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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	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 - Mandate for negotiations with the European Parliament

I. INTRODUCTION

1. On 9 July 2025, the Commission transmitted to the European Parliament and the Council the 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("ECHA Basic Regulation")[1].

   The proposal aims to establish a sound basis for the European Chemicals Agency ("ECHA") governance and safeguard a sufficient budget for the ECHA and its scientific committees to carry out their tasks.

[1] 11395/25 + ADD 1

2. During the Danish Presidency, the proposal was presented to the Working Party on the Environment on 15 July 2025. An Ad Hoc Working Party on the ECHA Basic Regulation ("AHWP ECHA") was subsequently established[2] to address the cross-sectoral matters covered by the proposal and carry out preparatory work for its examination within the Council. The proposal and any Presidency compromise text based on it have been examined and discussed in five AHWP ECHA meetings.

3. The proposal on the ECHA Basic Regulation is based on Article 114(1) of the Treaty on the Functioning of the European Union (TFEU), and the European Economic and Social Committee has therefore been consulted. The Committee adopted its opinion[3] on 21 October 2025.

4. In the European Parliament, the ENVI Committee has the lead on this proposal but the discussions have not started yet. It is expected that the European Parliament Plenary will vote on its final report on the proposal in May/June 2026.

II. STATE OF PLAY

5. After successful negotiations with the European Parliament were concluded, the "One Substance, One Assessment" legislative package was formally adopted on 13 November 2025 in first reading[4]. Delegations therefore welcomed the proposal on the ECHA Basic Regulation and considered it an important piece of legislation that complements that package.

6. Since the ECHA Basic Regulation is intended to remove Title X of the current Regulation (EC) No 1907/2006 ("REACH") on the "Agency", several delegations expressed their concerns about the proposal for a targeted revision of the other parts of REACH, which has been delayed several times and remains outstanding. Therefore, a guiding principle of the AHWP ECHA discussions has been to ensure the ECHA Basic Regulation's compatibility with any future revisions of REACH. Specific language was added to Recital 11 of the compromise text to serve as a reminder of that guiding principle.

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2 11660/25
3 NAT/965
4 14549/25, 14551/25 14552/25

7. The compromise text set out in the Annex to this Note aims to strike a balance between the positions of Member States. Changes to the Commission proposal are set out in ***bold/italics***, while ~~strikethrough~~ indicates deletions.

8. The ECHA is a crucial actor in the EU's regulatory ecosystem on chemicals. Therefore, it is of significant importance to provide the necessary clarity and legal certainty regarding how the ECHA functions on legal, scientific, and technical matters. The Presidency believes that the compromise text strikes a careful balance and serves as a good basis for further negotiations with the European Parliament.

III. MAIN ELEMENTS OF THE PRESIDENCY'S COMPROMISE TEXT

Scope, objectives, structure, and management of the ECHA

9. The ECHA Basic Regulation should provide the framework for all the tasks under the sectoral legislation listed in Annex I to the proposal. The legislation listed contains different definitions and scopes of chemicals, mixtures, articles, products, etc. The ECHA Basic Regulation should function by reference to all of them.

   Therefore, the compromise text refers to the more generic term 'chemicals' in most instances, such as in Recital 9, Art 4(1), Art 5(1)(d) and Art37(2). Where the intention is clearly to limit the term, the provision specifies which definition of which legislative act should apply, as is for instance the case in Recital 16 and Art 13(2)(b). This is also aligned with the approach chosen in the "One Substance, One Assessment" legislative package.

10. The language on prevention and management of conflicts of interest has been strengthened throughout the text. A summary of issues was added in Recital 11a while Recital 12 includes a reference to the independence of the Committees from the ECHA staff, and Recital 18a contains a reminder that the Committees' rules of procedure should include provisions on the prevention and management of conflicts of interest.

In Art 4(4) the compromise text underlines the need to prevent and manage conflicts of interests and ensure the ECHA's independence and credibility. A more specific provision was introduced as regards the nomination or appointment of Committee members in Article 14(5a). In Art 17(4) it was further clarified that Member States should refrain from giving Forum members instructions that are incompatible with the Forum's tasks.

