



**2024/2030(DEC)**

11.12.2024

# **AMENDMENTS**

## **1 - 105**

**Draft opinion**

**Antonio Decaro**

(PE764.979v02-00)

2023 discharge: General budget of the EU - Agencies  
(2024/2030(DEC))



**Amendment 1**  
**Beatrice Timgren, Kristoffer Storm**

**Draft opinion**  
**Paragraph 1**

*Draft opinion*

1. Welcomes the constructive cooperation between the European Parliament and the European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA), the European Environment Agency (EEA), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA) (the Agencies), illustrated, inter alia, by the annual exchanges of views that took place in 2023 in the Committee on the Environment, Public Health and Food Safety (ENVI);

*Amendment*

1. Welcomes the constructive cooperation between the European Parliament and the European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA), the European Environment Agency (EEA), the European Food Safety Authority (EFSA) and the European Medicines Agency (EMA) (the Agencies), illustrated, inter alia, by the annual exchanges of views that took place in 2023 in the Committee on the Environment, Public Health and Food Safety (ENVI); ***calls for the consolidation of overlapping functions among the Agencies to reduce redundancies, streamline operations, and ensure that resources are directed towards core functions that provide tangible value to EU citizens in the area of environmental, public health, and food safety objectives;***

Or. en

**Amendment 2**  
**Pär Holmgren**  
on behalf of the Greens/EFA Group

**Draft opinion**  
**Paragraph 1 a (new)**

*Draft opinion*

*Amendment*

***1 a. Welcomes the involvement of the EU Agencies in establishing a common data platform on chemicals as proposed by the Commission; regrets, however, the special treatment proposed for EMA to include only data submitted to it after the***

*entry into force of the new Regulation, and only on certain substances, thus withholding the very large majority of data that it holds on chemicals from the common data platform; stresses that inclusion of all chemicals-related data that EMA holds would greatly help to develop predictive toxicity testing and thus to develop alternatives to animal testing; calls on the EMA and the Commission to reconsider their position accordingly;*

Or. en

**Amendment 3**  
**Alexandr Vondra**

**Draft opinion**  
**Paragraph 2**

*Draft opinion*

2. Considers that regular visits to the Agencies are a key aspect of the scrutiny exercised by the European Parliament over them; notes *to* this regard the success of the ENVI delegation to EMA in February 2023 and to ECHA in April 2023;

*Amendment*

2. Considers that regular visits to the Agencies are a key aspect of the scrutiny exercised by the European Parliament over them; notes *in* this regard the success of the ENVI delegation to *the* EMA in February 2023 and to *the* ECHA in April 2023, *which facilitated constructive dialogue, enhanced transparency, and strengthened the Parliament's oversight role.*

Or. en

**Amendment 4**  
**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

**Draft opinion**  
**Paragraph 2**

*Draft opinion*

2. Considers that regular visits to the

*Amendment*

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Agencies are a key aspect of the scrutiny exercised by the European Parliament over them; notes to this regard the success of the ENVI delegation to EMA in February 2023 and to ECHA in April 2023;

*from* the Agencies are a key aspect of the scrutiny exercised by the European Parliament over them; notes to this regard the success of the ENVI delegation to EMA in February 2023 and to ECHA in April 2023;

Or. en

**Amendment 5**  
**Beatrice Timgren, Kristoffer Storm**

**Draft opinion**  
**Paragraph 3**

*Draft opinion*

3. Expresses its satisfaction that the European Court of Auditors (ECA) has declared the transactions of the Agencies underlying the annual accounts for the financial year 2023 to be legal and regular in all material respects, and that their financial position, at 31 December 2023, is fairly represented in all material respects;

*Amendment*

3. Expresses its satisfaction that the European Court of Auditors (ECA) has declared the transactions of the Agencies underlying the annual accounts for the financial year 2023 to be legal and regular in all material respects, and that their financial position, at 31 December 2023, is fairly represented in all material respects; ***requires the Agencies to adopt zero-based budgeting practices, ensuring that every expense is justified from the ground up, and calls for a significant reduction in administrative costs to focus funding on essential activities such as environmental, public health, and food safety objectives;***

Or. en

**Amendment 6**  
**Alexandr Vondra**

**Draft opinion**  
**Paragraph 3**

*Draft opinion*

3. Expresses its satisfaction that the European Court of Auditors (ECA) has ***declared*** the transactions ***of the Agencies***

*Amendment*

3. Expresses its satisfaction that the European Court of Auditors (ECA) has ***confirmed the legality and regularity, in***

underlying the annual accounts for the financial year 2023 ***to be legal and regular in all material respects, and that*** their financial position, ***at 31 December 2023, is fairly represented in all material respects;***

***all material respects, of*** the transactions underlying the ***Agencies'*** annual accounts for the financial year 2023, ***as well as the fair representation of*** their financial position ***as of*** 31 December 2023;

Or. en

#### **Amendment 7**

**Beatrice Timgren, Kristoffer Storm**

#### **Draft opinion**

#### **Paragraph 4**

##### *Draft opinion*

4. Welcomes the measures taken by the agencies in light of the European Parliament recommendations in its discharge for the financial year 2022; stresses the importance of increasing the Agencies' efforts in terms of cooperation with other agencies and international organisations, digitalisation, and gender and geographical balance in senior management positions;

##### *Amendment*

4. Welcomes the measures taken by the Agencies in light of the European Parliament recommendations in its discharge for the financial year 2022; stresses the importance of increasing the Agencies' efforts in terms of cooperation with other agencies and international organisations, digitalisation, and gender and geographical balance in senior management positions; ***proposes a comprehensive audit of the Agencies to identify and eliminate non-essential activities, ensuring that resources are concentrated on critical areas of public health, safety, and environmental protection; recommends that appointments to senior management positions in the Agencies be based on merit and expertise, ensuring optimal performance, while remaining unbiased with regard to gender;***

Or. en

#### **Amendment 8**

**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

#### **Draft opinion**

#### **Paragraph 4**

*Draft opinion*

4. Welcomes the measures taken by the agencies in light of the European Parliament recommendations in its discharge for the financial year 2022; stresses the importance of increasing the Agencies' efforts in terms of cooperation with other agencies and international organisations, **digitalisation, and** gender and geographical balance in senior management positions;

*Amendment*

4. Welcomes the measures taken by the Agencies in light of the European Parliament recommendations in its discharge for the financial year 2022; stresses the importance of increasing the Agencies' efforts in terms of cooperation with other agencies and international organisations, **stresses the importance of intensifying efforts to achieve** gender and geographical balance **among institutional staff and** in senior management positions, **reminds the Agencies in this regard of the importance of protecting the work-life balance not least among parent staff and to continuously develop strategies to protect workers' health and well-being;**

Or. en

**Amendment 9**

**Beatrice Timgren, Kristoffer Storm**

**Draft opinion**

**Paragraph 5**

*Draft opinion*

5. Welcomes the fact that the Agencies took effective corrective actions following most of the 2022 observations from the ECA; takes note of 2023 observations for the Agencies, in particular observations related to ex-ante checks, and calls on them to ensure an effective follow-up.

*Amendment*

5. Welcomes the fact that the Agencies took effective corrective actions following most of the 2022 observations from the ECA; takes note of 2023 observations for the Agencies, in particular observations related to ex-ante checks, and calls on them to ensure an effective follow-up; **demands that Agencies failing to implement corrective actions within stipulated timelines face reductions in their administrative budgets, with the aim of improving the efficiency of funding for essential activities such as environmental protection, public health, and food safety objectives in the long run;**

Or. en

**Amendment 10**  
**Alexandr Vondra**

**Draft opinion**  
**Paragraph 5**

*Draft opinion*

5. Welcomes the fact that the Agencies **took** effective corrective actions **following** most of the 2022 observations from the ECA; takes note of 2023 observations **for** the Agencies, **in particular observations** related to ex-ante checks, and calls on **them to ensure** an effective follow-up.

*Amendment*

5. Welcomes the fact that the Agencies **have implemented** effective corrective actions **in response to** most of the 2022 observations from the ECA; takes note of **the** 2023 observations **regarding** the Agencies, **particularly those** related to ex-ante checks, and **emphasises the importance of addressing these issues promptly and thoroughly**; calls on **the Agencies to maintain their commitment to transparency and accountability through an effective and timely follow-up process**;

Or. en

**Amendment 11**  
**Michalis Hadjipantela**  
on behalf of the EPP Group  
**Dan-Ştefan Motreanu, Gabriella Gerzsenyi, Radan Kanev**

**Draft opinion**  
**Paragraph 5 a (new)**

*Draft opinion*

**5 a. Acknowledges the importance of localized initiatives that strengthen health systems and environmental initiatives, while increasing collaboration with Member States and Agencies.**

*Amendment*

Or. en

**Amendment 12**  
**Michalis Hadjipantela**  
on behalf of the EPP Group



Dan-Ştefan Motreanu, Gabriella Gerzsenyi, Radan Kanev

**Draft opinion**  
**Paragraph 5 b (new)**

*Draft opinion*

*Amendment*

**5 b. Calls for improvement in the funding distribution approach, prioritizing the reduction of administrative burdens and channelling resources directly to final recipients by simplifying procedures to enhance accessibility to economic players on the ground.**

Or. en

**Amendment 13**  
**Beatrice Timgren, Kristoffer Storm**

**Draft opinion**  
**Paragraph 1**

*Draft opinion*

*Amendment*

1. Acknowledges the **key** role of the ECDC in identifying and assessing current and emerging threats to human health from communicable diseases **and related special health issues, in order to enhance the capacity of the Union and the Member States to protect human health through the prevention and control of communicable diseases in humans and related special health issues;**

1. Acknowledges the role of the ECDC in identifying and assessing current and emerging threats to human health from communicable diseases, **emphasizing the need to prioritize cost-effective measures and avoid duplicating Member State efforts;**

Or. en

**Amendment 14**  
**Pär Holmgren**  
on behalf of the Greens/EFA Group

**Draft opinion**  
**Paragraph 2**

### *Draft opinion*

2. Notes that the ECDC mandate was extended following the adoption of Regulation (EU) 2022/2370<sup>1</sup> which entered into force on 13 December 2022 in order to strengthen the Union's health security framework in the fields of epidemiological surveillance; welcomes the fact that the ECDC began to implement its new mandate by reviewing the modalities of collaboration with its main partners and stakeholders, as well as the structure and content of its Strategy 2021-2027;

