



TEXTS ADOPTED

P10_TA(2026)0140

European Chemicals Agency and amending Regulations

Amendments adopted by the European Parliament on 29 April 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 - C10-0141/2025 - 2025/0207(COD))¹

(Ordinary legislative procedure: first reading)

¹ The matter was referred back for interinstitutional negotiations to the committee responsible, pursuant to Rule 60(4), fourth subparagraph (A10-0093/2026).

Amendment 1

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.**

Amendment 2

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)^{1a} 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 45, 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)).

Amendment 3

Proposal for a regulation Recital 11

Text proposed by the Commission

Amendment

(11) The structure of the Agency

(11) The structure of the Agency

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

Amendment 4

Proposal for a regulation Recital 11 a (new)

Text proposed by the Commission

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.

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.

Amendment 5

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

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Amendment 6

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, on the basis of predetermined criteria.

Amendment 7

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

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, 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.

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>).

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>).

Amendment 8

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.

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 9

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

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 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.***

Amendment 10

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.

Amendment 11

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.

Amendment 12

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.

Amendment 13

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 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.

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 improve its 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. ***The establishment of such a***

reserve for a partially self-financed EU agency operating under the universal budgetary model is a unique case and does not set a precedent for other EU agencies.

Amendment 14

Proposal for a regulation Recital 26

Text proposed by the Commission

Amendment

(26) In order to be able to address the large fluctuations in the Agency's revenues from fees, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union (TFEU) should be delegated to the Commission in respect of amending the specific conditions defined for the reserve. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making²⁰. 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.

deleted

²⁰ OJ L 123, 12.5.2016, p. 1,
ELI:
[http://data.europa.eu/eli/agree
_interinstit/2016/512/oj](http://data.europa.eu/eli/agree_interinstit/2016/512/oj).

Amendment 15

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 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.**

Amendment 16

Proposal for a regulation Recital 31 a (new)

(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 those 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.

Amendment 17

Proposal for a regulation Recital 37 a (new)

Text proposed by the Commission

Amendment

(37a) The implications of this Regulation for the Union budget have been assessed^{1a} 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^{1b}.

^{1a} 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).

^{1b} 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>).

Amendment 18

Proposal for a regulation Article 3 - paragraph 1

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)***²⁵ .

Amendment

The Agency shall have its seat in Helsinki, Finland.

²⁵ 2004/97/EC, Euratom: Decision taken by common agreement between the Representatives of the

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

Amendment 19

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.

Amendment 20

Proposal for a regulation Article 4 - paragraph 2

Text proposed by the Commission

2. In the fulfilment of its objectives, the Agency shall **aim to** contribute to a high level of protection of human health and the environment, **to the free circulation of substances in the internal market and** coherence and consistency in

Amendment

2. 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,**

chemicals assessment and management across the Union, while enhancing competitiveness and innovation, taking into account the specific needs of small and medium-sized enterprises ('SMEs') as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized 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>)

coherence and consistency in chemicals assessment and management across the Union ***which is key to ensuring the free circulation of 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>)

Amendment 21

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

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***,

scientifically possible;

occupational health standards, the specific needs of SMEs and the requirement of replacing animal testing with non-animal approaches where scientifically possible;

Amendment 22

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;

Amendment 23

Proposal for a regulation

Article 4 - paragraph 5 - point k a (new)

Text proposed by the Commission

Amendment

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

Amendment 24

Proposal for a regulation

Article 4 - paragraph 5 - point k b (new)

Text proposed by the Commission

Amendment

(kb)provide annual training for staff and committee members, and share knowledge with all

stakeholders.

Amendment 25

Proposal for a regulation

Article 4 - paragraph 5 a (new)

Text proposed by the Commission

Amendment

5a. 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.

Amendment 26

Proposal for a regulation

Article 5 - paragraph 1 - point c

Text proposed by the Commission

Amendment

(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;

(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;

Amendment 27

Proposal for a regulation

Article 5 - paragraph 1 - point d

Text proposed by the Commission

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

(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**;

measures on **chemicals**;

Amendment 28

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;

Amendment 29

Proposal for a regulation

Article 5 - paragraph 1 - point i

Text proposed by the Commission

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 to the Committees and the Forum, and ensure appropriate coordination between them;

(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;

Amendment 30

Proposal for a regulation

Article 6 - paragraph 1 - point c

Text proposed by the Commission

Amendment

(c) two **experts** appointed by

(c) two **independent persons**

the European Parliament.

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.***

Amendment 31

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.

Amendment 32

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;***

Amendment 33

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

Text proposed by the Commission

Amendment

(da)non-animal approaches;

Amendment 34

Proposal for a regulation Article 6 - paragraph 4

Text proposed by the Commission

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.

Amendment 35

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

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 ***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.

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

Amendment 36

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.**

Amendment 37

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;**

Amendment 38

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 30 May 2001 regarding public access to

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>).

European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43, ELI: <http://data.europa.eu/eli/reg/2001/1049/oj>).

Amendment 39

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.***

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

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

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).

Amendment 40

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.

Amendment 41

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**;

Amendment 42

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;

Amendment 43

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;

Amendment 44

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;

Amendment 45

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;

Amendment 46

Proposal for a regulation

Article 12 - paragraph 6 a (new)

Text proposed by the Commission

Amendment

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

Amendment 47

Proposal for a regulation

Article 13 - paragraph 2 - point b

Text proposed by the Commission

Amendment

(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.