11. Capacity building and training to the Committees and the Forum has been added as important task of the ECHA's Secretariat (Art 5(1)(i)).

12. The renewability of Management Board members' terms of office in Art 6(5) has been one of the more controversial issues during the AHWP ECHA discussions. While several delegations wanted to remove any limitations on renewing the term, which aligns with the Common Approach on EU Decentralised Agencies from 2012, others wanted to maintain the status quo, which allows for renewal once. As a compromise, it was proposed that the term be renewable twice, which ensures that renewal of office cannot be done indefinitely, while providing sufficient flexibility to Member States.

13. In Art 9(1), it has been clarified that the Management Board should also appoint the Chairs of the Committees and adopt decisions on the remuneration of Committees or their employers.

14. Art 12(5)(ea) has been inserted, to ensure that the Executive Director coordinates with other Union bodies with regard to potential divergences of scientific opinions between the ECHA and those bodies referred to in Art 45. The language in Art 45 was also further clarified, and Art 45(4) removed due to a duplication with the recently adopted "One Substance, One Assessment" legislative package.

Tasks, membership and functioning of the ECHA Committees

15. The obligation of Member States to nominate two candidates for the membership of the Committee for Risk Assessment ("RAC") in Art 14(1) and the Committee for Socio-economic Analysis ("SEAC") in Art 14(2) have been the most discussed provisions of the Commission proposal. Several delegations supported the ambition of the proposal. However, many delegations emphasized the practical challenges of such an obligation, as the pool of potential candidates in smaller Member States with limited resources would be quite small.

After exploring several iterations to address the Member States' concerns, the final compromise text keeps an obligation of Member States to nominate one candidate each for RAC and SEAC, with the possibility to nominate three candidates for each Committee on a voluntary basis. In Recital 19 it was also clarified that Member States are encouraged to nominate more than one candidate for each Committee. In addition to this, a new Art 14(2a) and new language in Recital 19 was introduced to ensure that ECHA helps the Member States at their request with the identification of any candidates for the membership of Committees.

16. As regards the membership of the Scientific Committee on Consumer Safety ("SCCS") the Presidency clarified in Art 14(5)(b) that the SCCS should consist of 20 members but that the number of members could be adapted depending on the workload.

17. Articles 14(15) and a new paragraph 15a clarified the remuneration mechanism for committee members or their employers, as well as the transfer of fees to a member state for the work of a committee member employed by that state. This mechanism is further explained in a new Recital 19a.

18. As regards the functioning of the Committees, and in particular regarding their rules of procedure to be adopted, a few issues were clarified in Art 15. Instead of approval by the Commission representatives, it is foreseen that the Executive Director will consult the Commission on the rules of procedure for RAC, SEAC and SCCS (Art 15(4)). In Art 15(5) (further explained in Recital 18a) it is underlined that a procedure for a simplified or urgent adoption of opinions should be laid down in the rules of procedure, and a new provision Art 15(5a) requests that the rules of procedure for RAC should establish the conditions under which it is appropriate that RAC working groups adopt opinions on RAC's behalf.

Other

19. The tasks of the Forum were further clarified in Art 18(1) and (2).

20. As regards the structure of the ECHA budget, the revised Recital 23 specifies the sources of general and voluntary contributions, as well as possible revenues.

    In addition, in Art 29(6) it was clarified that, when the Commission reviews the conditions of the reserve, the fluctuations in the ECHA's fee revenues should be taken into account.

21. The Committee procedure in Art 47 was aligned with the usual legal practice (see for instance Regulation (EU) 2019/1021 on persistent organic pollutants).

22. In a new Art 54(2a) it was listed what the first evaluation after two years should in particular assess (splitting RAC, set-up of sub-committees, etc.).

IV. CONCLUSION

23. In view of the above, the Permanent Representatives Committee is invited to examine the Presidency revised compromise text set out in the Annex to this Note, with a view to reach an agreement on a mandate for negotiations with the European Parliament.

24. In accordance with the approach to legislative transparency endorsed by Coreper on 14 July 2020[5], and in full consistency with Regulation (EC) 1049/2001 and the Council's Rules of Procedure, the text of the mandate once agreed will be made public unless the Permanent Representatives Committee objects.