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<sup>1</sup> Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (OJ L 314, 6.12.2022, p. 1–25 ELI: <http://data.europa.eu/eli/reg/2022/2370/oj>)

### *Amendment*

2. Notes that the ECDC mandate was extended following the adoption of Regulation (EU) 2022/2370<sup>1</sup> which entered into force on 13 December 2022 in order to strengthen the Union's health security framework in the fields of epidemiological surveillance; ***invites the Commission to strengthen investments in the public health workforce and enhance coordination mechanisms for responding to emerging threats, such as infectious disease outbreaks***; welcomes the fact that the ECDC began to implement its new mandate by reviewing the modalities of collaboration with its main partners and stakeholders, as well as the structure and content of its Strategy 2021-2027; ***emphasizes the importance of maintaining the annual declarations of interest of all management board members, advisory forum members and their alternates updated and accessible*** ;

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<sup>1</sup> Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (OJ L 314, 6.12.2022, p. 1–25 ELI: <http://data.europa.eu/eli/reg/2022/2370/oj>)

Or. en

## **Amendment 15** **Alexandr Vondra**

### **Draft opinion** **Paragraph 2**

#### *Draft opinion*

2. Notes that the ECDC mandate was extended following the adoption of Regulation (EU) 2022/2370<sup>1</sup> which entered into force on 13 December 2022 in order to

#### *Amendment*

2. Notes that the ECDC mandate was extended following the adoption of Regulation (EU) 2022/2370<sup>1</sup> which entered into force on 13 December 2022 in order to

strengthen the Union's health security framework in the fields of epidemiological surveillance; welcomes the fact that the ECDC began to implement its new mandate by reviewing the modalities of collaboration with its main partners and stakeholders, as well as the structure and content of its Strategy 2021-2027;

strengthen the Union's health security framework in the fields of epidemiological surveillance; welcomes the fact that the ECDC began to implement its new mandate by reviewing the modalities of collaboration with its main partners and stakeholders, as well as the structure and content of its Strategy 2021-2027, ***while emphasising the importance of ensuring accountability and transparency throughout this process;***

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<sup>1</sup> Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (OJ L 314, 6.12.2022, p. 1–25 ELI: <http://data.europa.eu/eli/reg/2022/2370/oj>)

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<sup>1</sup> Regulation (EU) 2022/2370 of the European Parliament and of the Council of 23 November 2022 amending Regulation (EC) No 851/2004 establishing a European centre for disease prevention and control (OJ L 314, 6.12.2022, p. 1–25 ELI: <http://data.europa.eu/eli/reg/2022/2370/oj>)

Or. en

## **Amendment 16** **Antonio Decaro, Tiemo Wölken**

### **Draft opinion** **Paragraph 3**

#### *Draft opinion*

3. Welcomes the continued development of the One Health Framework and the creation of the One Health Task Force to strengthen collaboration with EMA, EFSA, EEA and ECHA; highlights the importance of ensuring good and fair cooperation between the Agencies;

#### *Amendment*

3. Welcomes the continued development of the One Health Framework and the creation of the One Health Task Force to strengthen collaboration with EMA, EFSA, EEA and ECHA; ***considers these important steps to further strengthen the One Health approach ensuring the inclusion of human, animal and plant health, as well as their interactions with the environment;*** highlights the importance of ensuring good and fair cooperation between the Agencies;

Or. en

**Amendment 17**  
**Alexandr Vondra**

**Draft opinion**  
**Paragraph 3**

*Draft opinion*

3. Welcomes the continued development of the One Health Framework and the creation of the One Health Task Force to strengthen collaboration with EMA, EFSA, EEA and ECHA; highlights the importance of ensuring good and fair cooperation between the Agencies;

*Amendment*

3. Welcomes the continued development of the One Health Framework and the creation of the One Health Task Force to strengthen collaboration with EMA, EFSA, EEA and ECHA; highlights the importance of ensuring good and fair cooperation between the Agencies, ***while cautioning against inefficiencies, duplication of efforts, and overlapping mandates;***

Or. en

**Amendment 18**  
**Michalis Hadjipantela, Dan-Ştefan Motreanu, Radan Kanev**

**Draft opinion**  
**Paragraph 3**

*Draft opinion*

3. Welcomes the continued development of the One Health Framework and the creation of the One Health Task Force to strengthen collaboration with EMA, EFSA, EEA and ECHA; highlights the importance of ensuring good and fair cooperation between the Agencies;

*Amendment*

3. Welcomes the continued development of the One Health Framework and the creation of the One Health Task Force to strengthen collaboration with EMA, EFSA, EEA and ECHA; highlights the importance of ensuring good and fair cooperation between the Agencies ***and increased collaboration with Member States;***

Or. en

**Amendment 19**  
**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

**Draft opinion**

## Paragraph 4 a (new)

*Draft opinion*

*Amendment*

**4 a.** *Notes the discrepancy between ECDC and ECA on the 2022 qualified opinion provided by ECA demonstrating that the accounts were reliable but that the transactions underlying the accounts were partly not legal and regular; stresses the importance of such discrepancies to be harmonised, urges ECDC to adhere to the standards provided by ECA <sup>1a</sup>;*

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*1a*

*[https://www.ecdc.europa.eu/sites/default/files/documents/consolidated-annual-activity-report-2023\\_1.pdf](https://www.ecdc.europa.eu/sites/default/files/documents/consolidated-annual-activity-report-2023_1.pdf), page 56*

Or. en

## Amendment 20

**Olivier Chastel, Christine Singer, Gerben-Jan Gerbrandy, Vlad Vasile-Voiculescu, Sigrid Friis, Yvan Verougstraete, Martin Hojsik**

**Draft opinion**

**Paragraph 4 a (new)**

*Draft opinion*

*Amendment*

**4 a.** *Stresses that gender balance in the composition of the top management of our agencies and institutions must be a guideline; notes that the Agency's senior management is currently composed of 67% men and 33% women, according to the figures communicated; calls on the Agency to take this into consideration in future recruitments;*

Or. en

## Amendment 21

**Michalis Hadjipantela, Dan-Ştefan Motreanu, Radan Kanev**

**Draft opinion**  
**Paragraph 4 a (new)**

*Draft opinion*

*Amendment*

**4 a. Acknowledges the lessons learnt during the COVID-19 pandemic, calling for the need for pandemic preparedness and a unified EU response strategy, that utilises digital early warning systems for prompt and efficient decision making.**

Or. en

**Amendment 22**

**Olivier Chastel, Christine Singer, Gerben-Jan Gerbrandy, Vlad Vasile-Voiculescu, Yvan Verougstraete, Martin Hojsik**

**Draft opinion**  
**Paragraph 4 b (new)**

*Draft opinion*

*Amendment*

**4 b. Welcomes the agency's efforts towards an Eco-Management and Audit Scheme (EMAS) certification, which was finally granted in January 2024;**

Or. en

**Amendment 23**

**Olivier Chastel, Christine Singer, Gerben-Jan Gerbrandy, Vlad Vasile-Voiculescu, Sigrid Friis, Yvan Verougstraete, Martin Hojsik**

**Draft opinion**  
**Paragraph 4 c (new)**

*Draft opinion*

*Amendment*

**4 c. Welcomes the fact that the ECDC has adopted its charter on diversity and inclusion in 2023;**

Or. en

**Amendment 24**

**Olivier Chastel, Christine Singer, Gerben-Jan Gerbrandy, Vlad Vasile-Voiculescu, Yvan Verougstraete, Martin Hojsik**

**Draft opinion**

**Paragraph 4 d (new)**

*Draft opinion*

*Amendment*

**4 d. Notes that 22,7 % of the Agency's staff are nationals of the Member State where it is located; recalls the importance of geographical balance and encourages the Agency to continue to take the necessary measures to have a balanced and fair geographical representation;**

Or. en

**Amendment 25**

**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

**Draft opinion**

**Paragraph 5 a (new)**

*Draft opinion*

*Amendment*

**5 a. Encourages ECDC to further cooperate with Member States to ensure an approach based on the solidarity principle in vaccine distribution and preparedness, notes that in the case of Mpox Member States undermined the ECDC capacity to face transmittable diseases by withholding vaccines;**

Or. en

**Amendment 26**

**Beatrice Timgren, Kristoffer Storm**

**Draft opinion**

**Paragraph 1**

*Draft opinion*

1. Acknowledges ***that the ECHA is key*** in implementing ***a growing number of*** Union legislation ***that regulates*** chemicals ***for the benefit of*** public health and the environment, ***as well as for*** innovation and competitiveness; ***recognises that the ECHA collects, evaluates and disseminates a vast amount of information on chemicals, helps companies comply with legislation and promotes the safe use of chemicals;***

*Amendment*

1. Acknowledges ***the ECHA's crucial role*** in implementing ***core*** Union legislation ***on*** chemicals ***and emphasizes the need to focus strictly on essential regulatory functions that directly protect*** public health and the environment, ***while also fostering*** innovation and competitiveness, ***and avoiding unnecessary expansion of its mandate;***

Or. en

**Amendment 27**

**Antonio Decaro, Tiemo Wölken**

**Draft opinion  
Paragraph 1**

*Draft opinion*

1. Acknowledges that the ECHA is key in implementing a growing number of Union legislation that regulates chemicals for the benefit of public health and the environment, as well as for innovation and competitiveness; recognises that the ECHA collects, evaluates and disseminates a vast amount of information on chemicals, helps companies comply with legislation and promotes the safe use of chemicals;

*Amendment*

1. Acknowledges that the ECHA is key in implementing a growing number of Union legislation that regulates chemicals for the benefit of ***protecting*** public health and the environment, as well as for innovation and competitiveness; recognises that the ECHA collects, evaluates and disseminates a vast amount of information on chemicals, helps companies comply with legislation and promotes the safe use of chemicals;

