

14 September 2022

## European Chemicals Agency report on the follow-up to the 2020 budgetary discharge

Article 107 of the Financial Regulation of the European Chemicals Agency (ECHA) foresees that:

- (1) *the Executive Director shall take all appropriate steps to act on the observations accompanying the European Parliament's discharge decision and on the comments accompanying the recommendation for discharge adopted by the Council; and that*
- (2) *at the request of the European Parliament or the Council, the Executive Director shall report on the measures taken in the light of those observations and comments. The Executive Director shall send a copy thereof to the Commission and the Court of Auditors.*

For the discharge 2021, the Secretariat of the European Parliament Committee on Budgetary Control asked all EU Decentralised Agencies for a follow-up report to the 2020 budgetary discharge to be submitted by 16 September 2022.

This report follows the requirements of the Financial Regulation and the request of the Committee. It provides an overview of the relevant observations and recommendations from the European Parliament Resolution of 4 May 2022<sup>1</sup> on discharge in respect of the implementation of the budget of ECHA for the financial year 2020, together with the measures ECHA has taken in light of these. It is to be noted that no comments accompanied the Council's Recommendation<sup>2</sup> of 16 February 2022 on the discharge of the Agency for the financial year 2020.

On 4 May 2022 the European Parliament adopted also the resolution on discharge in respect of the implementation of the budget of the European Union agencies for the financial year 2020: performance, financial management and control (2021/2157(DEC)). This resolution is a horizontal report containing recommendations and observations that accompanied the individual 2020 discharge reports for each of the Agencies and Joint Undertakings. The follow-up actions to these recommendations, where a collective response was prepared by the EU Agencies Network, will be presented in a separate report being prepared by the Agency holding the Chairing role of the EU Agencies' Network. ECHA has contributed to this report by providing information in relation to its own actions.

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<sup>1</sup> [https://www.europarl.europa.eu/doceo/document/TA-9-2022-0174\\_EN.pdf](https://www.europarl.europa.eu/doceo/document/TA-9-2022-0174_EN.pdf)

<sup>2</sup> <https://data.consilium.europa.eu/doc/document/ST-6003-2022-ADD-1/en/pdf>

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## Annex

	Observation of the Discharge Authority	Response and measures taken by the Agency	Status/ Reference
1.	<p>3. Stresses the need to ensure that the Agency is able to fulfil its mandate in the long term; <b>calls, in this regard, for the lack of predictability of the Agency's budget income to be addressed</b>; while acknowledging the positive developments in the governance and financing structure of the Agency, notes the declining trend in fee income and believes that <b>a new stable financing model should be developed and introduced without delay</b>; highlights the fact that, despite previous observations made by the Parliament and the Court of Auditors, an unforeseen and significant drop of EUR 7,0 million in fee income under Regulation (EC) No 1907/2006 was reported by the Agency in 2020;</p>	<p>The Commission, in its Chemicals Strategy for Sustainability<sup>3</sup>, committed to making a proposal to strengthen the governance of ECHA and increase the sustainability of its financing model. According to the Commission<sup>4</sup>, the proposal is expected to be published in the second quarter of 2023 and will include a review of the REACH fee system with a view to making it predictable, less burdensome and reflecting workload, as well as explore the possibility of allocating one EU contribution to the Agency instead of the current three.</p> <p>ECHA is contributing with technical input to the Commission's preparatory work, as requested, to achieve stable and predictable funding for its operations.</p>	On-going
2.	<p>14. Notes that the Agency cooperates closely with other Union agencies, such as the European Food Safety Authority, the European Centre for Disease Prevention and Control and the European Medicines Agency, by means of memoranda of understanding, to improve the exchange of information, to achieve better mutual understanding and, where appropriate, on joint projects; underlines the importance of such an approach as regards ensuring that the work of each agency is consistent with that of the other agencies and to meet the requirements of sound financial management; welcomes the sharing of services such as the Agency's internal audit capability with the European Union Agency for the Space Programme, and <b>encourages</b></p>	<p>As stated, the Agency cooperates closely with other Union agencies, such as the <b>European Food Safety Authority (EFSA)</b>, the <b>European Centre for Disease Prevention and Control (ECDC)</b> and the <b>European Medicines Agency (EMA)</b>, by means of memoranda of understanding. ECHA will continue this proactive stance to cooperation with other EU Agencies working in the field of environment and human health protection to ensure consistency and sound financial management.</p> <p>Concrete current examples are that ECHA shares its internal audit capability with the <b>EU Agency for the Space Programme (EUSPA)</b>, and its cooperation with <b>EFSA</b>. With EFSA, working arrangements are in place to avoid diverging scientific opinions and, in addition, ECHA provides IT services (ECHA Cloud Services) to EFSA for its work under the Plant Protection Products Regulation. Furthermore, since 2022, ECHA participates in a joint social media initiative on Instagram with ECDC, the European Environment Agency (EEA), EFSA and EMA, focused on 'One Health, One Environment' and aimed at showcasing the work of</p>	On-going

