

Compromise Amendment 1

Compromise amendment replacing Amendments: 13-18, 139-162, 256

Proposal for a regulation

Article 3

Text proposed by the Commission

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).**

Amendment

The Agency shall have its seat in Helsinki, Finland.

Proposal for a regulation

Article 4 – paragraph 1

Text proposed by the Commission

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

Amendment

1. The Agency shall contribute to the implementation and enforcement of Union legislation and policies related to the hazards, risks, safe use **and environmental sustainability** of chemical substances, mixtures and articles, provide scientific opinions and advice and independent information on all matters within that field, **monitor emerging chemical risks and collect or generate data on chemicals**, and communicate on those matters.

Proposal for a regulation

Article 4 – paragraph 2 – subparagraph 1

Text proposed by the Commission

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

Amendment

In the fulfilment of its objectives, the Agency shall contribute to **ensuring** a high level of protection of human health and the environment, **including the protection of vulnerable groups. The Agency shall aim to deliver quality**, coherence and consistency in chemicals assessment and management across the Union **which is key to ensuring the free circulation of**

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 enterprises²⁶ and promoting *alternatives to animal testing*.

²⁶ 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>)

substances in the internal market, while *contributing to* enhancing *the* 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 enterprises²⁶ and promoting *and strengthening expertise in the substitution of harmful chemicals and groups of harmful chemicals as well as the development, and use of non-animal approaches and emerging methodologies*.

²⁶ 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>)

Proposal for a regulation **Article 4 – paragraph 5 – point b**

Text proposed by the Commission

(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;

Amendment

(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 *objectives of ensuring a high level of protection of human health and the environment, occupational health standards, the* specific needs of SMEs and the *requirement* of replacing animal testing with *non-animal approaches* where scientifically possible;

Proposal for a regulation
Article 4 – paragraph 5 – point g a (new)

Text proposed by the Commission

Amendment

(ga) ensure that conflicts of interest are prevented or managed, so as to ensure its independence and credibility with stakeholders and the general public;

Proposal for a regulation
Article 4 – paragraph 5 – point h

Text proposed by the Commission

Amendment

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

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

Proposal for a regulation
Article 4 – paragraph 5 – point k a (new)

Text proposed by the Commission

Amendment

(k a) upon request from the European Parliament or a Member State, provide scientific opinions and technical assistance in a field falling within its competences;

Proposal for a regulation
Article 4 – paragraph 5 – point k aa (new)

Text proposed by the Commission

Amendment

(kaa) provide annual training for staff and committee members, and share knowledge with all stakeholders.

Proposal for a regulation
Article 4 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. Requests received under paragraph 5, points (c), (d), (e), (k) and (ka), of this Article and under Article 13(2), point (b), as well as a regular update on their status shall be made publicly available on the Agency's website.

Compromise Amendment 2

Compromise amendment replacing Amendments: 19-36, 163-192

Proposal for a regulation

Article 5 – paragraph 1 – point c

Text proposed by the Commission

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

Amendment

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

Proposal for a regulation

Article 5 – paragraph 1 – point d

Text proposed by the Commission

(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***;

Amendment

(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 ***chemicals***;

Proposal for a regulation

Article 5 – paragraph 1 – point h a (new)

Text proposed by the Commission

Amendment

(ha) an Assembly of accredited stakeholders, as established in Article 41a, which shall aim to reinforce the relationship between accredited stakeholders and the Agency, and facilitate their contribution to the tasks of the Agency;

Proposal for a regulation
Article 5 – paragraph 1 – point i

Text proposed by the Commission

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

Amendment

(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, **capacity building and training**, to the Committees and the Forum, and ensure appropriate coordination between them;

Proposal for a regulation
Article 6 – paragraph 1 – point c

Text proposed by the Commission

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

Amendment

(c) two **independent persons** appointed by the European Parliament, **those persons shall be independent in the performance of their duties and shall neither seek nor take instructions from any Union institution, body, office or agency, any government or from any other public or private body.**

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission

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

Amendment

2. The representatives of the Member States, the representatives of the Commission and **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.

Proposal for a regulation
Article 6 – paragraph 3 – point b

Text proposed by the Commission

(b) trade unions;

Amendment

(b) trade unions, ***including occupational health and safety;***

Proposal for a regulation
Article 6 – paragraph 3 – point d b (new)

Text proposed by the Commission

Amendment

(db) ***non-animal approaches;***

Proposal for a regulation
Article 6 – paragraph 4

Text proposed by the Commission

Amendment

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.

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 ***due regard of their*** relevant managerial, administrative and budgetary skills. In accordance with the principle of equal treatment of ***all genders***, 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.

Proposal for a regulation
Article 6 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. ***Members of the Management Board shall be nominated and appointed in accordance with the rules for conflicts of interest adopted by the Management Board pursuant to Article 9(1), point (e).***

Proposal for a regulation

Article 6 – paragraph 6

Text proposed by the Commission

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

Amendment

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

Proposal for a regulation

Article 9 – paragraph 1 – point m

Text proposed by the Commission

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

Amendment

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

Proposal for a regulation

Article 9 – paragraph 1 – point s

Text proposed by the Commission

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

Amendment

(s) adopt the rules of procedure of the Committees, the Forum, ***and the Assembly of stakeholders;***

Proposal for a regulation

Article 9 – paragraph 1 – point y

Text proposed by the Commission

(y) adopt the practical arrangements for complying with Regulation (EC) No 1049/2001 of the European Parliament and of the Council²⁸, including appeals or remedies necessary for reviewing a partial or full rejection of a confidentiality request;

Amendment

(y) adopt the practical arrangements for complying with Regulation (EC) No 1049/2001 of the European Parliament and of the Council²⁸, including appeals or remedies necessary for reviewing a partial or full rejection of a confidentiality request ***as referred to in Article 37a;***

²⁸ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of

²⁸ 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>).