Or. en

**Amendment 28**

**Alexandr Vondra**

**Draft opinion  
Paragraph 1**

*Draft opinion*

*Amendment*



1. Acknowledges that the ECHA is key in implementing a growing number of Union legislation that regulates chemicals for the benefit of public health and the environment, as well as for innovation and competitiveness; recognises that the ECHA collects, evaluates and disseminates *a vast amount of* information on chemicals, *helps* companies *comply* with legislation and promotes the safe use of chemicals;

1. Acknowledges that the ECHA is key in implementing a growing number of Union legislation that regulates chemicals for the benefit of public health and the environment, as well as for innovation and competitiveness; recognises that the ECHA collects, evaluates, and disseminates *extensive* information on chemicals, *assists* companies *in complying* with legislation, and promotes the safe use of chemicals;

Or. en

## **Amendment 29**

**Pär Holmgren**

on behalf of the Greens/EFA Group

### **Draft opinion**

#### **Paragraph 2**

##### *Draft opinion*

2. Observes that the Agencies budget relies on collected fees and a contribution from the Union's general budget; takes note with concern that after a rise in 2022, in 2023 the ECHA's fee income has again decreased, increasing the reliance on the Union to finance its operations; stresses the need to address the lack of predictability of the ECHA's fee income *and* reiterates its previous calls to the Commission to improve the ECHA's budgetary certainty by presenting its proposal to strengthen the governance of ECHA in line with its commitment expressed in the Chemicals Strategy for Sustainability;

##### *Amendment*

2. Observes that the Agencies budget relies on collected fees and a contribution from the Union's general budget; takes note with concern that after a rise in 2022, in 2023 the ECHA's fee income has again decreased, increasing the reliance on the Union to finance its operations; stresses the need to address the lack of predictability of the ECHA's fee income *which is hindering its ability to implement its Work Programme effectively*; reiterates its previous calls to the Commission to improve the ECHA's budgetary certainty by *urgently* presenting its proposal *for a founding regulation for the ECHA* to strengthen the governance of ECHA *and to secure sustainable financing*, in line with its commitment expressed in the Chemicals Strategy for Sustainability;

Or. en

## **Amendment 30**

**Antonio Decaro, Tiemo Wölken**

**Draft opinion**  
**Paragraph 2**

*Draft opinion*

2. Observes that the *Agencies* budget relies on collected fees and a contribution from the Union's general budget; takes note with concern that after a rise in 2022, in 2023 the ECHA's fee income has again decreased, increasing the reliance on the Union to finance its operations; stresses the need to address the lack of predictability of the ECHA's fee income and reiterates its previous calls to the Commission to improve the ECHA's budgetary certainty by presenting its proposal to strengthen the governance of ECHA in line with its commitment expressed in the Chemicals Strategy for Sustainability;

*Amendment*

2. Observes that the *Agency's* budget relies on collected fees and a contribution from the Union's general budget; ***highlights the need to ensure full transparency of collected fees***; takes note with concern that after a rise in 2022, in 2023 the ECHA's fee income has again decreased, increasing the reliance on the Union to finance its operations; stresses the need to address the lack of predictability of the ECHA's fee income and reiterates its previous calls to the Commission to improve the ECHA's budgetary certainty by presenting its proposal to strengthen the governance of ECHA in line with its commitment expressed in the Chemicals Strategy for Sustainability;

Or. en

**Amendment 31**

**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

**Draft opinion**  
**Paragraph 3**

*Draft opinion*

3. Recalls the necessity of ensuring adequate staffing reflecting the needs of the European Green Deal and the Union Chemical Strategy for Sustainability, Circular Economy Action Plan and, in particular, the zero pollution target, and the associated increase in tasks;

*Amendment*

3. Recalls the necessity of ensuring adequate staffing reflecting the needs of the European Green Deal and the Union Chemical Strategy for Sustainability, Circular Economy Action Plan and, in particular, the zero pollution target, and the associated increase in tasks; ***laments indicators from the 2023 internal staff survey showing that only 42% agree fully that their units operate in an efficient manner<sup>1b</sup>, reiterates the need for ECHA to continuously work with staff satisfaction, worker health and well-being, ensuring***

*gender and geographical balance in the work place and facilitating the participation in the work life by parent staff;*

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*1b*

*[https://echa.europa.eu/documents/10162/7362407/annual\\_Report\\_2023\\_en.pdf/ca16f5a4-a8ae-ac22-21f1-57af476f0bb1?t=1713865234883](https://echa.europa.eu/documents/10162/7362407/annual_Report_2023_en.pdf/ca16f5a4-a8ae-ac22-21f1-57af476f0bb1?t=1713865234883) , page 57*

Or. en

### **Amendment 32**

**Pär Holmgren**

on behalf of the Greens/EFA Group

#### **Draft opinion**

##### **Paragraph 3**

###### *Draft opinion*

3. Recalls the necessity of ensuring adequate staffing reflecting the needs of the European Green Deal and the Union Chemical Strategy for Sustainability, Circular Economy Action Plan and, in particular, the zero pollution target, and the associated increase in tasks;

###### *Amendment*

3. Recalls the necessity of ensuring adequate staffing reflecting the needs of the European Green Deal and the Union Chemical Strategy for Sustainability, Circular Economy Action Plan and, in particular, the zero pollution target, and the associated increase in tasks; ***highlights that ECHA's expanding workload, coupled with delays in the REACH revision process, can potentially jeopardize its capacity to fulfil its central role in ensuring science-based regulation and a high level of protection while supporting the single market;***

Or. en

### **Amendment 33**

**Beatrice Timgren, Kristoffer Storm**

#### **Draft opinion**

##### **Paragraph 3**

*Draft opinion*

3. Recalls the ***necessity of ensuring adequate staffing reflecting the needs of the European Green Deal and the Union Chemical Strategy for Sustainability, Circular Economy Action Plan and, in particular, the zero pollution target, and the associated increase in tasks;***

*Amendment*

3. Recalls the ***importance of prioritizing efficient resource allocation over increasing staffing levels and stresses the need to allocate staff primarily to scientific roles critical to achieving ENVI objectives, while avoiding unnecessary expansion of the Agency's workforce;***

Or. en

**Amendment 34**  
**Alexandr Vondra**

**Draft opinion**  
**Paragraph 3**

*Draft opinion*

3. Recalls the necessity of ensuring adequate staffing reflecting the needs of ***the European Green Deal and*** the Union Chemical Strategy for Sustainability, Circular Economy Action Plan and, in particular, the zero pollution target, and the associated increase in tasks;

*Amendment*

3. Recalls the necessity of ensuring adequate staffing reflecting the needs of the Union Chemical Strategy for Sustainability, Circular Economy Action Plan and, in particular, the zero pollution target, and the associated increase in tasks;

Or. en

**Amendment 35**  
**Beatrice Timgren, Kristoffer Storm**

**Draft opinion**  
**Paragraph 3 a (new)**

*Draft opinion*

***3 a. Cautions against overburdening the ECHA with additional regulatory tasks introduced by new directives and regulations, and emphasizes the importance of maintaining focus on its primary responsibilities under REACH and CLP;***

*Amendment*

**Amendment 36**  
**Antonio Decaro, Tiemo Wölken**

**Draft opinion**  
**Paragraph 4**

*Draft opinion*

4. Acknowledges that in 2023 the ECHA delivered its regulatory tasks under the Union chemicals legislation, in particular REACH and CLP, provided scientific-technical support to the Commission in the implementation of the Chemicals Strategy for Sustainability, as well as preparing and starting work on the implementation of new regulatory tasks under the Drinking Water Directive, the Batteries Regulation and the Serious Cross-Border *Threads* to Health Regulation;

*Amendment*

4. Acknowledges that in 2023 the ECHA delivered its regulatory tasks under the Union chemicals legislation, in particular REACH and CLP, provided scientific-technical support to the Commission in the implementation of the Chemicals Strategy for Sustainability, as well as preparing and starting work on the implementation of new regulatory tasks under the Drinking Water Directive, the Batteries Regulation and the Serious Cross-Border *Threats* to Health Regulation;

Or. en

**Amendment 37**  
**Alexandr Vondra**

**Draft opinion**  
**Paragraph 5 a (new)**

*Draft opinion*

*Amendment*

***5 a. Notes that, despite falling short of fulfilling key indicators for the identification and prioritisation of hazardous substances, the Agency's 2023 annual report highlights that ECHA screened 61 groups covering approximately 1,380 substances, surpassing its initial target, and identified 320 substances for potential risk management, 280 requiring further data, and 540 requiring no further action; furthermore, acknowledges that by the end of 2023, ECHA had assessed 92% of***

*substances registered above 100 tonnes,  
leaving fewer than 400 high-tonnage  
substances still to be evaluated;*

Or. en

**Amendment 38**  
**Pär Holmgren**  
on behalf of the Greens/EFA Group

**Draft opinion**  
**Paragraph 5 a (new)**

*Draft opinion*

*Amendment*

*5 a. Calls on the ECHA to enhance its communication strategies to prevent the misinterpretation of its progress on the PFAS restriction process; stresses the urgent need to address the growing evidence of health and environmental harm caused by PFAS, including their presence in human tissues, and to ensure these risks are fully considered in the socio-economic assessment of the restriction;*

Or. en

**Amendment 39**  
**Pär Holmgren**  
on behalf of the Greens/EFA Group

**Draft opinion**  
**Paragraph 5 b (new)**

*Draft opinion*

*Amendment*

*5 b. Reaffirms the importance of the precautionary principle as a cornerstone of EU chemicals regulation and calls on ECHA to prioritize precautionary approaches when scientific evidence indicates potential risks to human health or the environment; calls on the ECHA to further refine its stakeholder engagement*

*processes to achieve a more proportional balance between industry, civil society, and independent scientific expertise, ensuring that the voices of all stakeholders are adequately represented and that public and environmental health are not subordinated to economic interests;*

Or. en

#### **Amendment 40**

**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

#### **Draft opinion Paragraph 6**

##### *Draft opinion*

6. Welcomes the ECHA's efforts to promote the use of alternatives to animal testing for the regulatory assessment of chemicals and to foster understanding of the opportunities and challenges in moving away from animal testing while ensuring a high level of protection of human health and the environment;