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[5] 9493/20.

ANNEX

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[1]

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

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[1] OJ C , , p. .
[2] OJ C , , p. .

Whereas:

(1) The European Chemicals Agency ('the Agency') was established by Article 75(1) of Regulation (EC) No 1907/2006[3] 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 Regulation (EU) No 528/2012[4], 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.

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[3] 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).

[4] 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).

(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[5], 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')[6] 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[7]. The CSS also announced a Commission proposal to strengthen the governance of the Agency and increase the sustainability of its financing model.

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5 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).

6 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).

7 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.

(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 Commission on decentralised agencies[8] ('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)[9]~~,~~. That decision should be reflected accordingly in this Regulation.

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

[9] 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).

(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~~ ***chemicals*** in order to achieve a high level of protection of human health***, including taking into account the specific needs of vulnerable population groups,*** 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~~,~~***. The Agency should*** engage with relevant stakeholders and collaborate with other Union Agencies and ***the*** Member States ***authorities or bodies carrying out tasks under this Regulation and the sectoral Union legislation (‘***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***. The Agency's structure should be suitable for its current and future tasks and fluctuations in workload.*** 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.

(11a) The Agency should be central to ensuring that chemicals legislation and the decision-making processes and scientific basis underlying it have credibility with all stakeholders and the public. As trust and confidence in the Agency and its opinions and advice by the Union institutions, the Member States, the general public and interested parties is vital, the Agency's independence and that of RAC, SEAC, MSC, Scientific Committee on Consumer Safety ('SCCS')[10], and Biocidal Products Committee ('BPC') (individually 'Committee', and collectively, the 'Committees') should be ensured. Therefore, the Agency and its Committees should have rules on the prevention and management of conflicts of interest. Persons should not be nominated or appointed as members of the Committees if there are reasonable grounds to believe that they have a conflict of interest. Members of the Committees should refrain from any action incompatible with their duties or the performance of their tasks and should be required to make annual declarations of interest.

(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 Committee on Consumer Safety ('SCCS')[11],, Biocidal Products Committee ('BPC') (collectively, the '~~***the*** Committees~~'),~~ and the Forum ***while ensuring the independence of the Committees and respecting the clear division of tasks***.

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[10] ***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.***

~~[11] 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.~~

(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~~***, SEAC and SCCS*** 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[12]. Articles 16, 16a and 18a of Directive 2004/37/EC of the European Parliament and of the Council[13] and Articles 18c and 22a of Directive 2009/148/EC of the European Parliament and of the Council[14] 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.

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12 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).

13 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).

14 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).

(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 in cosmetic products, as managed by Regulation (EC) No 1223/2009[15]. 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 ***and*** working groups. In order for the Commission to exercise its oversight, the Commission representatives in the Management Board should ~~approve~~ ***be consulted on*** the rules of procedure, without compromising the independence of the Committees and their working groups.

(18a) The rules of procedure of the Committees should include provisions on the prevention and management of conflicts of interest. The rules of procedure should also include arrangements for adopting opinions through a simplified procedure. The Rules of Procedure for RAC should also include conditions under which the working groups can adopt opinions on behalf of RAC, including the conditions under which these opinions would still have to be adopted in the RAC plenary.

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15 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).

(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~~ ***one member*** for RAC and SEAC respectively and should be entitled to nominate up to ~~two~~ ***three*** additional members***. Member States are encouraged to nominate more than the one candidate. Member States should continue to be able to nominate persons from any nationality as members of RAC and SEAC. There is no requirement of nationality, or employment as public servants. The nominees should meet the requirements to membership of RAC and SEAC. Upon request from a Member State, the Agency should facilitate finding suitable candidates for RAC and SEAC. If the Agency considers it appropriate, it can establish a list of qualified candidates that could be nominated by Member States for RAC and SEAC***. 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.

(19a) The Agency should provide clear information to the Member States on the expected workload for the RAC and SEAC members, when those members are employed by the public service of the Member States or work under contract with the public service of the Member States. Those members can be compensated either by remuneration or transfer of fees, as foreseen in the financial arrangements established by the Management Board, following a positive opinion by the Commission. The Members of the Committees, including where they are employed in the public service of the Member State should be remunerated by the Agency where and as foreseen in the financial arrangements established by the Management Board, and following a positive opinion by the Commission. Where sectoral Union legislation provides for a transfer of fees to Member States as compensation for work of members of the Committees employed by the Member State, the Member States should be compensated.