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>).

Proposal for a regulation
Article 10 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Proposal for a regulation
Article 10 – paragraph 3

Text proposed by the Commission

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) 2019/715²⁹ 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.***

Amendment

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) 2019/715²⁹ 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.

²⁹ 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

²⁹ 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).

Council (OJ L 122, 10.5.2019, p. 1, ELI: http://data.europa.eu/eli/reg_del/2019/715/oj).

Proposal for a regulation **Article 11 – paragraph 2**

Text proposed by the Commission

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.

Amendment

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.

Proposal for a regulation **Article 12 – paragraph 3**

Text proposed by the Commission

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.

Amendment

3. Without prejudice to the powers of the Commission and of the Management Board, the Executive Director shall be independent in the performance of **their** 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.

Proposal for a regulation
Article 12 – paragraph 5 – point d

Text proposed by the Commission

(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;

Amendment

(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 ***and of the independence of those opinions;***

Proposal for a regulation
Article 12 – paragraph 5 – point e

Text proposed by the Commission

(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;***

Amendment

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

Proposal for a regulation
Article 12 – paragraph 5 – point e a (new)

Text proposed by the Commission

Amendment

(ea) ensure an appropriate and timely coordination with other Union bodies, including in relation to potential divergence of scientific opinion as referred to in Article 45;

Proposal for a regulation
Article 12 – paragraph 5 – point h a (new)

Text proposed by the Commission

Amendment

(ha) ensure appropriate and timely response to reports of attempts to exert pressure or attempts of undue influence made pursuant to Article 19(3a); a record of all those reports and responses shall be included in the annual activity report referred to in point (q) of this paragraph; with anonymisation of those who have reported;

Proposal for a regulation
Article 12 – paragraph 5 – point p a (new)

Text proposed by the Commission

Amendment

(pa) appoint the Agency's representative to the task force as referred to in Article 44;

Proposal for a regulation
Article 12 – paragraph 5 – point q

Text proposed by the Commission

Amendment

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

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

Proposal for a regulation
Article 12 – paragraph 5 – point s

Text proposed by the Commission

Amendment

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

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

Proposal for a regulation
Article 12 – paragraph 6

Text proposed by the Commission

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.

Proposal for a regulation
Article 12 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

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.

Amendment

6 a. The Executive Director shall ensure a psychologically healthy workplace by giving due consideration to measures beneficial to mental health at work.

Compromise Amendment 3

Compromise amendment replacing Amendments: 37-64, 193-244

Proposal for a regulation

Article 13 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Proposal for a regulation

Article 13 – paragraph 2 – point b

Text proposed by the Commission

(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.

Amendment

(b) all other matters not already covered by paragraph 1 or paragraph 2(a), related to the hazards, risks and safe use of 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.

Proposal for a regulation

Article 13 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. In addition to the tasks referred to in paragraph 1, the Committees shall, at the Executive Director's request,

(a) provide technical and scientific support for steps to improve cooperation among the Union, Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on the sound management of chemicals in developing countries.

(b) draw up an opinion on any other aspects concerning the safety of substances on their own, in mixtures or in articles.

Proposal for a regulation
Article 13 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2 b. The European Parliament or a Member State may submit a request to the Agency to issue a scientific opinion on matters falling within its competences. The request shall be accompanied by background information explaining the scientific issue to be addressed and the Union interest.

The Agency may refuse or propose amendments to a request for an opinion in consultation with the European Parliament or the Member State(s) that made the request. Justifications for the refusal shall be given to the European Parliament or the Member State(s) that made the request.

Proposal for a regulation
Article 13 – paragraph 3

Text proposed by the Commission

Amendment

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

3. The number of 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.

Proposal for a regulation
Article 14 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

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

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

Proposal for a regulation
Article 14 – paragraph 4

Text proposed by the Commission

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.***

Amendment

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.

Proposal for a regulation
Article 14 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. At the request of a Member State, the Agency shall assist that Member State to identify possible candidates for nomination by that Member State pursuant to paragraphs 1 and 2. The obligation to nominate a candidate shall however remain with the Member States.

Proposal for a regulation
Article 14 – paragraph 5 – subparagraph 1

Text proposed by the Commission

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.

Amendment

The members of SCCS shall be ***selected and*** appointed by the Management Board from a list of suitable candidates ***drawn up by the Executive Director. The list shall be drawn up on the basis of applications received following*** a call for expression of interest launched by the Agency ***and shall aim to include at least twice the number of candidates necessary to fill the posts in the SCCS and for each field of expertise.***

Proposal for a regulation

Article 14 – paragraph 5 – subparagraph 2 – point a – point iv

Text proposed by the Commission

Amendment

(iv) exposure and risk assessment;

(iv) exposure and risk assessment;

Proposal for a regulation

Article 14 – paragraph 5 – subparagraph 2 – point a – point iv a (new)

Text proposed by the Commission

Amendment

(iv a) safety assessment of nanomaterials;

Proposal for a regulation

Article 14 – paragraph 5 – subparagraph 2 – point a – point v

Text proposed by the Commission

Amendment

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

(v) ***non-animal approaches***, and emerging methodologies, including new approach methodologies and in vitro/ or in silico techniques;

Proposal for a regulation

Article 14 – paragraph 5 – subparagraph 2 – point b

Text proposed by the Commission

Amendment

(b) independence and absence of conflicts of interest.

(b) independence and absence of conflicts of interest, ***in compliance with rules adopted pursuant to Article 9(1), point (e).***

Proposal for a regulation

Article 14 – paragraph 5 – subparagraph 3

Text proposed by the Commission

Amendment

The SCCS shall consist of ***maximum*** 20 members.

