Assessment on occupational exposure limits (OELs) have become structural tasks. Given that they are not going to be discontinued, they must become part of ECHA's mandate and should be financed from the EU contribution to ECHA.

EUCLEF and EUON tasks are integrated in the proposal for a regulation on a common data platform[31]. The task of providing opinions by RAC on OELs to the Commission is integrated into this proposal. This will contribute to enhancing transparency on the financing of the Agency and will also contribute to reducing ECHA's administrative burden deriving from separate accounting and reporting obligations under the ad hoc agreements between the Commission and the Agency.

- ***Participation of the Agency in research in the framework of EU research programmes***

(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, ELI: http://data.europa.eu/eli/reg/2017/745/oj).

27 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, ELI: http://data.europa.eu/eli/reg/2002/178/oj).

28 Commission 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 2023/0131(COD)).

29 Commission proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals (COM(2023) 783 final 2023/0455 (COD)) and Commission proposal for a Directive of the European Parliament and of the Council amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (COM(2023) 781 final 2023/0454 (COD)).

30 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, ELI: http://data.europa.eu/eli/reg/2009/401/oj).

31 Commission proposal for a Regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals (COM(2023) 779 final 2023/0453 (COD)).

The participation of the Agency in research in the framework of EU research programmes is clarified by introducing clear provisions in the proposal.

- ***Role of Member States***

It is necessary to ensure close cooperation between the Agency and the competent authorities working within the Member States so that the scientific opinions and assessments of RAC, SEAC, the Member State Committee (MSC) and the Biocidal Products Committee (BPC) are based on the broadest possible scientific and technical expertise available within the EU. To the same end, these committees should be able to rely on additional specific expertise where needed.

The re-attribution of tasks to agencies will increase the workloads of ECHA's committees, in particular RAC and SEAC. The current proposal therefore provides that the Member States must in future nominate more members to these committees, with an obligation to nominate at least two members for RAC and two members for SEAC.

The Member States should exercise oversight over the Agency through the Management Board in which they are represented.

- ***Increasing the sustainability of the financial model of the Agency***

ECHA has a **complex** financial framework with **three different segregated budgets** for REACH/CLP, BPR and other environmental legislation. Currently, rules enshrined in the BPR, PIC and POPs Regulations oblige ECHA to maintain a **strict separation** of funding between the regulations that it implements. In addition, the various contribution agreements and the service level agreements that give effect to some of ECHA's tasks require their own budgeting and reporting in accordance with Articles 7 and 10(4) of the Framework Financial Regulation for Decentralised Agencies[32].

The European Court of Auditors noted in its special report 22/2020[33]:

> '*The financial and administrative framework in which ECHA operates is **more complex than for other agencies**, as ECHA **has three separate budgets** (and staffing plans) under three different regulations, each with a different partner DG. This further **limits ECHA's flexibility** to deal with fluctuations in workload*.'

The funding separation requirements create an operational impediment affecting human resources management, agility, and responsiveness. This creates an additional administrative burden in budgeting, budget implementation, accounting, and reporting. The segregation of budgets in those pieces of legislation is addressed by this proposal. To simplify the Agency's financing model, the requirement for segregated budgets established under Regulation (EU) No 649/2012, Regulation (EU) 2019/1021 and Regulation (EU) No 528/2012 should be abolished, by deleting the relevant provisions in those Regulations, so that the Agency will receive one unitary annual contribution from the EU budget.

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32 Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council (OJ L 122, 10.5.2019, p.1, ELI: http://data.europa.eu/eli/reg_del/2019/715/oj).

33 European Court of Auditors, Special Report 22/2020: Future of EU agencies – Potential for more flexibility and cooperation, https://op.europa.eu/webpub/eca/special-reports/agencies-performance-audit-22-2020/en/.

In addition, in a context of unpredictability of ECHA fee income payable by duty holders under both REACH and BPR, this proposal envisages the possibility for ECHA to maintain a limited fund reserve from income from fees and charges, subject to the specific conditions set out in this proposal. Its aim is solely to mitigate the fluctuation and compensate for shortfall of the fee income. This measure is implementable through the modification of ECHA Financial Regulation[34].

Other measures are being explored outside the current regulation proposal to increase the sustainability of the Agency's financial model. These include the following actions implementable through the revision of the Regulations concerning the fees payable to ECHA (Commission Implementing Regulations)[35] or the revision of ECHA Financial Regulation[36]:

- actions to increase ECHA income from fees by adapting them to inflation.
- new fee income streams will be explored. The new fee income streams should reflect the costs of the services delivered by ECHA to undertakings.
- actions to rationalise and streamline the treatment of SMEs under the REACH Fee Regulation by putting in place an ex ante verification of companies' size to increase the predictability of fees and charges income, reduce the administrative burden for duty holders and the Agency and further the level playing field.

1.2 Consistency with existing policy provisions in the policy area

This proposal takes account of the legislation implemented by the European Chemicals Agency. It will provide ECHA with a legal framework to manage the tasks deriving from various pieces of legislation and will contribute to further improving the consistency, efficiency, and transparency of chemical assessments across legislation implemented by the Agency.

This legislative proposal also takes account of the cooperation of ECHA with other EU decentralised agencies, in particular EMA, EFSA, EEA, ECDC and the European Agency for Safety and Health at Work (EU-OSHA)[37], but also other EU decentralised agencies and bodies.

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34 ECHA Financial Regulation, Management Board Decision 30/2019 Internal (reference to document MB/29/2019 final) of 20 June https://echa.europa.eu/documents/10162/23711/echa_financial_regulation_en.pdf/c262c957-3344-4d11-b7af-1d6da7ac4cda

35 Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 107 17.4.2008, p.6, ELI: http://data.europa.eu/eli/reg/2008/340/oj); Commission Regulation (EU) No 440/2010 of 21 May 2010 on the fees payable to the European Chemicals Agency pursuant to Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (OJ L 126, 22.5.2010, p.1, ELI: http://data.europa.eu/eli/reg/2010/440/oj); Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 19.6.2013, p.17, ELI: http://data.europa.eu/eli/reg_impl/2013/564/oj).

36 Financial Regulation of the European Chemicals Agency of 20 June 2019 (MB/29/2019 final).

37 Regulation (EU) 2019/126 of the European Parliament and of the Council of 16 January 2019 establishing the European Agency for Safety and Health at Work (EU-OSHA), and repealing Council Regulation (EC) No 2062/94 (OJ L 30, 31.1.2019, p. 58, ELI: http://data.europa.eu/eli/reg/2019/126/oj).

New tasks have already been proposed for re-attribution to ECHA as part of the following proposals already adopted by the Commission:

- proposal for a Directive 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[38];
- proposal for a Regulation on the safety of toys[39];
- proposal for a Directive amending Directive 2000/53/EC on end-of-life vehicles[40];
- proposals under the 'One Substance, One Assessment' approach, i.e. the two proposals regarding the re-attribution of scientific and technical tasks and improving cooperation between EU agencies in the area of chemicals and the proposal for a regulation establishing the common data platform[41].

The proposal contributes to ensuring consistency by allowing the Agency to coordinate its activities with the broader EU chemical policies, promote harmonised approaches to risk assessment and enable transparent and adaptable processes that respond to evolving scientific and policy landscapes.

1.3 Consistency with other EU policies

The proposal is consistent with other European Union policies addressing environmental protection, health and consumer safety, industrial development, international cooperation, and product safety. It reflects the EU's commitment to effective chemicals management, promoting sustainability, and safeguarding human health and the environment.

The proposal enhances the Agency's cooperation with other EU decentralised agencies, in particular EFSA, EU-OSHA, EMA and EEA, to avoid divergent scientific opinions and to foster assessments in line with the 'One Substance, One Assessment' approach.

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38 Commission 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 (COM/2022/540 final).

39 Commission proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC (COM/2023/462 final).

40 Commission 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).

41 Commission proposal for a Directive of the European Parliament and of the Council amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (COM(2023) 781 final 2023/0454 (COD)), Commission proposal for a Regulation of the European Parliament and of the Council amending Regulations (EC) No 178/2002, (EC) No 401/2009, (EU) 2017/745 and (EU) 2019/1021 of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks and improving cooperation among Union agencies in the area of chemicals (COM(2023) 783 final 2023/0455 (COD)) and Commission proposal for a Regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals (COM(2023) 779 final 2023/0453 (COD)).

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

2.1 Legal basis

This proposal has as its legal basis in Article 114 of the Treaty on the Functioning of the European Union (TFEU).

The proposal amends four regulations, which have two different legal bases. Regulation (EC) No 1907/2006, which establishes ECHA and which contains the majority of the provisions that are included in this proposal, is based on Article 114 TFEU. Regulation (EU) No 528/2012 is also based on Article 114 TFEU. On the other hand, Regulation (EU) No 649/2012 is based on Articles 192(1) and 207 TFEU and Regulation (EU) 2019/1021 is based on Article 192(1) TFEU.

The legal basis of this proposal should be determined based on the centre of gravity of the legislation that the Agency is to implement. The ECHA Regulation sets up a new regime on the basis of the provisions of the REACH Regulation, and only amends Regulation (EU) No 649/2012 and Regulation 2019/1021 in an incidental way without interfering in any significant manner with the operation of those acts. In addition, ECHA's work on the implementation of the regulations which are based on Article 114 TFEU (REACH, CLP and BPR) will continue to constitute the bulk (approximately 80 %) of ECHA activities. The centre of gravity of the act is therefore the internal market, making it appropriate to base this Regulation on Article 114 TFEU.

2.2 Subsidiarity (for non-exclusive competence)

In the same way as when the provisions on the founding of the Agency were initially adopted under the REACH Regulation, the objectives of this proposal cannot be sufficiently achieved at Member State level. This initiative is needed to align the basic legal provisions establishing ECHA with its current and future broader role. By their nature, these tasks can only be carried out at EU level. The proposal will also formalise and integrate tasks implemented by the Agency under the contribution agreements and a service level agreement. The nature of these tasks means that they can only be carried out at EU level.

This legislative proposal will lead to considerable **EU added value**. Adopting a self-standing regulation is necessary to enable the Agency to address current and future challenges, especially, in view of the wide range of tasks entrusted or in the process of being entrusted to the Agency through various legislative proposals (existing or under preparation). The adoption of this proposal is a reaction to these developments.

2.3 Proportionality

The proposal provides for targeted changes not going beyond what is necessary to achieve the set objectives to improve the governance of the Agency and the sustainability of its financial model. The targeted changes focus on improving the functioning of ECHA, its bodies and in particular the scientific committees (RAC and SEAC) whose tasks have increased overtime since the creation of the Agency. The proposals under preparation include new tasks deriving from the implementation of the CSS, which will further extend the tasks and the workload of the Agency and its scientific committees.

The proposal also seeks solutions which aim to simplify the complex financial model of the Agency.

There are no negative social, economic or environmental impacts that would outweigh the positive effect of the proposed measures for ECHA's governance and financial sustainability (see Section 3.4).

2.4 Choice of the instrument

The proposed instrument is a regulation, given that the initial provisions on the establishment of ECHA were adopted as part of the REACH Regulation. ECHA is now implementing not only REACH but also a wide range of EU chemicals legislation. Proceeding with a self-standing, dedicated regulation for ECHA would allow all the tasks under the mandate of ECHA stemming from this EU legislation to be covered.

3. RESULTS OF EXPOST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

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

An impact assessment was not required for this proposal since assessments were carried out by the Commission in the context of the revisions of some of the other EU legislation assigning tasks to the Agency, among others the revision of the CLP Regulation and the proposed Toys Regulation (see Section 3.4).

In the context of the preparation of the 'One Substance, One Assessment' proposals, and particularly, the proposal on the re-attribution of tasks to agencies, the Commission undertook a comprehensive assessment of the cumulative impacts of all proposals for reattribution since 2020[42].

In addition, an evaluation of ECHA's performance[43] was carried out as part of the second REACH review in 2018[44]. The evaluation covered the full range of ECHA's operations and processes under its mandate at that time[45].

The evaluation study assessed the obligations stemming from REACH, CLP, BPR and PIC and contrasted them with the activities implemented. The Agency's organisation, its resource allocation, the use of tools and the results achieved were compared with what was expected from the Agency. The data collection tools used to gather the relevant information comprised

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42 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 of the Council amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (SWD(2023) 850 final.

43 Directorate-General Internal Market, Industry, Entrepreneurship and SMEs, Review of the European Chemicals Agency (ECHA) established under Regulation (EC) No 1907/2006, https://ec.europa.eu/docsroom/documents/24301/attachments/1/translations/en/renditions/native.

44 Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Commission General Report on the operation of REACH and review of certain elements (COM(2018) 116 final).

45 Specifically: Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging (CLP), Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR) and Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (PIC).

a document review[46], stakeholder interviews[47], an online company survey[48], a comparative analysis with similar EU agencies and a limited process analytics exercise[49].

The evaluation confirmed that ECHA has been effective in executing the tasks allocated to it in all its work areas, but also concluded that there was still room for improvement by reducing costs and speeding up processes:

(a) the efficiency of the Management Board could be improved through flexible working methods and through creating a two-level governance structure in line with the Common Approach on decentralised EU agencies. Under this governance structure, the Management Board would be in charge of providing strategic direction and be assisted by an enlarged working group. This is expected to further increase effectiveness and efficiency, since the enlarged working group would provide members of the Management Board with experience in budgetary, financial, audit and human resources matters.

(b) on the scientific committees (RAC and SEAC) and their members, the evaluation concluded that sufficient capacity and expertise of the members is required to ensure that the committees can fulfil their duties properly and in a timely manner.

(c) RAC and SEAC may face increased workloads in the future due to the number of applications for authorisation under the REACH Regulation and the increased complexity of some files. Both committees should be enhanced to enable the Agency to deliver the opinions required in light of its future mandate.

Based on the evaluation of the Agency, the Commission General Report[50] on the operations for REACH concluded the following:

> *'ECHA has been instrumental in the implementation of REACH and has now built up a significant competence in chemicals management. ECHA has established a user-friendly website enabling stakeholders to easily access the world's largest database on chemicals. ECHA has also established scientific cooperation with the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA), as well*

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46 This covered amongst others ECHA's planning and monitoring documents, organisational strategies, policies and procedures, internal and external audit reports.

47 Analysing the results of ECHA's Stakeholder Annual Surveys and staff surveys as well as position papers of external stakeholders See: ECHA, Report on the operation of REACH and CLP 2021, https://echa.europa.eu/documents/10162/17226/operation_reach_clp_2021_en.pdf/e271b3c8-137a-48ad-30ad-499249235ee5?t=1622474863671, and ECHA, ECHA's 2021 staff engagement survey (MB/36/2021), https://echa.europa.eu/documents/10162/10340573/final_mb_36_2021_1_echa_staff_engagement_survey_mb63_en.pdf/cd21ec0b-0b60-ae86-e572-906329e2bb15, and Report archive - ECHA (europa.eu).Interviews were conducted with ECHA staff and management, members of the Agency's bodies, Commission officials, EU agencies, Member States Competent Authorities, peer agencies in third countries, Organisation for Economic Co-operation and Development (OECD), industry associations and individual companies and NGOs.

48 The online survey covered a representative selection of companies involved in ECHA's activities.

49 To compare the functioning of ECHA on specific indicators with practices implemented by other EU agencies, such as the organisational structure, management and governance as well as on communication resources and activities.

50 Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee Commission General Report on the operation of REACH and review of certain elements Conclusions and Actions Conclusions and Actions, COM/2018/0116 final, 5 March 2018.

as with other non-EU agencies, which should be further reinforced to ensure coherence and profit from synergies.'

Since then, the Agency has taken action to improve the working methods of its scientific committees under the REACH Regulation (RAC and SEAC). Nevertheless, some of the measures required (on structure and capacity) can only be implemented through the present proposal. Retrospective evaluations of ECHA bodies have also concluded that the functioning of the scientific committees needs to be reformed to increase their capacity. The nomination of RAC and SEAC members by Member States has been declining in the last years, against a background of increasing workload and complex dossiers. RAC and SEAC are working at their capacity limits, and are forced to deal with high turnover and a significant untapped potential for Member States to nominate more members to these committees. This has also resulted in certain competence gaps. The above factors risk hampering the efficient and effective performance of RAC and SEAC.

A process analysis covering BPC's work on socio-economic analysis and the analysis of alternatives (which are required by certain provisions of BPR) has also been carried out by the Agency. The analysis concluded that BPC currently lacks the specific expertise needed to perform such tasks.

In addition, the fitness check of the most relevant chemicals legislation (assessing over 40 pieces of legislation other than REACH) of 2019[51] showed that there are significant opportunities for streamlining EU agencies' technical and scientific work. This would improve efficiency across 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).

3.2 Stakeholder consultations

A public consultation was conducted under the second REACH review, which covered the review of ECHA. The results are published on the Europa webpage[52].

Stakeholders were informed and consulted on this initiative during the **Information Session on One Substance, One Assessment with Stakeholders** held on 1 June 2022. Some 800 participants followed this online event. Generally, there was large support for the initiative.

Representatives of Member States and EU agencies were informed about the initiative at the meeting of the Expert Group on **One Substance, One Assessment**[53] on 2-3 June 2022. They were supportive of the initiative.

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51 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 (COM/2019/264 final).

52 Results of the public consultation of the second REACH review (REACH Refit evaluation), https://single-market-economy.ec.europa.eu/sectors/chemicals/reach/reach-refit-evaluation-reach-review_en.

53 Register of Commission Expert Groups and other Similar Entities, https://ec.europa.eu/transparency/expert-groups-register/screen/expert-groups/consult?lang=en&groupID=3792.

A call for evidence[54] for this initiative was published by the Commission on the Commission website 'Have your say' on 12 September 2022. The public and stakeholders were invited to provide feedback on this initiative by 10 October 2022.

Generally, there was strong support for this initiative. A total of 57 submissions were received, the majority being from business associations and companies (in total around 63%), followed by non-governmental organisations (18%), public authorities (12%) and citizens (7%).

On ECHA's committees

The call for evidence has shown general agreement to carefully consider the capacities and, breadth of expertise of ECHA's bodies and workload they can deal with, while engaging with the process of updating ECHA's role and strengthening its governance. Moreover, some respondents suggested measures to improve the efficiency and the effectiveness of the Agency's committees by granting sufficient **flexibility** to the Agency to set up the committees and to decide how the committees operate, facilitating the use of more **external expertise** to support the existing committees (particularly RAC) on a 'need to have' basis, and to increase the capacity of both RAC and SEAC.

On new approach methodologies (NAMs)

The call for evidence has shown a consensus among the NGOs active in animal welfare on the need to **strengthen ECHA's contribution** to the use of non-animal methods and to the transition away from animal testing.

On cooperation with peer agencies

Most of the replies welcomed the **cooperation of the European Chemicals Agency with other agencies** and wished for strengthened coordination and cooperation with them and the facilitation of data sharing.

On financing of the Agency

Some respondents, in particular industry organisations drew attention to **fees** payable by undertakings to the Agency, which should be **proportionate** and cover only the services provided by the Agency. The Agency should remain a partially **fee financed agency** and should receive a balancing EU contribution.

On the Forum

In general, the replies identified the need to **clarify the role of the Forum** and increase the **resources for enforcement**.

On the need for an impact assessment

Some of the respondents advised undertaking **an impact assessment** as part of the preparation of the proposal.

Impact assessments have been carried out (see Section 3.4) when relevant for preparing the proposals entrusting the Agency with tasks.

[54] European Commission, Have your say – Public Consultations and Feedback, Published Initiatives, European Chemicals Agency – proposal for a basic regulation, https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13554-European-Chemicals-Agency-proposal-for-a-basic-regulation_en

3.3 Collection and use of expertise

The legal proposal is based on a body of material and studies. External expertise was used for the study supporting the evaluation on the performance of ECHA in 2017[55] in the context of the second REACH review[56]. This study assessed the efficiency, effectiveness, coherence and added value of the Agency. The Commission also took into account the input from ECHA, in particular the retrospective evaluations conducted in the context of ECHA evaluation programme on committees, the Board of Appeal and ECHA's financial model. The Commission also sought the advice of ECHA's Management Board and the Forum through surveys on the functioning of these two ECHA bodies.

The proposal addresses the recommendations of the Council[57] and Parliament[58] on how the Agency is financed. The initiative will also address the recommendations on ECHA in the European Court of Auditors Special Report 22/2020.