(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[16].

(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 ***general budget of the*** Union, fees ***and charges*** payable by duty holders ***where these are due under sectoral Union legislation assigning tasks to the Agency, and any*** ~~and~~ voluntary contributions from Member States ***and contributions from third countries participating in the work of the Agency***. No financial contribution received by the Agency from Member States, third countries, or other entities or persons should compromise its independence and impartiality***. In exceptional and duly justified cases, the Agency should also be in a position to receive delegation agreements or ad hoc grants, and to charge for publications and any services provided***. The Union budgetary procedure should be applicable as far as the Union contribution and any other subsidies chargeable to the general budget of the Union are concerned, while the auditing of accounts should be carried out by the European Court of Auditors.

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[16] 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)**.**

(24) The financial and administrative framework in which the Agency operates is more complex than for other Union agencies[17], as the Agency is partially financed by fees for its activities under Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008[18] 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[19] and (EU) 2019/1021[20]. 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. ***To ensure transparency, the Agency should maintain an analytical monitoring of the income from fees and charges by activity.*** The removal of the segregation of budgets should not affect existing obligations of financial contributions by third countries to the Agency.

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

18 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).

19 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).

20 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).

(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 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[21]. 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.

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

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

(33) ~~The implementing powers relating to determining~~ ***In order to ensure uniform conditions for the implementation of*** the qualifications required for the members of the Board of Appeal, which were set out in Commission Regulation (EC) 1238/2007[22], and the procedures of the Board of Appeal***, implementing powers should be conferred to the Commission. Those powers*** should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and Council[23].

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[22] 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).

[23] 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).

(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[24] and Regulation (EU) 2023/1542 of the European Parliament and of the Council[25], 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. ***In order to ensure the continuity of the SCCS, it is also necessary to lay down transitional provisions for members of the SCCS which were appointed in accordance with Commission Decision (EU) 2024/1514.***

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[24] 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).

[25] 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).

(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 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)[26].

Article 4

Objectives and tasks of the Agency

1. The Agency shall contribute to the implementation and enforcement of ***relevant*** Union legislation and policies related to the hazards, risks and safe use of ~~chemical substances, mixtures and articles~~***chemicals***, 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 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[27] and promoting alternatives to animal testing. ***The Agency shall aim to contribute to objectives of the sectoral Union legislation assigning tasks to it.***

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[26] 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).

[27] 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)**.**

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. ***The Agency shall in particular ensure that conflicts of interest are prevented or managed, so as to ensure its independence and credibility with stakeholders and the public.***

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***, within its mandate and expertise,*** 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;

(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***, amongst others,*** 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 ***and hazards*** 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~~ ***chemicals***;

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

(f) ~~the~~ ***a*** 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~~ ***carry out the tasks assigned to it pursuant to sectoral Union legislation***;

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

(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 ***and capacity building and training*** 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 ***and appointed by the Council***;

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

(c) two ~~experts~~ ***independent persons*** appointed by the European Parliament.

2. The representatives of the Member States, the representatives of the Commission and ~~experts~~ ***the independent persons*** 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 ***the most concerned*** non-governmental ***organisations and*** 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~~ ***twice***. 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 ***with voting rights***.

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)[28], on the appointing authority and on the authority empowered to conclude a contract of employment (the 'appointing authority powers');

[28] 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).

(m) adopt, in agreement with the Commission, appropriate implementing rules for giving effect ~~torticle~~ ***to Article*** 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);

(sa) appoint the Chairpersons of the Committees;

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

(ta) adopt decisions on the remuneration of members of the Committees or their employers

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

(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[29], 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.

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[29] 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).

Article 10

Voting rules of the Management Board

1. The Management Board shall act by a ~~two third~~ ***two-thirds*** 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[30] on the Framework financial regulation for decentralised 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).

[30] 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).