The SCCS shall consist of 20 members ***and shall aim to include at least two members for each field of expertise represented.***

Proposal for a regulation
Article 14 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. Members of the Committees shall be nominated and appointed in accordance with the rules for conflicts of interest adopted by the Management Board pursuant to Article 9(1), point (e).

Proposal for a regulation
Article 14 – paragraph 6

Text proposed by the Commission

Amendment

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

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 **and taking into account geographical diversity**. The maximum number of co-opted members for **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.

Proposal for a regulation
Article 14 – paragraph 7 a (new)

Text proposed by the Commission

Amendment

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

Proposal for a regulation
Article 14 – paragraph 9

Text proposed by the Commission

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

Amendment

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 **allowing their effective participation** and shall facilitate the activities of the committees and their working groups.

Proposal for a regulation
Article 14 – paragraph 10

Text proposed by the Commission

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

Amendment

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. **Those members** and members of MSC and BPC shall act in the public interest **and in the interest of the Union**. They shall refrain from any action incompatible with their duties or the performance of their tasks.

Proposal for a regulation
Article 14 – paragraph 11

Text proposed by the Commission

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.

Amendment

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.

Proposal for a regulation
Article 14 – paragraph 12

Text proposed by the Commission

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

Amendment

12. The members of the **MSC, and the BPC** that are appointed by a Member State shall ensure that there is appropriate coordination between the **work in the Committees** and the work **in** their Member State competent authorities.

Proposal for a regulation
Article 14 – paragraph 15

Text proposed by the Commission

15. The member concerned, or that person's employer as referred to in paragraph **13**, shall be remunerated by the Agency in accordance with the financial arrangements established by the Management Board following a positive opinion by the Commission. The list of tasks for which remuneration may be paid shall be established by the Management Board following a positive opinion of the Commission. Where the member concerned fails to fulfil any of those tasks, the Executive Director may withhold remuneration.

Amendment

15. The member concerned, or that person's employer as referred to in paragraph **14**, shall be remunerated by the Agency in accordance with the financial arrangements established by the Management Board following a positive opinion by the Commission. The list of tasks for which remuneration may be paid shall be established by the Management Board following a positive opinion of the Commission. Where the member concerned fails to fulfil any of those tasks, the Executive Director may withhold remuneration.

Proposal for a regulation
Article 15 – paragraph 1

Text proposed by the Commission

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.

Amendment

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.

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission

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**.

Amendment

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 **made publicly available on the Agency's website**.

Proposal for a regulation
Article 15 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Proposal for a regulation
Article 15 – paragraph 4

Text proposed by the Commission

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

Amendment

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. **When preparing** the rules of procedure of RAC, **SEAC and SCCS, the Executive Director** shall **consult** the representatives of the Commission in the Management Board.

Proposal for a regulation
Article 15 – paragraph 5

Text proposed by the Commission

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

Amendment

5. The rules of procedure of each Committee shall lay down the procedures for replacing and co-opting members, for the creation and organisation of working groups and for delegating certain tasks to such working groups, if applicable. **The adoption of opinions shall not be delegated to those working groups.** 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 **made publicly available on the Agency's website**.

Proposal for a regulation
Article 15 – paragraph 6

Text proposed by the Commission

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

Amendment

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

Proposal for a regulation
Article 15- paragraph 6 a (new)

Text proposed by the Commission

Amendment

6a. For all Committee meetings detailed summaries shall be made available to the public in due time, to allow the public to follow the progress made on dossiers and other items discussed,

Proposal for a regulation
Article 16 – paragraph 4

Text proposed by the Commission

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.

Amendment

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 *as well as the qualifications of those experts*.

Proposal for a regulation
Article 16 – paragraph 5

Text proposed by the Commission

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

Amendment

5. The provisions on independence in Article **14(10)**, on contractual arrangements in Article 14(**14**) and on the financial arrangements for remuneration in Article 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.

Proposal for a regulation
Article 17 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Proposal for a regulation
Article 19 – paragraph 1

Text proposed by the Commission

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.

Amendment

1. The membership of the Committees and of the Forum **and the list of experts referred to in Article 16(4)** shall be published by the Executive Director on the Agency’s website. Individual members **and experts** 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.

Proposal for a regulation
Article 19 – paragraph 3

Text proposed by the Commission

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.

Amendment

3. At **each meeting**, the members of the Management Board, the Executive Director, chairpersons and members of the Committees and the Forum and any participating experts **and advisers** 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.

Proposal for a regulation
Article 19 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3a. Members of the Management Board, chairpersons and members of the Committees and the Forum and any participating experts and advisers shall report without delay to the Executive Director any attempts to exert pressure or attempts of undue influence of which they are the target.

Proposal for a regulation
Article 20 – paragraph 5

Text proposed by the Commission

Amendment

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

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

Proposal for a regulation
Article 24 – paragraph 2

Text proposed by the Commission

Amendment

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.

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 sectoral Union legislation.

Proposal for a regulation
Article 24 – paragraph 3

Text proposed by the Commission

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.

Amendment

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

Proposal for a regulation
Article 25 – paragraph 4

Text proposed by the Commission

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

Amendment

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

Compromise Amendment 4

Compromise amendment replacing Amendments: 65-67, 246-255, BUDG3-BUDG10
(BUDG AM shown for completeness, not for vote in ENVI)

Proposal for a regulation

Article 27 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

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

Proposal for a regulation

Article 27 – paragraph 1 – point a

Text proposed by the Commission

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

Amendment

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

Proposal for a regulation

Article 27 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

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

Proposal for a regulation

Article 27 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

(da) an assessment of the adequacy of its financial and human resources to carry out its current and upcoming tasks;

Proposal for a regulation
Article 27 – paragraph 1 – point d b (new)

Text proposed by the Commission

Amendment

(db) a strategy on the effective use of members and experts referred to in Article 14, paragraph 6, and Articles 16 and 35 respectively;

Proposal for a regulation
Article 27 – paragraph 1 – point d c (new)

Text proposed by the Commission

Amendment

(dc) a strategy on the expected needs and expenses resulting from secondment pursuant to Article 35(2a) and on any decision to grant financial support to national authorities, agencies and research institutes for the implementation of certain tasks within the meaning of Article 41b.