3.4 Impact assessment

An impact assessment was not required for this proposal given that assessments have been carried out by the Commission in the context of the revision of other EU legislation (among others the revision of the CLP Regulation and the planned Toys Regulation) assigning tasks to the Agency.

Moreover, there is little discretion in policy choice to achieve the objectives of strengthening ECHA's governance and increasing the sustainability of its financing model[59]. This applies, in particular, to the reduced and unpredictable fee income following the last registration deadline under the REACH Regulation in 2018 and the planned reassignment of scientific and technical work to EU agencies. Only a dedicated regulation for ECHA could allow this to be done at the EU level in a comprehensive manner.

The expected positive impact on ECHA's governance and financial sustainability are set out in the next section.

The proposed measures will not imply costs to businesses or have significant economic impact at EU scale. Neither will they have any significant social or environmental impacts. The initiative will have an impact on the Agency's resources and capacity needs of the scientific committees. The impact of the proposed measures were assessed quantitatively in

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55 Directorate-General Internal Market, Industry, Entrepreneurship and SMEs, Review of the European Chemicals Agency (ECHA) established under Regulation (EC) No 1907/2006. Final Report; https://ec.europa.eu/docsroom/documents/24301.

56 Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Commission General Report on the operation of REACH and review of certain elements (COM(2018) 116 final).

57 Council of the European Union, Council recommendations on the discharge to be given to the bodies set up under the TFEU and the Euratom Treaty in respect of the implementation of the budget for the financial year 2018 (5761/20 ADD 1, FIN 59 PE-L 5), https://data.consilium.europa.eu/doc/document/ST-5761-2020-ADD-1/en/pdf.

58 European Parliament, Report on discharge in respect of the implementation of the budget of the European Chemicals Agency for the financial year 2018 (2019/2086(DEC)), https://www.europarl.europa.eu/doceo/document/A-9-2020-0063_EN.pdf.

59 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 (COM(2020) 667 final), Section 2.3.1.

detail in cooperation with the Agency in the Staff Working Document[60] accompanying proposals under the 'One Substance, One Assessment' approach and will be further illustrated in the next section.

3.5 Regulatory fitness and simplification

This proposal is linked to the 'One Substance, One Assessment' proposals on the re-attribution of tasks to agencies and on the common data platform:

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 that of the chemical assessments. Re-attributing tasks to EU agencies will enable efficient use of resources by:

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

The proposal for a regulation on a common data platform will promote interoperability and findability of data and facilitate digitalisation, in line with its objective to remove technical barriers to sharing data. It will lay down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establish a monitoring and outlook framework for chemicals.

The 'One Substance, One Assessment' proposals have 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 the event of regulatory action on a chemical. Furthermore, assessment and consultation procedures and IT tools used to submit data and information will be more standardised across legislation, making them easier to manage and follow. Strengthening the coherence of assessments and reducing the potential for divergent scientific outcomes across legislation will reduce the uncertainty for companies stemming from potential divergent scientific outcomes across legislation.

In this context, this proposal intends to make ECHA's work more effective, efficient, and coherent by clarifying the legal framework in which it will operate. This is considered against the increase in the number of its existing tasks and the new tasks deriving from different CSS initiatives. The proposal for the regulation on ECHA should improve the use of the combined resources and simplify planning the Agency's budget and work.

- **Improved functioning of ECHA's committees and efficient delivery of assessments and opinions**

[60] 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 of the Council amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (SWD(2023) 850 final.

The legal framework of ECHA and its bodies, particularly RAC, SEAC, MSC, the Forum, and BPC, need to be clarified to enable the Agency to meet its future obligations. This proposal will also strengthen the capacity of RAC and SEAC, by increasing the number of members to be nominated and appointed to the committees and the number of co-opted members. This will ensure that the committees are well equipped to carry out their current and additional tasks[61] and deliver opinions in a timely manner. This proposal will also formalise the work that RAC currently carries out on providing assessments on occupational exposure limits (OELs), based on an ad hoc, service level agreement between the Commission and ECHA.

- **Strengthening the sustainability of the Agency's financing model**

The proposal will abolish the requirement for the segregation of the different budget strands of the Agency (REACH/CLP, BPR, environmental legislation strands) which impact ECHA's daily management. This will allow for more flexibility to deal with fluctuations in workload, which corresponds to the recommendations of the European Court of Auditors (CoA)[62]. Other measures are being explored outside the current proposal to make the Agency's resourcing more sustainable. There are plans to revise the REACH, CLP and BPR Fee Regulations to increase income from fees and charges and also to find mechanisms for reducing the volatility of income from fees payable to the Agency by duty holders.

- **Alignment and strengthening of the Agency's governance**

The Agency's governance structure will be updated and aligned with the Common Approach on EU agencies, where applicable, as concerns the planning of the Agency's activities, the financial rules, fraud prevention, the management of conflicts of interest, the independence of scientific committees and the Board of Appeal, the supervisory role of the Management Board, the headquarters agreement etc. This also includes the continuous, periodic evaluation of the Agency, which is not provided for under the REACH Regulation, which has regulated the Agency until now.

The periodic evaluation would assess the effectiveness and efficiency of the Agency and of its working practices and may address any potential need to review its structure, operation, field of action and the financial implications of this. The periodic evaluation would also contribute to enhancing public trust.

Moreover, the proposal will set out clearer provisions on the Agency's involvement in international activities and its participation in research and development projects in the context of EU research programmes.

- **Strengthened coherence of scientific output**

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61 In the future, the Committee for Risk Assessment will issue scientific opinions on chemical substances based on existing tasks and tasks deriving from initiatives under preparation, such as the additions to or redefinitions of existing tasks related to the revision of legislation at proposal stage, i.e. the CLP Regulation , tasks laid down in existing EU legislation (e.g. the Drinking Water Directive), and tasks that may be transferred to the Agency from the Scientific Committee for Health, Environmental and Emerging Risks, the Water Framework Directive, the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS), or in the field of safety, under the Toy Safety Directive as well as in the proposed Regulation on the safety of toys.

62 European Court of Auditors, Special Report 22/2020: Future of EU agencies – Potential for more flexibility and cooperation, https://op.europa.eu/webpub/eca/special-reports/agencies-performance-audit-22-2020/en/.

The provisions on the Agency's cooperation with other EU bodies, especially in cases of divergent opinions are clarified in line with the 'One Substance, One Assessment' approach and corresponding proposals for other EU bodies, i.e. EFSA, EU-OSHA, EMA and EEA.

3.6 Fundamental rights

The proposal has no consequences for the protection of fundamental rights. Processing of personal data will be performed in a way that ensures that the obligations on personal data protection laid down in Regulation (EU) 2016/679[63] and Regulation (EU) 2018/1725[64] are respected.

4. BUDGETARY IMPLICATIONS

The European Chemicals Agency has been established under the REACH Regulation since 2007. It is financed with balancing EU contributions and with fees and charges payable to the Agency by duty holders for activities under REACH, CLP and BPR Regulations. The Agency also receives an EU contribution for its activities implementing the environmental legislation (such as PIC, POPs, Batteries, DWD). The provisions on fees payable to the Agency are enshrined in the relevant Union legislation implemented by the Agency.

In the context of the implementation of CSS, each legislative proposal entrusting ECHA with new tasks has been accompanied by a legislative financial statement, except for the CLP and the Toys proposals and the Regulation on serious cross-border threats to health[65] (SCBHT), adopted in 2022. The resources for the first two proposals are to be covered by redeployment of existing resources under the REACH and CLP strand of ECHA's budget; these resources derive from Heading 1 –Single Market, Digital and Innovation of the budget under the current multiannual financial framework 2021-2027. EUCLEF and EUON are building blocks of the common data platform proposal. The human resources for EUON will be covered by the resources already authorised under the ad hoc agreements signed between the Commission and the Agency. As for EUCLEF, the human resources will need to be covered by redeployment within the Agency. The financial resources for both EUON and EUCLEF are covered by the ad hoc agreements until mid-2027.

Regarding the tasks delegated to ECHA in the frame of the SCBHT, the financial and budgetary resources are covered by a Contribution agreement between DG SANTE and ECHA until end 2027. Both the budgetary impact and financial resources under this Contribution Agreement are to be covered in the future under this extended mandate, resulting in an increase of the Agency's establishment plan with 1 (one) TA and an increase in the EU contribution.

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63 Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj).

64 Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).

65 Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU, PE/40/2022/REV/1 (OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).

However, the global resources of the Agency will have to be reassessed as part of the preparation of the next multiannual financial framework (2028-2035) to take into account, if necessary, the outcome of the legislative proposals currently pending.

The current proposal impacts the budget of the Agency as regards the activities of the SCCS and under occupational exposure limits (OELs). The legislative financial and digital statement accompanying this proposal covers the resource needs of the Agency for the tasks which have been implemented by the Agency under an ad hoc agreement (service level agreement) signed between the Commission and ECHA for the Agency's Committee for Risk Assessment to provide opinions on OELs to the Commission. This task has become structural and as it will not be discontinued, it needs to be part of the Agency's mandate and financed from the EU contribution to the Agency from 2028 onwards.

The additional staff that will need to be added in 2028 to the ECHA staff for this task amounts to 3 Temporary Agents (TA) and 2 Contractual Agents (CA).

Due to the new tasks related to the management of SCCS, it can be expected that the yearly operational expenditure would amount to EUR 500,000.00. The administrative costs of the additional 3 staff members ensuring the smooth operation of SCCS, rated at EUR 451,000 will come on top of those costs.

The resources for the other tasks remain unchanged at this stage. Any adjustments are to be dealt with in accordance with the Interinstitutional Agreement of 16 December 2020[66], in specifically the arrangements on Agencies.

5. OTHER ELEMENTS

5.1 Implementation plans and monitoring, evaluation and reporting arrangements

The monitoring and evaluation of the Agency's performance would largely be covered by the applicable mechanisms under this proposal. Periodic evaluation will cover in particular the effectiveness, efficiency and added value of the Agency and of its working practices. It may also address the possible need to modify the structure, operation, field of action and tasks of the Agency and the financial implications of any such modification. Further to this evaluation, the Commission will draw data through its representation in the Agency's Management Board meetings and the supervision, of the Agency's work that it carries out alongside the Member States.

5.2. Structure and content of the proposal

This proposal for an ECHA Regulation introduces a number of new provisions on the Agency, that were not previously featured under REACH. An overview of the articles which changed the most compared to the provisions currently in REACH or are new is set out below:

1. Objectives and tasks of ECHA[67]

66 Interinstitutional Agreement of 16 December 2020 between the European Parliament, the Council of the European Union and the European Commission on budgetary discipline, on cooperation in budgetary matters and on sound financial management, as well as on new own resources, including a roadmap towards the introduction of new own resources (OJ L 433, 22.12.2020, ELI: http://data.europa.eu/eli/agree_interinstit/2020/1222/oj).

67 Article 4 of the proposal for the Regulation on ECHA.

The Agency's objectives and extended scope of tasks, stemming from different pieces of other EU legislation is reflected in the corresponding provisions of this proposal. The other EU legislation assigning tasks is reflected in Annex I of this proposal to ensure that the Agency's responsibilities under other EU legislation are coherently and transparently reflected in this Regulation.

2. Organisational structure of ECHA[68]

The current organisational structure of the Agency, including all bodies of the Agency established under REACH and BPR, is laid down in this proposal to provide a coherent overview of the Agency's structure, which has expanded, together with its tasks, since the adoption of REACH. The SCCS is listed as a stand-alone scientific committee among ECHA committees and bodies. The rules on the governance of the Agency's committees are moved to this proposal, while the provisions on the specific tasks of the committees remain in REACH and BPR and are referred to in this proposal.

3. The role of the Executive Director[69]

Compared to the provisions in REACH, the rules on the appointment of the Executive Director in this proposal better specify their employment and provide for the evaluation of their performance and accountability[70]. The tasks of the Executive Director laid down in this proposal include, in addition to the existing tasks, drafting the Agency's financial rules and clarifying the Executive Director's role in coordinating between the different committees within the Agency in case of divergence between their scientific opinions[71]. The rules on the appointment, responsibilities and tasks of the Executive Director also aim to strengthen the diversity of the Agency's staff and its transparency and to reflect the attribution of new tasks to the Agency as a whole, taking into account the Common Approach.

4. Composition and functioning of RAC and SEAC[72]

To strengthen the governance of ECHA and ensure timely opinion development, the nomination by Member States of members for RAC and SEAC is no longer voluntary but mandatory. In addition, the number of co-opted members for both committees is no longer limited. Both measures aim to provide the required obligations and flexibility to address the expertise gaps in the membership and expertise of RAC and SEAC.

5. Composition and functioning of SCCS

To ensure that SCCS members have the specific qualifications and expertise, this proposal provides that the members of the SCCS are selected through the open call for the expression of interests, as it is currently the case under the 2015 Commission Decision. The terms of office of SCCS members should be 5 years, renewable once for the same period. The proposal should specify the maximum number of SCCS members. The Management Board should be able to agree that the committee co-opts additional members and/or external expertise depending on the existing or expected workload of this committee.

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68 Article 5 of the proposal for the Regulation on ECHA.
69 Articles 11 and 12 of the proposal for the Regulation on ECHA.
70 Article 11 of the proposal for the Regulation on ECHA.
71 Article 12 of the proposal for the Regulation on ECHA.
72 Article 14 of the proposal for the Regulation on ECHA.

6. Tasks of RAC and SEAC[73]

Compared to their responsibilities under REACH, the tasks of RAC and SEAC are extended in this proposal to reflect the other EU legislation assigning tasks to them. In addition, RAC's task to provide opinions on occupational exposure limits (OELs) and other aspects relevant to occupational exposure to hazardous chemicals such as biological limit values for hazardous chemicals to be carried out in accordance with Article 3 of Council Directive 98/24/EC, Articles 16, 16a and 18a of Directive 2004/37/EC of the European Parliament and of the Council and Articles 18c and 22a of Directive 2009/148/EC of the European Parliament and of the Council is included in this Regulation, since this work has become structural. Until now, it was carried out on the basis of an ad hoc agreement.

7. More flexibility in rules on rapporteurs and use of experts[74]

The conditions for the Agency to rely on the services of experts for the discharge of its tasks are further specified.

8. Financial provisions[75]

These include the rules on the single programming document of the Agency, which includes the three-year planning, the work programme of the following year and reporting requirements. The changes in the financial provisions result from the implementation of the Common Approach and the currently applicable financial rules for EU decentralised agencies. The changes introduced to the budget procedures and the presentation of accounts and discharge are minor. A new provision on the possibility to charge fees by the Agency for capacity building has been introduced. The proposal also allows ECHA to maintain a limited fund reserve from income form fees and charges, subject to the specific conditions set out in this proposal.

9. Delivery of decisions[76]

The proposal includes a provision clarifying that decisions of the Agency are delivered to the addressee via an information system designated by the Agency.

10. Divergence of opinions[77]

The requirements to monitor and, where possible, remedy diverging opinions between different scientific bodies have been aligned with the approach taken under the 'One Substance, One Assessment' proposals.

11. Delegation to the Commission[78]

The proposal includes a delegation of powers to the Commission and relevant provisions on the exercise of these powers. This allows the Commission to amend this Regulation, as required by the development of EU chemicals, to include relevant EU acts assigning tasks to the Agency. The proposal also includes a delegation of powers to the Commission to amend the limit of the fee reserve that the Agency may maintain.

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73 Article 13 and 15 of the proposal for the Regulation on ECHA.
74 Article 16 of the proposal for the Regulation on ECHA.
75 Chapter III on financial provisions (Articles 27-33) of the proposal for the Regulation on ECHA.
76 Article 39 of the proposal for the Regulation on ECHA.
77 Article 44 of the proposal for the Regulation on ECHA.
78 Article 46 of the proposal for the Regulation on ECHA.

12. Removal of rules on segregation of budgets[79]

Amendments to other legislation are required and envisaged by this proposal to delete the requirement for segregation of budgets from Article 78(2) of Regulation (EU) No 528/2012 on making available on the market and use of biocidal products, Article 24(2) of Regulation (EU) No 649/2012 concerning export and import of hazardous chemical and Article 16(2) of Regulation (EU) 2019/1021 on persistent organic pollutants. These amendments aim to strengthen the financial sustainability of ECHA.

13. Potential involvement of SEAC in analysis of alternatives under the BPR[80]

This proposal introduces the possibility for SEAC to contribute to the work of the Biocidal Products Committee on the analysis of the derogation criteria to allow the approval of active substances meeting the exclusion criteria. This analysis includes socio-economic considerations (an analysis of the impact on society of not approving the active substance compared to the risks to human health, animal health and the environment arising from the use of the substance, taking into account the availability of suitable and sufficient alternative substances or technologies).

14. Recurrent evaluation of ECHA by the Commission[81]

The periodic evaluation of ECHA is not required under the provisions on the Agency in REACH, but is required under the Common Approach. The evaluations will take place within two years of the entry into force of the ECHA Regulation, and every five years thereafter. Such evaluations also makes it possible to evaluate whether the Agency's mandate allows it to carry out the activities required by other EU legislation assigning tasks to the Agency.

In addition, the proposal incorporates the existing provisions on the Agency from REACH, which have become relevant for the Agency's functioning beyond REACH and applicable to the Agency's work under the sectoral EU legislation. These provisions are included in the proposal, subject to slight improvements to accommodate the Common Approach on EU Agencies and other horizontal issues (liability, combatting fraud, transparency and communication). Moreover, some provisions are incorporated with amendments to allow for sufficient flexibility for the application of specific rules set out in other EU legislation, for instance on the appointment of committee members, appeals, confidentiality of information and sharing of information in the context of international cooperation.[82]

As a result, these provisions (all Articles of Title X, except Articles 75(1), 77(2), 77(3), 91 and 111 and paragraph (2) of Article 118 in Title XII) are deleted from REACH. References to the deleted Articles of the REACH Regulation in other EU legislation should be construed as references to the proposed ECHA Regulation in accordance with the correlation table included in the proposal.

In addition, amendments to other legislation are required and envisaged by this proposal (see points 11 and 12 above).

79 Articles 47-50 of the proposal for the Regulation on ECHA.
80 Article 49(2) of the proposal for the Regulation on ECHA.
81 Article 54 of the proposal for the Regulation on ECHA.
82 See Articles 15(4), 23(3), 36(6) and 40(6) of the proposal on the ECHA Regulation.

5.3 Detailed explanation of the specific provisions of the proposal

The proposal is structured as follows:

(1) Chapter I (Articles 1 to 4) includes the subject matter of the Regulation as well as the legal status, the seat, and general and specific tasks of the Agency. In particular, the new provisions provide that Helsinki, Finland, has been chosen as its seat by common agreement between the representatives of Member States (Article 3). Further, new provisions reflect the Agency's objectives and the extended scope of its tasks under the different pieces of sectoral EU legislation (set out in Annex I) as well as under this Regulation (Article 4).

(2) Chapter II (Articles 5 to 26) addresses the internal organisation of the Agency. The Agency's administrative and management structure (Article 5) provides an overview of the different bodies of the Agency and their main tasks. This includes the Biocidal Products Committee established under the Biocidal Products Regulation, to ensure that the overview is comprehensive. The relevant governance rules for each of the different bodies of the Agency are set out in the remaining Articles of Chapter II and explained below.

(3) Articles 6 to 10 on the composition and function of the Management Board further clarify and strengthen the Agency's governance and aim, in particular to enhance the Agency's actions on fraud and the management of fees, and to adequately reflect the Agency's task to co-operate with other EU bodies, stakeholders and relevant actors at the international level. This includes provisions on the Management Board's Chairperson (Article 7), meetings (Article 8), functions (Article 9), and voting (Article 10).

(4) Article 11 on the appointment of the Executive Director specifies the Executive Director's employment conditions and provides for the evaluation of their performance and their accountability. The Executive Director's tasks and responsibilities (Article 12) are set out in detail. They include the drafting of the Agency's financial rules and clarify the Executive Director's role in coordinating between the different bodies within the Agency in case of divergence between their scientific opinions and in protecting the EU's financial interests. The new provisions on both appointment of the Executive Director and their responsibilities and tasks also aim to strengthen the diversity of the Agency's staff and transparency. This reflects the attribution of new tasks to the Agency as a whole, taking into account the principles of the Common Approach.