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~~;

(ea) ensure coordination with other Union bodies with regard to potential divergence of scientific opinion 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[31] 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.

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[31] 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).

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.

   (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 ***pursuant to paragraph 2*** 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~~ ***one candidate*** for membership of RAC and may nominate up to ~~two~~ ***three*** 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~~ ***one candidate*** for membership of SEAC and may nominate up to ~~two~~ ***three*** additional candidates.

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

2a. At the request of a Member State, the Agency shall assist that Member State with the identification of possible candidates for nomination by that Member State pursuant to paragraphs 1 and 2.

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;

(iva) safety assessment of nanomaterials

(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. ***The Executive Director may propose to the Management Board that the number of members is adjusted depending on the workload of the SCCS.***

5a. Member States shall not nominate or appoint, and the Management Board shall not appoint, members of the Committees where, inter alia, based on an analysis, there are reasonable grounds to believe that a conflict of interest exists.

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~~ ***the Committees*** 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.

7a. Only members of the Committees shall have voting rights. Co-opted members, experts, advisers and stakeholders shall not have voting rights.

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***, and administrative support*** to those members of the Committees that they have nominated or appointed and shall facilitate ***their effective participation in*** 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~~ ***The members of all the Committees mentioned in this paragraph*** 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~~ ***work in the Committees*** and the work ~~of~~ ***in*** their ***respective*** 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~~ ***of a Committee, or the Member State by which the*** person~~'s employer as referred to in paragraph 13~~ ***is employed or under contract***, shall be remunerated by the Agency ***where and as foreseen*** 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~~ ***is to*** 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.~~

By derogation to the first subparagraph, where the member concerned fails to fulfil any of those tasks, the Executive Director may withhold remuneration.

15a. Where a transfer of fees to Member States as compensation for the work of a member of the Committee employed by the Member State is established in sectoral Union legislation, the Member States shall be compensated by the Agency where and as foreseen in the financial arrangements established by the Management Board following a positive opinion by the Commission.

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 ***on the website of the Agency***.

3. The Secretariat shall provide scientific and administrative support to the technical and scientific work of the Committees ***and the Forum, including training***.

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. ***For*** the rules of procedure of RAC ~~and SEAC~~***, SEAC and SCCS, the Executive Director*** shall ~~require the approval of~~ ***consult*** the representatives of the Commission in the Management Board***, when preparing the rules for adoption by the Management Board***.

5. The rules of procedure of each Committee shall ***in particular*** 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.~~***:***

(a) replacing and co-opting members,

(b) the creation and organisation of working groups, if applicable,

(c) delegating certain tasks to such working groups, if applicable,

(d) a simplified or urgent adoption of opinions, and

(e) the management of conflicts of interest.

The rules of procedure of each Committee shall be published.

5a. The rules of procedure of RAC shall establish the conditions under which its working groups may, where appropriate, adopt opinions on RAC's behalf.

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 Committee,*** 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. ***This list shall be published on the website of the Agency.***

5. The provisions on independence in Article ~~14(9)~~ ***14(10)***, on contractual arrangements in Article 14(~~13~~ ***14***) and on the financial arrangements for remuneration in Article 14(~~14~~ ***15***) 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. ***The*** Member States shall ~~not instruct the members of~~ ***refrain from giving*** the Forum~~,~~ ***members*** or their ~~scientific and technical~~ advisers and experts ***any instruction which is incompatible with the individual tasks of those persons or with the tasks and responsibilities of the Forum***.

5. The Forum shall draft a proposal for its own rules of procedure to the Management Board. The rules of procedure shall ***in particular*** 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~~ ***act as a horizontal platform to promote coherence, synergies, and the exchange of information and best practices between enforcement authorities, supporting the effective enforcement of*** sectoral Union legislation.

2. The Forum shall ~~coordinate a network of Member States competent authorities responsible for the enforcement of~~ ***facilitate the organisation of joint activities. The Forum shall undertake the tasks assigned to it under*** 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~~ ***shall*** 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~~ ***shall*** adopt implementing acts determining the procedures of the Board of Appeal and its Registry***, including on the use of alternates and additional members***. 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~~ ***a proposal*** by the Executive Director, the Management Board shall endorse ~~a~~ ***the*** draft single programming document containing the following:

   (a) ***multiannual and annual programming and*** all the ***other*** 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***, referred to in paragraph 1, point (a),*** 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~~ ***multiannual*** programming referred to in paragraph 1***, point (a)***. 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~~ ***multiannual*** 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~~ ***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~~ ***taking into account fluctuations in the Agency's fee revenues over successive years and any other possible mitigation measures***.