Proposal for a regulation
Article 27 – paragraph 5

Text proposed by the Commission

Amendment

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

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

Proposal for a regulation
Article 27 – paragraph 8

Text proposed by the Commission

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

Amendment

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

Proposal for a regulation
Article 29 – paragraph 4

Text proposed by the Commission

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

Amendment

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

Article 29 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. Fees and charges levied under Union sectoral legislation shall be set at a level sufficient to cover the costs of the services provided in accordance with that legislation;

Proposal for a regulation
Article 29 – paragraph 4 b (new)

Text proposed by the Commission

Amendment

4 b. Within the limits of the budget adopted in accordance with Union budgetary rules, the Agency shall determine the internal allocation of financial resources across its activities and tasks, in line with its mandate and programming documents;

Proposal for a regulation
Article 29 – paragraph 5 – point a

Text proposed by the Commission

(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;

Amendment

(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 the last amended budget approved by the Agency Management Board*** in a given year;

Proposal for a regulation
Article 29 – paragraph 5 – point b

Text proposed by the Commission

(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;***

Amendment

(b) at any moment, the reserve included in the year N in the draft budget for the year N+1 shall not exceed **15%** of the ***average of the total actual amount realised in the last five years*** of the Agency's revenues from the fees and charges referred to in paragraph 3, point (b)

Proposal for a regulation
Article 29 – paragraph 5 – point c a (new)

Text proposed by the Commission

(ca) the Agency shall report annually, as part of its Annual Activity Report, on the reserve's opening balance, inflows, outflows, and justifications;

Amendment

**Proposal for a regulation
Article 29 – paragraph 6**

Text proposed by the Commission

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.*

Amendment

6 The Commission *shall present an assessment of the functioning of the reserve to the European Parliament and to the Council at the end of the fourth year of operation of the reserve. Where appropriate, the Commission shall present a legislative proposal to the European Parliament and to the Council with a view to adapting the reserve.*

**Proposal for a regulation
Article 30 – paragraph 2 a (new)**

Text proposed by the Commission

Amendment

2a. *The Agency shall monitor its costs and the Executive Director shall provide, in a timely manner as part of the Annual Activity Report delivered to the European Parliament, the Council, the Commission and the Court of Auditors, detailed and substantiated information on the costs to be covered by fees and charges that are within the scope of this Regulation.*

**Proposal for a regulation
Article 30 a (new)**

Text proposed by the Commission

Amendment

Article 30a

Revision of the fees

1. *No later than two years after the [date of application of this Regulation] and every three year thereafter, the Commission shall evaluate the budgetary adequacy and adapt accordingly the fees payable to the Agency, notably with regard to ensuring that the revenue derived from the fees when combined with other sources of the*

Agency's revenue is sufficient to cover the cost of the services delivered.

2. No later than two years after the [date of application of this Regulation] and every three year thereafter, the Commission shall report to the European Parliament and to the Council on the budgetary adequacy of the fees payable to the agency and on the coherence and consolidation of the fees.

Compromise Amendment 5

Compromise amendment replacing Amendments: 70-72

Proposal for a regulation

Article 35 – title

Text proposed by the Commission

Seconded national experts and other staff

Amendment

Seconded national experts and other staff
seconded *in the interest of the service*

Proposal for a regulation

Article 35 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2a. Officials and other servants employed by the Agency may, in the interest of the service and in accordance with Article 37 of the Staff Regulations of Regulation No 31 (EEC), 11 (EAEC) and Article 51 of the Conditions of Employment of Other Servants of Regulation No 31 (EEC), 11 (EAEC), be seconded to the competent authorities of the Member States or to other public bodies entrusted with tasks related to the Agency's mandate.

Such secondment shall not impact on the capacity, tasks and work of the Agency and shall not affect the independence of the staff concerned and shall be subject to appropriate safeguards concerning conflicts of interest and confidentiality.

Proposal for a regulation

Article 35 – paragraph 2 b (new)

Text proposed by the Commission

Amendment

2b. The Management Board may adopt a decision laying down the conditions under which temporary assignments or secondments in the interest of the service as referred to in

paragraph 2a shall take place.

Compromise Amendment 6

Compromise amendment replacing Amendments: 73, 74, 245, 257-261

Proposal for a regulation

Article 37 – paragraph 2

Text proposed by the Commission

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 where such information is not of a confidential nature as defined in sectoral Union legislation.

Amendment

2. For all ***regulatory, scientific and technical information held by the Agency concerning the safety of substances on their own, in mixtures or in articles and not covered by paragraph 1, Article 37a shall apply, without prejudice to specific provisions in Union legislation on disclosure of information.***

Proposal for a regulation

Article 37 a (new)

Text proposed by the Commission

Amendment

Article 37a

Access to documents

1. Regulation (EC) No 1049/2001 and Regulation (EC) No 1367/2006^{1a} of the European Parliament and the Council shall apply to documents held by the Agency.

2. The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001 and Articles 6 and 7 of Regulation (EC) No 1367/2006, ensuring access that is as wide as possible to documents in its possession.

3. Decisions taken by the Agency

pursuant to Article 8 of Regulation (EC) No 1049/2001 may be the subject of a complaint to the Ombudsman or of an action before the Court of Justice, under the conditions laid down in Articles 228 and 263 TFEU, respectively.