(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.

Amendment 48

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.

Amendment 49

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

Text proposed by the Commission

Amendment

2b. 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.

Amendment 50

Proposal for a regulation Article 13 - paragraph 3

Text proposed by the Commission

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.

Amendment

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.

Amendment 51

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.

Amendment 52

Proposal for a regulation

Article 14 - paragraph 4 a (new)

Text proposed by the Commission

Amendment

4a. 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.

Amendment 53

Proposal for a regulation

Article 14 - paragraph 5 - subparagraph 1

Text proposed by the Commission

Amendment

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

The 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.**

Amendment 54

Proposal for a regulation

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

Text proposed by the Commission

Amendment

(iva) safety assessment of nanomaterials;

Amendment 55

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;

Amendment 56

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).**

Amendment 57

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.**

Amendment 58

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 on conflicts of interest adopted by the Management Board pursuant to Article 9(1), point (e).

Amendment 59

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.

Amendment 60

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.

Amendment 61

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.

Amendment 62

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.

Amendment 63

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.

Amendment 64

**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.

Amendment 65

**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.

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 **published**.

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**.

Amendment 66

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.

Amendment 67

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

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 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**.

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.***

Amendment 68

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,

Amendment 69

Proposal for a regulation Article 16 - paragraph 4

Text proposed by the Commission

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.

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.***

Amendment 70

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.

Amendment 71

**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.

Amendment 72

**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

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

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.

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 73

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.

Amendment 74

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.

Amendment 75

Proposal for a regulation

Article 27 - paragraph 1 - introductory part

Text proposed by the Commission

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

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:

Amendment 76

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 the Agency's financial and human resources to carry out its current and upcoming tasks;

Amendment 77

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(6), and Articles 16 and 35 respectively;

Amendment 78

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.

Amendment 79

**Proposal for a regulation
Article 29 - paragraph 4 a (new)**

Text proposed by the Commission

Amendment

4a. 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.

Amendment 80

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

Text proposed by the Commission

Amendment

4b. 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.

Amendment 81

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;

Amendment 82

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)

Amendment 83

Proposal for a regulation

Article 29 - paragraph 5 - point c a (new)

Text proposed by the Commission

Amendment

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

Amendment 84

Proposal for a regulation

Article 29 - paragraph 6

Text proposed by the Commission

Amendment

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.***

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.***

Amendment 85

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.

Amendment 86

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.

Amendment 87

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***

Amendment 88

**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.

Amendment 89

**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.

Amendment 90

Proposal for a regulation Article 37 - paragraph 2

Text proposed by the Commission

Amendment

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.

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.**

Amendment 91

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 of the European Parliament and of

the Council^{1a} 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 Union institutions and bodies (OJ L 264, 25.9.2006, p. 13, ELI: <http://data.europa.eu/eli/reg/2006/1367/oj>).

Amendment 92

Proposal for a regulation Article 38 - paragraph 3

Text proposed by the Commission

3. Members of the Management Board, the Executive Director,

Amendment

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 93

Proposal for a regulation Article 41 a (new)

Text proposed by the Commission

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.

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').**
- 2. The Assembly shall aim to reinforce the relationship between accredited stakeholders and the Agency and facilitate their contribution to the tasks of the Agency**
- 3. 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.**
- 4. 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.

Amendment 94

**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.

Amendment 95

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

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***

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.

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.**

1a 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>).

Amendment 96

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.

Amendment 97

Proposal for a regulation Article 44 - paragraph 1

Text proposed by the Commission

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.

Amendment

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.

Amendment 98

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.

Amendment 99

**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.

Amendment 100

**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.

Amendment 101

**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.

Amendment 102

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 to 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.

Amendment 103

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.

Amendment 104

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.

Amendment 105

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.

Amendment 106

Proposal for a regulation Article 44 - paragraph 1 i (new)

Text proposed by the Commission

Amendment

1i. 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.

Amendment 107

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

Text proposed by the Commission

Amendment

1j. 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.

Amendment 108

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

Text proposed by the Commission

Amendment

1k. 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.

Amendment 109

Proposal for a regulation Article 44 - paragraph 11 (new)

Text proposed by the Commission

Amendment

11. The framework for action referred to in paragraph 11 shall be consistent with the respective mandates of each agency and shall not hinder their statutory activities.

Amendment 110

Proposal for a regulation Article 45 - paragraph 2

Text proposed by the Commission

Amendment

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

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

information is shared and in order to identify the potentially contentious scientific or technical issues.

all relevant scientific or technical information is shared and in order to identify the potentially contentious scientific or technical issues.

Amendment 111

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.

Amendment 112

Proposal for a regulation Article 46

Text proposed by the Commission

Article 46
Delegated powers

Amendment

deleted

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-Making³⁸ .

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.

³⁸ OJ L 123, 12.5.2016, p. 1, ELI:
http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

Amendment 113

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;

Amendment 114

Proposal for a regulation Article 54 - title

Text proposed by the Commission

Amendment

Evaluation

Evaluation **and review**

Amendment 115

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 Articles 14 and 15 of this Regulation.***

Amendment 116

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.***