##### *Amendment*

6. Welcomes the ECHA's efforts to promote the use of alternatives to animal testing for the regulatory assessment of chemicals and to foster understanding of the opportunities and challenges in moving away from animal testing while ensuring a high level of protection of human health and the environment *and encourages ECHA to promote the use of non-animal testing methods;*

Or. en

#### **Amendment 41**

**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

#### **Draft opinion Paragraph 7**

##### *Draft opinion*

7. Notes with concern the difficulty to recruit sufficient experts from Member States to the ECHA's Scientific Committees, posing a risk to the ECHA's

##### *Amendment*

7. Notes with concern the difficulty to recruit sufficient experts from Member States to the ECHA's Scientific Committees, posing a risk to the ECHA's

ability to meet legal deadlines and targets in regulatory processes that are dependent on the Committees' outputs, in particular in the light of increasing tasks being attributed to the ECHA;

ability to meet legal deadlines and targets in regulatory processes that are dependent on the Committees' outputs, in particular in the light of increasing tasks being attributed to the ECHA, ***stresses the importance of the Commission working actively to ensure Agencies can recruit adequate competence to fulfil their missions, encourages in this regard an increased cooperation with universities and other relevant institutions;***

Or. en

#### **Amendment 42**

**Michalis Hadjipantela, Dan-Ştefan Motreanu, Radan Kanev**

#### **Draft opinion**

##### **Paragraph 7**

#### *Draft opinion*

7. Notes with concern the difficulty to recruit sufficient experts from Member States to the ECHA's Scientific Committees, posing a risk to the ECHA's ability to meet legal deadlines and targets in regulatory processes that are dependent on the Committees' outputs, in particular in the light of increasing tasks being attributed to the ECHA;

#### *Amendment*

7. Notes with concern the difficulty to recruit sufficient experts from Member States to the ECHA's Scientific Committees, posing a risk to the ECHA's ability to meet legal deadlines and targets in regulatory processes that are dependent on the Committees' outputs, in particular in the light of increasing tasks being attributed to the ECHA; ***identifies a need for increased localised collaboration with universities, research centers and specialised national services from the Member States;***

Or. en

#### **Amendment 43**

**Olivier Chastel, Christine Singer, Gerben-Jan Gerbrandy, Vlad Vasile-Voiculescu, Sigrid Friis, Yvan Verougstraete, Martin Hojsik**

#### **Draft opinion**

##### **Paragraph 7 a (new)**



*Draft opinion*

*Amendment*

**7 a. Stresses that gender balance in the composition of the top management of our Agencies and institutions must be a guideline; notes that the Agency's senior management is currently composed of 73% men and 27% women, according to the figures communicated; calls on the Agency to take this into consideration in future recruitments;**

Or. en

#### **Amendment 44**

**Olivier Chastel, Christine Singer, Gerben-Jan Gerbrandy, Vlad Vasile-Voiculescu, Yvan Verougstraete, Martin Hojsik**

**Draft opinion**

**Paragraph 7 b (new)**

*Draft opinion*

*Amendment*

**7 b. Notes that 29.1 % of its staff are nationals of the Member State where the Agency is located; recalls the importance of geographical balance and encourages the Agency to continue to take the necessary measures to have a balanced and fair geographical representation;**

Or. en

#### **Amendment 45**

**Beatrice Timgren, Kristoffer Storm**

**Draft opinion**

**Paragraph 8**

*Draft opinion*

*Amendment*

8. Welcomes the ECHA Strategy Statement for 2024 - 2028 adopted in December 2023, which sets out the priorities for the ECHA in implementing its evolving mandate.

8. Welcomes the ECHA Strategy Statement for 2024 - 2028 adopted in December 2023, which sets out the priorities for the ECHA in implementing its evolving mandate **and calls for its**

*implementation to prioritize efficiency, financial sustainability, and a reduction in regulatory burdens on businesses and Member States, in order to improve effectiveness in delivering ENVI-related objectives;*

Or. en

## **Amendment 46**

**Pär Holmgren**

on behalf of the Greens/EFA Group

### **Draft opinion**

#### **Paragraph 1**

##### *Draft opinion*

1. Stresses that the EEA provides sound, independent information on the environment; commends the quality of its outputs released in 2023, such as Pathways towards circular plastics in Europe — good practice examples from countries, business and citizens, Assessing the costs and benefits of climate change adaptation and European forest ecosystems: key allies in sustainable development;

##### *Amendment*

1. Stresses that the EEA provides sound, independent information on the environment; commends the quality of its outputs released in 2023, such as Pathways towards circular plastics in Europe — good practice examples from countries, business and citizens, Assessing the costs and benefits of climate change adaptation and European forest ecosystems: key allies in sustainable development; *appreciates the EEA's support of members of the ENVI committee by providing excellent, up-to-date data and information;*

Or. en

## **Amendment 47**

**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

### **Draft opinion**

#### **Paragraph 1**

##### *Draft opinion*

1. Stresses that the EEA provides sound, independent information on the environment; commends the quality of its

##### *Amendment*

1. Stresses that the EEA provides sound, independent information on the environment; commends the quality of its

outputs released in 2023, such as Pathways towards circular plastics in Europe — good practice examples from countries, business and citizens, Assessing the costs and benefits of climate change adaptation and European forest ecosystems: key allies in sustainable development;

outputs released in 2023, such as Pathways towards circular plastics in Europe — good practice examples from countries, business and citizens, Assessing the costs and benefits of climate change adaptation and European forest ecosystems: key allies in sustainable development, ***acknowledges the utmost importance of the EEA to reach the Union's climate goals;***

Or. en

**Amendment 48**  
**Antonio Decaro, Tiemo Wölken**

**Draft opinion**  
**Paragraph 1**

*Draft opinion*

1. Stresses that the EEA provides sound, independent information on the environment; commends the quality of its outputs released in 2023, such as Pathways towards circular plastics in Europe — good practice examples from countries, business and citizens, Assessing the costs and benefits of climate change adaptation and European forest ecosystems: key allies in sustainable development;

*Amendment*

1. Stresses that the EEA provides sound, independent ***and up-to-date scientific*** information on the environment; commends the quality of its outputs released in 2023, such as Pathways towards circular plastics in Europe — good practice examples from countries, business and citizens, Assessing the costs and benefits of climate change adaptation and European forest ecosystems: key allies in sustainable development;

Or. en

**Amendment 49**  
**Pär Holmgren**  
on behalf of the Greens/EFA Group

**Draft opinion**  
**Paragraph 2**

*Draft opinion*

2. Acknowledges the adaptability of the EEA, which, in addition to its planned publications for 2023, released additional

*Amendment*

2. Acknowledges the adaptability of the EEA, which, in addition to its planned publications for 2023, released additional

works on topics ranging from extreme weather to human health, such as The importance on restoring nature in Europe, demonstrating its capacity to inform and fuel current policy debates arising from evolving circumstances;

works on topics ranging from extreme weather to human health, such as The importance on restoring nature in Europe, demonstrating its capacity to inform and fuel current policy debates arising from evolving circumstances; ***emphasizes that, as climate and environment have become horizontal priorities with the European Green Deal, the EEA provides further added value through its broad and interconnected knowledge base; notes that, through its Eionet network and digitalisation work, the EEA is well-placed to support the implementation of the European Green Deal on the ground;***

Or. en

**Amendment 50**  
**Beatrice Timgren, Kristoffer Storm**

**Draft opinion**  
**Paragraph 2**

*Draft opinion*

2. ***Acknowledges the adaptability of the EEA, which, in addition to its planned publications for 2023, released additional works on topics ranging from extreme weather to human health, such as The importance on restoring nature in Europe, demonstrating its capacity to inform and fuel current policy debates arising from evolving circumstances;***

*Amendment*

2. ***Stresses the need for the EEA to prioritize the production of essential reports directly tied to measurable policy outcomes; calls on the EEA to exercise caution in expanding its scope beyond planned publications, focusing instead on delivering core outputs efficiently without overextending its resources;***

Or. en

**Amendment 51**  
**Alexandr Vondra**

**Draft opinion**  
**Paragraph 2**

*Draft opinion*

*Amendment*

2. Acknowledges the adaptability of the EEA, which, in addition to its planned publications for 2023, **released** additional works on topics ranging from extreme weather to human health, **such as** The importance **on** restoring nature in Europe, demonstrating its capacity to inform and **fuel current** policy debates arising from evolving circumstances;

2. Acknowledges the adaptability of the EEA, which, in addition to its planned publications for 2023, **produced** additional works on topics ranging from extreme weather to human health, **including** The Importance **of** Restoring Nature in Europe, demonstrating its capacity to inform and **contribute to** policy debates arising from evolving circumstances;

Or. en

## **Amendment 52**

**Michalis Hadjipantela, Dan-Ştefan Motreanu, Radan Kanev**

### **Draft opinion Paragraph 3**

#### *Draft opinion*

3. Notes that the EEA is tasked with tracking progress towards the 8th Environment Action programme ('8th EAP'), which builds on the European Green Deal and sets the framework for Union environmental policy until 2030, with a long-term priority objective for 2050 of living well within planetary boundaries; welcomes the release of its first annual monitoring report in December 2023, on the basis of a set of 28 headline indicators and corresponding targets such as climate change mitigation and adaptation, circular economy and biodiversity;

#### *Amendment*

3. Notes that the EEA is tasked with tracking progress towards the 8th Environment Action programme ('8th EAP'), which builds on the European Green Deal and sets the framework for Union environmental policy until 2030, with a long-term priority objective for 2050 of living well within planetary boundaries, **while investing in competitiveness as outlined in the Draghi report**; welcomes the release of its first annual monitoring report in December 2023, on the basis of a set of 28 headline indicators and corresponding targets such as climate change mitigation and adaptation, circular economy and biodiversity;

Or. en

## **Amendment 53**

**Beatrice Timgren, Kristoffer Storm**

### **Draft opinion Paragraph 3**

*Draft opinion*

3. ***Notes that the EEA is tasked with tracking progress towards the 8th Environment Action programme ('8th EAP'), which builds on the European Green Deal and sets the framework for Union environmental policy until 2030, with a long-term priority objective for 2050 of living well within planetary boundaries; welcomes the release of its first annual monitoring report in December 2023, on the basis of a set of 28 headline indicators and corresponding targets such as climate change mitigation and adaptation, circular economy and biodiversity;***