(5) Chapter II includes an article specifying the tasks of RAC, SEAC, MSC BPC and SCCS (Article 13). Article 14 on the membership of the committees and Article 15 on the functioning of the committees aim, in particular, to increase the capacity of RAC and SEAC (to address their increasing workloads) by enshrining the obligation to nominate two members per Member State for RAC and two members for SEAC. The number of co-opted members is currently limited to five members for RAC and five members for SEAC, as well as five members for MSC. Article 14 allows for more flexibility on the number of co-opted members for RAC and SEAC but leaves it to the Agency to decide on the appropriate procedures. Moreover, provisions on the appointment of the rapporteurs and co-rapporteurs and the use of experts by those committees are contained in Articles 14 and 16 respectively.

(6) Chapter II also contains provisions on the composition and functioning (Article 17) and the tasks (Article 18) of the Forum, as well as on the qualifications and declaration

of interest of the members of RAC, SEAC, MSC, BPC, SCCS and the Forum (Article 19).

(7) Lastly, Chapter II contains the relevant provisions on the composition and membership of the Agency's Board of Appeal (Articles 20 and 21), including on exclusions and objections (Article 22). It sets out which decisions are appealable (Article 23), under what conditions (Article 24) and contains provisions on the examination and decisions on appeals (Article 25) as well as the right to bring actions before the General Court and Court of Justice of the European Union (Article 26). The new rules on the members of the Board of Appeal clarify the procedure for the renewal of the terms of office. Other amendments to the current rules made in Chapter II are necessary to provide for the link to all relevant pieces of EU legislation.

(8) Chapter III (Articles 27 to 33) on the financial provisions of the Agency sets out the requirements concerning single programming documents (Article 27), the establishment, structure, and implementation of the budget (Articles 28 to 30), as well as the presentation of accounts and discharge (Article 31), financial rules (Article 32) and combatting of fraud (Article 33).

(9) Chapter IV (Articles 34 to 35) concerns the staff of the Agency, including general provisions (Article 34) and specific rules on seconded national experts and other staff (Article 35) while also setting out which privileges and immunities apply to staff (Article 36).

(10) Chapter V (Articles 37 to 39) on information and communication, concerns the information held by the Agency, covering the rules on transparency and communication (Article 37) and security rules on the protection of sensitive non-classified information (Article 38). Chapter V also contains a provision specifying how decisions of the Agency are delivered to the addressee (Article 39).

(11) Chapter VI (Articles 40 to 45) on cooperation addresses the Agency's cooperation with Member States (Article 40), stakeholders (Article 41), international organisations and third parties (Article 42) and the Agency's involvement in research and innovation to allow ECHA to take part in EU research programmes (e.g. Partnership for the Assessment of Risks from Chemicals 'PARC') (Article 43). It also contains rules on relations with relevant EU bodies (Article 44) and potential conflicts of opinion with other bodies (Article 45).

(12) Chapter VII concerns the delegated powers and the conditions related to the exercise of the delegation by the Commission (Article 46) and the committee procedure applicable to the implementing power by the Commission (Article 47).

(13) Chapter VIII (Articles 48-51) includes the necessary provisions to abolish the segregation of the Agency's budget in the legislation implemented by the Agency, *i.e.* the BPR, PIC and POPs Regulations.

(14) Chapter IX (Articles 52 and 53) contains transitional provisions with regard to the Executive Director, the members of the Management Board, RAC, SEAC, MSC, BPC, and the Forum and staff (Article 52) as well as transitional budgetary provisions (Article 53).

(15) Chapter X (Articles 54 to 57) contains the final provisions. This includes Article 54 on the evaluation of the performance of ECHA, which introduces provisions to allow for a recurrent evaluation of the performance of the Agency (initially within two years and every five years thereafter). Moreover, the chapter covers the Agency's liability

(Article 55), headquarters agreement (Article 56), language arrangements (Article 57) and entry into force (Article 58).

(16) The two annexes to the proposal contain the list of relevant EU legislation assigning tasks to the Agency (Annex I) and the correlation table, setting out how references to provisions of the REACH Regulation deleted by this proposal are to be construed as references to specific provisions of this Regulation (Annex II).

ANNEXES TO THE EXPLANATORY MEMORANDUM

Annex 1 – Additional tasks to the Agency

In the context of the implementation of the 'one substance, one assessment' approach, new and additional tasks for the Agency have been proposed and/or agreed as part of the following proposals for chemicals legislation:

1. Industrial Emissions Directive[83]

The revised Industrial Emissions Directive aims to **formalise a task** that **ECHA** carried out on an ad hoc basis and **extend it** to cover the holistic consideration of chemicals in the permits for Industrial Emissions Directive installations, from the presence of the chemicals in question in the (primary or secondary) raw materials to their presence in the emissions from the installations and in the waste and by-products generated. ECHA is requested to support the Commission in the review of the best available techniques reference (BREF) documents for the chemicals and industrial chemicals processes.

2. Water Framework Directive, Environmental Quality Standards Directive and Groundwater Directive[84]

The 2022 Commission proposal to revise the Water Framework Directive, the Environmental Quality Standard Directive and the Ground Water Directive aims to **reattribute existing tasks** performed by the Commission and the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) to **ECHA, attribute a new task** to **ECHA** and **expand the tasks** that **EEA** carries out. ECHA and its Committee for Risk Assessment are requested under the Environmental Quality Standard Directive to take over assessment activities underpinning the amendment of the list of priority substances in surface waters, the derivation of Environmental Quality Standards, including for selected river basic specific pollutants, and the amendment of the surface-water 'watch list'. ECHA and its Committee for Risk Assessment are requested under the Ground water Directive to perform new assessments underpinning the review of Annexes I and II including quality standards and threshold values for chemicals in ground water, and amendment of the groundwater 'watch list'. For both watch lists, analysis of the monitoring data and support in relation to the identification of monitoring methods is requested, as well as coordination between those two 'watch list' activities and the watch list under the Drinking Water Directive. EEA is requested to expand its task of collecting monitoring data from surface and groundwaters generated by Member States.

3. CLP Regulation[85]

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83 Directive (EU) 2024/1785 of the European Parliament and of the Council of 24 April 2024 amending Directive 2010/75/EU of the European Parliament and of the Council on industrial emissions (integrated pollution prevention and control) and Council Directive 1999/31/EC on the landfill of waste (OJ L, 2024/1785, 15.7.2024, ELI: http://data.europa.eu/eli/dir/2024/1785/oj).

84 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 (COM(2022) 540 final).

85 Regulation (EU) 2024/2865 of the European Parliament and of the Council of 23 October 2024 amending Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (OJ L, 2024/2865, 20.11.2024, ELI: http://data.europa.eu/eli/reg/2024/2865/oj).

The proposal for the revision of the CLP Regulation aims to attribute a **new task** to **ECHA** and the European Food and Safety Authority (**EFSA)** and **expand the existing tasks** of **ECHA**. ECHA and EFSA are required to prepare dossiers for the harmonised classification of substances at the request of the Commission. ECHA's Committee for Risk Assessment is then expected to prepare opinions on the dossiers prepared by ECHA and EFSA, which will be submitted to the Commission for potential amendments to Annex VI of CLP.

4. Packaging and Packaging Waste[86]

The revision of the EU legislation on packaging and packaging waste proposes to **extend the scope of ECHA's task** to process, or potentially also to prepare, a proposal for a restriction under REACH that covers or is focused on the presence of a substance in packaging. Such restriction will fall under the scope of REACH, and will therefore rely on the existing REACH tasks.

5. Directive on Restriction of Hazardous Substances (RoHS) in electrical and electronic equipment

The proposal for the amendment of the RoHS Directive adopted as part of the 'one substance, one assessment package'[87] aims to **reattribute the existing tasks** carried out by the Commission to **ECHA** and to **improve the execution of those tasks**. ECHA is required to prepare a restriction dossier for substances in electrical and electronic equipment at the request of the Commission. This dossier can be also prepared by a Member State. ECHA's Committees for Risk Assessment and for Socio-Economic Analysis are then requested to prepare an opinion on the restriction dossier (prepared by itself or by a Member State) and to submit this opinion to the Commission. ECHA is also requested to receive applications for granting, renewing or revoking an exemption from the substance restrictions, verify their completeness, obtain the opinion of its Committee for Socio-Economic Analysis and, if necessary, from its Committee for Risk Assessment and submit the opinions to the Commission.

6. POPs Regulation

The proposal for amendment of the POPs regulation via the omnibus regulation on (re)attribution of tasks aims to **reattribute the existing tasks** carried out by the Commission to **ECHA** and **EEA** and **improve how those tasks are executed**. At the request of the Commission, ECHA is expected to provide assessments underpinning introducing and modifying concentration limit values set for substances subject to waste management provisions as part of the review of Annexes IV and V of the POPs regulation. As part of that assessment, ECHA is required to prepare a report on the assessment with the proposal for introducing or modifying concentration limit values, obtain the opinion of its Committee for Socio-Economic Assessment on the report and submit the opinion to the Commission as an

86 Regulation (EU) 2025/40 of the European Parliament and of the Council of 19 December 2024 on packaging and packaging waste, amending Regulation (EU) 2019/1020 and Directive (EU) 2019/904, and repealing Directive 94/62/EC (OJ L, 2025/40, 22.1.2025, ELI: http://data.europa.eu/eli/reg/2025/40/oj)

87 Commission proposal for a Directive of the European Parliament and of the Council amending Directive 2011/65/EU of the European Parliament and of the Council as regards the re-attribution of scientific and technical tasks to the European Chemicals Agency (COM(2023) 781 final 2023/0454 (COD).

input for the amendment of Annexes IV and V through a delegated act. EEA is expected to host the chemical monitoring data in the environment of the POPs listed in Annex III, Part I.

7. Medical Devices Regulation

The proposal for amendment of the medical product regulation via the omnibus regulation on (re-)attribution of tasks aims to **reattribute the existing tasks** carried out by SCHEER to **ECHA**. ECHA is required to review the guidelines on how to perform the benefit-risk assessment of the presence of phthalates in medical devices every five years. In addition, at the request of the Commission, ECHA is required to prepare and review the guidelines on how to perform the benefit-risk assessment of the presence of carcinogenic, mutagenic, reprotoxic or endocrine-disrupting substances in medical devices.

8. Common Data Platform on Chemicals and a Monitoring and Outlook Framework[88]

The proposal for a regulation on a common data platform assigns **new tasks** to **ECHA, EEA, EFSA, EMA** and **EU-OSHA**. ECHA is requested to set up and operate the common data platform on chemicals, including the database of standard formats and controlled vocabularies. All agencies are requested to make the data on chemicals they hold available to the platform in appropriate formats for sharing among the authorities, to set formats and controlled vocabularies in their area of competence so data can be easily shared and to cooperate with ECHA and with each other in developing and operating the common data platform.

- **Information Platform for Chemical Monitoring (IPCHEM)**

The proposal for a regulation on a common data platform aims to **reattribute the existing task** carried out by the Commission to **ECHA** and **EEA**. ECHA is required to operate the IPCHEM as part of the common data platform on chemicals and to host occupational monitoring data, including occupational human biomonitoring data. EEA is requested to collect and host the human biomonitoring data other than from occupational studies and to host environmental occurrence data and indoor air quality data. The proposal will also formalise the tasks of ECHA, EFSA, EEA, EMA and EU-OSHA to provide available chemical monitoring data to ECHA for integration into IPCHEM.

- **Repository of reference values**

The proposal for a regulation on a common data platform attributes a **new task** to **ECHA, EFSA, EEA, EMA** and **EU-OSHA**. ECHA is requested to set up, operate and populate a repository of reference values with scientific and regulatory reference values and to collate the regulatory reference values in it. EFSA, EEA, EMA and EU-OSHA are required to cooperate with ECHA in the operation of the repository and provide the scientific reference values they derive from their work to ECHA.

- **Information on regulatory processes on chemicals**

The proposal for a regulation on a common data platform aims to formalise and **expand the task that ECHA** already carries out with the (Public) Activities Coordination Tool

[88] Commission proposal for a Regulation of the European Parliament and of the Council establishing a common data platform on chemicals, laying down rules to ensure that the data contained in it are findable, accessible, interoperable and reusable and establishing a monitoring and outlook framework for chemicals (COM(2023) 779 final 2023/0453 (COD)).

('(P)ACT'). ECHA is required to continue the operation of (P)ACT and extend it to cover all relevant pieces of legislation on chemicals.

- **Information on obligations under EU acts on chemicals**

The proposal for a regulation on a common data platform proposes to formalise and **expand the existing task ECHA** is already carrying out with the EU chemicals legislation finder ('EUCLEF'). ECHA is required to continue the operation of EUCLEF and extend it to cover all relevant legislative pieces on chemicals.

- **Database on environmental sustainability related data**

The proposal for a regulation on a common data platform attributes a **new task** to **ECHA**. ECHA is requested to set up and operate a database with environmental sustainability data on chemicals. ECHA, EEA, EFSA, EMA and EU-OSHA are required to make any environmental sustainability related data they host or hold available to ECHA. The agencies also need to provide the necessary technical cooperation to ECHA to enable the integration of the data into the common data platform on chemicals.

- **Data generation mechanism**

The proposal for a regulation on a common data platform attributes a **new task** to **ECHA** and **EFSA**. ECHA is enabled to commission studies in support of the implementation of chemicals legislation and to contribute to the support, evaluation or development of EU chemicals policy. ECHA can do this either on its own initiative or at the request of the Commission. The procedure is complementary to the existing procedure operated by EFSA under Article 32 of the General Food Law, and ECHA and EFSA should cooperate in designing and commissioning the studies under both procedures.

- **Mechanism for notification of studies and database for study notifications**

The proposal for a regulation on a common data platform attributes a **new task** to **ECHA**. ECHA is required to set up a database of study notifications for studies beyond the food sector (*i.e.* for studies not already subject to the notification obligation of Article 32b of the General Food Law and notified to EFSA). ECHA and EFSA are required to cooperate to ensure the compatibility of the respective systems

- **Early warning and action system for emerging chemical risks and framework of indicators**

The proposal for a regulation on a common data platform attributes a **new task** on an early warning and action system to **EEA, ECHA, EFSA, EMA** and **EU-OSHA**. It also proposes to **formalise the task** on an indicator framework that **EEA** and **ECHA** already carry out. For the early warning system, EEA is required to compile and collect the early warning signals annually into a report to be presented to the Member State authorities, relevant EU agencies and the Commission, which will consider whether any regulatory action is needed. ECHA, EFSA, EMA and EU-OSHA are required to cooperate with EEA and provide early warning signals from their areas of responsibility. For the framework of indicators, EEA and ECHA are required to operate and populate the indicator framework for chemicals policy.

- **Observatory for specific chemicals with potential contribution to emerging chemical risks**

The proposal for a regulation establishing a common data proposes to formalise the task that ECHA already carries out and to expand its scope. ECHA is required to continue operating

the existing observatory for nanomaterials and to extend its scope to chemicals and materials of potential emerging risk.

9. Directive on end-of-life vehicles[89]

The proposal for the revision of the Directive on end-of-life vehicles **reattributes an existing task** to **ECHA**. ECHA's Committee for Socio-Economic Assessment will be required to provide assessments underpinning the review of exemptions from existing restriction on lead, mercury, cadmium or hexavalent chromium. ECHA is also required to provide assessments underpinning restriction of hazardous substances in end-of-life vehicles as part of REACH process. Such restriction will be under the scope of REACH, and therefore relies on the existing REACH task.

10. Toy Safety Regulation[90]

The proposal for the new toy safety regulation **reattributes existing tasks** to **ECHA** and **extends** some of them. ECHA's committees for risk assessment and socio-economic analysis are required to provide assessments to grant derogations for the use of substances subject to generic bans in toys. In addition, ECHA may be requested to provide assessments underpinning the establishment or strengthening of chemical limit values in toys, the amendment of the limit values for heavy metals in toys and the amendments to the lists of allergenic fragrances that are prohibited in toys or that must be labelled if present in toys.

11. Cross-border Threats to Health Regulation[91]

The regulation aims to strengthen coordination and cooperation for a more effective response to serious cross-border health threats at both the European Union and EU Member State levels by:

- strengthening prevention, preparedness and response planning;
- reinforcing epidemiological surveillance and monitoring;
- improving data reporting; and
- strengthening EU intervention.

ECHA contributes to the tasks under the regulation together with the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), the European Food Safety Authority (EFSA), the European Environment Agency (EEA), the European Union Drugs Agency (EUDA), and the European Union Agency for Law Enforcement Cooperation (Europol). This Regulation proposes to attribute or formalise the following additional tasks to the Agency:

1. Scientific opinions on occupational exposure limits (OELs)

89 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 Regulation (EU) 2018/858 and 2019/1020 and repealing Directives 2000/53/EC and 2005/64/EC (COM (2023) 451 final).

90 Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC (COM(2023) 462 final).

91 Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26–63, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).

This proposal for the ECHA Regulation aims to integrate **into ECHA's mandate an existing task** that has been carried out by the Agency in line with an ad hoc agreement with the Commission. ECHA and its Committee for Risk Assessment will be given a legal mandate to provide opinions on occupational exposure limits in support of the Directive on carcinogens, mutagens or reprotoxic substances at work[92], the Chemical Agent Directive[93] and the Asbestos Directive[94].

2. Involvement of SEAC in the Biocidal Products Regulation

This proposal for the ECHA Basic Regulation attributes a **new task to SEAC**. It envisages the committee's contribution to the work of the Biocidal Products Committee on the analysis of the derogation criteria to allow the approval of active substances meeting the exclusion criteria, including socio-economic considerations.

3. European Partnership for the Assessment of Risks from Chemicals (PARC)

PARC is a seven-year partnership funded by Horizon Europe that started in May 2022 and aims to advance research, share knowledge and improve skills in chemical risk assessment. **ECHA** took a **new task** to provide input and support to the project to ensure maximum links with and benefits for the regulatory risk assessments of chemicals. The proposed provisions formalise the participation of ECHA in research funded by EU programmes.

4. The Scientific Committee on Consumer Safety (SCCS)

This proposal for the ECHA Regulation aims to integrate **into ECHA's mandate a new task** that was previously carried out by the Commission Directorate-General on Health and Food Safety. The Scientific Committee on Consumer Safety (SCCS) was established in 2015 by a Commission Decision[95] and was responsible for various health and safety related risk assessments. However, in ECHA, the SCCS will be responsible for the scientific opinions and advise relating to the safety of substances used in cosmetic products.

92 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50, ELI: http://data.europa.eu/eli/dir/2004/37/oj).

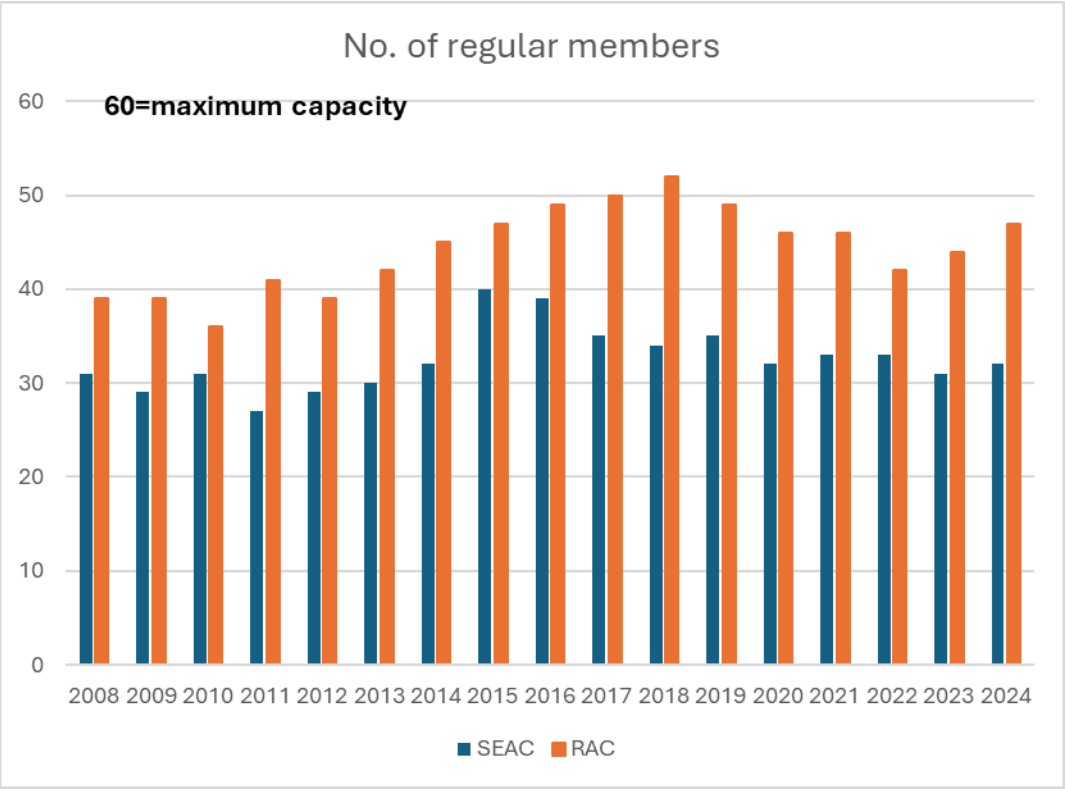
93 Council Directive 98/24/EC of 7 April 1998 on the protection of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11, ELI: http://data.europa.eu/eli/dir/1998/24/oj).

