

## **Sharon McGuinness – speech at the Chemicals Strategy Conference, Dublin, 18 October 2023**

Good morning, everyone. My thanks to my former colleagues in the Health and Safety Authority and the Environmental Protection Agency for the invite to speak to you today.

My thanks also to my European Commission colleague Cristina De Avila for providing the latest information on their plans for the implementation of the Chemicals Strategy for Sustainability (CSS). As you can see, the legislative framework for making the CSS a reality is well underway and ECHA, like other stakeholders is getting ready to meet both the new and changed requirements.

Before I discuss further the future landscape for ECHA, I might take a moment to introduce the Agency and the work we do.

- ECHA is **one of the currently 35** EU decentralised agencies, all found across the EU.
- We are based in Helsinki and have been in existence since 2007.
- We have 600 staff, so are the 6<sup>th</sup> biggest EU agency, based on the staff number.
- ECHA also has a double **legal basis**: health and environment protection + internal market and competitiveness of the chemicals industry.
- Currently we implement 10 different EU regulations and directives + 6 specific agreements with COM, other agencies (EFSA) or the scientific community (PARC).

### **We implement our mandates by**

- Carrying out technical, scientific, and administrative tasks related to the implementation of the EU's chemicals legislation and policy
- Providing consistent, independent and high-quality scientific opinions and decisions, which shall serve as the basis for the drafting and adoption of Union measures
- Collaborating and partnering with EU Institutions and other bodies and Member State authorities
- Providing tools, advice, and support to industry, with a particular focus on SMEs, in fulfilling their duties under chemical legislation
- Ensuring that the public and interested parties receive relevant, reliable, and objective information

**So that is who we are and now I would like to discuss what our future will be as a result of the CSS. These changes are occurring in our existing legal mandate areas as well as bringing new legislation and new legal tasks.**

In relation to existing legislation, the CLP Regulation has already been revised and is making its way through the decision-making process. Following the plenary debate in the European Parliament recently, the EP has adopted its position on the CLP regulation revision proposal and as a result trilogue discussions can now start.

The proposal to amend the CLP regulation to take account of new hazards such as endocrine disruption, persistence and mobility will ensure these hazards are centrally and clearly identified. This will then allow for further action under more specific and relevant legislation.

That change will bring greater clarity to hazard identification across all legislation and will allow regulators and stakeholders to take appropriate action. It also realises the CSS ambition for

**one substance one assessment** – in other words, to address inconsistencies in hazard identification between different types of “chemicals” because of their particular use – industrial chemical, biocide, pesticide.

As the hazard classes themselves have already been introduced into the CLP Annexes, ECHA is now working to implement these new changes through the development of guidance as well as establishing processes and systems to enable us to prepare CLH dossiers when requested by the COM in the future.

We are also working with our Risk Assessment Committee experts so they too will be ready to address these new classifications, and, in this regard, we will be using existing competence and knowledge available in ECHA.

With respect to the REACH Regulation, we are working closely with COM colleagues providing input and advice on their policy considerations. The REACH Regulation revision is very important for ECHA not only because it will build on the experience to date in implementing the requirements and provide further clarity and predictability to stakeholders and duty holders, but it is also important as the COM is also developing proposals for an ECHA founding regulation, which I will come back to later.

As the COM is still in discussions on possible policy options for the REACH revision, and which Cristina just shared, I only want to mention a few points in relation to the revision.

After 16 years plus implementing REACH, we do see the need for change. For example, on registration, we have been calling for revocation of registration numbers in the past and if introduced, it will ensure a level playing field as well as supporting the goal of zero tolerance to non-compliance (no data, no market).

We would also like to ensure that industry provides ongoing and regular updates to information in registration dossiers. Simply submitting a dossier and not considering further updates is no longer a viable option.

Levelling the playing field for all operators across the EU is a consistent theme. Together with our Member State (MS) colleagues in the Forum on Enforcement, we have been providing inputs to the COM on aspects such as engagement with Customs Control. In this regard, the format of and the experience built up by the Forum, is invaluable and can be used to good effect to support the CSS drive for zero tolerance for non-compliance.

We will continue to work closely with COM colleagues as they finalise their proposal and we look forward to supporting the COM, EP and Council when decision making commences.

As a result of the CSS, the Agency has and is widening further its mandate from starting as a REACH specific Agency to a more general Chemicals Agency.

In many ways, this transition has been underway since our establishment, as we already have assumed a much wider portfolio than just REACH and with the CSS we will continue this transition.

For example, we have added the **Drinking Water Directive** as well as the **Serious Cross Border Threats to Health Regulation** to our widening legal mandate.