The Commission is empowered to adopt delegated acts in accordance with Article 46(1) to amend paragraph 5, where the review, referred to in the first subparagraph, indicates that amendments to paragraph 5 are necessary.

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[32].

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.

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[32] 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[33] 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)[34]. 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[35].

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33 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).

34 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).

35 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).

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[36].

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.

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[36] 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).

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[37], 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 on their own, in mixtures or in articles~~ ***chemicals*** where such information is not of a confidential nature as defined in sectoral Union legislation.

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[37] [+][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.]

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[38] 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.

[38] 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).

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.

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~~ ***originating*** Union ~~legislation, under which the information has been submitted and~~ ***act, as defined by Article 2(7) of Regulation (EU) XX/XXX[+], and is*** 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.

[+] ***[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.]***

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 ***as referred to in paragraph 1***, it shall contact the ***other*** 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 ***other*** body concerned shall cooperate to resolve the ***any*** divergence. If the Agency and the ***other*** 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 ***any*** relevant uncertainties in the data and ***give*** the underlying reasons for the ~~diverging~~ ***divergence of*** opinions, including on ***reasons related to*** methodological differences~~, and~~. ***The report shall*** be made publicly available ***on the website of the Agency***. Where the ***other*** body concerned is a Union agency or a scientific committee, the Agency shall ***also*** 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[39].

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.

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. ***Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act, and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.***

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

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]~~ ***[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]~~ ***[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]~~ ***[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.

2a. The first evaluation shall in particular assess:

(a) the functioning of RAC, including the possibility of splitting RAC;

(b) the necessity to introduce sub-committees of Committees;

(c) the necessity of a systematic involvement of Member States in the SCCS.

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~~ ***In accordance with paragraph 3***, 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[40] 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.

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[40] 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).

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*

ANNEX I

SECTORAL UNION LEGISLATION REFERRED TO IN ARTICLES 4, 5, 9, 12, 13, 14, 16, 18, 23, 24, 37, 42

1. 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[1];

2. 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[2];

3. 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[3];

4. 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) [4];

5. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives[5];

6. 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)[6];

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1 OJ L 396, 30.12.2006, p. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj
2 OJ L 353, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj
3 OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj
4 OJ L 201, 27.7.2012, p. 60, ELI: http://data.europa.eu/eli/reg/2012/649/oj
5 OJ L 312, 22.11.2008, p. 3, ELI: http://data.europa.eu/eli/dir/2008/98/oj
6 OJ L 435, 23.12.2020, p. 1, ELI: http://data.europa.eu/eli/dir/2020/2184/oj

7. 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[7];

8. 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[8];

9. 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[9];

10. 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[10];

11. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy[11];

12. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration[12];

13. Directive 2008/105/EC on environmental quality standards in the field of water policy[13];

14. Commission Directive 2009/90/EC of 31 July 2009 laying down, pursuant to Directive 2000/60/EC of the European Parliament and of the Council, technical specifications for chemical analysis and monitoring of water status[14];

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7 OJ L 114, 12.4.2022, p. 22, ELI: http://data.europa.eu/eli/dec/2022/591/oj
8 OJ L 314, 6.12.2022, p. 26, ELI: http://data.europa.eu/eli/reg/2022/2371/oj
9 OJ L 191, 28.7.2023, p. 1, ELI: http://data.europa.eu/eli/reg/2023/1542/oj
10 OJ L, 2024/1785, 15.7.2024, ELI: http://data.europa.eu/eli/dir/2024/1785/oj
11 OJ L, 327, 22.12.2000, p. 1, ELI: http://data.europa.eu/eli/dir/2000/60/oj
12 OJ L 372, 27.12.2006, p. 19, ELI: http://data.europa.eu/eli/dir/2006/118/oj
13 OJ L 348, 24.12.2008, p. 84, ELI: http://data.europa.eu/eli/dir/2008/105/oj
14 OJ L 201, 1.8.2009, p. 36, ELI: http://data.europa.eu/eli/dir/2009/90/oj