^{1a} Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies (OJ L 264, 25.9.2006, pp. 13–19, ELI: <http://data.europa.eu/eli/reg/2006/1367/oj>).

Proposal for a regulation
Article 38 – paragraph 3

Text proposed by the Commission

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.

Amendment

3. Members of the Management Board, the Executive Director, members of the Committees, the Board of Appeal and the Forum, 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.

Compromise Amendment 7

Compromise amendment replacing Amendments: 75-95, 262-276

Proposal for a regulation Article 41 – paragraph 1

Text proposed by the Commission

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.

Amendment

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.

Proposal for a regulation Article 41 a (new)

Text proposed by the Commission

Amendment

Article 41a

Assembly of accredited stakeholders

1. For the purpose of Article 41, the Agency shall establish and coordinate an Assembly of accredited stakeholders. (the ‘Assembly’)

1a. The Assembly shall aim to reinforce the relationship between accredited stakeholders and the Agency and facilitate their contribution to the tasks of the Agency

2. The Executive Director or a representative of the Executive Director shall be entitled to attend all the meetings of the Assembly. The Assembly shall be chaired by a representative of the Agency. A list of Agency accredited stakeholders shall be made publicly available on the Agency's website.

3. The Management Board shall draw up a list of the members of the Assembly that are selected among stakeholders referred to in Article 15(1) and ensure a balanced representation of industry representatives and civil society organisations among those members.

Proposal for a regulation
Article 41 b (new)

Text proposed by the Commission

Amendment

Article 41b

***Networking of national authorities,
agencies and research institutes***

1. The Agency shall facilitate the networking of national authorities, agencies and research institutes operating in the areas of competence of the Agency. The aim of such networking is, in particular, to facilitate a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects, and the exchange of expertise and best practices in the areas of competence of the Agency.

2. For the purpose of this Article, the Management Board, acting on a proposal from the Executive Director, shall draw up a list, to be made publicly available on the Agency's website, of national authorities, agencies and research institutes referred to in paragraph 1 designated by the Member States which may assist the Agency, either individually or in networks, with its tasks. Without prejudice to the tasks entrusted to the Agency in sectoral legislation, the Agency may entrust to those national authorities, agencies and research institutes certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging risks. Some of those tasks may be eligible for financial support in accordance with paragraph 3.

3. The Management Board shall adopt decisions to grant financial support to national authorities, agencies and research institutes on the list referred to in paragraph 2 for the implementation of certain tasks.

Proposal for a regulation
Article 42 – paragraph 1

Text proposed by the Commission

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.

Proposal for a regulation
Article 43 – paragraph 1

Text proposed by the Commission

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.

Amendment

1. In so far as is necessary to achieve the objectives set out in this Regulation and 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.

Amendment

1. The Agency shall assist Member States and the Commission in promoting the substitution of the most harmful **and other hazardous** chemicals **and groups thereof** by safer and more sustainable alternative substances and technologies and in the development, **regulatory acceptance, uptake and international validation** of relevant scientific methodologies, including **non-animal** 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, **contribution to define data generation needs**, as well as participation in and facilitation of relevant research, development, and innovation activities within the scope of the relevant Union sectoral legislation, **including Regulation (EU) 2021/695 of the European Parliament and of the Council^{1a}, and exposomics where appropriate.**

1^a Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L 170, 12.5.2021, p. 1, ELI: <http://data.europa.eu/eli/reg/2021/695/oj>)

Proposal for a regulation
Article 43 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The Agency shall publish an annual report presenting its recommendations on knowledge and data gaps in terms of regulatory science and regulatory needs, as well as exploratory and fundamental science, in any field within its competence, taking into account emerging risks, and in close cooperation and permanent interaction with relevant Union and international bodies.

Proposal for a regulation
Article 44 – paragraph 1

Text proposed by the Commission

Amendment

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.

1. The Agency shall cooperate with other bodies established under Union law, including but not limited to the European Centre for Disease Prevention and Control (**ECDC**), the European Environment Agency (**EEA**), the European Food Safety Authority (**EFSA**), the European Medicines Agency (**EMA**) and the European Agency for Safety and Health at Work (**EU-OSHA**), 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 **non-animal** approaches, for the assessment of chemicals.

Proposal for a regulation
Article 44 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. The Agency shall ensure cooperation with the European Union Reference Laboratory for alternatives to animal testing (EURL ECVAM), in particular with regard to the development of scientific methodologies and training activities.

Proposal for a regulation
Article 44 – paragraph 1 b (new)

Text proposed by the Commission

Amendment

1b. A permanent task force (the 'task force') shall be established with the Agency, EFSA, EMA, ECDC, EEA, and EU-OSHA.

Proposal for a regulation
Article 44 – paragraph 1 c (new)

Text proposed by the Commission

Amendment

1c. The task force shall focus on cross-sectoral issues that can benefit from a One Health and exposome approach. The task force shall build on existing mechanisms of cooperation, maximising synergies and avoiding duplication.

Proposal for a regulation
Article 44 – paragraph 1 d (new)

Text proposed by the Commission

Amendment

1d. The Agency shall coordinate the work of the task force for 12 months after the task force is established. The coordination and chairing of the work of the taskforce, including leading the coordination of the task force meetings and activities shall rotate among the agencies every 12 months thereafter in accordance with its framework for action referred to in paragraph 1l.