In relation to the **Drinking Water Directive**, the Agency is primarily tasked with delivering Article 11 of the DWD, which sets out the framework for minimum hygiene requirements for materials in contact with drinking water.

ECHA will support the European Commission in this work by preparing:

- European positive lists of starting substances, compositions and constituents that are authorised for use in the manufacture of materials in contact with drinking water.
- Risk assessment methodologies and information requirements for reviewing starting substances, compositions and constituents that could be added to the positive lists.
- Administrative procedures for updating the positive lists.

After the positive lists are published, ECHA will continue keeping the lists up to date, by adding new entries and amending or removing existing entries. With the DWD, ECHA is moving to very specific uses of chemicals, which will be a change for us.

The other legislation I mentioned is the **Serious Cross Border Threats to Health Regulation**, the Agency will, together with other EU Agencies such as ECDC, EFSA, EEA and EMA, be involved in carrying out a risk assessment for different categories of serious cross-border threats to health: such as threats of chemical origin; or threats of environmental origin, including those due to the climate

And the most recent legislation for which we have been given a mandate is the Batteries Regulation, which entered into force on 17 August 2023.

When it comes to **Batteries**, the Agency will assist in the development of a Commission report into substances of concern found in batteries or used in their manufacturing, that have negative impacts on human health, the environment or recycling for safe and high-quality raw materials. The report, expected by 31 December 2027, will identify the substances and consider follow-up measures, such as possible Union-wide restrictions. It is expected that ECHA will begin its work toward this report in 2024.

Additionally, the Commission may request ECHA to prepare restriction proposals on harmful substances in batteries and waste batteries.

The Agency will also provide an opinion, through its committees for Risk Assessment and Socio-Economic Analysis, on the restriction proposal's effectiveness in managing the risk and its impact on society.

Possible future legislative changes for the Agency are either on their way through the decision-making process or are under consideration by the Commission.

For example, the Industrial Emissions Directive and the Groundwater, Water Framework and Environmental Quality Standard (EQS) directives are all going through decision making and each will bring new tasks to the Agency.

The COM have also recently published proposals on the Toys Directive as well as the End of Life Vehicles Directive.

As you can see, that is a particularly long list of legislation where ECHA does and could have a future role. There are also other proposals being considered by the COM, which I will come back to later. Each of these will assign new tasks and widen further ECHA's legal mandate. However, we are not daunted by this. After 16 years in operation, we have built up significant competence and experience not just on the protection of EU citizens and the environment from hazardous chemicals but on managing and disseminating vast quantities of data, working with stakeholders as well as adding to overall scientific and technical understanding.

I would like to perhaps in the last few minutes discuss some particular areas of focus under the CSS where ECHA is or will be addressing in our current legislation or indeed in future legislation.

### **The first of these aspects is - GROUPING**

We acknowledge and recognise that one of the steps that can be taken to increase efficiency in opinion and decision making is to address groups of chemicals rather than each individual chemical. The Agency is already using grouping to help us map the chemical universe and screen for possible regulatory action for groups of chemicals, the so-called assessment of regulatory needs or ARNs.

We, together with Member States, are also now working with grouping in determining if restrictions or harmonised classification and labelling are required.

On restrictions, you will all no doubt be aware of the current PFAS dossier prepared by Denmark, the Netherlands, Germany, Sweden, and Norway. This universal PFAS proposal is a good example of grouping substances together for regulatory action. It is also a good example of MS and ECHA working together already on the CSS goal to target actions on PFAS substances.

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.

Grouping substances for regulatory action is essential and legislative proposals will need to be able to allow for individual and groups of substances to be addressed. We have for example already seen this in the recent CLP regulation revision proposal from the EP.

### **Secondly, USING Alternatives to Animal Testing (NAMs)**

In terms of data generation, the COM has already outlined several elements under consideration including reducing the need for animal testing, if possible, by including novel alternative methods (NAMs) or animal free methods. On the latter topic, ECHA has put in place a range of actions to further promote the use of alternative methods in existing legislation and we will continue to prioritise work in this area.

Data on animals has been the cornerstone of our legislation for hazard and risk assessment of chemicals. If we want to speed up hazard assessment of industrial chemicals, the goal of reducing animal testing for industrial chemicals may seem difficult to achieve. However, with increased calls from citizens, NGOs and industry, there is an onus on us all – COM, ECHA, MS 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.

### **THIRDLY, SIMPLIFICATION**

Another CSS goal I'd like to discuss is the plan to coordinate and simplify actions across EU Chemical Legislation.