<sup>3</sup> <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strategy.pdf>

<sup>4</sup> [https://environment.ec.europa.eu/events/information-session-one-substance-one-assessment-stakeholders-and-citizens-2022-06-01\\_en](https://environment.ec.europa.eu/events/information-session-one-substance-one-assessment-stakeholders-and-citizens-2022-06-01_en)

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	<b>cooperation among the Union agencies where and whenever possible;</b>	<p>the health and environment agencies.</p> <p>In 2021, ECHA also started a joint project with the <b>European Environment Agency (EEA)</b> to support the Commission with developing a framework of indicators on chemicals to monitor the drivers and impacts of chemical pollution and measure the effectiveness of chemicals legislation (under the EU's 8<sup>th</sup> Environmental Action Programme).</p> <p>In addition, ECHA is an active member of the <b>European Union Agencies Network</b> which facilitates cooperation and cohesion among EU Agencies and, during 2020, ECHA acted as Chair of this Network.</p>	
3.	<p>19. Regrets that the Agency, with regard to senior and middle management positions, reports that 23 (76,6 %) positions are filled by men and 7 (23,3 %) by women, and, with regard to the management board, that 14 positions are filled by men (37,8%) and 23 by women (62,2 %); notes that this gender imbalance has persisted for a long time; notes with regard to staff overall that the Agency reports to employ 266 men (46,7 %) and 306 women (53,3 %); <b>asks the Agency to pro-actively ensure gender balance at management level in the future</b>; reiterates its call on the Commission and the Member States to take the importance of ensuring gender balance into account when appointing their members to the management board of the Agency;</p>	<p>ECHA is committed to attaining gender balance at management level in the future and has proactively taken tangible actions to realise this commitment. As of 30 June 2022, 55% of all staff at ECHA were women and 45% men, while 23% of management positions (including Committee chairs) were filled by women and 77% by men. With respect to senior management positions, 43% will be filled by women and 57% by men when ECHA's new Executive Director takes up her role in Q4 2022. Importantly, for Team Leader (Head of Sector) positions, which constitutes an important talent pool for future management positions at ECHA, 39% are filled by women and 61% by men.</p> <p>In addition, in March 2022, ECHA adopted its Charter on Diversity<sup>5</sup> and Inclusion and, as part of its implementation of this Charter, ECHA's internal working group on diversity and inclusion coordinates the implementation of a related action plan. The actions include steps with respect to recruitment and selections (using gender-neutral wording, increasing the visibility of women managers, raising awareness about ECHA's commitment to diversity and inclusion), raising staff awareness through training and sharing relevant content, collecting, monitoring, and sharing data with respect to staff diversity and striving for gender balanced representation in mentoring and succession planning.</p> <p>ECHA also actively participates in the diversity and inclusion working group of the EU Agencies' Network, which benefits from input from the Commission's specialised services. A recent example of the outputs of this cooperation is a video campaign<sup>6</sup> promoting EU Agencies as workplaces where diversity is valued.</p>	On-going