Proposal for a regulation
Article 44 – paragraph 1 e (new)

Text proposed by the Commission

Amendment

1e. *The task force shall consist of staff from each agency referred in paragraph 1b. The Executive Director of each agency shall appoint a representative to the task force and the representatives shall report to their respective Executive Directors on progress. A representative from the Commission shall be invited to participate in the meetings of the task force to ensure close cooperation between the task force and the Commission.*

Proposal for a regulation
Article 44 – paragraph 1 f (new)

Text proposed by the Commission

Amendment

1f. *Each agency referred to in paragraph 1b shall establish a focal point within that agency to coordinate its respective input to joint activities and convey the position of that agency on strategic matters. Each focal point shall keep its own management and interagency mechanisms informed of relevant developments under the task force.*

Proposal for a regulation
Article 44 – paragraph 1 g (new)

Text proposed by the Commission

Amendment

1g. *Task force members may seek to engage other representatives from within each agency for input and advice to support the implementation of the actions, as needed.*

Proposal for a regulation
Article 44 – paragraph 1 h (new)

Text proposed by the Commission

Amendment

1h. Observers and external experts may attend meetings of the task force as and when required, in agreement with the members of the task force.

Proposal for a regulation
Article 44 – paragraph 1 j (new)

Text proposed by the Commission

Amendment

1j. The task force shall not act as a decision-making body. The task force may propose recommendations for action to the senior management of the agencies. Representatives of each agency in the task force shall have an advisory role to the Executive Directors and senior management of its own agency and shall engage with the Commission and other stakeholders for input and advice, as appropriate.

Proposal for a regulation
Article 44 – paragraph 1 k (new)

Text proposed by the Commission

Amendment

1k. The task force shall meet at least six times a year, with at least one annual physical meeting of a more strategic nature. Ad hoc meetings may be organised, as needed.

Proposal for a regulation
Article 44 – paragraph 1 l (new)

Text proposed by the Commission

Amendment

1l. By 31 December each year, members of the task force shall draw up and endorse an annual framework for action describing a plan for the joint One Health and exposome work of the agencies referred to in paragraph 1b.

The framework for action shall include objectives to be pursued by the task force, concrete actions and outcomes to achieve them, and an approximate timeline for the implementation of such actions, and shall be built around the following objectives with regards to One Health and exposome:

- (a) facilitate strategic coordination in its implementation;**
- (b) promote research coordination;**
- (c) enhance capacity building;**
- (d) strengthen communication and stakeholders' engagement;**
- (e) support the development of joint partnerships.**

Proposal for a regulation
Article 44 – paragraph 1 m (new)

Text proposed by the Commission

Amendment

1m. The framework for action referred to in paragraph 1l shall be consistent with the respective mandates of each agency and shall not hinder their statutory activities.

Proposal for a regulation
Article 45 – paragraph 2

Text proposed by the Commission

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

Amendment

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.

Proposal for a regulation
Article 45 – paragraph 3

Text proposed by the Commission

3. The Agency and the body concerned shall cooperate to resolve the divergence. If the Agency and the body concerned are not able to resolve the divergence, they shall draw up a joint report. The report shall clearly outline the contentious scientific issues, identify the relevant uncertainties in the data and the underlying reasons for the *diverging* opinions, including *on* methodological differences, *and* be made publicly available. Where the body concerned is a Union agency or a scientific committee, the Agency shall present the joint report to the Commission.

Amendment

3. The Agency and the *other* body concerned shall cooperate to resolve the divergence, *taking into consideration the objective of a high level of protection of health and the environment*. 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 relevant uncertainties in the data and *give* the underlying reasons for the *divergence of* opinions, including *reasons related to* methodological differences. *The report shall* be made publicly available. Where the *other* body concerned is a Union agency or a scientific committee, the Agency shall *also* present the joint report to the Commission.

Compromise Amendment 8

Compromise amendment replacing Amendments: 96-100, 277-284

Proposal for a regulation Article 46

Text proposed by the Commission

Amendment

Article 46

deleted

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-Making¹³².*
- 4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the*

Council.

5. A delegated act adopted pursuant to paragraph 1 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and to the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

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

**Proposal for a regulation
Article 48 – paragraph 1 – point 3**

Text proposed by the Commission

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

Amendment

(3) in Article 77, paragraph 1, **and paragraph 3, points (b), and (c), are** deleted;

**Proposal for a regulation
Article 48 – paragraph 1 – point 6**

Text proposed by the Commission

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

Amendment

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

**Proposal for a regulation
Article 54 – title**

Text proposed by the Commission

Amendment

Evaluation

Evaluation **and review**

Proposal for a regulation
Article 54 – paragraph 1

Text proposed by the Commission

Amendment

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.

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.

Proposal for a regulation
Article 54 – paragraph 2

Text proposed by the Commission

Amendment

2. The evaluation shall address the possible need to modify the mandate of the Agency, and the financial implications of any such modification.

2. The evaluation shall address the possible need to modify the mandate of the Agency, and the financial implications of any such modification. ***The evaluation shall also assess the functioning of the Committees and whether it would be appropriate to align or adapt the provisions in Articles 14 and 15 of this Regulation.***

Proposal for a regulation
Article 54 – paragraph 3

Text proposed by the Commission

Amendment

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.

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 Commission shall, where appropriate, submit a legislative proposal to the European Parliament and to the Council.*** The findings of the evaluation

shall be made public by the Commission.

