Sharon McGuinness – speech at the Health Summit Conference, Uppsala, 24-25 October 2023

Good morning, everyone. My thanks for the invite to speak at this Chemical Pollution and One Health Conference. I've already learned a lot listening to the previous speakers and I look forward to learning and discussing more over the next two days.

Before I discuss the topic of chemical pollution and one health, I might take a moment to introduce ECHA and the work we do.

- ECHA is **one of the currently 35** EU decentralised agencies, all found across the EU. We are a regulatory agency, with our mandate set by the European Parliament and Member States and we receive funding from the EU budget and from industry fees.
- We are based in Helsinki and have been in existence since 2007.
- We have 600 staff, so are the 6th 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 are part of implementing 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

Of the 10 or more pieces of legislation ECHA has responsibility for, two of the more well-known ones are the Registration, Evaluation and Authorisation of Chemicals or REACH Regulation and the Classification, Packaging and Labelling or CLP Regulation.

The REACH regulation has a number of aims – to ensure a high level of protection of health and the environment, provide for the free circulation of substances on the internal or single market while enhancing competitiveness and innovation. It also promotes alternative methods for the assessment of hazards to substances. The regulation covers the manufacture, import and use of chemicals and has a number of different elements including:

- Registration of substances above 1 tonne per annum. The registration requires industry, who are deemed the duty holder, to provide an increasing level of information to the Agency, on their substance as the tonnage level increases. Registration gives market access to companies for these substances. As a general rule, testing on animals (to provide information on substances) cannot be done without providing a testing proposal, which is evaluated by ECHA. As of 30 Sept 2023, we have some 104,078 registrations covering 22,502 substances from 17,168 companies.

- Evaluation – this is where the registration dossier is checked for compliance or where a testing proposal submitted by a registrant is assessed. This is called Dossier Evaluation. There is also Substance Evaluation, where a Member State may decide to assess a substance where they have grounds for considering that a given substance constitutes a risk to health or the environment. ECHA supports and coordinates MS work in substance evaluation and runs the respective committee composed of MS experts.

These two steps are the very start of the chain to assess a chemical and determine what, if any, further risk assessment or management might be needed. The two main pathways for Risk Management in REACH are Authorisation and Restriction.
Authorisation is where substances of very high concern (CMRs, EDCs, PBT, vPvB and those with equivalent levels of concern) may not be used unless they are authorised for a particular use by a particular company for a particular period of time with a view to their eventual substitution. There are presently 235 substances included in the candidate list, which result in specific obligations on companies in terms of reporting and once added to list of substances subject to Authorisation, then applications for particular use.

Restriction is the process whereby a substance, or indeed a group of substances, for which it is deemed there is an unacceptable risk across the EU, are either banned or restricted for manufacture, use or placing on the market.

The other risk management legislation is the CLP regulation, which identifies the hazards of a substance. Depending on the nature of the hazard identified, a chemical may be banned for consumer use (for example, CMRs as substances or mixtures), require particular management in the workplace or may not be allowed to be used in downstream uses (toys, etc).

In December 2019, the European Commission published its EU Green Deal, which is an ambitious plan for Europe to tackle many different challenges. A key pillar is zero pollution, and, under this umbrella, the COM has published in 2020, the Chemicals Strategy for Sustainability, which sets out a number of actions under different areas –

- Innovating for Safe and Sustainable Chemicals
- Strengthening Legislation
- Simplification and Coherence
- Knowledge and Science
- Global

Some of the key actions include:

- Introducing a ban on the most harmful chemicals in consumer products – allowing those chemicals only where their use is essential.
- Paying attention to the cocktail effect of chemicals when assessing chemical risks.

- Phasing out per- and polyfluoroalkyl substances (**PFAS**) in the EU, unless their use is essential.
- Boosting investment and innovative capacity for the production and use of chemicals that are safe and sustainable by design throughout their lifecycle.
- Establishing a simpler "one substance, one assessment" process for assessing the risks and hazards of chemicals.
- Playing a leading role globally by championing and promoting high chemical safety standards and not exporting chemicals banned in the EU.

I would like now to discuss some particular areas of focus, arising from the CSS and our own experience, which ECHA is or will be addressing. Each of these will have a relevance for how we tackle the topic of chemical pollution and health in the future.

In relation to existing legislation, the COM has already prepared a number of proposals including the revision of the CLP Regulation, which is making its way through the EU decision-making process.

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.

Bringing these endpoints will also 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.

The COM, with ECHA support, is also working to bring these hazards into the Globally Harmonised System (GHS) with the aim that in the future all EDs/PBT, PMT etc., hazards will be identified in the same way globally. Something that is especially important given the far-reaching consequences of many of these chemicals.

With respect to the REACH Regulation, we are working closely with COM colleagues providing input and advice on their policy considerations for a future revision of this regulation. This work is still going on.

However, the Commission is already taking specific actions related to the current REACH regulation, and in this regard, it has **developed a restrictions roadmap** to ensure progress on restricting the most harmful groups of substances is progressed. The **restrictions roadmap provides a balance** between the need for flexibility on when and how to act while securing progress on restricting the most harmful groups of substances set out in the strategy.

Another aim of the roadmap is to provide transparency to stakeholders on planned restriction work. This is so interested parties are ready to anticipate (potential) future restrictions and focus on plans to substitute.

