# Sharon McGuinness – Opening statement in the annual exchange of views of the ECHA Executive Director in the ENVI Committee 29 November 2023

Thank you, Chair, Honourable Members,

It's my pleasure to be back in the ENVI Committee.

This is our first annual exchange of views, but I have been pleased to work with many of you on various topics since I took office in December 2022.

A personal highlight for me in these engagements was welcoming your official delegation (Martin, Maria, Cesar) to Helsinki this April.

Today, I will outline the main items in ECHA's focus during the past year, explain our current priorities and challenges and, by doing so, invite your feedback.

## 1. Introduction

The ambitious objectives you set in the beginning of this term for human health and environment protection, expressed in the Green Deal and in the Chemicals Strategy for Sustainability, meant a step change for the network of authorities working on chemicals safety – including ECHA.

The expansion of our mandate is speeding up. ECHA is now truly a 'chemicals' agency, not just the 'REACH' one.

Even today, we closely follow further legislative developments to anticipate what is needed from us and how we can best deliver.

Having said that, being an implementing agency, our focus has been and will remain on delivering our legal mandate.

## 2. Main work items in the past year and outlook

Our annual and specific reports provide you with detailed information on the full range of topics we work on.

Conscious of time, today, I will highlight elements that are, in my view, important in terms of deliverables and, for ECHA's future development.

One of our many contributions to the implementation of EU chemicals policy is **the provision of transparent, independent and high-quality scientific opinions and decisions.**

In this respect, to date in 2023 we provided opinions on risk- and socio-economic assessment for 4 restriction proposals, ca 40 harmonised classification proposals and for ca 60 uses of chemicals which are subject to authorisation.

ECHA's Risk Assessment Committee also provided five opinions on occupational exposure limits, important for workers' safety. Since 2020[1], we have adopted 11 opinions in this area, including on chemicals that the Parliament also worked on, such as lead, asbestos, cadmium

[1] https://echa.europa.eu/rac-opinions-on-scientific-evaluations-of-oels

and cobalt.

In the future, we will keep producing transparent, independent and high-quality scientific outputs and this will include a wider spectrum of uses, such as chemicals in contact with drinking water or in batteries.

Our other important area is delivering our **technical, scientific, and administrative tasks.**

As of 31 Oct 2023, we have some 104,376 registrations covering 22,529 substances above 1t from 17,222 companies. We need to make sure that ECHA, Commission and Member State regulators get the best use out of this unprecedented dataset in Europe. I might point out that our Management Board is finalising our future strategy, which will have a strong focus on data.

As per our commitments made in 2019, we continued to check the compliance of REACH registration dossiers. We reached the 20% legal target, and we are taking stock of the progress together with the Commission and our Management Board in the next year.

Another example of our work is our work on the Prior Informed Consent Regulation (implementing the Rotterdam Convention), which addresses the international trade of hazardous chemicals. We submitted our third report[2] on the operation of this Regulation one month ago, covering the last three years.

Via the report, we provide advice to the policy makers on how to make the operation of PIC more transparent and effective, for example by clarifying the legal text and adapting current practices.

ECHA has put in place a range of actions to further promote the use of alternative methods instead of animal testing and we continue to prioritise work in this area. We also enjoyed a fruitful dialogue with this Parliament on this point, and I thank you for it.

We recognise that with increased calls from citizens, NGOs and industry to move to non-animal methods, there is an onus on us all, – Commission, ECHA, Member State regulators, industry, animal and environmental NGOs – to work together and determine how we can deliver the goal of reducing animal testing for industrial chemicals whilst still protecting health and the environment to the highest extent possible.

In pursuit of this, we organised a workshop[3] this spring to bring stakeholders together and develop a common understanding of what New Approach Methodologies, NAMs, can achieve in the short and long term. Thank you to Tilly Metz for having delivered introductory words.

We also published our fifth report[4] on the use of alternatives to testing on animals for the REACH Regulation. Data shows that there has been a notable increase in the use of in vitro test methods. For example, around 50% of the studies conducted between 1990 and 2022 for skin and eye irritation have been performed in vitro. For new studies conducted in 2019-2022, this percentage rises to approximately 90%.

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2 https://echa.europa.eu/documents/10162/18272234/report_pic_art_22_2023_en.pdf/4175e2cc-be0a-ffc4-8406-598abc3212a8

3 https://echa.europa.eu/-/new-approach-methodologies-workshop-towards-an-animal-free-regulatory-system-for-industrial-chemicals

4 https://echa.europa.eu/documents/10162/23919267/230530_117_3_alternatives_test_animals_2023_en.pdf/9cfc291e-9baf-ffa2-466c-2bc2c6f06b8e?t=1685428213290

We continue to work with the Commission and all partners including at international level to support EU efforts for a roadmap to phase out animal testing.

In all our tasks, we **collaborate and partner with EU Institutions and other bodies and Member State authorities** as well as international partners.

ECHA is an Associated Partner within the European Partnership on the Assessment of Risk from Chemicals (PARC), which includes 200 partners, from 23 Member States and three EU agencies[5]. Within PARC, we recently contributed an overview of future research needs, called 'Key areas of regulatory challenge'[6]. Our objective with this report is to steer scientific research to better regulatory applicability.