Compromise amendment 9 - Recitals

This compromise amendment covers: 2-12, 101-138, BUDG1, BUDG2 (BUDG AM shown for completeness, not for vote in ENVI)

Proposal for a regulation

Recital 9

Text proposed by the Commission

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

Amendment

(9) The Agency should continue to contribute to the implementation and enforcement of Union legislation and policies related to the hazards, risks, safe use, **and environmental sustainability** of chemical substances **and groups thereof, mixtures and articles** in order to achieve a high level of protection of human health and the environment, **including the protection of vulnerable groups**, 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 **to safeguard and further enhance occupational health standards and promoting non-animal approaches and emerging methodologies. By achieving its objectives and tasks, the Agency will contribute to the full implementation of the objectives of the Treaties and, in particular, pursuant to Article 191(2) TFEU, that environmental policy is to be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.**

Proposal for a regulation
Recital 10 a (new)

Text proposed by the Commission

Amendment

(10a) To reinforce the capacity and contribute to the work of the competent authorities of Member States, the Agency should be able to second officials and other servants in its employment, in the interest of the service and in accordance with Article 37 of the Staff Regulations of Regulation No 31 (EEC), 11 (EAEC) and Article 51 of the Conditions of Employment of Other Servants of Regulation No 31 (EEC), 11 (EAEC), to the competent authorities of the Member States or to other public bodies entrusted with tasks related to the Agency's mandate.

^{1a} 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 P 045 14.6.1962, p. 1385, ELI: [http://data.europa.eu/eli/reg/1962/31\(1\)/oj](http://data.europa.eu/eli/reg/1962/31(1)/oj)).

Proposal for a regulation
Recital 11

Text proposed by the Commission

Amendment

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

(11) The structure of the Agency should be suitable for its tasks and should take into account the experience gained from the Agency's functioning and performance since its establishment. It is essential to ensure that the Agency is equipped to perform its tasks with high scientific and technical capacities to ensure the highest possible quality.

transparently and efficiently.

**Proposal for a regulation
Recital 11 a (new)**

Text proposed by the Commission

Amendment

(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 general public. The Agency should also play a pivotal role in coordinating communication around chemicals legislation and its implementation. Trust in the Agency by the Union institutions, the Member States, the general public and interested parties is therefore essential. For that reason, it is vital to ensure its independence, high scientific, technical and regulatory capacities, as well as transparency and efficiency. In addition, clear and effective rules should be established to prevent and manage conflicts of interest, and experts should not be appointed to Committees where reasonable concerns about conflicts of interest exist.

**Proposal for a regulation
Recital 12**

Text proposed by the Commission

Amendment

(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')¹⁰, Biocidal Products Committee ('BPC') (collectively, the 'Committees'), and the Forum.

(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')¹⁰, Biocidal Products Committee ('BPC') (collectively, the 'Committees'), and the Forum.

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:

Proposal for a regulation

Recital 13

Text proposed by the Commission

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

Amendment

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

Proposal for a regulation

Recital 15 a (new)

Text proposed by the Commission

Amendment

(15a) The Agency's role as an independent scientific point of reference means that a scientific opinion can be requested not only by the Commission, but also by the European Parliament and the Member States. In order to ensure the manageability and consistency of the process of scientific advice, the Agency should be able to refuse or propose to amend a request, providing justification in the case of a refusal and on the basis of predetermined criteria.

Proposal for a regulation

Recital 16

Text proposed by the Commission

(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/EC¹¹. Articles 16, 16a and 18a of Directive 2004/37/EC of the European Parliament and of the Council¹² and Articles 18c and 22a of Directive 2009/148/EC of the European Parliament and of the Council¹³ 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.

¹¹ 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>).

¹² 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

Amendment

(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/EC¹¹. Articles 16, 16a and 18a of Directive 2004/37/EC of the European Parliament and of the Council¹² and Articles 18c and 22a of Directive 2009/148/EC of the European Parliament and of the Council¹³ 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, ***the European Parliament or the Member States*** 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.

¹¹ 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>).

¹² 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>).

¹³ 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>).

Proposal for a regulation **Recital 18**

Text proposed by the Commission

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

Proposal for a regulation **Recital 19**

Text proposed by the Commission

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

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>).

¹³ 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>).

Amendment

(18) The Management Board should adopt the rules of procedure of RAC, SEAC, MSC, BPC and SCCS, including the procedural arrangements for the Committees' working groups. In order for the Commission to exercise its oversight, the Commission representatives in the Management Board should ***be consulted by the Executive Director when preparing the rules of procedure of the RAC, SEAC and SCCS, maintaining*** the independence of the Committees and their working groups.

Amendment

(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 ***and to ensure that RAC and SEAC are fully operational, it is essential that*** each Member State ***nominates*** two members for RAC and SEAC respectively and be entitled to nominate up to two additional members. RAC, SEAC, BPC and SCCS should have the possibility to co-opt

workload, type of expertise needed and availability of financial resources.

members and to rely on the services of experts, taking into account the workload, type of expertise needed, *geographical balance* and availability of financial resources. *Committee members should reflect the expertise required for the proper fulfilment of the tasks allocated to the Agency. The Agency should be able to assist Member States in identifying relevant profiles for membership of the RAC, SEAC and BPC, where Member States so request.*

Proposal for a regulation
Recital 21 a (new)

Text proposed by the Commission

Amendment

(21a) The Agency should set up an Assembly of accredited stakeholders which should aim to reinforce the relationship with accredited stakeholders, and facilitate their contribution to the tasks of the Agency while ensuring a balanced representation between industry representatives and civil society representatives.

Proposal for a regulation
Recital 21 b (new)

Text proposed by the Commission

Amendment

(21b) In order to enhance scientific cooperation and support the Agency's work, it is necessary to promote the networking of national authorities, agencies and research institutes operating in areas of competence of the Agency's mandate. This networking aims to foster the exchange of information, coordination of activities, and the development of joint projects, as well as the sharing of expertise and best practices. To achieve this, a list of national authorities, agencies and research institutes designated by the Member States should be drawn up, enabling those national authorities, agencies and research institutes to assist

the Agency with tasks such as preparatory work for scientific opinions, data collection, and the identification of emerging risks.