94 Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p. 28, ELI: http://data.europa.eu/eli/dir/2009/148/oj).

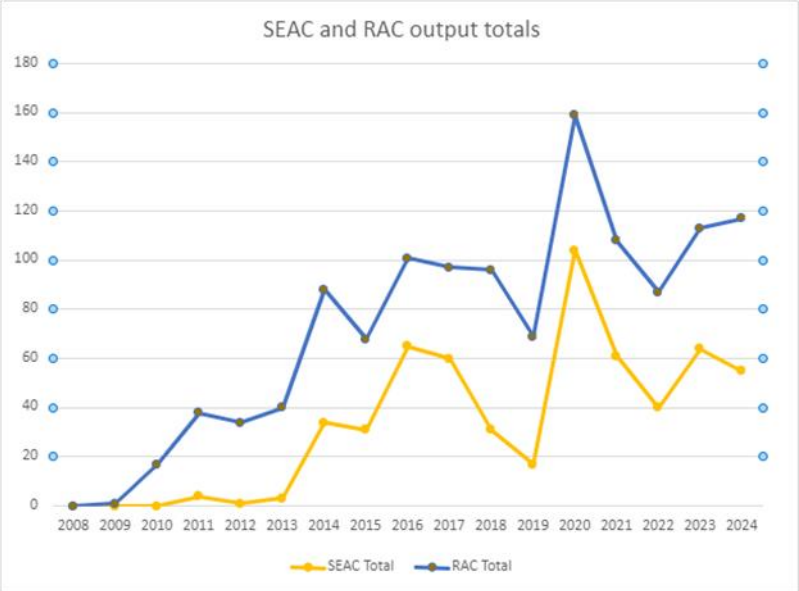
95 Commission Decision (EU) 2024/1514 of 7 August 2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment, OJ L, 2024/1514, 31.5.2024, ELI: http://data.europa.eu/eli/dec/2024/1514/oj.

Annex 2 – Current set-up and expected additional workload of RAC and SEAC

The table below shows the development of regular members in RAC and SEAC over the past years. Currently RAC membership is only at 50% capacity, as nominations by Member States have declined and some Member States have not nominated any members for RAC and SEAC.



The number of RAC opinions per year following the (re-)attribution of tasks is expected to increase by 72% compared to the present. It should be noted that the biggest increase is expected to derive from obligations under the Drinking Water Directive (50 to 150 opinions) and from the CLP Regulation (13.5 opinions on average). The remainder of the legislation is expected to account for an average of 16.5 opinions per year. The increase in the number of SEAC opinions is moderate. These estimations are indicative of the number of opinions to be delivered by RAC.



Source: The European Chemicals Agency

The table below gives an overview of the new tasks affecting the work of RAC and SEAC. These tasks result from legislation that has recently entered into force, new proposals for sectoral legislation and this Regulation:

No	Legislation in force	Tasks	Expected impact on committee's workload
1	Drinking Water Directive (2020/2184)	• Establishing and maintaining four EU positive lists for substances and compositions authorised to be used for the manufacturing of organic, cementitious, metallic and inorganic materials in contact with water intended for human consumption	**RAC:** 20-100 opinions / year
2	Batteries Regulation (2023/1542/EU)	• Assessment underlying the restriction of hazardous substances in batteries	**RAC:** 1 opinion / year **SEAC:** 1 opinion / year
No	**Proposed amendments of Union legislation**	**Tasks**	**Expected impact on committee's workload**
3	Amendments of the Water Framework Directive (2000/60/EC),	• Analysing chemical monitoring data from surface and groundwater (from	**RAC: 5** opinions / year **SEAC: 5** opinions /

	Environmental Quality Standards Directive (2008/105/EC) and the Groundwater Directive (2006/118/EC) (proposal)	monitoring of the 'watch list' substances) • Assessments underpinning the amendment of list of priority substances and derivation of environmental quality standards, also for river basin specific pollutants • Assessments underpinning the review of Annexes I and II to the Groundwater Directive • Technical and scientific work related to the amendment of the surface and groundwater 'watch lists' (under the EQSD and GWD) and coordination of the 'watch lists' including with the list under the Drinking Water Directive • Identification of suitable analytical methods where necessary	year
4	Amendment of the CLP Regulation (1272/2008) (proposal)	• Assessments of dossiers for harmonised classifications prepared on behalf of the Commission	**RAC:** 0 opinions / year
5	Amendment of the Packaging and Packaging Waste Directive (94/62/EC) (proposal)	• Assessments underpinning restrictions of substances in packaging **using REACH restriction** process • Performing a scoping exercise related to the presence of chemicals in packaging	**RAC:** 0 opinion / year **SEAC:** 0 opinion / year
6	Amendment of the RoHS Directive (2011/65/EU) (proposal)	• Assessments underpinning restrictions of hazardous substances in electrical and electronic equipment • Review of applications for exemptions from the restrictions	**RAC:** 1 opinions / year **SEAC:** 1 opinions / year **RAC:** 3 opinions / year **SEAC:** 30 opinions / year
7	Amendment of the POPs Regulation via	• Technical assistance in reviewing Annexes IV and V	**SEAC:** 2 opinions / year

	the Regulation on the (re-)attribution of tasks to the agencies (EU) (2019/1021) (proposal)	(by ECHA)	
8	Proposal for a Regulation on end-of-life vehicles (2000/53/EC) (proposal)	• Restriction of hazardous substances in end-of life vehicles via REACH process • Assessments underpinning the review of exemptions from restriction on lead, mercury, cadmium or hexavalent chromium	**RAC:** 0 opinion / year **SEAC:** 2.2 opinion / year
9	Proposal for a Regulation on the Safety of Toys, repealing the Toy Safety Directive (2009/48/EC) (proposal)	• Assessment underpinning chemical limit values in toys for children • Assessment underpinning setting the limit values for 'heavy metals' • Assessment underpinning amendments to the lists of allergenic fragrances that are prohibited in toys • Assessment underpinning a derogation for the use of substances subject to generic bans in toys	**RAC:** 6 opinions / year **SEAC:** 6 opinions / year
No	**This proposal**	**Tasks**	**Expected impact on committee's workload**
10	Scientific opinions on occupational exposure limits	• Assessments underpinning setting the EU occupational exposure levels (5 opinions/year) in support of the Carcinogens and Mutagens Directive (2004/37/EC), Chemical Agents Directive (98/24/EC) and asbestos at work directive (2009/148/EC)	**RAC:** 5 opinions / year but this is an existing task.
11	Involvement of SEAC in the Biocidal Product Regulation	• Contribution of SEAC to the work of the BPC on the assessment of active substances	**SEAC:** 5 contributions / year

Sum	**RAC: 116** **SEAC: 52**

2025/0207 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the European Chemicals Agency and amending Regulations (EC) No 1907/2006, (EU) No 528/2012, (EU) No 649/2012 and (EU) 2019/1021

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) 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[96]

Having regard to the opinion of the Committee of the Regions[97],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The European Chemicals Agency ('the Agency') was established by Article 75(1) of Regulation (EC) No 1907/2006[98] as the central entity to ensure the effective management of the technical, scientific and administrative aspects of that Regulation and their consistency at Union level, following the results of a feasibility study which concluded that an independent central entity offered a number of long-term advantages over other options.

(2) The structure of the Agency was set up taking into account experience gained from similar Union agencies, while adapting it to the specific needs of Regulation (EC) No 1907/2006. It comprises a Management Board, an Executive Director, a Committee for Risk Assessment ('RAC'), a Committee for Socio-economic Analysis ('SEAC'), a Member State Committee ('MSC'), a Forum for Exchange of Information on Enforcement ('the Forum'), a Secretariat and a Board of Appeal. With the adoption of

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96 OJ C , , p. .

97 OJ C , , p. .

98 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, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

Regulation (EU) No 528/2012[99], the Biocidal Products Committee ('BPC') was established within the Agency.

(3) The Agency and its bodies have been involved in each stage of the implementation of Regulation (EC) No 1907/2006, providing technical and scientific assessments, opinions, guidance and tools for the Commission, Member States and duty holders in the framework of the registration and evaluation of substances as well as for restrictions and authorisations. The Agency has also played an important role in coordinating the communication around Regulation (EC) No 1907/2006 and has provided administrative support to the Commission, national competent authorities and duty holders.

(4) Since its establishment under Regulation (EC) No 1907/2006, additional tasks and responsibilities have been assigned to the Agency and its committees by other Union legislation in the fields of, for instance, chemicals, product safety and environmental policy. The Agency should carry out the tasks assigned to it under both this Regulation and sectoral Union legislation. For transparency and to provide a coherent overview of the Agency's responsibilities under sectoral Union legislation, such legislation should be listed in Annex I of this Regulation.

(5) The 'One substance, One assessment' approach, which is part of the European Green Deal[100], calls for more transparent and simpler chemical safety assessment processes to reduce the burden for stakeholders, accelerate decision-making, as well as to increase consistency, coherence and predictability. Therefore the Chemicals Strategy for Sustainability ('CSS')[101] indicates that, part of the scientific and technical work on chemicals performed at Union level in support of Union legislation needs to be re-attributed to the most suitable agencies by targeted amendments of existing relevant chemicals legislation when those are revised and by the 'One substance, One assessment' legislative package[102]. The CSS also announced a Commission proposal to strengthen the governance of the Agency and increase the sustainability of its financing model.

(6) The Agency was established before the endorsement of the Common Approach of the European Parliament, the Council of the European Union and the European

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99 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj).

100 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).

101 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).

102 Regulation (EU) XXXX/XXX 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, Directive (EU) XXXX/XXX 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 and Regulation (EU) XXX/XXX 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.

Commission on decentralised agencies[103] ('Common Approach') which put in place a comprehensive set of guiding principles to make the functioning of the Union's decentralised agencies more coherent, effective and accountable.

(7) Against this background, the Agency should be governed by a single Regulation in order to cover in one act the Agency's extended tasks and involvement in the implementation of several pieces of legislation and to ensure its efficient and sustainable governance, taking into account the principles of the Common Approach. This Regulation should therefore replace the provisions of Regulation (EC) No 1907/2006 governing the Agency. The Agency was initially established by Article 75(1) of Regulation (EC) No 1907/2006. That establishment should not be affected by this Regulation.

(8) The seat of the Agency is in Helsinki, Finland, pursuant to the Decision taken by the common agreement between the representatives of the Member States, meeting at head of state or government level of 13 December 2003 (2004/97/EC, Euratom)[104],. That decision should be reflected accordingly in this Regulation.

(9) The Agency should continue to contribute to the implementation and enforcement of Union legislation and policies related to the hazards, risks and safe use of chemical substances in order to achieve a high level of protection of human health and the environment, the efficient functioning of the internal market and coherence and consistency in chemicals management across the Union, while enhancing competitiveness and innovation, taking into account the specific needs of small and medium-sized enterprises and promoting alternatives to animal testing.

(10) The Agency should, in particular, provide technical and scientific support, guidance and tools to facilitate the development, implementation and enforcement of the Union's legislation and policies on chemicals and to improve cooperation within the Union, between the Member States and on an international level. The Agency should also ensure that relevant, reliable, and objective information on chemicals is available to the general public, engage with relevant stakeholders and collaborate with other Union Agencies and Member States competent authorities.

(11) The structure of the Agency should be suitable for its tasks and should take into account the experience gained from the Agency's functioning and performance since its establishment. It is essential to ensure that the Agency is equipped to perform its tasks with high scientific and technical capacities to ensure the highest possible quality. As trust in the Agency by the Union institutions, the Member States, the general public and interested parties is vital, it should carry out its tasks transparently and efficiently.

(12) In the interest of efficiency, the staff of the Agency's Secretariat should be able to perform technical and administrative tasks in support of RAC, SEAC, MSC,Scientific

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103 Joint Statement of the European Parliament, the Council of the European Union and the European Commission on decentralised agencies – Common Approach, 2012.

104 2004/97/EC, Euratom: Decision taken by common agreement between the Representatives of the Member States, meeting at Head of State or Government level, of 13 December 2003 on the location of the seats of certain offices and agencies of the European Union (OJ L 29, 3.2.2004, p. 15, ELI: http://data.europa.eu/eli/dec/2004/97(1)/oj).

Committee on Consumer Safety ('SCCS')[105],, Biocidal Products Committee ('BPC') (collectively, the 'Committees'), and the Forum.

(13) The Management Board of the Agency should be entrusted with the necessary powers, in particular to appoint the Executive Director, the members of RAC and SEAC and of the Board of Appeal, and to adopt the consolidated annual activity report, the programming document, the annual budget, and the financial rules applicable to the Agency. The Commission, the European Parliament, and the Member States should be represented within the Management Board in order to effectively exercise oversight over it. In the interests of transparency, interested parties without voting rights should be appointed to the Management Board by the Commission.

(14) The Agency should be headed by an Executive Director assisted by one or more directors or heads of department to ensure the efficient execution of the Agency's tasks in an independent manner.

(15) To provide the Commission with thorough scientific assessments, RAC, SEAC, BPC, as well as SCCS, should continue to issue scientific opinions in accordance with relevant Union legislation assigning tasks to the Agency or its relevant Committees.

(16) RAC has, provided scientific opinions on evaluations of Occupational Exposure Limits ('OELs'), and other aspects relevant to occupational exposure to hazardous chemicals such as biological limit values for hazardous chemicals in the context of Article 3 of Council Directive 98/24/EC[106]. Articles 16, 16a and 18a of Directive 2004/37/EC of the European Parliament and of the Council[107] and Articles 18c and 22a of Directive 2009/148/EC of the European Parliament and of the Council[108] on the basis of an ad hoc agreement between the Commission and the Agency in the past. Since this task has become customary and in order to consolidate that practice, this Regulation should establish that RAC should provide such opinions upon request from the Commission. In addition, RAC should, upon a request from the Commission, provide scientific opinions on all other matters related to the hazards, risks and safe use of chemical substances, on their own, in mixtures or in articles as defined in Article 3, paragraphs 1, 2 and 3 of Regulation (EC) No 1907/2006.

(17) SCCS, established on 7 August 2015 by Commission Decision (EU) 2024/1514, plays a central role in the scientific assessment of the safety of substances and mixtures used

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105 The Scientific Committee on Consumer Safety was established by Commission Decision (EU) 2024/1514 of 7 August 2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment, OJ L, 2024/1514, 31.5.2024, ELI: http://data.europa.eu/eli/dec/2024/1514/oj.

106 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p.11, ELI: http://data.europa.eu/eli/dir/1998/24/oj).

107 Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p.50, ELI: http://data.europa.eu/eli/dir/2004/37/oj).

108 Directive 2009/148/EC of the European Parliament and of the Council of 30 November 2009 on the protection of workers from the risks related to exposure to asbestos at work (OJ L 330, 16.12.2009, p.28, ELI: http://data.europa.eu/eli/dir/2009/148/oj).

in cosmetic products, as managed by Regulation (EC) No 1223/2009[109]. While SCCS should form part of the administrative structure of the Agency as one of its committees, it is essential that it retains its characteristics distinct from other committees in the Agency. Those include, in particular, an open expert selection process, independence from other Agency committees and a five-year term of office for its members, which are fundamental to maintaining the committee's expertise.

(18) The Management Board should adopt the rules of procedure of RAC, SEAC, MSC, BPC and SCCS, including the procedural arrangements for the Committees working groups. In order for the Commission to exercise its oversight, the Commission representatives in the Management Board should approve the rules of procedure, without compromising the independence of the Committees and their working groups.

(19) The opinions of RAC and SEAC should be based on the broadest possible scientific and technical expertise available within the Union. To this end, each Member State should nominate two members for RAC and SEAC respectively and should be entitled to nominate up to two additional members. RAC, SEAC, BPC and SCCS should have the possibility to co-opt members and to rely on the services of experts, taking into account the workload, type of expertise needed and availability of financial resources.

(20) Through MSC, the Agency should aim to reach agreement amongst Member States authorities on specific issues under Regulation (EC) No 1907/2006 which require a harmonised approach.

(21) The Agency should continue to provide a Forum for Member States to exchange information and coordinate their activities related to the enforcement of chemicals legislation. To ensure that risk management measures can be properly enforced, the Forum should give advice on the enforceability of such measures where this is provided for in Union legislation.

(22) It is necessary to ensure that certain decisions made by the Agency can be appealed before the Board of Appeal of the Agency. Therefore, the Board of Appeal, originally established under Regulation (EC) No 1907/2006 , should assess appeals against those Agency's decisions for which a right to appeal has been established pursuant to the relevant Union legislation assigning tasks to the Agency. The Board of Appeal should continue to be assisted by the Registry, as established by Article 5(1) of Commission Regulation (EC) No 771/2008[110].

(23) The Agency should have the means to perform all the tasks assigned to it. In order to guarantee the full autonomy and independence of the Agency as well as its financial sustainability, it should be granted an autonomous budget, principally funded from a contribution from the Union, fees payable by duty holders and voluntary contributions from Member States. No financial contribution received by the Agency from Member States, third countries, or other entities or persons should compromise its independence and impartiality. The Union budgetary procedure should be applicable as far as the Union contribution and any other subsidies chargeable to the general

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109 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) (OJ L 342, 22.12.2009, p. 59, ELI: http://data.europa.eu/eli/reg/2009/1223/oj).

110 Commission Regulation (EC) No 771/2008 of 1 August 2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p.5, ELI: http://data.europa.eu/eli/reg/2008/771/oj)

budget of the Union are concerned, while the auditing of accounts should be carried out by the European Court of Auditors.

(24) The financial and administrative framework in which the Agency operates is more complex than for other Union agencies[111], as the Agency is partially financed by fees for its activities under Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008[112] and Regulation (EU) No 528/2012 and as it currently has three separate budgets under Regulation (EC) No 1907/2006, under Regulation (EU) No 528/2012, as well as under Regulations (EU) No 649/2012[113] and (EU) 2019/1021[114]. To simplify the Agency's financing model, the requirement for segregated budgets established under Regulation (EU) No 528/2012, Regulation (EU) No 649/2012, and Regulation (EU) 2019/1021 should be abolished, by deleting the relevant provisions in those Regulations, so that the Agency receives one unitary annual contribution from the Union budget. This will allow for more flexibility for the Agency to address workload fluctuations and will respond to the recommendations of the Court of Auditors and to the objective of the CSS to increase the sustainability of the Agency's financing model. The removal of the segregation of budgets should not affect existing obligations of financial contributions by third countries to the Agency.

(25) The Agency has experienced difficulties to accurately predict the income from fees and charges even with the most advanced statistical techniques due to the paucity of information on the drivers of demand from duty holders. This impacts the operations of the Agency and requires recurrent amendments to the budget by the Management Board. Therefore, the Agency should be allowed to create a reserve from the surplus of its revenues from fees and charges, subject to the conditions set out in this Regulation. This will allow the Agency to mitigate the consequences of large fluctuation in income from fees and charges. Specifically, the creation of such reserve will allow the Agency to increase the sustainability of its financing model without prejudice to the annual Union contribution and multiannual financial programming. The detailed rules on the parameters, the calculation and the operation of the reserve should be laid down in the Agency's financial rules and should include the requirements set out in this Regulation. The calculation of the amount of the annual contribution to the reserve or of the amount made available from the reserve, to be included in the draft budget of the Agency, should follow a methodology mechanically applied by the Agency every year.

(26) In order to be able to address the large fluctuations in the Agency's revenues from fees, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) should be delegated to the Commission in respect of amending the specific conditions defined for the reserve. It is of particular

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111 European Court of Auditors, Future of EU agencies, potential for more flexibility and cooperation, Special Report (2020), doi:10.2865/36103.