15. 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[15];

16. Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants ***(recast)***[16];

17. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC[17];

18. Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast)[18];

19. Regulation 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[19]

20. Directive of the European Parliament and 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[++];~~[20]~~

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15 OJ L, 2025/40, 22.1.2025, ELI: http://data.europa.eu/eli/reg/2025/40/oj

16 OJ L 169, 25.6.2019, p. 45, ELI: http://data.europa.eu/eli/reg/2019/1021/oj

17 OJ L 117, 5.5.2017, p. 1, ELI: http://data.europa.eu/eli/reg/2017/745/oj

18 OJ L 174, 1.7.2011, p. 88, ELI: http://data.europa.eu/eli/dir/2011/65/oj

19 [+][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.]

[++] ***[OP: Please insert in the text the number of the Directive contained in document COM (2023) 781 final (2023/0454 (COD)) and insert the number, date, title and OJ reference of that Directive in the footnote.]***

~~20~~ ~~[++][OP: Please insert in the text the number of the Regulation contained in document COM(2023) 781 final 2023/0454 (COD) and insert the number, date, title and OJ reference of that Regulation in the footnote.]~~

21. Regulation of the European Parliament and 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;[21]

22. Regulation of the European Parliament and 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[++++];~~[22]~~

23. Regulation of the European Parliament and Council on the safety of toys and repealing Directive 2009/48/EC~~[23]~~[+++++];

24. Regulation (EC) No 1223/2009 of the European Parliament and of the Council of ***30*** November 2009 on cosmetic products ***(recast)***[24];

25. Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC[25].

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21 [+++][OP: Please insert in the text the number of the Regulation contained in document COM(2023) 783 final 2023/0455 (COD) and insert the number, date, title and OJ reference of that Regulation in the footnote.]

[++++] ***[OP: Please insert in the text the number of the Regulation contained in document COM(2023) 451 final 2023/0284(COD) and insert the number, date, title and OJ reference of that Regulation in the footnote.]***

~~22~~ ~~[++++][OP: Please insert in the text the number of the Regulation contained in document COM(2023) 451 final 2023/0284(COD) and insert the number, date, title and OJ reference of that Regulation in the footnote.]~~

~~23~~ ~~[+++++][OP: Please insert in the text the number of the Regulation contained in document COM(2023) 426 final 2023/0290 (COD) and insert the number, date, title and OJ reference of that Regulation in the footnote.]~~

[+++++] ***[OP: Please insert in the text the number of the Regulation contained in document COM(2023) 426 final 2023/0290 (COD) and insert the number, date, title and OJ reference of that Regulation in the footnote.]***

24 OJ L 342, 22.12.2009, p. 59–209, ELI: http://data.europa.eu/eli/reg/2009/1223/oj

25 OJ L 135, 23.5.2023, p. 1–51, ELI: http://data.europa.eu/eli/reg/2023/988/oj

ANNEX II

Correlation table:

Regulation (EC) No 1907/2006	This Regulation
Article 75(2)	Article 54
Article 76	Article 5
Article 77(1)	Article 4
Article 78	Article 9
Article 79	Article 6
Article 80	Article 7
Article 81	Article 8
Article 82	Article 10
Article 83	Article 12
Article 84	Article 11
Article 85	Article 14
Article 86	Article 17
Article 87	Articles 14 (6) and (7) and Article 16
Article 88	Article 19
Article 89	Article 20
Article 90	Article 21
Article 92	Article 24
Article 93	Article 25
Article 94	Article 26
Article 95	Article 45
Article 96	Article 29
Article 97	Articles 30 and 31

Article 98	Article 33
Article 99	Article 32
Article 100	Article 2
Article 101	Article 55
Article 102	Article 36
Article 103	Articles 34 and 35
Article 104	Article 57
Article 105	Article 38
Article 106	Article 42
Article 107	Article 42
Article 108	Article 41
Article 109	Article 37
Article 110	Article 44