Proposal for a regulation
Recital 23 a (new)

Text proposed by the Commission

Amendment

(23a) Additional workload arising from an increase in tasks and responsibilities allocated to the Agency should be accompanied by the allocation of appropriate funding for staff and other necessary costs. As part of the draft single programming document, the Management Board should conduct an assessment of the adequacy of its financial and human resources to carry out its current and upcoming tasks.

Proposal for a regulation
Recital 24

Text proposed by the Commission

Amendment

(24) The financial and administrative framework in which the Agency operates is more complex than for other Union agencies¹⁶, as the Agency is partially financed by fees for its activities under Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008¹⁷ 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 649/2012¹⁸ and (EU) 2019/1021¹⁹. 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

(24) The financial and administrative framework in which the Agency operates is more complex than for other Union agencies¹⁶, as the Agency is partially financed by fees for its activities under Regulation (EC) No 1907/2006, Regulation (EC) No 1272/2008¹⁷ 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 649/2012¹⁸ and (EU) 2019/1021¹⁹. To simplify the Agency's financing model, the requirement for segregated budgets established under Regulation (EU) No 528/2012, Regulation (EU) No 649/2012, and Regulation (EU) 2019/1021 should be abolished, by deleting the relevant provisions in those Regulations, so that the Agency receives one unitary annual contribution from the Union budget. This will allow for more flexibility for the Agency to address workload fluctuations

and will respond to the recommendations of the Court of Auditors and to the objective of the CSS to increase the sustainability of the Agency's financing model. The removal of the segregation of budgets should not affect existing obligations of financial contributions by third countries to the Agency.

and will respond to the recommendations of the Court of Auditors and to the objective of the CSS to increase the sustainability of the Agency's financing model. The removal of the segregation of budgets should not affect existing obligations of financial contributions by third countries to the Agency.

¹⁶ European Court of Auditors, Future of EU agencies, potential for more flexibility and cooperation, Special Report (2020), doi:10.2865/36103.

¹⁶ European Court of Auditors, Future of EU agencies, potential for more flexibility and cooperation, Special Report (2020), doi:10.2865/36103.

¹⁷ 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>).

¹⁷ 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>).

¹⁸ 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>).

¹⁸ 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>).

¹⁹ 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>).

¹⁹ 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>).

Proposal for a regulation

Recital 25

Text proposed by the Commission

(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

Amendment

(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. ***The Agency commits to continuously improving its***

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.

forecasting methods. 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. ***While setting up reserve budget for the Agency is necessary due to its unique financing structure, it does not set a precedent for other EU agencies.***

Proposal for a regulation

Recital 26

Text proposed by the Commission

(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

Amendment

deleted

conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making¹¹⁵. 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.

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

Proposal for a regulation **Recital 28**

Text proposed by the Commission

(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.

Amendment

(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.

Proposal for a regulation **Recital 30**

Text proposed by the Commission

(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

Amendment

(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.

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.

Proposal for a regulation **Recital 31**

Text proposed by the Commission

(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.

Amendment

(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 other hazardous chemicals and groups thereof*** and in the development of scientific methods, notably ***non-animal approaches and emerging methodologies***, to assess hazards of chemicals ***and groups of chemicals*** as well as risks and socio-economic impacts of their use. ***Where appropriate, the Agency should contribute to the research on the links between exposure to hazardous chemicals and negative impacts on health in the field of exposomics, the integrated compilation of all the physical, chemical, biological and psychosocial factors, and their interactions, which have an impact on biology and health.***

Proposal for a regulation
Recital 31 a (new)

Text proposed by the Commission

Amendment

(31a) Strengthened collaboration between Union agencies can play a critical role by ensuring that scientific evidence is aligned, making knowledge more accessible to all relevant stakeholders, providing strategic direction to Union research funding, and facilitating engagement with ongoing research and innovation projects. The cross-agency One Health task force established in 2023 by the Agency, the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) and the European Environment Agency (EEA), has proven to be a successful initiative to strengthen transdisciplinary cooperation among five Union agencies in order to help them to better address challenges to human, animal, plant and environmental health and successfully contribute to the implementation of the One Health approach in Europe. As that initiative is to end in 2026, this Regulation should establish a more permanent and established form of transdisciplinary cooperation with a permanent task force aiming to build on the work of the One Health task force and to broaden the scope of its work to other approaches, such as exposome encompassing also the One System framework, providing for a holistic, systems-based approach towards environmental risk assessment of chemicals. EU-OSHA should also be included in this permanent framework. The Agencies composing the task force should outline a common vision and objectives for that task force, working toward a more permanent and established form of transdisciplinary cooperation between those Union agencies. They should be able to plan coordinated actions and to broaden the scope of their

cooperation through annual action plans.

Proposal for a regulation

Recital 32

Text proposed by the Commission

(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 on a regular basis and its mandate should be adapted accordingly, if needed.

Amendment

(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 on a regular basis and its mandate should be adapted accordingly, if needed.

Proposal for a regulation

Recital 37

Text proposed by the Commission

(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,

Amendment

(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,

Proposal for a regulation

Recital 38 a (new)

Text proposed by the Commission

Amendment

(38a) The implications of this Regulation for the Union budget have

been assessed⁺ pursuant to Article 310(4) of the Treaty on the Functioning of the European Union. Sufficient financial and human resources should be provided for its implementation, while considering the impact of the financing on other Union programmes or policies and ensuring its compatibility with the multiannual financial framework, the system of own resources and the corresponding interinstitutional agreement, as well as with the budgetary principles laid down in Regulation (EU, Euratom) 2024/2509 of the European Parliament and of the Council^[1].

⁺ Pro memoria: Budgetary assessment of the European Parliament's Committee on Budgets of (XX) 2026 on 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 (COM(2025)0386).

^[1] 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 (OJ L, 2024/2509, 26.9.2024, ELI: <http://data.europa.eu/eli/reg/2024/2509/oj>).