*Amendment*

3. ***Raises concerns about the practicality, financial sustainability, and scientific reliability of tracking progress towards long-term objectives, such as the 2050 planetary boundaries goal, and stresses the importance of prioritizing achievable, cost-effective short- and medium-term targets that align with current technological capabilities and deliver measurable benefits to Member States and citizens;***

Or. en

**Amendment 54**

**Pär Holmgren**

on behalf of the Greens/EFA Group

**Draft opinion**

**Paragraph 4 a (new)**

*Draft opinion*

*Amendment*

4 a. ***Notes that the work of the EEA is by nature trans-boundary and that the quality and usefulness of the EEA research and activities is significantly enhanced by the inclusion of non-EU EEA member countries and non-EU EEA cooperating countries, for example demonstrated by the excellent standing cooperation with the Western Balkan countries; hopes in the context of enlargement that the EEA will soon be able to welcome Moldova and Ukraine as cooperating or member countries; regrets also in this context that the United Kingdom has not yet returned as an EEA member or cooperating country following its exit from the European Union;***

Or. en

## Amendment 55

Pär Holmgren

on behalf of the Greens/EFA Group

### Draft opinion

#### Paragraph 5

##### *Draft opinion*

5. Welcomes the fact that, following the Discharge Authority's recommendations of 2022, the EEA has established regular progress monitoring processes for both the implementation of key reports and assessments and recently with a stronger focus on indicators, and has consecutively reached a budget execution rate of 100% of the annual budget, a 100% delivery rate of key reports and assessments, and high engagement with key stakeholders and network partners throughout the year;

##### *Amendment*

5. Welcomes the fact that, following the Discharge Authority's recommendations of 2022, the EEA has established regular progress monitoring processes for both the implementation of key reports and assessments and recently with a stronger focus on indicators, and has consecutively reached a budget execution rate of 100% of the annual budget, a 100% delivery rate of key reports and assessments, and high engagement with key stakeholders and network partners throughout the year; ***notes the need for more actionable recommendations and enhanced coordination with national agencies to ensure the effective application of EU environmental policies;***

Or. en

## Amendment 56

Olivier Chastel, Christine Singer, Gerben-Jan Gerbrandy, Vlad Vasile-Voiculescu, Sigrid Friis, Yvan Verougstraete, Martin Hojsik

### Draft opinion

#### Paragraph 5 a (new)

##### *Draft opinion*

##### *Amendment*

***5 a. Stresses that gender balance in the composition of the top management of our Agencies and institutions must be a guideline; welcomes the fact that the Agency's senior management is currently composed of 50% men and 50% women, according to the figures communicated;***

**Amendment 57**

**Olivier Chastel, Christine Singer, Gerben-Jan Gerbrandy, Vlad Vasile-Voiculescu, Yvan Verougstraete, Martin Hojsik**

**Draft opinion**

**Paragraph 5 b (new)**

*Draft opinion*

*Amendment*

**5 b. Notes that 20.1 % of its staff are nationals of the Member State where the Agency is located; recalls the importance of geographical balance and encourages the Agency to continue to take the necessary measures to have a balanced and fair geographical representation;**

Or. en

**Amendment 58**

**Pär Holmgren**

on behalf of the Greens/EFA Group

**Draft opinion**

**Paragraph 6**

*Draft opinion*

*Amendment*

6. Takes note with concern that despite the multi-year nature of the EEA's tasks, an imbalance exists concerning the numbers of permanent versus contractual posts, as well as operational staff versus support staff, leading to a constant need for reskilling as well as an overload of administrative work for scientists; considers that taking into account the substantial increase of workload, and in order to properly perform the tasks on the Union's goals for, inter alia, climate neutrality, circular economy and nature restoration, the EEA's staff number should continue to substantially grow in the years to come.

6. Takes note with concern that despite the multi-year nature of the EEA's tasks, an imbalance exists concerning the numbers of permanent versus contractual posts, as well as operational staff versus support staff, leading to a constant need for reskilling as well as an overload of administrative work for scientists; **takes note that the growing number of collaborations between Directorates-General in implementing the Green Deal has created a complex patchwork of agreements that results in heavy administrative burden for the EEA, whereby some tasks which are long-term in nature are funded by short-term**



*financial agreements*; considers that taking into account the substantial increase of workload, and in order to properly perform the tasks on the Union's goals for, inter alia, climate neutrality, circular economy and nature restoration, the EEA's staff number should continue to substantially grow in the years to come **and the EEA budget needs to increase in proportion in order to keep up with the necessary increase in staff numbers.**

Or. en

**Amendment 59**  
**Antonio Decaro, Tiemo Wölken**

**Draft opinion**  
**Paragraph 6**

*Draft opinion*

6. Takes note with concern that despite the multi-year nature of the EEA's tasks, an imbalance exists concerning the numbers of permanent versus contractual posts, as well as operational staff versus support staff, leading to a constant need for reskilling as well as an overload of administrative work for scientists; considers that taking into account the substantial increase of workload, and in order to properly perform the tasks **on** the Union's goals for, inter alia, climate neutrality, circular economy and nature restoration, the EEA's staff number should continue to substantially grow in the years to come.

*Amendment*

6. Takes note with concern that despite the multi-year nature of the EEA's tasks, an imbalance exists concerning the numbers of permanent versus contractual posts **in the Agency**, as well as operational staff versus support staff, leading to a constant need for reskilling as well as an overload of administrative work for scientists; considers that taking into account the substantial increase of workload, and in order to properly perform the **required** tasks **linked to** the Union's goals for, inter alia, climate neutrality, circular economy and nature restoration, the EEA's staff number should continue to substantially grow in the years to come **and this should be reflected in the financial resources allocated to the Agency.**

Or. en

**Amendment 60**  
**Beatrice Timgren, Kristoffer Storm**

**Draft opinion**  
**Paragraph 6**

*Draft opinion*

6. Takes note with concern that despite the multi-year nature of the EEA's tasks, an imbalance exists concerning the numbers of permanent versus contractual posts, as well as operational staff versus support staff, leading to a constant need for reskilling as well as an overload of administrative work for scientists; ***considers that taking into account the substantial increase of workload, and in order to properly perform the tasks on the Union's goals for, inter alia, climate neutrality, circular economy and nature restoration, the EEA's staff number should continue to substantially grow in the years to come.***

*Amendment*

6. Takes note with concern that despite the multi-year nature of the EEA's tasks, an imbalance exists concerning the numbers of permanent versus contractual posts, as well as operational staff versus support staff, leading to a constant need for reskilling as well as an overload of administrative work for scientists; ***opposes however substantial increases in staff numbers, calling instead for an internal review of staff allocation and responsibilities to improve effectiveness in delivering ENVI-related objectives; recommends the adoption of automation and digital solutions to alleviate administrative burdens on scientific staff, enabling them to focus on core research activities without requiring substantial increases in staff numbers;***

Or. en

**Amendment 61**  
**Alexandr Vondra**

**Draft opinion**  
**Paragraph 6**

*Draft opinion*

6. Takes note with concern that despite the multi-year nature of the EEA's tasks, an imbalance exists concerning the numbers of permanent versus contractual posts, as well as operational staff versus support staff, leading to a constant need for reskilling as well as an overload of administrative work for scientists; ***considers that taking into account the substantial increase of workload, and in order to properly perform the tasks on the Union's goals for, inter alia, climate neutrality, circular economy and nature***

*Amendment*

6. Takes note with concern that despite the multi-year nature of the EEA's tasks, an imbalance exists concerning the numbers of permanent versus contractual posts, as well as operational staff versus support staff, leading to a constant need for reskilling as well as an overload of administrative work for scientists; ***highlights the importance of aligning staff resources with the EEA's long-term responsibilities and growing demands, potentially requiring a gradual and strategic adjustment in staff numbers over***

*restoration, the EEA's staff number should continue to substantially grow in the years to come.* *time;*

Or. en

## **Amendment 62**

**Michalis Hadjipantela, Dan-Ştefan Motreanu, Radan Kanev**

### **Draft opinion**

#### **Paragraph 6**

##### *Draft opinion*

6. Takes note with concern that despite the multi-year nature of the EEA's tasks, an imbalance exists concerning the numbers of permanent versus contractual posts, as well as operational staff versus support staff, leading to a constant need for reskilling as well as an overload of administrative work for scientists; considers that taking into account the substantial increase of workload, and in order to properly perform the tasks on the Union's goals for, inter alia, climate neutrality, circular economy and nature restoration, the EEA's staff number should *continue to substantially grow in the years to come.*

##### *Amendment*

6. Takes note with concern that despite the multi-year nature of the EEA's tasks, an imbalance exists concerning the numbers of permanent versus contractual posts, as well as operational staff versus support staff, leading to a constant need for reskilling as well as an overload of administrative work for scientists; considers that taking into account the substantial increase of workload, and in order to properly perform the tasks on the Union's goals for, inter alia, climate neutrality, circular economy and nature restoration, the EEA's staff number should *reflect the scope and extent of its demanding work programme.*

Or. en

## **Amendment 63**

**Beatrice Timgren, Kristoffer Storm**

### **Draft opinion**

#### **Paragraph 6 a (new)**

##### *Draft opinion*

##### *Amendment*

**6 a. Cautions against overburdening the EEA with additional tasks arising from new directives and regulations, emphasizing the need to focus on its primary responsibilities; stresses the**

*importance of ensuring that resources are not diluted by attempting to address an overly broad range of objectives, which could compromise the quality and impact of its outputs;*

Or. en

#### **Amendment 64**

**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

#### **Draft opinion**

#### **Paragraph 6 a (new)**

*Draft opinion*

*Amendment*

**6 a. Reiterates the need for the EEA to adequately hire staff able to carry out the immense task devoted to the Agency, encourages in this regard the Commission to intensify its measures to assist Agencies in ensuring the competence required, reminds the EEA of the importance of achieving gender and geographical balance among staff, ensuring a healthy work-life balance for everyone but not least for parent staff and to continuously work with improving workers' health and well-being;**