<sup>5</sup> [https://echa.europa.eu/documents/10162/17100/echa\\_charter\\_on\\_diversity\\_and\\_inclusion\\_en.pdf/3ca93100-fc9d-09fb-2732-9c699a5ddb93?t=1654519919928](https://echa.europa.eu/documents/10162/17100/echa_charter_on_diversity_and_inclusion_en.pdf/3ca93100-fc9d-09fb-2732-9c699a5ddb93?t=1654519919928)

<sup>6</sup> <https://www.youtube.com/watch?v=SpMiOpy-3T8>

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4.	<p>21. <b>Underlines that the specific budget for training should ensure that Agency staff are properly trained regarding the latest NAMs</b>, to create increased internal capacity for tackling chemical pollution and its adverse effects properly, with the latest tools and concepts;</p>	<p>Learning and development make an important contribution to developing ECHA's competency base for current and future tasks. Learning and development needs are collected in line with ECHA's strategy and Work Programmes and are executed through various channels (training courses, e-learning, on-the-job learning, coaching, etc.).</p> <p>ECHA's learning and development priority areas for 2022, and the related budget, specifically include capacity building related to NAMs, in line with ECHA's stated priority to better articulate and focus its work in this important area. In the period 2023-2026, the Agency will continue to prioritise building and maintaining internal capacity on NAMs, including organising trainings for ECHA's scientists and Committees to increase the level of knowledge on NAMs.</p>	<p><b>On-going</b></p>
5.	<p>25. Notes that in 2020 an internal audit was conducted by the Internal Audit Service (IAS) of the Commission on "Integrated regulatory strategy-screening, evaluation and regulatory management option analysis in 2020" and that the audit provided three important recommendations: improve the planning, monitoring and reporting of the integrated regulatory strategy, document procedures and workflows for review and approval, review and improve tools, and document internal processes for managing comments from Member State competent authorities; <b>notes that the Agency is following up on those recommendations and that, furthermore, it is considering how to address one open action from the follow-up audit on performance management conducted in 2020, which is related to defining an approach for reclassification in cases where the third language eligibility criterion has not been fulfilled;</b></p>	<p>In 2021, the IAS performed a follow-up audit of open recommendations from its audit on the integrated regulatory strategy (2020) and concluded that all recommendations have been adequately and effectively implemented and will therefore be closed.</p> <p>With respect to the specified open action from the IAS follow-up audit on performance management (2020), the IAS performed a follow-up audit in 2021. Based on the results of this follow-up audit, the IAS concluded that the recommendation concerning the third language requirement for reclassification has been adequately and effectively implemented and it was, therefore, closed. Therefore, all recommendations from the audit on performance management addressed to ECHA have been closed.</p>	<p><b>Implemented</b></p>