112 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, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

113 Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals (OJ L 201, 27.7.2012, p.60, ELI: http://data.europa.eu/eli/reg/2012/649/oj).

114 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, ELI: http://data.europa.eu/eli/reg/2019/1021/oj).

importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[115]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(27) The application of Article 29(5) and (6) of this Regulation, allowing the Agency to maintain a reserve, and of Article 49(3) and Articles 50 and 51 of this Regulation, removing the requirement for segregated budgets, should be deferred to the date of application of the post-2027 Multiannual Financial Framework to allow alignment with the next Multiannual Financial Framework.

(28) Union citizens should have access to information about chemicals to which they may be exposed, in order to allow them to make informed decisions about their use of chemicals. The Agency should therefore provide the public with adequate information pertaining to the hazards, risks and safe use of chemicals.

(29) The Agency should respect the conditions on use of information which are communicated to the Agency, including rules on access to documents, information and data security and protection of confidential data. To this end, the confidentiality assessment and disclosure of information or data held by the Agency should be subject to specific rules on confidentiality and disclosure, set out in the respective Union legislation under which the information or data was generated or submitted to the Agency. The Agency should adopt its own security rules on the protection of sensitive non-classified information held by the Agency.

(30) The Agency should cooperate closely with relevant international organisations, other governmental and non-governmental bodies and relevant technical bodies from inside and outside the Union in the implementation of its tasks, notably to avoid duplication of work and to ensure access to all data and tools needed for achieving its objectives. In particular, the Agency should cooperate with the European Centre for Disease Prevention and Control, the European Environmental Agency, the European Food Safety Authority, the European Medicines Agency and the European Agency for Safety and Health at Work, to ensure coherence and efficiency of assessments related to chemicals across Union legislation, in line with the 'One Substance, One Assessment' approach. Since past cases of divergent opinions have led to increased uncertainty for operators, as well as to declined public trust in the scientific robustness and coherence of scientific decision-making, procedures for the resolution of divergences between scientific opinions between Union agencies should be reinforced.

(31) The Agency should continue to play an active role in research and innovation, assisting Member States and the Commission in the promotion of substitution of the most harmful chemicals and in the development of scientific methods, notably animal-free approaches, to assess hazards of chemicals as well as risks and socio-economic impacts of their use.

(32) To ensure that the Agency achieves its objectives in an efficient and effective manner and that it has the necessary means to fulfil its tasks, the Commission should conduct

[115] OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

an evaluation of the Agency's work on a regular basis and its mandate should be adapted accordingly, if needed.

(33) The implementing powers relating to determining the qualifications required for the members of the Board of Appeal, which were set out in Commission Regulation (EC) 1238/2007[116], and the procedures of the Board of Appeal should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and Council[117].

(34) In order for this Regulation to effectively govern the Agency, corresponding provisions previously set out in Regulation (EC) No 1907/2006 and Regulation (EU) No 528/2012 should be deleted. Since sectoral Union legislation, in particular Regulation (EC) No 1272/2008, Regulation (EU) 2022/2371 of the European Parliament and of the Council[118] and Regulation (EU) 2023/1542 of the European Parliament and of the Council[119], refer to articles related to the Agency in Regulation (EC) No 1907/2006, such references in sectoral Union legislation to deleted Articles of Regulation (EC) No 1907/2006 should be construed as references to this Regulation, in accordance with the correlation table set out in Annex II to this Regulation.

(35) In the context of Regulation (EU) No 528/2012, the Agency provides opinions on the approval or renewal of approval of biocidal active substances that meet the exclusion criteria set out in Article 5(1) of that Regulation and which should normally not be approved unless it is demonstrated that at least one of the derogation criteria set out in Article 5(2) of that Regulation is met. The analysis of the conditions for derogations may include socio-economic considerations. For reasons of efficiency and consistency across Union legislation, it is appropriate that SEAC contributes to the work of BPC for such analysis and that therefore Regulation (EU) No 528/2012 be amended accordingly.

(36) It is necessary to lay down transitional provisions related to the budget and to the Management Board, the Executive Director, the Board of Appeal, RAC, SEAC, MSC, BPC and the Forum and staff of the Agency to ensure the continuation of the Agency's activities pending the implementation of this Regulation.

(37) The objectives of this Regulation, namely the effective and sustainable governance of the Agency, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level. The Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In accordance with the principle of

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116 Commission Regulation (EC) No 1238/2007 of 23 October 2007 on laying down rules on the qualifications of the members of the Board of Appeal of the European Chemicals Agency (OJ L 280, 24.10.2007, p. 10, ELI: http://data.europa.eu/eli/reg/2007/1238/oj).

117 Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

118 Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p.26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).

119 Regulation (EU) 2023/1542 of the European Parliament and of the Council of 12 July 2023 concerning batteries and waste batteries, amending Directive 2008/98/EC and Regulation (EU) 2019/1020 and repealing Directive 2006/66/EC (OJ L 191, 28.7.2023, p.1, ELI: http://data.europa.eu/eli/reg/2023/1542/oj).

proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

The European Chemicals Agency ('the Agency'), established by Regulation (EC) No 1907/2006, shall continue to operate in accordance with this Regulation.

Article 2

Legal status

1. The Agency shall be a body of the Union and shall have legal personality.
2. In each of the Member States, the Agency shall enjoy the most extensive legal capacity accorded to legal persons under national law. It may, in particular, acquire or dispose of movable and immovable property, and be party to legal proceedings.
3. The Agency shall be represented by an Executive Director.

Article 3

Seat

The Agency shall have its seat in Helsinki, Finland, as decided by the Common Agreement between the Representatives of the Member States of 13 December 2003 (2004/97/EC, Euratom)[120].

Article 4

Objectives and tasks of the Agency

1. The Agency shall contribute to the implementation and enforcement of Union legislation and policies related to the hazards, risks and safe use of chemical substances, mixtures and articles, provide scientific opinions and advice and independent information on all matters within that field and communicate on those matters.
2. In the fulfilment of its objectives, the Agency shall aim to contribute to a high level of protection of human health and the environment, to the free circulation of substances in the internal market and coherence and consistency in chemicals

[120] 2004/97/EC, Euratom: Decision taken by common agreement between the Representatives of the Member States, meeting at Head of State or Government level, of 13 December 2003 on the location of the seats of certain offices and agencies of the European Union (OJ L 29, 3.2.2004, p. 15, ELI: http://data.europa.eu/eli/dec/2004/97(1)/oj).

assessment and management across the Union, while enhancing competitiveness and innovation, taking into account the specific needs of small and medium-sized enterprises ('SMEs') as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises[121] and promoting alternatives to animal testing.

3. The Agency shall provide the Member States and the institutions of the Union with the best possible scientific and technical advice on chemicals-related questions which fall within its remit and which are referred to in this Regulation or other Union legislation assigning tasks to the Agency ('sectoral Union legislation').

4. The Agency shall serve as a point of reference by virtue of the independence and scientific and technical quality of its assessments and opinions and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it.

5. The Agency shall have the following general tasks:

(a) carry out any duties assigned to it or its Secretariat pursuant to this Regulation;

(b) provide technical and scientific support, guidance, IT tools and digital infrastructure for the development, implementation and enforcement of this Regulation and sectoral Union legislation taking into account the specific needs of SMEs and the goal of replacing animal testing with alternatives where scientifically possible;

(c) upon request by the Commission, provide technical and scientific support with a view to improving cooperation among and between the Union, Member States, acceding countries, third countries and international organisations, as well as participate in technical assistance and capacity building activities on sound management of chemicals in developing countries;

(d) upon request by the Commission, provide technical and scientific support to the implementation of international agreements and conventions and to the work of international bodies.

(e) upon request by the Commission, provide scientific and technical assistance in any field within its competence, in the form of scientific or technical work involving the application of well-established scientific or technical principles not requiring scientific evaluation by the Committees or the working groups of those committees;

(f) participate in research activities in accordance with Article 43;

(g) ensure that the general public and interested parties have access to relevant, reliable, and objective information on the implementation of this Regulation and sectoral Union legislation;

(h) engage with relevant stakeholders as appropriate in matters falling within its competences;

[121] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj)

(i) collaborate with other Union agencies and national authorities as appropriate for the fulfilment of its tasks, in accordance with Articles 40 and 44;

(j) express its own conclusions, advice and opinions on matters falling within its competences where this is foreseen in sectoral Union legislation;

(k) upon request from the Commission, undertake any other task related to its objectives.

6. Sectoral Union legislation assigning specific tasks to the Agency is listed in Annex I.

CHAPTER II
ORGANISATION OF THE AGENCY

Article 5

Administrative and management structure of the Agency

1. The Agency's administrative and management structure shall comprise the following:

(a) a Management Board, which shall exercise the functions set out in Article 9;

(b) an Executive Director, who shall exercise the responsibilities set out in Article 12;

(c) a Committee for Risk Assessment ('RAC'), which shall be responsible for preparing opinions of the Agency relating to risks of chemicals to human health or the environment;

(d) a Committee for Socio-economic Analysis ('SEAC'), which shall be responsible for preparing opinions of the Agency relating to the socio-economic impact of possible legislative measures on substances;

(e) a Member State Committee ('MSC'), which shall carry out the tasks assigned to it pursuant to sectoral Union legislation;

(f) the Biocidal Products Committee ('BPC') established under Article 75(1) of Regulation (EU) No 528/2012 which shall be responsible for preparing opinions of the Agency in accordance with that Regulation;

(g) a Scientific Committee on Consumer Safety ('SCCS'), which shall carry out the tasks assigned to it in Regulation (EC) No 1223/2009;

(h) a Forum for Exchange of Information on Enforcement ('the Forum') which shall coordinate a network of Member States authorities responsible for enforcement of sectoral Union legislation, where that legislation assigns such tasks to the Forum;

(i) a Secretariat, which shall work under the leadership of the Executive Director and undertake the work required of the Agency in accordance with sectoral Union legislation, provide technical, scientific and administrative support to the Committees and the Forum, and ensure appropriate coordination between them;

(j) a Board of Appeal, which shall decide on appeals against decisions taken by the Agency, where such a right of appeal is established in sectoral Union legislation.

2. The committees and the Forum may establish working groups. For this purpose, they shall adopt, in accordance with their respective rules of procedure, detailed arrangements for delegating certain tasks to such working groups.

Article 6

Composition of the Management Board

1. The Management Board shall be composed of:

   (a) one representative from each Member State, nominated by that Member State;

   (b) six persons appointed by the Commission, namely, three representatives of the Commission and three persons representing interested parties,

   (c) two experts appointed by the European Parliament.

2. The representatives of the Member States, the representatives of the Commission and experts appointed by the European Parliament shall have voting rights. The persons representing interested parties, appointed by the Commission, shall not have voting rights.

3. The persons representing interested parties shall be appointed by the Commission following a call for expressions of interest. They shall be chosen, with regard to ensuring broad representation, from non-governmental stakeholders in the field of:

   (a) industry;

   (b) trade unions;

   (c) environment;

   (d) health;

   (e) consumer protection

4. Members of the Management Board shall be appointed on the basis of their knowledge and relevant experience in the field of chemical safety or regulation of chemicals, taking into account relevant managerial, administrative and budgetary skills. In accordance with the principle of equal treatment between men and women, all parties nominating and appointing members of the Management Board shall aim to achieve gender balance on the Management Board. Members, alternates and observers of the Committees and the Forum or their working groups shall not be eligible to become members of the Management Board.

5. The term of office for members of the Management Board shall be four years and may be renewed once. All parties represented in the Management Board pursuant to Article 6 shall make efforts to limit the turnover of their representatives.

6. Members of the Management Board shall act exclusively in the interests of the Agency.

7. The Management Board may establish working sub-groups to assist it with carrying out its tasks, including with the preparation of its decisions and with the monitoring of the implementation thereof.

Article 7

Chairperson of the Management Board

1. The Management Board shall elect a Chairperson and a Deputy Chairperson from among its members with voting rights, by a majority of two-thirds of those members.

   The Deputy Chairperson shall automatically replace the Chairperson if the Chairperson is prevented from performing their duties.

2. The term of office of the Chairperson and of the Deputy Chairperson shall be two years, and may be renewed once. If their membership of the Management Board ends during their term of office, their term of office shall automatically expire on that date.

Article 8

Meetings of the Management Board

1. The Chairperson shall convene the meetings of the Management Board.
2. The Executive Director of the Agency shall take part in the meetings of the Management Board, without the right to vote.
3. The Management Board shall hold at least two ordinary meetings a year. In addition, it shall meet on the initiative of its Chairperson, at the request of the Commission, or at the request of at least one third of its members.
4. The Management Board may invite any other person, whose opinion may be of interest, to attend its meetings as an observer.
5. The members of the Management Board may, in accordance with the rules of procedure, be assisted at the meetings by advisers or experts.
6. The Chairpersons of the Committees and the Forum, shall be entitled to attend the meetings of the Management Board, without the right to vote.
7. When a member has a conflict of interest regarding a point on the agenda, the Management Board shall discuss and decide on that point on the agenda without the presence of that member. Detailed rules for the application of this provision may be laid down in the rules of procedure of the Management Board.
8. The Secretariat shall provide administrative and legal support to the Management Board under the responsibility of the Executive Director.

Article 9

Functions of the Management Board

1. The Management Board shall:
   (a) adopt the general orientation for the Agency's activities in the form of a strategy statement;
   (b) endorse the draft single programming document and adopt the final single programming document in accordance with Article 27;
   (c) adopt the annual budget of the Agency and exercise other functions in respect of the Agency's budget in accordance with Articles 27 to 30;
   (d) adopt the financial rules applicable to the Agency;
   (e) adopt rules for the prevention and management of conflicts of interest in respect of its members, the members of the Committees, the Forum and the

Board of Appeal, seconded national experts, experts and other staff not employed by the Agency as referred to in Article 34, and ensure that the declarations of interests referred to in Article 19(2) are published annually on the Agency's website;

(f) adopt and regularly update the communication and dissemination plans referred to in Article 37(3);

(g) adopt working arrangements to implement the dialogue referred to Article 41;

(h) approve the international cooperation framework referred to in Article 42, and the technical assistance programmes referred to in sectoral Union legislation;

(i) invite, where it deems appropriate and in agreement with the relevant committee or the Forum, representatives of third countries and international organisations with interest in the field of chemicals regulation to participate as observers in the work of the Agency;

(j) develop, in agreement with the Commission, appropriate contacts between the Agency and relevant stakeholder organisations;

(k) adopt and make publicly available its rules of procedure;

(l) exercise, with respect to the staff of the Agency, the powers conferred by Regulation No 31 (EEC), 11 (EAEC)[122], on the appointing authority and on the authority empowered to conclude a contract of employment (the 'appointing authority powers');

(m) adopt, in agreement with the Commission, appropriate implementing rules for giving effect torticle 110 of the Staff Regulations of Regulation No 31 (EEC), 11 (EAEC);

(n) appoint the Executive Director and, where relevant, decide on an extension of the term of office or a removal from office of the Executive Director;

(o) adopt the internal rules and procedures of the Agency and ensure that they are made public;

(p) appoint an accounting officer, who shall be independent in the performance of duties;

(q) appoint the members of RAC and SEAC following nomination by the Member States;

(r) appoint the members of SCCS following a call for the expression of interests;

(s) adopt the rules of procedure of the Committees, and of the Forum on the Forum's proposal in accordance with Article 17(5);

(t) appoint the Chairperson, members and alternates of the Board of Appeal in accordance with Article 20(3);

(u) adopt decisions on the transfer of compensation to Member States, where applicable under sectoral Union legislation;

[122] Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community (OJ 45, 14.6.1962, p. 1385, ELI: http://data.europa.eu/eli/reg/1962/31(1)/oj).

(v) adopt decisions, where necessary, on the level of fees for capacity-building programmes for third countries, where such programmes are not covered by a dedicated Union funding;

(w) adopt its own security rules for the protection of sensitive non-classified information in accordance with Article 38;

(x) ensure adequate follow up to findings and recommendations stemming from internal or external audit reports and evaluations and from investigations of the European Anti-fraud Office (OLAF) and of the European Public Prosecutor's Office (EPPO), as referred to in Article 33;

(y) adopt the practical arrangements for complying with Regulation (EC) No 1049/2001 of the European Parliament and of the Council[123], including appeals or remedies necessary for reviewing a partial or full rejection of a confidentiality request;

(z) endorse the Executive Director's proposal on the establishment and, where necessary, the modification of the Agency's internal structures, taking into consideration the Agency's activity needs and having regard to sound budgetary management.

2. The Management Board shall adopt, in accordance with Article 110 of the Staff Regulations of Regulation No 31 (EEC), 11 (EAEC), a decision based on Article 2(1) of the Staff Regulations and on Article 6 of the Conditions of Employment of Other Servants of Regulation No 31 (EEC), 11 (EAEC, delegating relevant appointing authority powers to the Executive Director and setting out the conditions under which that delegation of powers can be suspended. The Executive Director shall be authorised to sub-delegate those powers. Where exceptional circumstances so require, the Management Board may, by way of a decision, temporarily suspend the delegation of the appointing authority powers to the Executive Director and those sub-delegated by the Executive Director, and exercise them itself or delegate them to one of its members or to a staff member other than the Executive Director.

Article 10

Voting rules of the Management Board

1. The Management Board shall act by a two third majority of all its members with voting rights.

2. The Management Board shall adopt rules of procedure for voting, including the conditions under which a member is allowed to vote on behalf of another member.

3. In the event that the Commission raises serious concerns on a decision proposal presented to the Management Board on matters related to Commission Delegated Regulation (EU) 2019/715[124] on the Framework financial regulation for decentralised

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123 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43, ELI: http://data.europa.eu/eli/reg/2001/1049/oj).

124 Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council (OJ L 122, 10.5.2019, p. 1, ELI: http://data.europa.eu/eli/reg_del/2019/715/oj).

regulatory agencies or to the Staff Regulations and the Conditions of Employment of Other Servants of Regulation No 31 (EEC), 11 (EAEC), the Management Board shall postpone the adoption of the decision. Within 15 days, the Management Board shall re-examine and adopt it, possibly amended, in second reading, either with a two-thirds majority, including the Commission representatives, or by a four fifths majority of the representatives of the Member States.

Article 11

Appointment, renewal of the term of office and removal from office of the Executive Director

1. The Executive Director shall be engaged as a temporary agent of the Agency under Article 2, point (a), of the Conditions of Employment of Other Servants of Regulation No 31 (EEC), 11 (EAEC).

2. The Executive Director of the Agency shall be appointed by the Management Board on the basis of a list of candidates proposed by the Commission following a call for expressions of interest published in the *Official Journal of the European Union* and in other periodicals or on Internet sites. The selection procedure shall be open and transparent and shall respect the principles of equal treatment and of gender balance.

3. The Executive Director shall be appointed on the grounds of merit and documented administrative and management skills, as well as of experience relevant to the fulfilment of the Agency's tasks.

4. Before the Management Board appoints a person to the post of Executive Director, the candidate selected by the Management Board may be invited, without delay, to make a statement before the competent committee or committees of the European Parliament and answer questions from the committee members. After hearing the statement and the responses, the European Parliament may set out its views and submit them to the Management Board.

5. For the purpose of concluding the contract of the Executive Director, the Agency shall be represented by the Chairperson of the Management Board.

6. The term of office of the Executive Director shall be five years. In due time before the end of that period, the Commission shall carry out an assessment based on an evaluation of the performance of the Executive Director and the Agency's future tasks and challenges.

7. The Management Board, acting on a proposal from the Commission based on the assessment referred to in paragraph 6, may extend the term of office of the Executive Director once for another five years.

8. An Executive Director whose term of office has been extended shall not be eligible to participate in any future selection procedures.

9. The Executive Director may be removed from office only upon a decision of the Management Board acting on a proposal from the Commission.

10. The Management Board shall reach decisions referred to in this Article on the basis of a two-thirds majority of its members with voting rights.

Article 12

Tasks and responsibilities of the Executive Director

1. The Executive Director shall manage the Agency and shall be accountable to the Management Board.

2. The Executive Director shall perform his or her duties in the interest of the Union, and independently of any specific interests.

3. Without prejudice to the powers of the Commission and of the Management Board, the Executive Director shall be independent in the performance of his or her duties and shall neither seek nor take instructions from any Union institution, body, office or agency, nor from any government or from any other public and private body.The Executive Director shall report to the European Parliament or the Council on the performance of tasks under this Regulation when invited to do so by the respective institution.

