Sharon McGuinness – speech at the Chemical Watch conference Brussels, 19 April 2023

ECHA Update -preparing for implementation of new legislative requirements

- **What might change?**
- **Opportunities and challenges ahead**
- **How to use our experience to best effect**

Good morning, everyone. My thanks to Chemical Watch for the invite to speak here today in what is my first conference as the Executive Director of ECHA.

My thanks also to my European Commission colleague Cristina De Avila for providing the comprehensive update on their plans for 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 that will come our way in the near future. The CSS is both ambitious and wide ranging and while there are many elements to the strategy, not all aspects are ones that will impact on ECHA and the work we do.

So what will change for us?

One of the fundamental changes that the CSS will bring to the Agency is that we will move from being a REACH specific Agency to a Chemicals Agency. In many ways, this transition is already underway as since our establishment, we have assumed a much wider portfolio than just REACH. Our current mandate includes legislation and tasks such as:

- REACH
- CLP
- PIC
- Biocides
- Waste Framework Directive (SCIP Database)
- 8th Environmental Action Programme
- Persistent Organic Pollutants/UN Stockholm Convention
- Exposure limits for workers (OEL)
- EU Chemicals Legislation Finder
- EU Nanomaterials Observatory
- Support to accession countries (IPA)

Because of COVID and the CSS, we have also taken on

- Drinking Water Directive
- Cross border threats to health

At this moment, we know that there is pending legislation that will assign new tasks to ECHA
- Battery Regulation
- Industrial Emissions Directive
- Groundwater, Water Framework and Environmental Quality Standard (EQS) directives.

We are closely following discussions regarding an Omnibus Regulation to reattribute work under the ROHS directive, the POPs Regulation, and the Medical Devices Regulation. In addition, we are awaiting proposals on a Data Regulation, which we anticipate will provide for ECHA to implement and run an EU Common Data Platform on Chemicals (EU-CDPC).

Other legislative areas where ECHA may be given a role include the Toys Directive, Cosmetics Regulation, and the End-of-Life Vehicles (ELV) directive.

As you can see, that is a particularly long list of legislation where ECHA does and could have a future role. However, we are not daunted by this.
ECHA is 16 years old and in that time, 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.

All this competence and experience is ready and available to meet and deliver on the ambition of the CSS.

While our mandate has expanded since our establishment, and as we have seen will continue to expand, REACH (and CLP) remain(s) central to our day-to-day work and overall functions. Our challenge will be to adapt to current and future REACH and CLP requirements whilst at the same time onboard new and different legislative functions.

I would like to now discuss a few of the different goals and actions under the CSS where ECHA has or may have a particular role.

As a regulator, our first and foremost function is to ensure EU citizens and the environment they live and work in, is protected from the harmful effects of chemicals. Together with the Commission, legislators, and others, we also play a role in promotion of alternative methods for assessment of hazards of substances and more generally on the free movement of chemicals and competitiveness and innovation.

Therefore, we are fully supportive of the COM plan to strengthen the legal framework to rapidly respond to scientific findings, making it more coherent, simple, and predictable for all actors.
We welcome the COM plan to reinforce the REACH and CLP Regulations as EU's cornerstones for regulating chemicals, alongside plans to adopt coherent approaches to assess and manage chemicals in existing sectorial legislation.

The recently published 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 the 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.

ECHA is already 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.

16 years of REACH implementation has also given all of us a real understanding of what is

needed to realise the goals of the CSS. The world around us, citizen's expectations, and our knowledge of what needs to be done to protect health and the environment has also changed and evolved since REACH was first implemented in 2007.

We have more data to hand on chemicals since then. We also know what works and what does not work in helping us achieve our goal of protecting health and the environment.

As an Agency, we need to have the relevant information at the right time in order to provide robust, independent, and scientific opinions in an efficient and effective manner so that our decision makers can then take the right decisions.

And as we look forward to the future proposals to implement the CSS, two questions are relevant to ask. One, do we need to gather more information to be able to take actions and if so, how much more do we need? Two, how do we make good use of the data we do have to arrive at faster decision making to protect health and the environment.

Based on the COM's presentation just now and the overall goals of the CSS, both approaches are being considered and our ultimate hope is that these will work in tandem in a smooth and consistent manner.

For example, on registration, we have been calling for revocation 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.

ECHA has also been supporting the COM in its work on the different measures it may take to improve enforcement. 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 build 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 acknowledge and recognise that one of the steps that can be taken to increase efficiency in opinion making is to address groups of chemicals under REACH rather than each individual chemical. The Agency is already using grouping to help us map the chemical universe and identify possible regulatory action for groups of chemicals, the so-called assessment of regulatory needs.