Or. en

#### **Amendment 65**

**Beatrice Timgren, Kristoffer Storm**

#### **Draft opinion**

#### **Paragraph 1**

*Draft opinion*

*Amendment*

1. **Welcomes** the EFSA's' **contribution to** the safety of the Union food and feed chain, **and its considerable efforts in** providing **risk managers with comprehensive,** independent **and up-to-**

1. **Acknowledges** the EFSA's **essential role in ensuring** the safety of the Union food and feed chain **and** providing independent, up-to-date scientific advice; **stresses the need for the EFSA to focus on**

date scientific advice *on questions linked to the food chain, communicating clearly to the public on its outputs and the information on which they are based, and cooperating with interested parties and institutional partners to promote coherence and trust in the food safety system;*

its *core responsibilities, avoiding unnecessary expansion into non-essential initiatives that may dilute its effectiveness;*

Or. en

#### **Amendment 66**

**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

#### **Draft opinion Paragraph 1**

##### *Draft opinion*

1. Welcomes the EFSA's' contribution to the safety of the Union food and feed chain, *and its considerable efforts in providing risk managers with comprehensive, independent and up-to-date scientific advice on questions linked to the food chain, communicating clearly to the public on its outputs and the information on which they are based, and cooperating with interested parties and institutional partners to promote coherence and trust in the food safety system;*

##### *Amendment*

1. Welcomes the EFSA's' contribution to the safety of the Union food and feed chain, *however expresses deep concern over some of the aspects of the Agency's work relating to inadequate actualisation of regulation regarding pesticides and other toxins, deplors the close ties between the agency and agrochemical industry and reiterates the need for a thorough investigation into these ties;*

Or. en

#### **Amendment 67 Alexandr Vondra**

#### **Draft opinion Paragraph 2**

##### *Draft opinion*

2. Welcomes the involvement of the EFSA in ENVI's work and more generally

##### *Amendment*

2. Welcomes the involvement of the EFSA in ENVI's work and more generally

the engagement of EFSA with initiatives related to the Farm to Fork and the Union Chemical strategies, with a particular emphasis on pesticides, nutrition, animal welfare, and chemical risk assessment, including *establishing an* Union chemicals data platform;

the engagement of EFSA with initiatives related to the Farm to Fork and the Union Chemical strategies, with a particular emphasis on pesticides, nutrition, animal welfare, and chemical risk assessment; *stresses the need for these efforts to remain firmly grounded in robust, evidence-based policy-making, including the establishment of a* Union chemicals data platform, *to ensure that decisions are informed by the best available scientific data and promote effective and balanced regulatory outcomes;*

Or. en

**Amendment 68**  
**Beatrice Timgren, Kristoffer Storm**

**Draft opinion**  
**Paragraph 2 a (new)**

*Draft opinion*

*Amendment*

**2 a.** *Cautions against overburdening the EFSA with additional tasks linked to broader initiatives such as the Farm to Fork and Union Chemical strategies, emphasizing that its primary focus should remain on food safety and core chemical risk assessments;*

Or. en

**Amendment 69**  
**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

**Draft opinion**  
**Paragraph 2 a (new)**

*Draft opinion*

*Amendment*

**2 a.** *Believes that EFSA should continue to pay special attention to the public opinion, and commit itself to*

*increased openness, transparency and scrutiny to and by the public and independent scientists;*

Or. en

## **Amendment 70**

**Michalis Hadjipantela, Dan-Ştefan Motreanu, Radan Kanev**

### **Draft opinion**

#### **Paragraph 3**

##### *Draft opinion*

3. Notes that the EFSA closed 660 scientific questions in 2023, slightly below the target of 673 but better than the result achieved since 2020; highlights the need to decrease the amount of questions in stock; welcomes the measures put in place to increase the speed of the Risk Assessment process;

##### *Amendment*

3. Notes that the EFSA closed 660 scientific questions in 2023, slightly below the target of 673 but better than the result achieved since 2020; highlights the need to decrease the amount of questions in stock; welcomes the measures put in place to increase the speed of the Risk Assessment process; ***proposes the establishment of an expedited assessment track for urgent health concerns and response mechanisms for discrepancies between Union standards and trade obligations, to reduce backlog and respond to trade obligations;***

Or. en

## **Amendment 71**

**Antonio Decaro, Tiemo Wölken**

### **Draft opinion**

#### **Paragraph 3**

##### *Draft opinion*

3. Notes that the EFSA closed 660 scientific questions in 2023, slightly below the target of 673 but better than the result achieved since 2020; highlights the need to decrease the amount of questions in stock; welcomes the measures put in ***please*** to increase the speed of the Risk Assessment

##### *Amendment*

3. Notes that the EFSA closed 660 scientific questions in 2023, slightly below the target of 673 but better than the result achieved since 2020; highlights the need to decrease the amount of questions in stock; welcomes the measures put in ***place*** to increase the speed of the Risk Assessment

process;

process;

Or. en

**Amendment 72**

**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

**Draft opinion**

**Paragraph 3 a (new)**

*Draft opinion*

*Amendment*

***3 a. Reiterates its regrets that the EFSA, in relation to the two-year cooling off period, still includes in its independence policy the obligation to screen experts' interests only in relation to the mandate of the scientific group to which the expert is applying, and reiterates its regrets that the research funding from companies in the Authority's remit is not considered relevant to the cooling off period as long as amounts at stake do not rise above 25 % of the total research budget managed by the expert and/or their research team, and that the threshold is applied to individual sources as opposed to all private sources combined; highlights that the Authority's refusal to address these two very serious issues in relation to the Authority's prevention and management of conflicts of interests is unacceptable and needs to be resolved immediately;***

Or. en

**Amendment 73**

**Antonio Decaro, Tiemo Wölken**

**Draft opinion**

**Paragraph 4**

*Draft opinion*

*Amendment*



4. **Takes note** that, according to the Annual Strategy Survey launched by the EFSA asking for feedback from its customers, partners, and stakeholders who are directly or indirectly involved in the delivery of the EFSA's scientific opinions, the EFSA's ability to provide its advice in a timely manner remains a point of attention as in the previous year; calls on the EFSA to implement the necessary measures to improve this aspect;

4. **Notes with concern** that, according to the Annual Strategy Survey launched by the EFSA asking for feedback from its customers, partners, and stakeholders who are directly or indirectly involved in the delivery of the EFSA's scientific opinions, the EFSA's ability to provide its advice in a timely manner remains a point of attention as in the previous year; calls on the EFSA to implement the necessary measures to improve this aspect;

Or. en

#### **Amendment 74**

**Pär Holmgren**

on behalf of the Greens/EFA Group

#### **Draft opinion**

#### **Paragraph 4 a (new)**

*Draft opinion*

*Amendment*

**4 a. Calls on the Commission to increase the budget of EFSA and stresses the necessity of ensuring adequate staffing to reflect the needs of the more systematic implementation of a 'One Health' approach to risk assessment;**

Or. en

#### **Amendment 75**

**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

#### **Draft opinion**

#### **Paragraph 5**

*Draft opinion*

*Amendment*

5. Highlights the need for the EFSA to develop strong cooperation with all its stakeholders, including the other Agencies for better connection and outputs dissemination; welcomes the fact that the

5. Highlights the need for the EFSA to develop strong cooperation with all its stakeholders, including the other Agencies for better connection and outputs dissemination; welcomes the fact that the

EFSA developed cooperation with Member States, including with the increase support of focal points, mainly focusing on support in the area of data collection and communication;

EFSA developed cooperation with Member States, including with the increase support of focal points, mainly focusing on support in the area of data collection and communication; ***encourages EFSA to even further increase its efforts to protect animal welfare and promote the use of non-animal testing methods, also in its cooperation with other institutions;***

Or. en

**Amendment 76**  
**Antonio Decaro, Tiemo Wölken**

**Draft opinion**  
**Paragraph 5**

*Draft opinion*

5. Highlights the need for the EFSA to develop strong cooperation with all its stakeholders, including the other Agencies for better connection and outputs dissemination; welcomes the fact that the EFSA developed cooperation with Member States, including with the ***increase*** support of focal points, mainly focusing on support in the area of data collection and communication;

*Amendment*

5. Highlights the need for the EFSA to develop strong cooperation with all its stakeholders, including the other Agencies for better connection and outputs dissemination; welcomes the fact that the EFSA developed cooperation with Member States, including with the ***increased*** support of ***the Focal Points Network***, mainly focusing on support in the area of data collection and communication;

Or. en

**Amendment 77**  
**Pär Holmgren**  
on behalf of the Greens/EFA Group

**Draft opinion**  
**Paragraph 5 a (new)**

*Draft opinion*

*Amendment*

***5 a. Recalls that since 2015, the Parliament has adopted 83 resolutions objecting to the placing on the market of GMOs for food and feed; highlights that***

*one reason for these objections are gaps in the risk assessment undertaken by the Authority's Panel on Genetically Modified Organisms; urges the Authority to address and close these gaps as a matter of urgency;*

Or. en

**Amendment 78**

**Olivier Chastel, Christine Singer, Gerben-Jan Gerbrandy, Vlad Vasile-Voiculescu, Sigrid Friis, Yvan Verougstraete, Martin Hojsik**

**Draft opinion**

**Paragraph 5 a (new)**

*Draft opinion*

*Amendment*

*5 a. Stresses that gender balance in the composition of the top management of our Agencies and institutions must be a guideline; notes that the EFSA's senior management is currently composed of 63% men and 38% women, according to the figures communicated; calls on the Agency to take this into consideration in future recruitments;*

Or. en

**Amendment 79**

**Pär Holmgren**

on behalf of the Greens/EFA Group

**Draft opinion**

**Paragraph 5 b (new)**

*Draft opinion*

*Amendment*

*5 b. Notes that a recent report<sup>1a</sup> highlighted that EFSA's 'GMO Panel', which is responsible for the assessment of genetically engineered organisms, includes a large number of researchers involved in the development of genetically engineered plants, some of whom have*

*links to the industry; urges the Authority to better address conflict of interests and to actively include more independent experts in its panels;*