In this regard, the COM is considering an Omnibus Regulation to reattribute work under the POPs Regulation, and the Medical Devices Regulation as well as revise the RoHS Directive. In addition, ECHA may be given a role in the future in relation to the Cosmetics Regulation.

We 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. We anticipate an increase in our overall mandate because of this reattribution work. Ideally, reattribution should take place where there are real synergies and benefits to be gained by centralising regulatory actions, whilst properly resourcing these new tasks.

In this regard, we believe that ECHA's experience can be used to good effect as we take on reattributed tasks close to the competences and processes within our current mandate. As we make plans to implement these new tasks, we are looking at these as standalone and specific pieces of legislation, with their own specific requirements as well as stakeholders.

Implementation may be done by aligning to current REACH processes already in place. However, this will not be done as a matter of course and ultimately implementation will follow the most efficient and effective way considering regulatory requirements and stakeholder needs and expectations.

#### **FOURTH, DATA**

In the REACH revision, the COM is as we have just seen considering the data information requirements with a view to bringing clarity as well as ensuring that regulators and ECHA have the necessary information to use and deliver our opinions and decisions.

The COM is also considering a legislative proposal to establish an EU Common Data Platform on chemicals to facilitate the sharing, access, and re-use of information on chemicals coming from all sources. ECHA expects to play a lead role due in part to our experience to-date on managing, using, and disseminating data.

As we all know, data is an incredibly important and valuable tool in our world today. However, for a regulator, it is important that the data we have access to is "relevant and useable" in a regulatory context. There is a lot of information out there on chemicals and their uses, which may be good to capture as a general goal. However, we need to ensure as a regulator, that in all the data captured, we have what we need to deliver independent and science-based opinions that inform our decision makers in COM, European Parliament and Council.

We also need to ensure that we have the most up to date and relevant data and this is where industry needs to play its part to ensure dossiers are complete and updated on a regular basis.

#### **FIFTH, 1 substance, 1 assessment**

On One Substance, One Assessment (OSOA), ECHA along with other EU Agencies is working with the COM to establish how this can be done in practice. Being aware of other regulator's actions and having access to the same data are two basic pillars to further build progress towards One substance, one assessment. Measures such as the use of the PACT, the EU data platform and the reattribution of tasks will all help in making OSOA a reality.

However, as a regulator, we are bound by the legal mandate we have. We are also bound by the scientific and technical experts we work with to develop opinions. Therefore, in the absence of full alignment between regulations, each regulator will still need to meet requirements for their own legal mandates.

However, as mentioned earlier, the revised CLP proposal will ensure that the CLP Regulation is the central piece for hazard classification. Centralising hazard identification under one regulation is a key step in delivering on the one substance, one assessment goal.

The hazard of a chemical is an intrinsic property and shouldn't be looked at differently just because that chemical is used in an industrial process, in a pesticide or medical device.

## **SIXTH – MAINTAINING STRONG GOVERNANCE AND BEING FIT FOR ACTION**

With all these changes in legislation, ECHA will need to have the appropriate governance, structures and finances in place. The COM plans to propose, alongside the REACH revision, a Basic or Founding 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.

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.

Another important aspect for ECHA is to assure the capacity, competence and capability of our scientific and technical committees. ECHA does not implement or deliver its mandates alone. We rely on the Commission; our Member State colleagues and experts and the industry duty holders to ensure that we can meet our legal obligations. Our committees, the MSC, RAC, SEAC and BPC as well as the many expert working groups are all vital to implementing REACH, CLP and Biocides legislation and have over the years contributed fully to delivering robust opinions and decisions.

Ensuring these committees can continue in a sustainable manner is important not just to ECHA but to all stakeholders too. The Basis Regulation will consider how to ensure our committees can continue to work and deliver consistent, independent and high quality opinions and decisions.

**In conclusion**, while legislation will inform the Agency about what it needs to do, we also know that to implement our legal mandate, we need to work with stakeholders to determine priorities and focus and make corresponding choices. This year, with the ECHA Management Board, we will be developing the next five-year strategy for the Agency. The focus will be on ensuring that we deliver on our current and future legal mandate and meet the goals of the CSS and the EU Green Deal. Implementing the CSS will require concerted and coordinated action by regulators and stakeholders alike. ECHA is looking forward to working with all stakeholders as we realise the CSS ambitions and through this work take real measures to address the three big crisis of climate, biodiversity loss and chemical pollution.

Thank you.

Another good example of grouping is the recently published Microplastics restriction, where ECHA provided the scientific and technical opinions that informed the decision makers who agreed the restriction.