The roadmap published in April 2022, **has a rolling list of substances** scheduled for restriction.

It also has a **rolling list of REACH Article 69(2) assessments** by ECHA. These assessments are for substances listed in Annex 14 (substances subject to authorization) to see if the risks from these substances when they are contained in articles are controlled – the results of these assessments are published on ECHA website.

Because they are Rolling lists they are subject to ongoing regular review.

This year one of the most significant restrictions agreed is the microplastics restriction. The aim of this restriction is to prevent pollution from intentionally added microplastics.

The restriction concerns synthetic polymer microparticles (SPM) below five millimetres that are organic, insoluble and resist to degradation. The restriction applies from 17 October 2023, but there are some time-limited derogations.
The expectation is that it will prevent the release of half a million (500,000) tonnes of microplastics over 20 years. ECHA prepared the restriction upon COM's request, and its two committees, RAC and SEAC, were responsible for preparing the opinion, which ultimately led to this particular decision of the Commission.

There are a number of elements under the CSS and also which ECHA's experience has identified, that could provide future opportunities for addressing chemical pollution and protecting the health of each us as well as the planet.

The first of these 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 legislation that supports the management of individual and groups of substances is important.

Grouping is also important as it can prevent regrettable substitution. For example, we have seen that when Bisphenol A was identified as an SVHC, we unfortunately saw industry move to the next Bisphenol (BP S etc). Therefore, in order to prevent this type of action, tackling groups of substances in a single regulatory action is needed. Industry also needs to realise that even if it is only one substance in a family that is regulated, substituting to another substance in the group may be meeting the letter of the law, but it is certainly not meeting the spirit of it.

Secondly, USING Alternatives to Animal Testing (NAMs)

As I mentioned already, one of the aims of REACH is the promotion of alternatives for the assessment of hazards to chemical substances. In this regard, 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. This includes quantitative structural activity relationships, grouping, in vitro methods etc.

Under the CSS, reducing the need for animal testing is highlighted, with a view to improving the quality, efficiency and speed of chemical hazard and risk assessments. However, as you know, data on animals has been the cornerstone of our legislation for hazard and risk assessment of chemicals. At present, the goal of reducing animal testing for industrial chemicals may seem difficult to achieve given our need to speed up hazard assessment of industrial chemicals. 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.

THIRD, 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 data out there on chemicals and their uses, which is good to capture. We in ECHA have one of the largest databases on chemicals globally.

However, for a regulator, we need to ensure that in all the data captured, we have the knowledge we need to deliver independent and science-based opinions that inform our decision makers.

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

There is also a huge amount of data in lots of different places and for lots of different reasons – regulatory, environmental monitoring, occupational hygiene, academic, industrial, epidemiological, to name but a few. However, turning this data into knowledge in a consistent and faster way is a challenge. For example, while academic studies may report a particular finding, this finding while important, may not allow for regulatory action.

The divergence between academic studies and regulatory needs is a challenge that ECHA, through its work with PARC (the Partnership for the Risk Assessment of Chemicals) is working to address. We recently published a report – Key Areas of Regulatory Challenge – which highlights the regulatory areas where it is difficult to address using current tests or understanding. We aim to report such challenges on a regular basis so that academic and other researchers can see which areas of research or study might be needed.

FOURTH, 1 substance, 1 assessment

I mentioned earlier the Chemicals Strategy for Sustainability and its push for 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.

Regulators, however, are bound by the legal mandate they have been given. We are also bound by the scientific and technical experts we work with to develop opinions and make decisions. Equally, there are legal limits to the data that may be shared between regulators (agencies) under different pieces of regulations. Therefore, even if regulators work closely together, in the absence of full alignment between regulations, each regulator will still need to meet requirements for their own legal mandates and this therefore may mean a similar substance is treated differently under different legislation.

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.

From my own experience, each piece of legislation or regulation is important. However, each needs to be seen in the context of how they are implemented not only by regulators but

industry and others too. A challenge in addressing chemical pollution and one health is how to ensure that all regulations that deal with chemicals work in tandem to achieve the ultimate aim of protecting health and the environment.

FIFTH – GOVERNANCE AND COMPETENCE

Maintaining proper governance, and keeping high standards in terms of independence, conflicts of interest and transparency are important not only for the Agency but for the public trust and stakeholders alike.

We believe that collaboration with the relevant stakeholders, including industry, civil society organisations and academia, is necessary to achieve overall aims. However, collaboration, does not and should not stop us taking the necessary regulatory action to address chemicals of concern.

Another important aspect for us all is to ensure we have the necessary competence amongst all our scientific and technical experts. ECHA does not implement or deliver its mandates alone. We rely on our Member State colleagues and experts and the industry duty holders to ensure that we can meet our legal obligations.

With the ever-increasing types of expertise needed to address issues, ensuring that we collectively maintain and increase skills and competence is something that also needs to be kept in mind.

It might seem as if tackling the challenge of chemical pollution and protecting the health of all of us, particularly those who are most vulnerable as well as the wider environment, is too big a problem. However, I believe that by collaborating together we can develop and use science to generate the knowledge we need to address the challenge of chemical pollution.

I'd like to thank you for your time, and I look forward to collaborating, discussing and listening to the collective scientific knowledge over the next few days.

Thank you.