4. The Executive Director shall be the legal representative of the Agency.

5. The Executive Director shall be responsible to implement the following tasks assigned to the Agency:

   (a) ensure the day-to-day administration of the Agency;

   (b) make proposals for endorsement to the Management Board for the establishment and, if necessary, modification of the Agency's internal structures, taking into consideration the Agency's activity needs and having regard to sound budgetary management;

   (c) manage all the Agency's resources as necessary for carrying out its tasks;

   (d) ensure the fulfilment of the time-limits laid down in sectoral Union legislation for the adoption of opinions by the Agency and by the Committees;

   (e) ensure appropriate and timely coordination between the different bodies within the Agency, including with regard to potential divergence between their scientific opinions, in accordance with Article 45;

   (f) conclude and manage necessary contracts with service providers;

   (g) provide the secretariat for the Management Board;

   (h) prepare the rules of procedure proposed by the Committees and of the Forum for adoption by the Management Board;

   (i) make arrangements, on request of the Management Board, for the implementation of any request addressed to the Agency by the Commission;

   (j) establish and maintain a regular dialogue with the European Parliament;

   (k) determine the terms and conditions for use of software packages;

   (l) rectify any decision made by the Agency following an appeal, after consulting the Chairperson of the Board of Appeal, in accordance with Article 25(1);

   (m) implement decisions adopted by the Management Board;

   (n) prepare draft financial rules for the Agency and ensure their compliance;

   (o) prepare the draft single programming document referred to in Article 27 and submit it to the Management Board for adoption;

   (p) implement the single programming document referred to in Article 27 and report to the Management Board on its implementation;

(q) prepare a consolidated annual activity report on the Agency's activities and present it to the Management Board for assessment;

(r) protect the financial interests of the Union, by applying preventive measures against fraud, corruption and any other illegal activities, without prejudicing the investigative competence of OLAF and EPPO, by effective checks and, if irregularities are detected, by recovering amounts wrongly paid and, where appropriate, by imposing effective, proportionate and dissuasive administrative penalties and by reporting any criminal conduct to the EPPO in accordance with Article 24 of Council Regulation (EU) 2017/1939[125] in respect of which the EPPO could exercise its competence;;

(s) prepare the Agency's provisional draft estimate of revenue and expenditure referred to in Article 28 and implement the Agency's budget.

6. The Executive Director shall be responsible for all staff matters for which authority has been delegated pursuant to Article 9(2). In the recruitment of the Agency's staff, the Executive Director shall promote diversity and inclusion and aim to achieve gender balance and broad geographical representation.

7. The Executive Director shall decide whether it is necessary to locate staff in one or more Member States for the purpose of carrying out the Agency's tasks in an efficient and effective manner. Before deciding to establish a local office, the Executive Director shall obtain the prior consent of the Commission, the Management Board and the host Member State concerned. The decision shall specify the scope of the activities to be carried out at the local office in a manner that avoids unnecessary costs and duplication of administrative functions of the Agency. An agreement to set up a local office with the host Member State concerned may be concluded by the Executive Director.

8. The Executive Director may be assisted by one or more directors or heads of department. The Executive Director may appoint one of the directors or heads of department as an interim replacement in case of the Executive Director's absence.

Article 13

Tasks of the committees

1. Each committee of the Agency shall perform the tasks assigned to it under sectoral Union legislation.

2. In addition to the tasks referred to in paragraph 1, RAC shall, upon request from the Commission, provide scientific opinions on:

(a) evaluations of occupational exposure limits, and other aspects relevant to occupational exposure to hazardous chemicals such as biological limit values for hazardous chemicals, in the context of Article 3 of Directive 98/24/EC, Articles 16, 16a and 18a of Directive 2004/37/EC and Articles 18c and 22a of Directive 2009/148/EC.

[125] Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office (the EPPO) (OJ L 283, 31.10.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/1939/oj).

(b) all other matters not already covered by paragraph 1 or paragraph 2(a), related to the hazards, risks and safe use of chemical substances, on their own, in mixtures or in articles as defined in Article 3, paragraphs 1, 2 and 3 of Regulation (EC) No 1907/2006.

3. The number of such scientific opinions to be delivered and the timelines for their provision shall be decided between the Commission and the Agency on an annual basis.

Article 14

Membership of the committees

1. Each Member State shall nominate two candidates for membership of RAC and may nominate up to two additional candidates.

   The Management Board shall appoint the members of RAC based on their role and experience in performing the tasks assigned to RAC.

2. Each Member State shall nominate two candidates for membership of SEAC and may nominate up to two additional candidates.

   The Management Board shall appoint the members of SEAC based on their role and experience in performing the tasks assigned to SEAC.

3. Each Member State shall appoint one member to MSC and may appoint one alternate member to MSC.

4. Each Member State shall appoint one member to BPC and may appoint one alternate member to BPC. BPC members shall be appointed on the basis of their role and experience in performing the tasks assigned to BPC and may work within a competent authority.

5. The members of SCCS shall be appointed by the Management Board from a list of suitable candidates, established following a call for expression of interest launched by the Agency.

   The Management Board shall appoint members of SCCS based on the following criteria:

   (a) a high level of scientific expertise and experience in at least one of the following fields:

      (i) toxicology;

      (ii) medicine (with a focus on dermatology, epidemiology, and endocrinology);

      (iii) chemistry;

      (iv) exposure and risk assessment;

      (v) alternative testing methods, and emerging methodologies, including new approach methodologies and in vitro/ or in silico techniques;

      (vi) other relevant scientific disciplines related to the hazard and risk assessment of cosmetic ingredients;

   (b) independence and absence of conflicts of interest.

   The SCCS shall consist of maximum 20 members.

6. All Committees shall have a broad range of relevant expertise among their members. The Committees may co-opt additional members chosen on the basis of their specific competence. The maximum number of co-opted members for RAC, SEAC and SCCS shall be set and adjusted by the Management Board on the basis of a proposal from the Executive Director, taking into account the workload of the committees, the type of expertise needed and the availability of financial resources. The MSC and BPC may co-opt a maximum of five additional members.

7. Where a committee is required to provide an opinion under sectoral Union legislation or where verification of submissions by the committee is foreseen in sectoral Union legislation, it shall appoint one of its members as a rapporteur. The committee concerned may, as necessary, appoint one or several other members to act as co-rapporteurs.

8. Rapporteurs and co-rapporteurs shall act in the interest of the Union and shall disclose any potential impediment or conflict that may prevent them from doing so. A member of a committee shall not be appointed rapporteur or co-rapporteur for a particular case if that member indicates any interest that might be prejudicial to their independent consideration of that case. The committee concerned may replace the rapporteur or co-rapporteur by another of its members at any time, if the rapporteur or co-rapporteur is unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.

9. Member States shall provide adequate scientific and technical resources to those members of the committees that they have nominated or appointed and shall facilitate the activities of the committees and their working groups.

10. The members of RAC, SEAC and SCCS shall be independent and they shall neither seek nor take instructions from any government or other institution, body, office or entity. The members of MSC and BPC shall act in the public interest. They shall refrain from any action incompatible with their duties or the performance of their tasks.

11. The members of RAC, SEAC, MSC and BPC shall be appointed for a term of three years and the members of SCCS for a term of five years. Those terms may be renewed.

12. The members of the Committees that are nominated or appointed by a Member State shall ensure that there is appropriate coordination between the tasks of the Agency and the work of their Member State competent authorities.

13. The members of the Committees may be accompanied by advisers on scientific, technical, or regulatory matters.

14. The provision of services by the members of the Committees that are not employed in the public service of a Member State or under contract by the public service of a Member State, shall be governed by a written contract between the Agency and the member concerned, or where appropriate between the Agency and the employer of the member concerned. Where the member concerned fails to fulfil their duties, the Executive Director may terminate or suspend the contract.

15. The member concerned, or that person’s employer as referred to in paragraph 13, shall be remunerated by the Agency in accordance with the financial arrangements established by the Management Board following a positive opinion by the Commission. The list of tasks for which remuneration may be paid shall be established by the Management Board following a positive opinion of the

Commission. Where the member concerned fails to fulfil any of those tasks, the Executive Director may withhold remuneration.

Article 15

Functioning of the committees

1. The Executive Director or a representative of the Executive Director as well as Commission representatives shall be entitled to attend all the meetings of the Committees and their working groups as observers. Stakeholders may also be invited to attend such meetings as observers in accordance with the committee's rules of procedure.

2. When preparing an opinion, the committees shall use their best endeavours to reach a consensus among their members. The opinion shall include the grounds for the position of the committee. If a consensus cannot be reached, the opinion shall consist of the position of the majority of the members the minority positions and the grounds for the respective majority and minority positions. The opinion shall be published.

3. The Secretariat shall provide scientific and administrative support to the technical and scientific work of the Committees.

4. Each committee shall draft a proposal for their own rules of procedure, which shall be prepared for adoption by the Executive Director and then adopted by the Management Board. The rules of procedure of RAC and SEAC shall require the approval of the representatives of the Commission in the Management Board.

5. The rules of procedure of each committee shall lay down the procedures for replacing and co-opting members, for the creation and organisation of working groups and for delegating certain tasks to such working groups, if applicable. The rules of procedure shall also establish a procedure for the urgent adoption of opinions and the management of conflicts of interest. The rules of procedure shall be published.

6. The Chairpersons of each committee shall be employees of the Agency.

Article 16

The use of experts

1. The Agency may rely on the services of experts to serve in a working group of the committees, of the Forum, or of other working groups of the Agency or for the performance of other tasks set out in this Regulation or sectoral Union legislation, where it is justified by the scientific and technical context, or the high level of expertise required. The procedure for and the scope of the use of experts shall be adopted by a decision of the Management Board.

2. The Management Board shall include the procedure for the use of experts to serve in working groups in the procedural arrangements of the respective Committees or working groups of the Agency. The Agency shall ensure the objective impartiality of the experts when providing expertise within the working group.

3. Member States shall transmit to the Agency the names of experts with documented experience with the tasks referred to in Article 4 that would be available to serve in working groups of the Committees or perform other tasks set out in this Regulation

or sectoral Union legislation. The names shall be accompanied by an indication of the qualifications and the specific areas of expertise of each expert.

4. The Agency shall keep a list of experts up-to-date, which shall include the experts referred to in Article 16(1) and other experts identified directly by the Agency.

5. The provisions on independence in Article 14(9), on contractual arrangements in Article 14(13) and on the financial arrangements for remuneration in Article 14(14) shall apply *mutatis mutandis* to any expert serving in a working group of the Committees or of the Forum or performing any other task for the Agency.

Article 17

Membership and functioning of the Forum

1. Each Member State shall appoint one member to the Forum and may appoint up to three alternates. Members to the Forum shall be chosen for their role and experience with the enforcement of relevant Union legislation and shall maintain relevant contacts with the competent authorities of the Member States.

2. The Forum shall have a broad range of relevant expertise among its members. In this regard, the Forum may additionally co-opt a maximum of five members chosen on the basis of their specific competence.

   The members, the alternates and the co-opted members shall be appointed for a term of three years, which may be renewed.

   The members of the Forum may be assisted by scientific and technical advisers.

   The Executive Director or a representative of the Executive Director, as well as Commission representatives shall be entitled to attend all the meetings of the Forum and its working groups. Stakeholders may be invited to attend meetings as observers at the request of a member of the Forum or of the Management Board.

3. The members of the Forum appointed by a Member State shall ensure that there is appropriate coordination between the Forum and the work of their Member State's competent authorities.

4. The members of the Forum shall be supported by the scientific and technical resources available to the competent authorities of the Member States. The competent authorities of the Member States shall facilitate the activities of the Forum and its working groups. Member States shall not instruct the members of the Forum, or their scientific and technical advisers and experts.

5. The Forum shall draft a proposal for its own rules of procedure to the Management Board. The rules of procedure shall lay down the procedures for appointing and replacing the Chairperson, for replacing members and for delegating certain tasks to working groups.

Article 18

Tasks of the Forum

1. The Forum shall undertake the tasks assigned to it in sectoral Union legislation.

2. The Forum shall coordinate a network of Member States competent authorities responsible for the enforcement of this Regulation and sectoral Union legislation.

Article 19

Qualification and interests

1. The membership of the Committees and of the Forum shall be published by the Executive Director on the Agency's website. Individual members may request that their names not be made public if they believe that such publication could place them at risk. The Executive Director shall decide whether to agree to such requests. When an appointment of a member is published, the professional qualifications of that member shall also be published.

2. Members of the Management Board, the Executive Director, Chairpersons, and members of the Committees and the Forum shall make a declaration of commitment to fulfil their duties and a declaration of interests identifying any interests which could be considered prejudicial to the members' obligations pursuant to Article 14(10). Those declarations shall be made annually in writing and shall be published on the Agency's website.

3. At meetings of the members of the Management Board, the Executive Director, chairpersons and members of the Committees and the Forum and any participating experts shall declare any additional interests which could be considered prejudicial to the members' obligations pursuant to Article 14(10)with respect to any points on the agenda. A person that has declared such interests shall not participate in voting on the relevant point.

Article 20

Composition of the Board of Appeal

1. The Board of Appeal shall be composed of a Chairperson and two other members.

2. The Chairperson and the two members shall have alternates to represent them in their absence.

3. Following a call for expressions of interest published in the *Official Journal of the European Union* and in other periodicals or on relevant Internet sites, the Commission shall provide the Management Board with a list of qualified candidates for potential appointment as Chairperson, members and alternates of the Board of Appeal. The Management Board shall appoint from that list the Chairperson, the other members and the alternates on the basis of their relevant experience and expertise in the field of chemical safety, natural sciences and regulatory and judicial procedures.

4. The Management Board may appoint additional members and their alternates, on a recommendation by the Chairperson of the Board of Appeal, following the procedure set out in the paragraph 3, if it is necessary to ensure that any appeals against decisions of the Agency can be processed at a satisfactory rate.

5. The Commission is empowered to adopt implementing acts determining the qualifications required for the members of the Board of Appeal in the field of chemical safety, natural sciences and regulatory and judicial procedures as set out in paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 47(2).

6. The Chairperson and the two members shall each have one vote.

7. The Board of Appeal shall be assisted by a Registry.

Article 21

Members of the Board of Appeal

1. The term of office of the members of the Board of Appeal, including the Chairperson, and the alternates shall be five years. Their terms of office may be renewed once by the Management Board.

2. The members of the Board of Appeal shall be independent and shall not perform any other duties in the Agency. They shall neither seek nor take instructions from any government or other institution, body, office or entity. They shall refrain from any action incompatible with their duties or the performance of their tasks.

3. The members of the Board of Appeal shall not be removed from office during their respective terms unless there are serious grounds for such removal. A decision to remove a member of the Board of Appeal shall be taken by the Commission acting on a proposal from the Management Board.

4. The rules on the publication of membership in Article 19(1) and on declarations of interest in Article 19(2) shall apply *mutatis mutandis* to the members of the Board of Appeal and their alternates.

Article 22

Exclusion and objection

1. The members of the Board of Appeal shall not take part in any appeal proceedings if they have any personal interest therein, if they have previously been involved as representatives of one of the parties to the proceedings, or if they participated in the adoption of the decision under appeal.

2. If a member of the Board of Appeal considers that, for any of the grounds referred to in paragraph 1, the member is not to take part in a specific appeal proceeding, that member shall inform the Board of Appeal accordingly. Any party to the appeal proceedings may object to the participation of any members of the Board of Appeal on any of the grounds referred to in paragraph 1, or if the member is suspected of partiality on any other ground. An objection may not be based on the nationality of a member.

3. The Board of Appeal shall decide on the action to be taken in the cases referred to in paragraphs 1 and 2 without the participation of the member concerned. For the purposes of taking such decision, the member concerned shall be replaced on the Board of Appeal by an alternate.

Article 23

Decisions subject to appeal

An appeal against a decision of the Agency may be brought before the Board of Appeal in accordance with sectoral Union legislation and under the terms and conditions set out in Articles 24 and 25.

Article 24

Right of appeal, time-limits, fees and form

1. Any natural or legal person may appeal against a decision adopted by the Agency addressed to that person in accordance with sectoral Union legislation, or against a decision which is not addressed to that person but which is of direct and individual concern to that person.

2. The appeal, together with the statements of the grounds thereof, shall be filed in writing to the Agency within three months of the notification of the decision to the person concerned, or in the absence of such notification, of the day on which the decision became known to the person concerned, unless otherwise provided for in the sectoral Union legislation.

3. A fee may be payable by persons bringing an appeal against a decision of the Agency, where that is set out in the sectoral Union legislation.

Article 25

Examination and decisions on appeal

1. If, after consultation with the Chairperson of the Board of Appeal, the Executive Director considers the appeal to be admissible and well-founded, the Executive Director may rectify the contested decision within 30 days of the appeal being filed.

2. In cases other than those referred to in paragraph 1, the Chairperson of the Board of Appeal shall examine whether the appeal is admissible within 30 days of the appeal being filed.

   If the Chairperson of the Board of Appeal does not decide on the admissibility of the appeal within that time limit, the appeal shall be remitted to the Board of Appeal for examination of the grounds and the admissibility of the appeal. The decision on the admissibility shall form part of the final decision.

   Parties to the appeal proceedings shall be entitled to make an oral presentation during the procedure.

3. The Board of Appeal may exercise any power within the competence of the Agency or remit the case to the competent body of the Agency for further action.

4. The Commission is empowered to adopt implementing acts determining the procedures of the Board of Appeal and its Registry. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 47(2).

Article 26

Actions before the Court of Justice of the European Union

1. Actions may be brought before the Court of Justice of the European Union for the annulment of acts of the Agency intended to produce legal effects vis-à-vis third parties, for failure to act, for non-contractual liability and, in case of an arbitration clause, contractual liability for damages caused by acts of the Agency.

2. Actions for the annulment of decisions of the Agency which can be appealed pursuant to Article 23 may be brought before the Court of Justice of the European Union only after all appeal procedures within the Agency have been exhausted.

CHAPTER III
Financial provisions

Article 27

Single programming document

1. By the end of each year, based on the draft by the Executive Director, the Management Board shall endorse a draft single programming document containing the following:

   (a) all the documents listed in Article 32(1) of Delegated Regulation (EU) 2019/715;

   (b) a justification on any potential transfers of financial and human resources between the different activities of the Agency;

   (c) the overall strategic programming including objectives, expected results and performance indicators which shall be updated when appropriate, and in particular to address the outcome of the evaluation referred to in Article 54;

   (d) the resource programming including multiannual budget and staff, which shall be updated annually.

2. The Management Board shall forward the draft single programming document to the European Parliament, to the Council and to the Commission by 31 January of the following year.

3. The Commission shall send its opinion on the draft single programming document to the Agency in a timely manner and in any case not later than 1 July of the year in which it received it. If the Agency does not fully take into account the Commission's opinion, it shall provide the Commission with adequate explanations.

4. After the adoption of the draft budget by the Commission, the draft single programming document shall be adopted by the Management Board. It shall become definitive after the final adoption of the Union budget setting the amount of the contribution and the establishment plan. If necessary, the budget of the Agency and its establishment plan shall be adjusted accordingly by the Agency.

5. The annual programming shall comprise detailed objectives and expected results including performance indicators. It shall also contain a description of the actions to be financed and an indication of the financial and human resources allocated to each action, in accordance with the principles of activity-based budgeting and management. The annual programming shall be coherent with the multi-annual programming referred to in paragraph 1. It shall clearly indicate tasks that have been added, changed or deleted in comparison with the previous financial year.

6. The Management Board shall amend the adopted annual programming when a new task is given to the Agency.

7. Any substantial amendment to the annual programming shall be adopted in accordance with the same procedure as the initial annual programming. The Management Board may delegate the power to make non-substantial amendments to the annual programming to the Executive Director.

8. The multi-annual programming and the annual programming shall be prepared in accordance with Article 32 of Delegated Regulation (EU) 2019/715.

Article 28

Establishment of the budget

1. Each year, the Executive Director shall draw up a provisional draft estimate of the Agency's revenue and expenditure for the following financial year, including the establishment plan, and send it to the Management Board.

2. The provisional draft estimate shall be based on the objectives and expected results of the annual programming in the single programming document and shall take into account the financial resources necessary to achieve those objectives and expected results, in accordance with the principle of performance-based budgeting.

3. The Management Board shall each year, based on the provisional draft estimate, adopt a draft estimate of the Agency's revenue and expenditure for the following financial year and send it to the Commission by 31 January.