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*<sup>1a</sup> [https://www.testbiotech.org/wp-content/uploads/2024/09/Testbiotech\\_EF\\_SA\\_GMO\\_Panel\\_2024-1.pdf](https://www.testbiotech.org/wp-content/uploads/2024/09/Testbiotech_EF_SA_GMO_Panel_2024-1.pdf)*

Or. en

**Amendment 80**

**Olivier Chastel, Christine Singer, Gerben-Jan Gerbrandy, Vlad Vasile-Voiculescu, Yvan Verougstraete, Martin Hojsik**

**Draft opinion**

**Paragraph 5 b (new)**

*Draft opinion*

*Amendment*

*5 b. Notes that 41.8 % of its staff are nationals of the Member State where the Agency is located; recalls the importance of geographical balance and encourages the Agency to continue to take the necessary measures to have a balanced and fair geographical representation;*

Or. en

**Amendment 81**

**Pär Holmgren**

on behalf of the Greens/EFA Group

**Draft opinion**

**Paragraph 5 c (new)**

*Draft opinion*

*Amendment*

*5 c. Highlights that the European Parliament adopted two resolutions at the beginning of the mandate to object to Maximum Residues Levels (MRLs) for pesticides due to cumulative and synergistic effects not having been taken*

*into account in EFSA's reasoned opinion;*

Or. en

## **Amendment 82**

**Pär Holmgren**

on behalf of the Greens/EFA Group

### **Draft opinion**

#### **Paragraph 6**

##### *Draft opinion*

6. Welcomes the fact that the EFSA continued implementing its new organisational structure that was put in place in 2022 to reflect the Transparency Regulation; highlights the need to improve efficiency and transparency in the EFSA's process architecture.

##### *Amendment*

6. Welcomes the fact that the EFSA continued implementing its new organisational structure that was put in place in 2022 to reflect the Transparency Regulation; ***notes that the Transparency Regulation required the Commission to develop and adopt a 'General Plan for Risk Communication', which has not been presented by the Commission despite the preparatory work completed by the EFSA;*** highlights the need to improve efficiency and transparency in the EFSA's process architecture.

Or. en

## **Amendment 83**

**Beatrice Timgren, Kristoffer Storm**

### **Draft opinion**

#### **Paragraph 6**

##### *Draft opinion*

6. Welcomes the fact that the EFSA continued implementing its new organisational structure that was put in place in 2022 to reflect the Transparency Regulation; highlights the need to improve efficiency and transparency in the EFSA's process architecture.

##### *Amendment*

6. Welcomes the fact that the EFSA continued implementing its new organisational structure that was put in place in 2022 to reflect the Transparency Regulation, ***but emphasizes the importance of ensuring that it leads to measurable efficiency gains, avoids increased administrative complexity or costs, and enhances effectiveness in***

**achieving ENVI-related objectives.**  
Highlights the need to improve efficiency and transparency in the EFSA's process architecture;

Or. en

**Amendment 84**  
**Antonio Decaro, Tiemo Wölken**

**Draft opinion**  
**Paragraph 6**

*Draft opinion*

6. Welcomes the fact that the EFSA continued implementing its new organisational structure that was put in place in 2022 to reflect the Transparency Regulation; highlights the need to improve efficiency and transparency in the EFSA's process architecture.

*Amendment*

6. Welcomes the fact that the EFSA continued implementing its new organisational structure that was put in place in 2022 to reflect the Transparency Regulation; highlights the need to ***continuously*** improve efficiency and transparency in the EFSA's process architecture.

Or. en

**Amendment 85**  
**Pär Holmgren**  
on behalf of the Greens/EFA Group

**Draft opinion**  
**Paragraph 6 a (new)**

*Draft opinion*

*Amendment*

***6 a. Stresses the need to preserve EFSA's independence by avoiding any ad-hoc future modification to its functioning, such as expanding the scope of pre-submission advice (article 32a of the Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety) to technical matters such as study***

*design and protocols to be tested; notes the potential damage to public trust in EFSA work from ad-hoc changes to its functioning;*

Or. en

**Amendment 86**  
**Biljana Borzan**

**Draft opinion**  
**Paragraph 6 a (new)**

*Draft opinion*

*Amendment*

**6 a.** *Encourages EFSA to expand its efforts in horizon scanning and early identification of emerging risks in the food and feed chain, particularly in areas linked to climate change and the increasing complexity of global supply chains; stresses the importance of adopting proactive approaches to risk assessment and mitigation to ensure the resilience of the Union's food system.*

Or. en

**Amendment 87**  
**Biljana Borzan**

**Draft opinion**  
**Paragraph 6 b (new)**

*Draft opinion*

*Amendment*

**6 b.** *Underlines the significance of enhancing public engagement and outreach activities, including leveraging digital tools to increase public access to scientific information and the rationale behind EFSA's decisions; calls for the development of user-friendly platforms that promote greater understanding and foster citizen participation in the food safety dialogue.*

**Amendment 88**  
**Biljana Borzan**

**Draft opinion**  
**Paragraph 6 c (new)**

*Draft opinion*

*Amendment*

**6 c. Notes the growing importance of alternative protein sources and novel foods in achieving the Union's sustainability goals; calls on the EFSA to prioritize the development of robust scientific frameworks for assessing the safety and nutritional impact of these products, ensuring that innovation is underpinned by rigorous risk assessment standards.**

Or. en

**Amendment 89**  
**Biljana Borzan**

**Draft opinion**  
**Paragraph 6 d (new)**

*Draft opinion*

*Amendment*

**6 d. Calls for closer collaboration between the EFSA and the ECDC to enhance the monitoring and assessment of zoonotic diseases and antimicrobial resistance; stresses the need for a unified approach to safeguarding public health through a 'One Health' perspective.**

Or. en

**Amendment 90**  
**Beatrice Timgren, Kristoffer Storm**



**Draft opinion  
Paragraph 1**

*Draft opinion*

1. Reiterates the key role of the EMA in protecting human and animal health by assessing and supervising medicines for human or veterinary use **and protecting public health by raising awareness on key issues including antimicrobial resistance and prevention of communicable diseases through vaccination**;

*Amendment*

1. Reiterates the key role of the EMA in protecting human and animal health by assessing and supervising medicines for human or veterinary use; **emphasizes the importance of focusing resources on its core responsibilities and avoiding unnecessary expansion into broader public health awareness campaigns**;

Or. en

**Amendment 91**

**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

**Draft opinion  
Paragraph 1 a (new)**

*Draft opinion*

*Amendment*

**1 a. Expresses deep concern over reports of conflict of interest and influence of the pharmaceutical industry over EMA <sup>1d</sup>, reiterates that the agency serves the public interest of safe and affordable medicine, regrets inaction shown by the agency to tackle accusations of "revolving doors" in the case of scientific experts and their involvement with big pharmaceutical companies, regrets with profound concern the unwillingness of the Agency to challenge financial interests and to properly prioritise public health concerns;**

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<sup>1d</sup> <https://www.investigate-europe.eu/posts/deadly-prices-big-pharma-influence-hangs-over-europes-medicines-regulator>

Or. en

## Amendment 92

Michalis Hadjipantela, Dan-Ştefan Motreanu, Radan Kanev

### Draft opinion

#### Paragraph 2

##### *Draft opinion*

2. Notes that in 2023, the EMA recommended for marketing authorisation 77 new human medicines, including 39 new active substances, and 14 new veterinary medicines, including 9 new active substances; welcomes the fact that the EMA confirmed seventeen orphan-status designations under the Union framework for orphan medicines, the purpose of which is to encourage the development and marketing of medicines for patients with rare diseases;

##### *Amendment*

2. Notes that in 2023, the EMA recommended for marketing authorisation 77 new human medicines, including 39 new active substances, and 14 new veterinary medicines, including 9 new active substances; welcomes the fact that the EMA confirmed seventeen orphan-status designations under the Union framework for orphan medicines, the purpose of which is to encourage the development and marketing of medicines for patients with rare diseases, ***adopting an expedited mechanism under special conditions***;

Or. en

## Amendment 93

Beatrice Timgren, Kristoffer Storm

### Draft opinion

#### Paragraph 3

##### *Draft opinion*

3. Notes the EMA decision to lift its COVID-19 business continuity measures, in alignment with the World Health Organisation declaration of the end of COVID-19 as a public health emergency of international concern; welcomes the fact that it enabled the EMA to shift its focus to address other challenges, including the finalisation of the EMA's extended mandate obligations, of the medical devices and in vitro medical devices regulations (MDR/IVDR), and the first reflections on the EC proposal for the

##### *Amendment*

3. Notes the EMA decision to lift its COVID-19 business continuity measures, in alignment with the World Health Organisation declaration of the end of COVID-19 as a public health emergency of international concern; welcomes the fact that it enabled the EMA to shift its focus to address other challenges, including the finalisation of the EMA's extended mandate obligations, of the medical devices and in vitro medical devices regulations (MDR/IVDR), and the first reflections on the EC proposal for the

revision of the general Union pharmaceutical legislation for human medicines;

revision of the general Union pharmaceutical legislation for human medicines; *cautions against overburdening the EMA with growing obligations and instead highlights the need to focus on existing tasks in order to directly enhance human and animal health outcomes;*

Or. en

#### **Amendment 94**

**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

#### **Draft opinion Paragraph 4**

##### *Draft opinion*

4. Welcomes the EMA's efforts to contribute to Union priorities, including via inter alia the implementation of the Union Beating Cancer Plan, the Union Chemical Strategy for Sustainability and the European One Health Action Plan against Antimicrobial Resistance.