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6.	<p>28. Notes that the Agency made a smooth transition to large-scale teleworking for staff, continuing collaboration with external stakeholders and moving the operation of all of the Agency's bodies online following the outbreak of the pandemic; notes that, according to the Agency's report, the rapid transition to large-scale, long-term teleworking resulted in significant additional efforts for the Agency's security unit, not least because not all the Agency's contractors were prepared for such large-scale teleworking, and related arrangements had to be put in place, with high priority; <b>calls on the Agency to carefully evaluate the arrangements in place, including from a cyber-security perspective, and related risks for business continuity;</b></p>	<p>ECHA's business continuity management policy was evaluated and reviewed in June 2022, with the introduction of updated provisions to safeguard business information, staff, premises and ICT infrastructure and systems. In addition, a cyber-crisis exercise was conducted in 2022, with senior management actively participating. ECHA also reinforced its information security team in 2022 and is presently developing a new cybersecurity policy which will be adopted in November 2022.</p> <p>Furthermore, ECHA's Internal Audit Capability conducted an audit review of ECHA's IT Security Governance Framework in 2022. The review assessed the adequacy and effectiveness of the security policies and available resources (human and financial) in supporting ECHA's security objectives against evolving cyber security threats. This addressed the local area network in the ECHA building, the framework used for mandatory security training and raising staff awareness and assessed the security of tools used by staff, in the context of the long-term, large-scale teleworking. As a follow-up, the Agency has commenced an ECHA-wide information and ICT risk assessment, including ICT business continuity.</p>	Implemented
7.	<p>31. <b>Regrets that the Agency has not yet acted on the recommendations of the discharge authority in its decision on discharge in respect of the implementation of the budget of the Agency for the financial year 2019 with regard to pro-active measures and resourcing for speeding up, improving and quantifying reductions in the number of animal tests and the replacement of such tests by NAMs, as well as the establishment within the Agency of a team exclusively dedicated to animal protection and the promotion of non-animal test methods;</b></p>	<p>The promotion of alternatives to animal testing is among the aims of the REACH Regulation and, therefore, part of ECHA's mandate since its establishment. <b>ECHA's activities to promote alternatives to animal testing</b> are structured around three main pillars:</p> <ol style="list-style-type: none"> <li>1. Effective implementation of ECHA's integrated regulatory strategy to identify and address risks of chemicals of concern. This includes addressing chemicals in groups; supporting registrants to develop testing strategies based on read-across; implementing the mechanisms built in REACH to reduce unnecessary testing and supporting the Commission on the use of alternatives in the EU regulatory context. Examples of the latter include ECHA's involvement in the European Partnership for Alternative Approaches to Animal Testing (EPAA), which is a platform representing the European Commission, relevant EU Agencies and Industry, and aiming to progress towards the replacement, reduction and refinement of animal use for regulatory purpose.</li> </ol>	Implemented

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		<p>2. Investment in international activities promoting alternatives. This includes financing and co-managing the development of the OECD QSAR Toolbox, which is one of the most recognised tools at global level for assessing hazards of chemicals based on similarities in toxicological profile and modelling of the biotransformation pathways (the budget amounted to one million Euro over the past two years); contribution to the development of OECD test guidelines, in line with the requirements of refinement, reduction and replacement and steering flagship research projects aiming at developing alternatives suitable for regulatory needs.</p> <p>3. Making data available to the broad chemicals community, through the dissemination of registered information; as an example, IUCLID datasets are available for download (e.g., REACH studies' results, pharmaceutical industry data contribution). This information is essential to ensure the correct use of alternatives in the regulatory context, but it is also key for developing new alternatives.</p> <p>In 2022, ECHA consolidated the coordination of its activities in this area within a specific unit (including explicitly designating the unit's responsibilities for NAMs) and introduced a dedicated activity in its 2023 Work Programme to better explain, focus and target its work on NAMs in the period 2023-2026. Detailed actions, objectives and outputs will be included in ECHA's next Programming Document (2023-2026), which will be proposed for adoption of its Management Board in December 2022.</p> <p>In addition, for 2023, ECHA is committed to reviewing and consolidating its <b>internal organisation</b> for supporting NAMs by creating a horizontal taskforce within ECHA, responsible for NAMs/promotion of alternatives. This taskforce will possess relevant competences, will be responsible for coordinating internal activities, forming ECHA's views, and acting as liaison with the scientific community and stakeholders.</p>	
8.	32. Notes that the European Medicines Agency has a working group on the application of the 3Rs (Replacement, Reduction and Refinement) in Regulatory Testing of Medicinal Products and its 2025 strategy includes significant work on non-animal testing, and that the European Food Safety Authority includes in the remit of its Science Studies and Project Identification Office, the development of a roadmap to	<p>ECHA is committed to contributing to the scientific debate and regulatory work to replace animal testing while continuing to implement the policy lines and the regulatory frameworks adopted by the legislator.</p> <p>The promotion of NAMs has been identified as a priority area for ECHA in the next programming period (2023-2026) and the Agency has introduced a dedicated activity in its 2023 Work Programme to better explain, focus and target its work on NAMs in the period 2023-2026. This will focus on three main areas:</p>	On-going