4. On the basis of the draft estimate, the Commission shall enter in the draft general budget of the Union the estimates it considers necessary for the establishment plan and the amount of the Union subsidy to be charged to the general budget. It shall place those estimates and that amount before the budgetary authority in accordance with Articles 313 and 314 of the TFEU.

5. The budgetary authority shall authorise the appropriations for the contribution to the Agency.

6. The budgetary authority shall adopt the Agency's establishment plan.

7. The Agency's budget shall be adopted by the Management Board. It shall become final only following final adoption of the general budget of the Union. Where necessary, the Agency's budget adopted by the Management Board shall be adjusted by the Management Board to reflect the final adoption of the general budget of the Union.

Article 29

Structure of the budget

1. The financial year shall correspond to the calendar year.

2. The Agency's budget shall be balanced in terms of revenue and expenditure.

3. Without prejudice to other resources, the Agency's revenue shall comprise:

   (a) any balancing contribution from the Union entered in the general budget of the Union;

   (b) fees and charges payable to the Agency in the cases laid down in Union sectoral legislation;

   (c) any voluntary financial contribution from Member States;

   (d) any contribution from third countries participating in the work of the Agency, including those deriving from obligations under international agreements;

   (e) possible Union funding in the form of contribution agreements or ad-hoc grants in accordance with the Agency's financial rules referred to in Article

31 and with the provisions of the relevant instruments supporting the policies of the Union;

(f) charges for publications and any service provided by the Agency;

(g) charges for services for third countries, which are not covered by separate dedicated Union funding.

4. The expenditure of the Agency shall include staff remuneration, administrative and infrastructure expenses, and operational expenditure.

5. The Agency shall create a limited reserve from its revenues referred to in paragraph 3, point (b). The detailed rules related to the parameters, the calculation and the operation of the reserve shall be laid down in the Agency's financial rules. The financial rules shall stipulate that:

(a) the Agency shall make contributions to the reserve solely from end-of-year budget results within the meaning of Article 99(4) of Delegated Regulation (EU) 2019/715, where those results are positive and stemming from fee and charges revenues collected that are higher than the budgeted amounts in a given year;

(b) at any moment, the reserve included in the year N in the draft budget for the year N+1 shall not exceed 8% of the total actual amount realised in the year N-1 of the Agency's revenues from the fees and charges referred to in paragraph 3, point (b) and the Union contribution referred to in paragraph 3, point (a), and shall also not exceed 8% of the Agency's total actual amount of the administrative and operational expenditure realised in the year N-1, whatever amount is lower;

(c) the Agency shall first offset any negative budget result within the meaning of Article 99(4) of Delegated Regulation (EU) 2019/715 from the balance of the reserve, if available.

6. The Commission may review the conditions for the reserve set out in paragraph 5, and is empowered to adopt delegated acts in accordance with Article 46(1) to amend paragraph 5 on the basis of such review.

Article 30

Implementation of the budget

1. The Executive Director shall act as authorising officer and shall implement the Agency's budget.

2. Each year, the Executive Director shall send to the budgetary authority all information relevant to the findings of the evaluation procedures provided for in Article 54.

Article 31

Presentation of accounts and discharge

1. The Agency's accounting officer shall send the provisional accounts for the financial year (year N) to the Commission's Accounting Officer and to the Court of Auditors by 1 March of the following financial year (year N + 1).

2. The Agency's accounting officer shall also provide the required accounting information for consolidation purposes to the Commission's accounting officer, in the manner and format required by the Commission's accounting officer by 1 March of year N + 1.

3. The Agency shall send the report on the budgetary and financial management for year N to the European Parliament, the Council, the Commission, and the Court of Auditors by 31 March of year N + 1.

4. On receipt of the Court of Auditor's observations on the Agency's provisional accounts for year N, the Agency's accounting officer shall draw up the Agency's final accounts and be personally responsible for them. The Executive Director shall submit them to the Management Board for an opinion.

5. The Management Board shall deliver an opinion on the Agency's final accounts for year N.

6. The Agency's accounting officer shall, by 30 June of year N + 1 send the final accounts for year N to the European Parliament, the Council, the Commission, and the Court of Auditors, together with the Management Board's opinion.

7. A link to the pages of the website containing the final accounts of the Agency shall be published in the *Official Journal of the European Union* by 15 November of year N + 1.

8. The Executive Director shall send to the Court of Auditors, by 30 September of year N + 1, a reply to the observations made in its annual report. The Executive Director shall also send this reply to the Management Board and to the Commission.

9. The Executive Director shall submit to the European Parliament, at its request, any information required for the smooth application of the discharge procedure for year N, in accordance with Article 267(3) of Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council[126].

10. On a recommendation from the Council acting by qualified majority, the European Parliament shall, before 15 May of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.

Article 32

Financial rules

The financial rules applicable to the Agency shall be adopted by the Management Board after consulting the Commission. Those rules shall comply with the rules laid down in Delegated Regulation (EU) 2019/715, unless it is otherwise specifically required for the Agency's operation, after the Commission's prior consent to derogate from those rules.

The Agency shall establish and implement its budget in line with its financial rules and Regulation (EU, Euratom) 2024/2509.

126 Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council of 23 September 2024 on the financial rules applicable to the general budget of the Union (recast) (OJ L, 2024/2509, 26.9.2024, ELI: http://data.europa.eu/eli/reg/2024/2509/oj).

Article 33

Combatting fraud

1. In order to combat fraud, corruption and other unlawful activities, Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council[127] shall apply to the Agency without restriction.

2. The Agency shall be bound by the Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti-fraud Office (OLAF)[128]. Accordingly, appropriate provisions applicable to the Agency's staff shall be adopted using the template set out in the Annex to that Agreement.

3. The European Court of Auditors shall have the power of audit, on the basis of documents and on the spot, over all grant beneficiaries, contractors and subcontractors that have received Union funds from the Agency.

4. OLAF may carry out investigations, including on-the-spot checks and inspections with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant or a contract funded by the Agency, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 and Council Regulation (Euratom, EC) No 2185/96[129].

5. Without prejudice to paragraphs 1 to 4, cooperation arrangements with third countries and international organisations, contracts, grant agreements and grant decisions of the Agency shall contain provisions expressly empowering the European Court of Auditors and OLAF to conduct such audits and investigations, according to their respective competences.

6. In accordance with Regulation (EU) 2017/1939, EPPO may investigate and prosecute fraud and other illegal activities affecting the financial interests of the Union as provided for in Directive (EU) 2017/1371 of the European Parliament and of the Council[130].

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127 Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 193, 30.7.2018, p.1, ELI: http://data.europa.eu/eli/reg/2018/1046/oj).

128 Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti-fraud Office (OLAF) (OJ L 136, 31.5.1999, p.15, ELI: http://data.europa.eu/eli/agree_interinstit/1999/531/oj).

129 Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p.2-5, ELI: http://data.europa.eu/eli/reg/1996/2185/oj).

130 Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law (OJ L 198, 28.7.2017, p. 29, ELI: http://data.europa.eu/eli/dir/2017/1371/oj).

CHAPTER IV
STAFF

Article 34

General provision

Regulation No 31 (EEC), 11 (EAEC) on the Staff Regulations of Officials and the Conditions of Employment of Other Servants and the rules adopted by agreement between the institutions of the Union giving effect to that Regulation and those rules, shall apply to the staff of the Agency.

Article 35

Seconded national experts and other staff

1. The Agency may make use of seconded national experts or other staff not employed by the Agency. The Staff Regulations and the Conditions of Employment of Other Servants of Regulation No 31 (EEC), 11 (EAEC)shall not apply to seconded national experts or other staff not employed by the Agency.

2. The Management Board shall adopt a decision laying down rules on the secondment of national experts to the Agency.

Article 36

Privileges and immunities

Protocol No 7 on the Privileges and Immunities of the European Union annexed to TFEU shall apply to the Agency and its staff.

CHAPTER V
INFORMATION AND COMMUNICATION

Article 37

Transparency and Communication

1. The Agency shall ensure the public availability and transparency, in accordance with Regulation (EU) XX/XXX of the European Parliament and 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[+], of the chemicals data it holds.

2. For all other information and data not covered by paragraph 1, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules to ensure the availability to the public of regulatory, scientific and technical information concerning the safety of substances

[+] [**OP**: *Please insert in the text the number of the Regulation contained in document COM(2023) 779 final 2023/0453 (COD) and insert the number, date, title and OJ reference of that Regulation in the footnote*.]

on their own, in mixtures or in articles where such information is not of a confidential nature as defined in sectoral Union legislation.

3. The Agency may engage in communication activities on its own initiative within its field of competence. The allocation of resources to communication activities shall not be detrimental to the effective exercise of the tasks of the Agency. Communication activities shall be carried out in accordance with relevant communication and dissemination plans adopted by the Management Board.

4. The Management Board shall adopt rules on the appeal or remedies necessary for reviewing a partial or full rejection of a confidentiality request submitted in accordance with sectoral Union legislation.

5. The Management Board shall adopt measures for the application of Regulation (EU) 2018/1725 by the Agency, including those concerning the appointment of a Data Protection Officer, after consultation of the European Data Protection Supervisor.

Article 38

Protection of sensitive non-classified information

1. The Agency shall adopt its own security rules for the protection of sensitive non-classified information. Such rules shall be based on the principles and rules for protecting Union sensitive non-classified information laid down in Commission Decision (EU, Euratom) 2015/443[131] and shall include provisions for the exchange of sensitive non-classified information with third countries, and for the processing and storage of such information, which shall be compatible with the rules set out in that Decision.

2. The Management Board shall adopt the Agency's security rules referred to in paragraph (1) following approval by the Commission. When assessing the proposed security rules, the Commission shall ensure that they are compatible with Decision (EU, Euratom) 2015/443.

3. Members of the Management Board, the Executive Director, members of the Committees, the Board of Appeal and the Forum, external experts participating in working groups, and members of the staff of the Agency shall comply with the confidentiality requirements set out in Article 339 TFEU, even after their duties have ceased.

4. The Agency may take the measures necessary to facilitate the exchange of information relevant to its tasks with Member States and the Commission, and where appropriate, the relevant Union institutions, bodies, offices, and agencies.

Article 39

Notification of decisions and communications

1. The Agency shall notify its decisions and communications to the addressee via the information system designated by the Agency.

131 Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission, (OJ L 72, 17.3.2015, p. 41, ELI: http://data.europa.eu/eli/dec/2015/443/oj)

2. The Agency's decisions and communications shall be deemed to be notified either when they are opened for the first time by the party or its designated representative, or seven calendar days after the date on which they are made available to the addressee in the Agency's information system, whichever date is the earliest.

CHAPTER VI
Cooperation

Article 40

Cooperation with Member States and the Commission

With due regard for the different national legal systems, the Agency shall facilitate cooperation in the field of competence of the Agency between Member States and between Member States and the Commission, in accordance with Union legislation and taking into account best practices in Member States and agreed international standards.

Article 41

Cooperation with stakeholders

The Agency shall maintain a close dialogue with relevant civil society organisations, and relevant competent bodies operating in the field of its competence at national, Union and international level.

Article 42

International regulatory cooperation

1. In so far as is necessary to achieve the objectives set out in this Regulation and the sectoral Union legislation, and without prejudice to the respective competences of Member States and the institutions of the Union, the Agency may cooperate with the competent authorities of third countries and with international organisations that have entered into agreements with the Union to that effect.

2. To this end, the Agency may, subject to the approval of the Commission, establish working arrangements with the authorities of third countries and with international organisations in the field of its competence. Those arrangements shall not create legal obligations for the Union or Member States.

3. Under the relevant provisions of the agreements referred to in paragraph 1, the working arrangements referred to in paragraph 2 shall be developed by the Agency specifying the nature, extent and manner in which the third countries and international organisations concerned are to cooperate with the Agency or could participate in the work of the Agency, including provisions relating to participation in the initiatives undertaken by the Agency, financial contributions and staff. As regards staff matters, those arrangements shall, in any event, comply with the Staff Regulations.

4. The Management Board shall adopt a strategy for relations with third countries or international organisations concerning matters for which the Agency is competent.

5. The Commission shall ensure that the Agency operates within its mandate and the existing institutional framework by concluding an appropriate working arrangement

with the Agency's Executive Director. The Agency shall ensure that it is not seen as representing the Union to an outside audience or as committing the Union to international cooperation.

6. Information held by the Agency may be disclosed to any government or national authority of a third country or an international organisation, only where such disclosure is provided for in the sectoral Union legislation, under which the information has been submitted and subject to the conditions set out therein, in line with the originator principle.

Article 43

Research and innovation

The Agency shall assist Member States and the Commission in promoting the substitution of the most harmful chemicals by safer and more sustainable alternative substances and technologies and in the development of relevant scientific methodologies, including animal-free approaches, to assess hazards of chemicals as well as risks and socio-economic impacts of the use of chemicals. Such assistance shall include facilitation of information exchange as well as participation in and facilitation of relevant research, development, and innovation activities within the scope of the relevant Union sectoral legislation.

Article 44

Cooperation with other Union bodies

The Agency shall cooperate with other bodies established under Union law, including but not limited to the European Centre for Disease Prevention and Control, the European Environment Agency, the European Food Safety Authority, the European Medicines Agency and the European Agency for Safety and Health at Work, 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, including animal-free approaches, for the assessment of chemicals.

Article 45

Divergence of scientific opinion with other Union bodies

1. The Agency 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 Agency 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.

3. The Agency and the body concerned shall cooperate to resolve the divergence. If the Agency 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**,** identify the relevant uncertainties in the data and the underlying reasons for the diverging opinions, including on methodological differences, and be made publicly available. Where the body concerned is a Union agency or a scientific committee, the Agency shall present the joint report to the Commission.

4. Where relevant, and where the divergence concerns conflicting scientific opinions of the Agency and another Union body or agency on whether a substance fulfils the criteria laid down in Annex I to Regulation (EC) No 1272/2008, the Commission may request the 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 down in Article 37 of Regulation (EC) No 1272/2008. The Union body or agency concerned shall co-operate with the Agency in developing that proposal.

CHAPTER VII
Delegated powers and committee procedure

Article 46

Delegated powers

1. The power to adopt delegated acts referred to in Article 29(6) shall be conferred on the Commission subject to the conditions laid down in this Article and for a period of 5 years from [*OP please insert: the date of the entry into force of this Regulation*]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each five-year period.

2. The delegation of power referred to in paragraph 1 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

3. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[132].

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to paragraph 1 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to 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. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

[132] OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

Article 47

Committee procedure

1. The Commission shall be assisted by the REACH Committee established by Regulation (EC) No 1907/2006. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

CHAPTER VIII
Amendments

Article 48

Amendments to Regulation (EC) No 1907/2006

Regulation (EC) No 1907/2006 is amended as follows:

(1) in Article 75, paragraph 2 is deleted;

(2) Article 76 is deleted;

(3) in Article 77, paragraph 1 is deleted;

(4) Articles 78 to 90 are deleted;

(5) Articles 92 to 110 are deleted;

(6) in Article 118, paragraphs 1, 3 and 4 are deleted.

References to the provisions referred to in paragraph 1 shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex II.

Article 49

Amendments to Regulation (EU) No 528/2012

Regulation (EU) No 528/2012 is amended as follows:

(1) in Article 75, paragraphs 2, 3 and 4 are deleted;

(2) the following Article 75a is inserted:

‘Article 75a – Socio Economic Analysis Committee

The Committee for Socio-economic Analysis shall, upon request from the Biocidal Products Committee, contribute to the work of the Biocidal Products Committee by providing input for tasks carried out under Article 75(1) in connection with Article 5(2).’;

(3) in Article 78, paragraph 2 is deleted.

Article 50

Amendment to Regulation (EU) No 649/2012

In Article 24 of Regulation (EU) No 649/2012, paragraph 2 is deleted.

Article 51

Amendment to Regulation (EU) 2019/1021

In Article 16 of Regulation (EU) 2019/1021, paragraph 2 is deleted.

CHAPTER IX
Transitional provisions

Article 52

Transitional provisions concerning the administrative structure and staff of the Agency

1. The members of the Management Board, the Committees, the Forum and the Board of Appeal appointed on the basis of Regulation (EC) No 1907/2006, Regulation (EU) No 528/2012 or Commission Decision (EU) 2024/1514 shall remain in office until new members are appointed pursuant to this Regulation and shall, for the remaining periods of their term of office, exercise the functions as set out in this Regulation.

2. The Executive Director appointed on the basis of Article 84 of Regulation (EC) No 1907/2006 shall, for the remaining period of their term of office, carry out the tasks and responsibilities of the Executive Director as provided for in Article 12 of this Regulation. The other conditions of the contract shall remain unchanged.

3. In the case of an ongoing selection or appointment procedure for the Executive Director or members of the Management Board, the Committees, the Forum or the Board of Appeal at the time of the date of application of this Regulation, Articles 79, 84, 85, 86 and 89 of Regulation (EC) No 1907/2006, Article 75 of Regulation (EU) No 528/2012 and Article 4 of Commission Decision (EU) 2024/1514 as applicable on [***OP: please insert the date = one day before the date of application of this Regulation***] shall continue to apply until the finalisation of that procedure.

4. The rules of procedure of the Committees, the Forum and the Board of Appeal as well as procedural arrangements for working groups of the committees adopted on the basis of Regulation (EC) No 1907/2006 or Regulation (EU) No 528/2012 shall remain applicable until new rules are adopted pursuant to the relevant provisions in this Regulation.

5. This Regulation shall not affect contracts for the provision of services by the members of RAC and SEAC or any expert serving on a working group of RAC, SEAC or the Forum or performing any other task for the Agency concluded pursuant to Article 87(3) of Regulation (EC) No 1907/2006 as applicable on [***OP: please insert the date = one day before the date of application of this Regulation***].

6. This Regulation shall not affect the rights and obligations of staff engaged under Regulation (EC) No 1907/2006. Their employment contracts may be renewed under this Regulation in accordance with the Staff Regulations and the Conditions of Employment of Other Servants of Regulation No 31 (EEC), 11 (EAEC).

Article 53

Transitional budgetary provisions

The discharge procedure in respect of the budgets approved on the basis of Article 96 of Regulation (EC) No 1907/2006 as applicable on [***OP: please insert the date = one day before***

the date of application of this Regulation] shall be carried out in accordance with Article 97 of that Regulation as applicable on that date.

CHAPTER X
General and Final provisions

Article 54

Evaluation

1. Not later than two years after [*OP please insert: the date of application of this Regulation*], and every five years thereafter, the Commission shall initiate an evaluation of the Agency's performance in relation to its objectives, tasks and governance.
2. The evaluation shall address the possible need to modify the mandate of the Agency, and the financial implications of any such modification.
3. The Commission shall report to the European Parliament, to the Council, and to the Management Board on the findings of the evaluation. An action plan and a timetable shall be included, if appropriate. The findings of the evaluation shall be made public by the Commission.

Article 55

Liability

1. The Agency's contractual liability shall be governed by the law applicable to the contract in question.
2. The Court of Justice of the European Union shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Agency.
3. In the case of non-contractual liability, the Agency shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by it or by its staff in the performance of their duties.
4. The Court of Justice shall have jurisdiction in any dispute relating to compensation for any such damage.
5. The financial liability of Member States and the Union for the debts of the Agency shall be limited to their contribution already made for the administrative costs.

Article 56

Operating conditions

1. The Agency's host Member State shall provide the best possible conditions to ensure the functioning of the Agency, including multilingual, European-oriented schooling and appropriate transport connections.
2. Where exceptional circumstances so require, the Executive Director may decide whether it is necessary to establish a local office in another Member State for the purposes of carrying out the Agency's tasks in a more, efficient, effective, and coherent manner.

3. Before deciding to establish a local office, the Executive Director shall obtain the prior consent of the Commission, the Management Board and the potential host Member State. The decision shall be based on an appropriate cost-benefit analysis that demonstrates the added value of such decision. The decision shall specify the scope of the activities to be carried out at the local office in a manner that avoids unnecessary costs and duplication of administrative functions of the Agency.

Article 57

Language arrangements

1. The provisions laid down in Council Regulation No 1[133] shall apply to the Agency. Any submission generating a regulatory process received by the Agency shall be considered as a document within the meaning of Article 2 of that Regulation.

2. Translation and all other linguistic services required by the Agency, other than interpretation, shall be provided by the Translation Centre for the Bodies of the European Union.

Article 58

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.