##### *Amendment*

4. Welcomes the EMA's efforts to contribute to Union priorities, including via inter alia the implementation of the Union Beating Cancer Plan, the Union Chemical Strategy for Sustainability and the European One Health Action Plan against Antimicrobial Resistance; *urges the EMA to further cooperate with relevant agencies and actors to combat new, rare and difficult-to-diagnose cancers; reiterates the need to pay special attention to often misdiagnosed conditions among women and girls and to be conscious of class bias in health related issues and pharmacological needs;*

Or. en

#### **Amendment 95**

**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

#### **Draft opinion Paragraph 5**

*Draft opinion*

5. Recalls that the EMA is a fee-funded agency, with 88,21 % of its 2023 revenue stemming from fees for applications for marketing licenses for pharmaceutical products and for post-authorisation activities, 11,43 % stemming from the Union budget and 0,36 % from various other sources; highlights the need to ensure transparency of these revenues and welcomes the fact that in the future the EMA will have the obligation to publish in its activity report the annual revenue received per type of fee and charge according to Regulation (EU) 2024/568<sup>2</sup> ;

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<sup>2</sup> Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95 (OJ L, 2024/568, 14.2.2024, ELI: <http://data.europa.eu/eli/reg/2024/568/oj>).

*Amendment*

5. Recalls that the EMA is a fee-funded agency, with 88,21 % of its 2023 revenue stemming from fees for applications for marketing licenses for pharmaceutical products and for post-authorisation activities, 11,43 % stemming from the Union budget and 0,36 % from various other sources; highlights the need to ensure transparency of these revenues and welcomes the fact that in the future the EMA will have the obligation to publish in its activity report the annual revenue received per type of fee and charge according to Regulation (EU) 2024/568<sup>2</sup> ; ***reiterates the importance of scientific integrity and patient safety; commits to supporting the EMA to guard these principles regardless of the levels of fee-based incomes to the agency;***

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<sup>2</sup> Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95 (OJ L, 2024/568, 14.2.2024, ELI: <http://data.europa.eu/eli/reg/2024/568/oj>).

Or. en

**Amendment 96**

**Pär Holmgren**

on behalf of the Greens/EFA Group

**Draft opinion**

**Paragraph 5**

*Draft opinion*

*Amendment*

5. Recalls that the EMA is a fee-funded agency, with 88,21 % of its 2023 revenue stemming from fees for applications for marketing licenses for pharmaceutical products and for post-authorisation activities, 11,43 % stemming from the Union budget and 0,36 % from various other sources; highlights the need to ensure transparency of these revenues **and** welcomes the fact that in the future the EMA will have the obligation to publish in its activity report the annual revenue received per type of fee and charge according to Regulation (EU) 2024/568<sup>2</sup> ;

5. Recalls that the EMA is a fee-funded agency, with 88,21 % of its 2023 revenue stemming from fees for applications for marketing licenses for pharmaceutical products and for post-authorisation activities, 11,43 % stemming from the Union budget and 0,36 % from various other sources; ***stresses that despite the majority of funding coming from private sources, the EMA is a public authority; underlines that public trust in and guarantee of the Agency's independence and integrity is crucial and therefore*** highlights the need to ensure transparency of these revenues; welcomes the fact that in the future the EMA will have the obligation to publish in its activity report the annual revenue received per type of fee and charge according to Regulation (EU) 2024/568<sup>2</sup> ;

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<sup>2</sup> Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95 (OJ L, 2024/568, 14.2.2024, ELI: <http://data.europa.eu/eli/reg/2024/568/oj>).

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<sup>2</sup> Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95 (OJ L, 2024/568, 14.2.2024, ELI: <http://data.europa.eu/eli/reg/2024/568/oj>).

Or. en

**Amendment 97**  
**Antonio Decaro, Tiemo Wölken**

**Draft opinion**  
**Paragraph 5**

*Draft opinion*

5. Recalls that the EMA is a fee-funded agency, with 88,21 % of its 2023

*Amendment*

5. Recalls that the EMA is a fee-funded agency, with 88,21 % of its 2023

revenue stemming from fees for applications for marketing licenses for pharmaceutical products and for post-authorisation activities, 11,43 % stemming from the Union budget and 0,36 % from various other sources; highlights the need to ensure transparency of these revenues and welcomes the fact that in the future the EMA will have the obligation to publish in its activity report the annual revenue received per type of fee and charge according to Regulation (EU) 2024/568<sup>2</sup> ;

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<sup>2</sup> Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95 (OJ L, 2024/568, 14.2.2024, ELI: <http://data.europa.eu/eli/reg/2024/568/oj>).

revenue stemming from fees for applications for marketing licenses for pharmaceutical products and for post-authorisation activities, 11,43 % stemming from the Union budget and 0,36 % from various other sources; highlights the need to ensure **full** transparency of these revenues and welcomes the fact that in the future the EMA will have the obligation to publish in its activity report the annual revenue received per type of fee and charge according to Regulation (EU) 2024/568<sup>2</sup> ;

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<sup>2</sup> Regulation (EU) 2024/568 of the European Parliament and of the Council of 7 February 2024 on fees and charges payable to the European Medicines Agency, amending Regulations (EU) 2017/745 and (EU) 2022/123 of the European Parliament and of the Council and repealing Regulation (EU) No 658/2014 of the European Parliament and of the Council and Council Regulation (EC) No 297/95 (OJ L, 2024/568, 14.2.2024, ELI: <http://data.europa.eu/eli/reg/2024/568/oj>).

Or. en

## **Amendment 98**

**Pär Holmgren**

on behalf of the Greens/EFA Group

### **Draft opinion**

#### **Paragraph 6**

##### *Draft opinion*

6. Notes that in 2023 the EMA received 6 965 requests for information and 709 requests for access to documents and that the EMA applies a queuing system that leads to delays in the treatment of the requests; emphasises the importance of transparency in the EMA operations, hence the need to ensure a timely access to information and documents;

##### *Amendment*

6. Notes that in 2023 the EMA received 6 965 requests for information and 709 requests for access to documents and that the EMA applies a queuing system that leads to delays in the treatment of the requests; emphasises the importance of transparency in the EMA operations, hence the need to ensure a timely access to information and documents ***in order to***

*reinforce public trust in regulatory decisions and the medicines placed on the EU market;*

Or. en

**Amendment 99**

**Olivier Chastel, Christine Singer, Gerben-Jan Gerbrandy, Vlad Vasile-Voiculescu, Sigrid Friis, Yvan Verougstraete, Martin Hojsik**

**Draft opinion**

**Paragraph 6 a (new)**

*Draft opinion*

*Amendment*

**6 a. Stresses that gender balance in the composition of the top management of our agencies and institutions must be a guideline; notes that the Agency's senior management is currently composed of 60% men and 40% women, according to the figures communicated; calls on the Agency to take this into consideration in future recruitments;**

Or. en

**Amendment 100**

**Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen**

**Draft opinion**

**Paragraph 6 a (new)**

*Draft opinion*

*Amendment*

**6 a. Acknowledges that accessibility to medicine at affordable rates is a national competence; commits however to assuring that the EMA contributes to these ends; encourages the agency to find methods and practices that manages development costs of new pharmacological products;**

Or. en

**Amendment 101**

**Olivier Chastel, Christine Singer, Gerben-Jan Gerbrandy, Vlad Vasile-Voiculescu, Yvan Verougstraete, Martin Hojsik**

**Draft opinion**

**Paragraph 6 b (new)**

*Draft opinion*

*Amendment*

**6 b. Notes that the Agency has concluded an internal environmental audit in 2023 with a view to obtaining EMAS certification in 2024 ;**

Or. en

**Amendment 102**

**Pär Holmgren**

on behalf of the Greens/EFA Group

**Draft opinion**

**Paragraph 7**

*Draft opinion*

*Amendment*

7. Notes that the situation regarding the EMA's former premises in London became increasingly challenging in 2023, with a need for the EMA to dedicate significant levels of resources to managing commercial real estate in a third country, endangering its core activities; calls on the Commission to secure a long-term political resolution of this issue and to **allow** the EMA **to fully focus its efforts on its public health mission**.

7. Notes that the situation regarding the EMA's former premises in London became increasingly challenging in 2023, with a need for the EMA to dedicate significant levels of resources to managing commercial real estate in a third country, endangering its core activities; calls on the Commission **and the Council** to secure a long-term political resolution of this issue and to **ensure that** the EMA **has sufficient resources to carry out all of its activities and regulatory mechanisms including facilitating the development and access to medicines, supporting research and innovation and its responsibilities for monitoring and mitigating potential or actual shortages of critical medicines without any delay**.

Or. en



**Amendment 103**  
**Alexandr Vondra**

**Draft opinion**  
**Paragraph 7**

*Draft opinion*

7. Notes *that the* situation regarding the EMA's former premises in London *became increasingly challenging* in 2023, *with a need for the EMA to dedicate significant levels of resources to managing* commercial real estate in a third country, *endangering its core activities; calls on* the Commission to *secure* a long-term political resolution *of* this issue *and to allow* the EMA to *fully* focus its efforts on its public health mission.

*Amendment*

7. Notes *with concern the increasingly challenging* situation regarding the EMA's former premises in London, *which* in 2023 *required* significant resources to *manage* commercial real estate in a third country; *this burden risks diverting attention and resources from the EMA's core public health mission; urges* the Commission to *prioritise securing* a long-term political *and financial* resolution *to* this issue, *including exploring options such as renegotiating terms or repurposing the premises, to prevent unnecessary expenditure and enable* the EMA to focus its efforts on its public health mission.

Or. en

**Amendment 104**  
**Michalis Hadjipantela, Dan-Ştefan Motreanu, Radan Kanev**

**Draft opinion**  
**Paragraph 6 b (new)**

*Draft opinion*

**6 b. Recommends the establishment of a formal framework for joint procurement of essential medicines across Member States, modelled on the success of the COVID-19 vaccine procurement process, for ensuring equitable access to high-quality medicines through economies of scale.**

*Amendment*

Or. en

## Amendment 105

Jonas Sjöstedt, Sebastian Everding, Anja Hazekamp, Li Andersson, Catarina Martins, Per Clausen

### Draft opinion

#### Paragraph 1

##### *Draft opinion*

1. Recommends, based on the facts available, that discharge be granted to the Executive Directors of the Agencies in respect of the implementation of the budget of the EU agencies for the financial year 2023.

##### *Amendment*

1. Recommends, based on the facts available, that discharge ***should not*** be granted to the Executive Directors of the Agencies ***EFSA and EMA*** in respect of the implementation of the budget of the EU agencies for the financial year 2023, ***recommends that discharge be granted to all other Executive Directors of the Agencies*** .

Or. en