We also work closely with peer EU agencies. For instance, recently, we started work on the new Serious cross-border health threats regulation, where we are preparing to provide a risk assessment of the potential severity of the threat of chemical (and environmental) origin to public health.

We all know that complex public health threats are on the rise, reminding us of our deep connection to the health of plants, animals, and ecosystems. This also requires a collective and coordinated response. With ECDC, EFSA, EMA and the EEA, we're taking action[7] to address public health threats as part of the One Health agenda in Europe.

The one substance, one assessment (1S1A) principle under the Chemicals Strategy for Sustainability is another opportunity to work together with our partners. The forthcoming CLP revision will provide a stronger legal basis for putting 1S1A into action by putting hazard identification criteria for new hazards such as endocrine disruptors into the legislation. Ultimately this will help us address inconsistencies in hazard identification between different types of "chemicals" because of their particular use – industrial chemical, biocide, pesticide. We are now working together with colleagues in EFSA to determine how best to arrive at guidance that meets the needs of our respective and different legal frameworks.

A fourth work area is providing **tools, advice, and support to industry.**

Through our helpdesk, IT tools and website, we support companies to access and remain on the EU single market. Every year, we respond to ca 9 000-10 000 helpdesk questions, and we coordinate the work of helpdesks in the Member States. In the future, we will establish more regular engagement with SMEs to better understand and meet their specific needs.

With our IT tools, we have focused on improving user experience, streamlining the portfolio of tools, moving to the public cloud and investing in security.

Last, but not least, we work to ensure that relevant, reliable, and objective **information** is available for the public and interested parties.

We have started restructuring our data availability system (in 2022 our current public chemicals database received over 30 million views[8]). As our mandate expands, we need to cater for new data sources and types, and for this reason, we are revamping our database structure. The first version of the new system will go live early next year.

[5] https://www.eu-parc.eu/parc-figures
[6] https://echa.europa.eu/-/echa-identifies-research-needs-for-regulating-hazardous-chemicals
[7] https://www.linkedin.com/posts/european-chemicals-agency_onehealth-activity-7129767867369066497-zj-D?utm_source=share&utm_medium=member_desktop
[8] https://echa.europa.eu/-/new-echa-public-data-availability-system-part-1

All the above requires a robust governance and organisation for the ECHA secretariat and all our bodies.

In the past year, we have continued to adjust to partly remote work, as well as invested in mapping staffing competence needs. As an EU agency with a widening and diversifying legal mandate and a growing workload in current tasks, we are working on a new people strategy to ensure that we can attract and retain the necessary talent. Our people are our biggest asset, and it is my priority to set them up for success individually and collectively.

However, ECHA is much more than the 600+ staff members in Helsinki. Our outputs depend, to a very large degree, on contributions from many different parties and in particular from the Member States. This includes our committee and Enforcement Forum members and alternates. It also includes the authorities in the Member States that we work with (ca 84).

There is a lot of commitment on all sides even in the face of increasing workload.

Presently, committees are under strain in the on-going REACH authorisation application peak for chromium. This peak relates to so-called "upstream" applications, an area subject to Court cases and Parliamentary resolutions. We are applying mitigating measures, but committee members' commitment is essential to process the cases.

Our current committees, RAC and SEAC, are already under pressure with the workload under our current mandate. With the new tasks, the pressure will further grow.

## 3. Looking ahead

Looking ahead, policy initiatives and legislative changes will continue shaping ECHA's horizon. Much of this is of course outside our control – but we are ready for them and to assist you, the policy maker, with our scientific and technical input.

To conclude my opening, a few reflections on what is needed in the future for an improved performance of chemicals legislation.

Grouping substances for regulatory action is essential and we are already doing it. Legislative proposals will need to be able to allow for individual and groups of substances to be addressed.

A positive example of grouping for regulatory action is the recently published[9] microplastics restriction, where ECHA prepared the dossier and provided the scientific and technical opinions that informed the decision makers who agreed the restriction.

With the ever increasing need to address the challenges of climate, biodiversity loss and chemical pollution, we really have no longer the time to deal with individual substances one by one. By grouping, we also prevent the prospect of regrettable substitution.

Another aspect that is relevant and necessary for the future is coordinating and simplifying actions across EU chemicals legislation more. We therefore welcome the plan to rationalise the use of expertise and resources by proposing the reattribution of technical and scientific work on chemicals performed under the relevant pieces of legislation to European agencies.

Maintaining proper governance, and keeping high standards in terms of independence, conflicts of interest and transparency are important now for the Agency and will continue to be important in the future too.
However, to continue to deliver these high standards, we need the announced ECHA Basic

[9] https://ec.europa.eu/commission/presscorner/detail/en/ip_23_4581

regulation, which will set out the finances, governance, and functions of the Agency. This regulation is crucial to cover not only current tasks but also future ones as well.

## 4. Closing the opening statement

Dear Chair, members, this concludes my opening statement.
I look forward to your questions and discussing further on that basis.
Thank you.