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	use non-animal methods to routinely address data gaps by 2027; <b>regrets that the Agency lacks similar initiatives which could help to deliver the goal set out in the resolution of the European Parliament of 16 September 2021 on plans and actions to accelerate the transition to innovation without the use of animals in research, regulatory testing and education;</b>	<ol style="list-style-type: none"> <li>1. Investing further in the areas where the agency has relevant scientific-technical competences. This will include increased cooperation with relevant scientific-regulatory platforms in and outside Europe and strengthening the dialogue between different stakeholders to increase awareness of on-going work and potential synergies to develop a common understanding on what NAMs can achieve in short and longer term.</li> <li>2. Enhancing the cooperation with the European Commission and other institutional partners to support developments of a European roadmap towards full replacement of animal testing.</li> <li>3. Increasing the visibility and stakeholder engagement around this area of ECHA activities.</li> </ol> <p>Detailed actions, objectives and outputs will be included in ECHA's next Programming Document (2023-2026), which will be proposed for adoption of its Management Board in December 2022.</p>	
9.	34. Welcomes the Agency's decision to become climate-neutral in line with the Union's 2030 climate target and the <b>Agency's ambition to extend environmental certification to the Union's eco-management and audit scheme;</b>	<p>The EU Eco-Management and Audit Scheme (EMAS) is a premium management instrument developed by the European Commission for companies and other organisations to evaluate, report, and improve their environmental performance and environmental management system.</p> <p>In 2021, ECHA's updated environmental management system was successfully audited for EMAS registration by the National Competent Authority in Finland (SYKE), resulting in ECHA becoming the first public institution in its host country to be EMAS-registered<sup>7</sup> and, on 30 August 2022, SYKE renewed ECHA's registration.</p>	<b>Implemented</b>
10.	38. <b>Highlights the importance of increasing the digitalisation of the Agency in terms of internal operation and management but also the importance of speeding up the digitalisation of</b>	ECHA is an IT-based agency, viewing IT as a key enabler for its regulatory mandate. The availability of all data in digital format ensures accessibility and automation in the processing. Through this, ECHA is able to process a high number of files respecting legally	<b>On-going</b>

<sup>7</sup> [https://echa.europa.eu/documents/10162/17210/emas\\_certificate\\_fi.pdf/7b3ab483-abd7-b262-053b-74debd8d5a97?t=1652352578128](https://echa.europa.eu/documents/10162/17210/emas_certificate_fi.pdf/7b3ab483-abd7-b262-053b-74debd8d5a97?t=1652352578128)

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	<p><b>procedures; stresses the need for the Agency to continue to be proactive in this regard in order to avoid, at all costs, a digital gap between the agencies; draws attention, however, to the need to take all the necessary security measures to avoid any risk to the online security of the information processed; calls on the Agency to develop its cybersecurity policy more swiftly, so that it can be delivered before 31 January 2023 and to report back to the discharge authority on this matter;</b></p>	<p>binding deadlines, to perform automated checks and to disseminate the data.</p> <p>Investment in IT tools and operations comprise c.50% of ECHA's total IT budget. These tools enable efficiencies, both for companies who have regulatory obligations to submit data, and for authorities who are using those data for regulatory purposes. The IT tooling continued to function and adapt to support ECHA's functioning during the COVID-19 pandemic, including providing the tooling for authorities and committees.</p> <p>Over the past years, ECHA has implemented a comprehensive cybersecurity approach as part of the Integrated Management System and has invested in preventative measures, and in its detection and response capabilities. In 2022, in addition to implementing improvement proposals stemming from an internal audit review of the IT security governance, the Agency conducted a cyber-crisis exercise, implemented improvement actions in line with CERT-EU guidelines, introduced regular IT security and business continuity reporting to its Management Board and reinforced its information security team.</p> <p>ECHA is presently preparing for the implementation of the EU cybersecurity and information security regulations, in close cooperation with the CERT-EU.</p> <p>Finally, ECHA's new cybersecurity policy will be in place by end-November 2022.</p>	