It shall apply from [*OP please insert: the date **one year** from the entry into force of this Regulation*].

However, Article 29(5) and (6), Article 49(3) and Articles 50 and 51 shall apply from 1 January 2028.

This Regulation shall be binding in its entirety and directly applicable in all Member States in accordance with the Treaties.

Done at Brussels,

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

133 Council Regulation No 1 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385, ELI: http://data.europa.eu/eli/reg/1958/1(1)/oj).

LEGISLATIVE FINANCIAL AND DIGITAL STATEMENT – AGENCIES

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a regulation of the European Parliament and the of the Council on the European Chemicals Agency amending Regulations (EC) No 1907/2006, (EU) No 528/2012, (EU) No 649/2012 and (EU) 2019/1021.

1.2. Policy area(s) concerned

03 - Single Market, Innovation and Digital

07 - Investing in People, Social Cohesion and Values

09 - Environment & Climate Change

1.3. Objective(s)

1.3.1. General objective(s)

The Agency shall contribute to the implementation and enforcement of Union legislation and policies related to the hazards, risks and safe use of chemical substances, provide independent information on all matters within that field and communicate on risks.

In the fulfilment of its objectives, the Agency shall aim to contribute to a high level of protection of human health and the environment, the efficient functioning of the internal market and coherence and consistency in chemicals management across the Union, while enhancing competitiveness and innovation, taking into account the specific needs of small and medium-sized enterprises ('SMEs') and promoting alternatives to animal testing.

The Agency shall serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it.

Since its establishment under Regulation (EC) No 1907/2006, additional tasks and responsibilities were assigned to the Agency and its committees in other Union legislation in the fields of chemicals, product safety and environmental policy set out in Annex I of the proposal such as Regulation (EC) No 1272/2008, Regulation (EU) No 528/2012, Regulation (EU) No 649/2012, Directive 2008/98/EC, Regulation (EU) 2019/1021, Directive (EU) 2020/2184, Regulation (EU) 2023/1542 and Regulation (EU) 2022/2371.

The current proposal contributes and facilitates the achievement of the objectives of the 'One Substance, One Assessment' approach based on a more transparent, coherent, predictable and simpler chemical safety assessment processes across different pieces of legislation.

The Agency shall act in accordance with the aims of the Union legislation assigning tasks to it.

The Agency shall also act in accordance with the aims of the new tasks assigned to it in this proposal. This includes the management of the SCCS and the provision of

evaluations of the occupational exposure limits (OELs) thus contributing to the social dimension of the strategic objective on an economy that works for people[134].

1.3.2. Specific objective(s)

Specific objectives

This proposal, as a self-standing regulation, should ensure efficient and sustainable governance of the Agency and its implementation of all the legislative acts currently in place as stated in the Annex I and the new tasks entrusted to the Agency in this proposal.

This proposal also aims to increase the sustainability of the Agency's financing model.The main reforms will increase the capacity of the scientific committees to manage the extended tasks and will merge the three currently separated strands (Chemicals – REACH/CLP, Biocides and Environmental directives) into one entity. This will simplify the financing of the Agency for the EU budget and provide more flexibility in the use of resources deriving from different legislative acts assigning tasks to the Agency.

1.3.3. Expected result(s) and impact

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

Greater predictability: Streamlined processes and improved governance will enable the Agency to handle a projected doubling in the output of scientific committees. The Committee for Risk Assessment (RAC) and the Committee for socioeconomic analysis (SEAC) are expected to produce respectively additional 80 and 55 opinions annually. This will help reduce delays in chemical approvals and compliance checks, offering investment certainty and minimising supply chain disruptions.

Enhanced efficiency of procedures: Governance changes will expedite the opinion-forming process within the Agency's scientific committees. These include increased nominations of experts by Member States to RAC and SEAC and the possibility to co-opt experts as needed by RAC and SEAC, ensuring the committees can manage growing workloads and complex cases effectively while maintaining coherence in their scientific outputs.

The proposed financial framework reforms aim to simplify and strengthen the Agency's financial structure, offering the flexibility needed to address compliance challenges effectively and efficiently.

To simplify the Agency's financing model, the requirement for segregated budgets established under Regulation (EU) No 649/2012, Regulation (EU) 2019/1021 and Regulation (EU) No 528/2012 should be abolished, by deleting the relevant provisions in those Regulations, so that the Agency will receive one unitary annual contribution from the Union budget. This will allow for more flexibility for the Agency to address workload fluctuations and to respond to the recommendations of the Court of Auditors and the objective of the Chemicals Strategy for Sustainability to increase the sustainability of the Agency's financing model.

The proposal also foresees the possibility for the Agency to create and maintain a limited fund reserve from the surplus of the Agency's revenues from fees and charges, subject to the conditions set out in this Regulation.

134 DG EMPL Multiannual Strategic Plan 2020-2024

1.3.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

- Number of compliance check decisions concluded in the follow up to dossier evaluation
- Number of new and updated entries published in the Candidate List of REACH
- Number of opinions on biocidal active substances (approval & renewal) finalised and submitted to the Commission
- Number of opinions on Union authorisation (approval & renewal) of biocidal products finalised and submitted to the Commission
- Number of RAC opinions on OELs completed and provided to the Commission. Furthermore, the following additional data will be considered:
- Number of substances classified
- Number of substances for which occupational exposure limits are set
- Number of substances added to PACT/AC
- Number of RAC and SEAC opinions adopted on applications for authorisation (number of uses) and submitted to the Commission
- Number of RAC and SEAC opinions on restriction proposals delivered to the Commission
- Number of RAC opinions on proposals for harmonised classification and labelling adopted
- Number of opinions on applications for authorisation submitted to the Commission requiring further consideration by committees
- Number of opinions on restrictions submitted to the Commission requiring further consideration by committees (Art 77 (3)(c)) of REACH
- Number of requests from the Commission for a BPC opinion (pursuant to Article 75(1)(g)) to revise earlier adopted opinions
- Percentage of Scientific Committee (RAC and SEAC) membership positions filled
- Total number of opinions submitted to the Commission accepted without further consideration
- Positive feedback from institutions on ECHA opinions
- Number of safety assessments that the SCSC is working on per year
- number of SCCS opinions adopted per year
- number of new or revised guidelines or methodologies adopted by the SCSC.
- Number of Non Animal Methods (NAMs) projects initiated/completed
- Number of Member States NAMs cases supported
- Number of scientific publications related to the use and promotion of NAMs
- Number of legal appeals on the Agency’s decisions on REACH and BPR.
- Positive feedback from SMEs on our enhanced SME support approach

– Number of SME contacts received through dedicated support service

1.4. The proposal/initiative relates to:

☐ a new action

☐ a new action following a pilot project / preparatory action[135]

✓ the extension of an existing action

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

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

The Agency is an established EU body since 2007. The current proposal will provide it with updated and improved legal framework which would allow it to operate effectively and efficiently and also onboard new tasks seamlessly (see Annex I to the proposal).

The proposal will abolish the requirement for the segregation of the different budget strands of the Agency (Chemicals - REACH/CLP, Biocides, Environmental directives) and merge them in one entity. It will positively impact ECHA's daily management and allow for more flexibility in the use of the resources and streamline the financing of the Agency.

The requirements in the proposal are implemented as of its entry into force.

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

The objectives of this proposal cannot be sufficiently achieved at the Member State level. This initiative is needed to align the basic legal provisions establishing ECHA with its current and future broader role. By their nature, those tasks can only be carried out at EU level. The proposal will also formalise and integrate tasks implemented by the Agency in the framework of the contribution agreements and a service level agreement. The nature of these tasks can only be carried out at EU level.

This legislative proposal will lead to considerable EU added value. Adopting a self-standing regulation is necessary to enable the Agency to address current and future challenges, in particular the wide range of tasks entrusted or in the process of being entrusted to the Agency through various legislative proposals (existing or under preparation).

1.5.3. Lessons learned from similar experiences in the past

The current proposal is also the result of the performance assessment undertaken by the Commission in the context of the REACH review. The proposal addresses the

[135] As referred to in Article 58(2), point (a) or (b) of the Financial Regulation.

necessity to improve the governance and the sustainability of the Agency's financial model.

1.5.4. Compatibility with the multiannual financial framework and possible synergies with other appropriate instruments

Currently, the Agency is financed from three budget Headings of the 2021-2027 Multiannual Financial Framework.

The resources necessary for the new tasks under Toys regulation proposal and Classification, Labelling and Packaging Regulation (CLP) as assessed in Commission SWD(2023) 850 final, will be covered by the redeployment of existing resources within the Agency. The resources (5 full time equivalent) which have been temporarily transferred from REACH/CLP strand to Environment strand to implement and maintain the SCIP database[136] will have to be reinstated under REACH/CLP strand of ECHA budget.

The reforms of the current proposal targeting the functioning of the Agency's committees will increase synergies by streamlining of procedures for scientific opinion provision by these committees.

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

For the additional resources as assessed in SWD(2023) 850 final:

- CLP Regulation as revised: 5 FTE (2 TA + 3 CA). These resources are to be covered by redeployment of existing resources within the Agency under the allocation for REACH. **Toys safety regulation proposal**: 2 FTE (2 TA). These additional resources will not be added to the establishment plan and are to be covered by existing resources within the Agency.

- EU Chemicals Legislation Finder (EUCLEF): 3 FTE (2 TA + 1 CA). This initiative is being financed by DG GROW until end of 2026 under a contribution agreement. As the tasks have become structural, they are now proposed to be included in the ECHA's mandate as regulatory tasks to be assigned to ECHA. This initiative is now one of the building blocks of the common data platform regulation proposal. These additional resources will not be added to the establishment plan and are to be covered by existing resources within the Agency. The operational expenditure will be covered by using the EU contribution in 2027 under the current and next Multiannual Financial Framework.

- European Union Observatory for Nanomaterials (EUON): This initiative is being financed by DG GROW until end of 2026 under a contribution agreement. As the tasks have become structural, they are now included in the proposal as regulatory tasks assigned to ECHA. This initiative is now one of the building block of the common data platform regulation proposal. In the context of the agreement, ECHA was authorised to have 3 contract agents. The 3 contract agents will be added to the Agency's overall staff resources allocation. The operational expenditure will be covered by using the EU contribution in 2027 under the current and next Multiannual Financial Framework.

[136] Article 9 of Directive (EU) 2018/851 (Waste Framework Directive)

- Partnership for the Assessment of Risks from Chemicals (PARC): In the context of the participation of ECHA in the Horizon Europe research project, ECHA was authorised to use 2 contract agents. The 2 contract agents will be added to the Agency's overall staff resources.

- This proposal for the ECHA regulation proposes to integrate in the mandate of ECHA an existing task which been performed by the Agency in the framework of a service level agreement signed between the Agency and the Commission. ECHA and its Committee for Risk Assessment will be given a legal mandate to provide opinions on **occupational exposure limits (OELs)**. Additional resources will have to be allocated to the Agency for this task. 3 TA and 2 CA will be added to the Agency's staff overall allocation and EUR 200 k operational expenditure per year under Title 3 as of the next Multiannual Financial Framework.

- The **Scientific Committee on Consumer Safety** (SCCS) was established in 2015 by a Commission Decision[137]. Its mandate covers advice and opinions on health and safety risks, such as chemical, biological, mechanical, and other physical risks relating to non-food consumer products, especially cosmetic products and, exceptionally, textiles, clothing, household products and consumer services including tattooing and artificial sun tanning. The SCCS will be managed by the agency. Additional resources will have to be allocated to ECHA for management of this committee for the provision of scientific opinions. For this new task 2 AD temporary agents (TA) and 1 contractual agent (CA) are required in addition to EUR 500 k per annum for the operational expenditure under Title 3 In addition, appropriations are required for operational costs of the committee. This results in an increase of the Agency's establishment plan and an increase in the EU contribution.

The financing from 2028 onwards under the new Multiannual Financial Framework (MFF) is indicative, without pre-empting and pre-judging the Commission proposal and the agreement on the next MFF.

- Regarding the tasks, delegated to ECHA in the frame of the **Regulation on serious cross-border threats to health**[138] **(SCBHT),** the financial and budgetary resources are covered by a Contribution agreement between DG SANTE and ECHA until end 2027. Both the budgetary impact and financial resources under this Contribution Agreement are to be covered in the future under this extended mandate, resulting in an increase of the Agency's establishment plan with 1 (one) temporary agent (TA) and an increase in the EU contribution.

1.6. Duration of the proposal/initiative and of its financial impact

☐ **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**

137 Commission Decision (EU) 2024/1514 of 7 August 2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment, OJ L, 2024/1514, 31.5.2024, ELI: http://data.europa.eu/eli/dec/2024/1514/oj

138 Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU, PE/40/2022/REV/1 (OJ L 314, 6.12.2022, p.26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj).

- Implementation with a start-up period from YYYY to YYYY,
- followed by full-scale operation.

1.7. Method(s) of budget implementation planned[139]

☒**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 European Investment Bank 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 common foreign and security policy pursuant to Title V of the Treaty on European Union, and identified in the relevant basic act

– ☐ bodies established in a Member State, governed by the private law of a Member State or Union law and eligible to be entrusted, in accordance with sector-specific rules, with the implementation of Union funds or budgetary guarantees, to the extent that such bodies are controlled by public law bodies or by bodies governed by private law with a public service mission, and are provided with adequate financial guarantees in the form of joint and several liability by the controlling bodies or equivalent financial guarantees and which may be, for each action, limited to the maximum amount of the Union support.

Comments

The REACH regulation revision is underway and may therefore impact the Agency's resources depending on the scope of the revision/simplification.

[139] 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

The performance of the Agency in relation to the implementation of this regulation task will be assessed in the context of the periodic evaluation of the agency to be initiated by the Commission in accordance with the provisions of the basic regulation proposal.

The resources will be monitored on an annual basis in the framework of the draft budget procedure. The Commission issues an opinion on the single programming document of the agency which will cover the tasks in the mandate of the agency and the financial resources allocated to them.

2.2. Management and control system(s)

2.2.1. Justification of the budget implementation method(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 Agency for the activities related to, EUON, PARC, for the provisions by of opinions on OELs and assessing public health emergency preparedness as regards preparedness for chemical threats. EUON has been implemented by the Agency under contribution agreements signed between DG GROW and the Agency.

The provision of the Agency of opinions on OELs has been implemented under a Service Level Agreement signed between DG EMPL and the Agency.

Assessing public health emergency preparedness as regards preparedness for chemical threats is implemented until 2027 under a contribution agreement signed between ECHA and DG SANTE.

The Scientific Committee on Consumer Safety (SCCS) will be established in ECHA as envisaged by this proposal.

These tasks will now be part of the Agency's mandate. The financial and staff resources necessary to conduct these tasks will be included in the EU contribution to the Agency and in the overall staff allocation to the agency during the annual budgetary procedure.

The Commission, in the context of its supervision of decentralised entities, will apply its respective control strategies to this expenditure.

In addition, every financial year, the European Parliament, following a recommendation from the Council, grants discharge to each EU agency for the implementation of its budget; this procedure also applies to the Agency.

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

While the Commission will monitor 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 Agency will be covered by their internal control and risk management systems that are aligned with the relevant international standards. The Commission will apply the controls through its supervision of decentralised agencies. No specific risks are identified in relation with the implementation of the additional budget to be provided to the Agency.

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio between the control costs and the 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 the Commission is responsible for the regular payment of the contributions.

2.3. Measures to prevent fraud and irregularities

In addition to the controls stemming from the anti-fraud strategy of the Agency, 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 Commission services complement this by the 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.[140]	from EFTA countries [141]	from candidate countries and potential candidates [142]	From other third countries	other assigned revenue
	03.1001	Non-diff.	YES	NO	NO	NO

140 Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

141 EFTA: European Free Trade Association.

142 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

3.2.1.1. Appropriations from voted budget

The European Chemicals Agency (ECHA)	Year **2027**	**TOTAL MFF 2021-2027**	*Year **2028**[143]*
Budget line: 03.1001 / EU Budget contribution to the Agency	**0,577**	**0,577**	***2,956***

The EU budget contribution to the Agency's budget line 03.1001 in 2027 will be compensated by a corresponding reduction of the envelope of the programme: Single Market Programme/ SME pillar from which are currently financed the PARC and EUON contribution agreements.

However, without prejudice to the Commission proposal on the next Multiannual Financial Framework, the aim is to simplify the financing of the Agency and to group the EU contribution to this Agency into a EU contribution to only one budget line, e.g. 03.1001 under Heading 1.

			Year **2027**	**TOTAL MFF 2021-2027**	*Year **2028***
TOTAL operational appropriations (including contribution to decentralised agency)	Commitments	(4)	**0,577**	**0,577**	*2,956*
	Payments	(5)	**0,577**	**0,577**	*2,956*
TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)	0.000	0.000	*0.000*
TOTAL appropriations under HEADING 1 of the multiannual financial framework	Commitments	=4+6	**0,577**	**0,577**	*2,956*
	Payments	=5+6	**0,577**	**0,577**	*2,956*

3.2.2. Estimated human resources and the use of appropriations required in a decentralised agency

Staff requirements (full-time equivalent units)

143 The financing from 2028 onwards under the new Multiannual Financial Framework (MFF) is indicative, without pre-empting and pre-judging the Commission proposal and the agreement on the next MFF.

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Agency: ECHA	Year **2027**	*Year **2028***
Temporary agents (AD Grades)		5
Temporary agents (AST grades)		1
Temporary agents (AD+AST) subtotal[144]		*6*
Contract agents[145]	5	*8*
Seconded national experts		
Contract agents and seconded national experts subtotal	***5***	***8***
TOTAL staff	**5**	**14**

Appropriations in EUR million (to three decimal places)

Agency: ECHA	Year **2027**	**TOTAL2021 - 2027**	*Year **2028***
Title 1: Staff expenditure	0,577	**0,577**	***2,256***
Title 2: Infrastructure and operating expenditure	-	-	-
Title 3: Operational expenditure[146]			***0,700***
TOTAL of appropriations covered by the EU budget	**0,577**	**0,577**	***2,956***[147]

4. DIGITAL DIMENSIONS

4.1. Requirements of digital relevance

This specific initiative has no requirement of digital relevance for the following reasons:

- The European chemicals Agency is an established Agency since 2007. The current proposal only targets reforms of the governance of the Agency to allow it to meet it's the

144 Of which 3 TA corresponding to the integration of the OEL contribution agreement, 2 to support the work of the SCCS and one for the SCBHT in 2028.

145 Of which 3 CA corresponding to the integration of the EUON contribution agreement, 2 CA corresponding to the integration of the PARC contribution agreement, 1 CA for the SCCS, and 2 CA corresponding to the integration of the OEL as of 2028.

146 0,500 as of 2028 for the SCCS and an additional 0,200 as of 2028 for OEL

147 Without prejudice to the outcome of the post 2027 multiannual financial framework, the budgetary impact following the outsourcing of the SCCS to ECHA will not be funded by any programme for the Union's action in the field of health

obligations stemming from its existing, new / extended tasks and contributes to enhancing its financing model by removing the impediments to an efficient use of resources.

- The current proposal does not target any specific reforms on digital requirements. The Agency's IT environment is well established, and the digital requirements stem from the sectoral legislation which the Agency has been implementing. The Agency is largely an IT-based agency, viewing IT as key enabler for all the regulatory work that it carries out. The availability of all data in digital format ensures accessibility and automation in the processing of that data. Through this, the Agency is able to process a high number of submissions respecting the legally binding deadlines in the sectoral legislation and to perform automated checks on those dossiers and automated dissemination of the data.
- The Agency will continue to invest in IT tools to enable efficiencies, both for companies who have regulatory obligations to submit data to the Agency and to Member States, and for Authorities who are using those data under the regulatory processes under the regulations, and for any potential future roles in adjacent areas of chemicals regulation.
- A large portion of the total budget for IT is invested in tools and operations, supporting not only the Agency but also industry and Authorities. Without these tools, the work would simply stop. Without efficient tools, the work will significantly slow down, and less progress (output) would be achieved.
- The Financial regulation of the Agency (Article 29) allows for the evaluation of the IT tools. In addition, the Commission's 2nd General Report on REACH carried out as part of the Regulatory Fitness and Performance (REFIT) in accordance with the Commission's Better Regulation guidelines. It is accompanied by a staff working document (SWD(2018) 58 final) providing the detailed analysis and presenting evidence to substantiate its conclusions. The last REACH review touched upon the digital dimension as relevant.