We, together with Member States, are also working with grouping in determining if restrictions are required – the current PFAS dossier prepared by Denmark, the Netherlands, Germany, Sweden, and Norway. being a good example of this. It is also a good example of MS and ECHA working together already on the CSS goal to target actions on PFAS substances.

I might at this point take a moment to address some specific elements around grouping in the context of our integrated regulatory strategy and assessment of regulatory needs.

When faced with the challenge to screen the thousands of chemicals registered under REACH to identify chemicals of potential concern, grouping and our integrated regulatory strategy were our way to trigger the often-heavy regulatory processes where the impact of such processes is expected to be high.

Putting chemicals together in groups is also meant to avoid unnecessary duplication of efforts by all stakeholders. The ARNs were published to transparently share our first 'take' on these thousands of chemicals including our proposed next steps. They are meant to warn industry on what chemicals are under authorities' radar so that they can be prioritised when assessing their portfolios and for example deciding where to focus further data generation.

These early prioritisation stages do not require the same basis as the next steps in the regulatory processes, where both groups, concerns and regulatory decisions are clarified via well-established processes and where input from all stakeholders is foreseen.

We have however taken note of concerns, and we will be clarifying the role of ARNs in an upcoming webinar.

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 new alternative methods (NAMs) or animal free methods. This is a complex topic that needs actions from all stakeholders, and ECHA is ready to play its role. On the latter topic, I would like to note that ECHA recently has put in place a range of actions to further promote the use of alternative methods in existing legislation. Actions centre around several areas, such as:

1. Use of alternative methods in ECHA's processes
2. Translation of NAMs into regulatory applications
3. Input to harmonisation and reporting
4. Computational methods and data availability
5. Organisation of trainings and promotion of proper use in the regulatory context
6. Interactions with sister agencies and key stakeholders

On 31st May, we are looking forward to hosting a NAM workshop – towards an animal free regulatory system for industrial chemicals where regulators, industry, animal welfare, and environmental NGOs as well as scientists will come together to discuss the future of NAMs and how we can all contribute to the goal of reducing animal testing for industrial chemical Another CSS goal I'd like to discuss is the plan to cordinate and simplify actions across EU Chemical Legislation.

We welcome the COM's proposal to use a single 'Public Activities Coordination Tool' to provide an up-to-date overview of all planned and ongoing initiatives on chemicals by authorities across legislation. This will build upon the PACT tool that ECHA developed and provides to stakeholders so they know in advance what regulatory action might be planned for a particular chemical.

We also 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. As already mentioned, 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.

We are working closely with the COM and other EU Agencies on the development of a common open data platform on chemicals to facilitate the sharing, access, and re-use of information on chemicals coming from all sources. Again, our experience to-date on managing, using, and disseminating data can be used to good effect to achieve this goal. To realise this goal, clear rules on the sharing of data and reuse by regulatory authorities and others will be needed.

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.

On the One Substance, One Assessment (OSOA) approach, 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 alignment between regulations, each regulator will still need to meet requirements for their own legal mandates.

However, I am pleased to see the COM is already taking steps through the revised CLP proposal to ensure that the CLP Regulation is the central piece for hazard classification. As someone who started my regulatory life working on classification of chemical substances, 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.

Coming back to ECHA, a fundamental change for us will be the introduction of 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. Putting the Agency on a clear and stable financial footing in the future will be important in allowing us to implement our full legal mandate.

Maintaining proper governance, and keeping high standards in terms of independence, conflicts of interest and transparency will also be important to keep in place.

Another important element for the Basic Regulation will be how ECHA committees operate and function. 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 stakeholders too.

Consultation, collaboration, and communication are cornerstones of how we do our work, and, in this regard, our committees are essential.

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 a) we deliver on our current obligations, b) get ready for future requirements, c) develop our people and our systems and processes in a manner that allows us to demonstrate our competence, our independence, and our scientific expertise.

Before I conclude, I would point out that while a lot of focus is naturally on the CSS, the REACH and CLP revisions etc., in the Agency, we are still implementing and delivering on our current legal mandate. So, it is still business as usual for us.

However, ECHA sees the CSS as a real opportunity for concerted action by regulators and stakeholders alike. There is, unlike in 2006/2007 when REACH came into force, an independent, centralised, competent, and knowledgeable regulator in place and we look forward to working with all stakeholders as we realise the CSS ambitions.

Many thanks for your attention.