The chemicals strategy for sustainability: issues, ambitions and challenges

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Mayer Brown Europe senior scientific and regulatory adviser, Andrew Fasey says the job facing regulators in turning the objectives of the EU's chemicals strategy for sustainability into a regulatory framework that is workable, efficient and effective is immense

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When the white paper on the 'strategy for a future chemicals policy' (the REACH white paper) was published in February 2001, it was seen as revolutionary: the biggest change to the regulatory management of chemicals in prospect in a generation. On the one hand, many thought it would never be implemented – or that it would destroy EU industry. On the other hand, many saw it as an attempt, long overdue, to deal with the burden of the past. Many also praised the REACH white paper's ambition to put responsibility on industry for the safe management of its products, and to give regulatory authorities real powers to control chemicals and protect human health and the environment.

After long and protracted negotiations the REACH Regulation was adopted. And it has been a 'game changer'. REACH has had a massive effect on the management of chemicals and the attitude towards them and their risks both in the EU and globally. After operating almost 15 years, it is regarded by some as having stood the test of time, largely working despite (or perhaps because of) the scale of its ambition. Others, however, believe that the time has come for changes to be made.

Chemicals strategy for sustainability

In October 2020 the European Commission published the 'Chemicals Strategy for Sustainability – Towards a Toxic-Free Environment'. The CSS is an extremely ambitious blueprint for the biggest changes to the EU's approach to the management of chemicals since REACH. Assuming it is implemented in a way that fulfils its many objectives, it will also be a game changer that goes further than the changes introduced by REACH. And it must be remembered that it is just one part of the even more ambitious Green Deal.

To be clear, many things need to be done in the interests of the planet on sustainability, climate change and more. There is also nothing wrong with challenging, and far-reaching, objectives. However, it is legitimate to ask how these objectives can be achieved in a workable, legal and scientifically sound regulatory framework.

This article discusses some of the issues that the aims of the CSS bring to regulators and stakeholders. The

challenges facing regulators, starting with the European Commission, to turn the ambitions and objectives of the CSS into a regulatory framework that is workable, efficient and effective – all within the constraints of limited resources – are immense. Getting REACH 'over the line' was a huge task. The CSS goes way beyond the ambitions of REACH.

Issues and challenges

The timetable for the introduction of the CSS is ambitious. The generation of REACH took place over more than eight years, starting with a detailed review of the existing legislation. This was followed by the preparation of the REACH white paper, the setting up of working groups on different issues, the drafting of the European Commission proposal for REACH, and then a lengthy co-decision process. At every stage, there was extensive stakeholder involvement culminating in a regulation that has, in many respects, stood the test of time well. The REACH white paper, while not covering every detail, gave the regulators a clear path to the preparation of a coherent legal text and regulatory framework that was largely workable in practice.

By contrast the Commission adopted the CSS with little consultation over its objectives, whether they are needed, whether there might be better approaches, and how they might best be implemented. In an article for the Archives of Toxicology published in June 2021, the German Federal Institute for Risk Assessment (BfR) says: "With the exception of a few public consultations on very general roadmaps, the Commission has sought scientific input almost exclusively from its own services and agencies."

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This approach risks 'group think' as well as failing to take advantage of the extensive experience of regulators, industry and other stakeholders with the current regulatory regime. The BfR paper also says: "The justification for the measures proposed by the CSS often lacks rigour with respect to the critical, systematic and unbiased review of available scientific evidence required for such a project … It runs the risk of strong interpretation bias … and of merely amplifying arbitrary concerns instead of following an evidence-based approach."

The CSS regulators are now being tasked with preparing legal texts and a regulatory framework that must be workable in practice and meet ambitious, wide-ranging objectives. However, in contrast to the REACH white paper, the CSS lacks a basic framework and contains many currently undefined 'wishes', objectives and terms. To many it is not coherent or consistent and lacking the basis for rigorous science to frame the decision making that will be required. With so much still open, it is a huge challenge for the regulators to draft a legal text(s) that is coherent, consistent and workable.

The many stakeholders wanting input into the process are left with so many open issues that it is hard to formulate ideas and proposals. For example, the CSS introduces the concept of essential use, the 'generic approach to risk management' (GRA) as well as proposing the review and reform of the authorisation and restriction elements of REACH. Currently it appears that these three vital components are being considered largely in isolation from each other; the recent paper from the Commission on the latest developments on the review of the authorisation and restrictions processes says many times that the "[essential use] concept is still under development in a separate process and contract".

This is just not realistic. The three elements are so inter-linked that they must be addressed together to ensure coherence and consistency. It is not possible to meaningfully contribute to the debate about the reform of the authorisation and restrictions processes without having some idea about the 'direction of travel' with regard to the implementation of the essential use concept. It is a concern for many that there will not be sufficient time and space for stakeholders to have input into the process in order to arrive at a system that all can broadly accept.

Hazard versus risk

For example, the CSS talks about risk management in terms of groups of substances based on hazard categories and structural similarity. There is already a possible contradiction here. While a GRA already applies in relation to carcinogens in consumer products – and its extension has some obvious benefits for vulnerable populations – its application more widely is a potentially significant change that needs careful consideration.

As noted in the BfR paper, the move from a broadly risk-based to a hazard-based system would be a major change of approach and bring with it its own challenges. It states: "There is a repeatedly noted intention of the CSS to move

away from a risk-based to a hazard-based assessment paradigm … [This] is bound to create a range of problems and will likely result in a system that by design would be inherently arbitrary and inconsistent." The BfR paper further notes: it is "important to clearly distinguish between hazard, exposure and risk … the fact that chemicals with hazardous properties can cause harm does not mean that they indeed do so at all doses or by all exposure routes. It would therefore be wrong to conclude that just because a chemical has hazardous properties it is a threat to human health."

Essential use

The CSS introduces the concept of 'essential uses', as used in the Montreal Protocol, to exempt those deemed so from some restrictions and/or potentially other risk management measures. But currently there is no clarity about what is meant by it, what the criteria are to meet the definition and the scope of its application. Yes, one assumes that this concept will be clarified but without this absolutely crucial information, it is impossible to see how the GRA will work and what the implications might be. Once again, the BfR paper has some strong comments on the essential use concept. It says: "The understanding that chemicals with hazardous properties can in principle be used safely has been one of the cornerstone(s) of modern developed societies … most if not all of the technologies needed to bring about the change towards sustainability at the core of the CSS require the use of hazardous chemicals … the list of uses for hazardous chemicals that may be called 'essential' by society is, in fact, virtually endless." Introducing the essential use concept has a number of issues associated with its implementation that need to be carefully considered to ensure that its objectives are met while recognising that we, rightly or wrongly, live in a largely industrial society.

Furthermore, without any information on how the concept will be applied, or at least the direction of travel, how can stakeholders contribute to the negotiations and discussions on the regulatory form of the revision of REACH? How can industry start to prepare for what is likely to be a momentous change? How can NGOs, member states and other interested parties assess what contribution the GRA will make to the achievement of the goals in the CSS and the Green Deal?

Interface

There are many new ideas and concepts, and developments of existing processes, in the CSS. How they interact is crucial to the delivery of its objectives. At the moment it is difficult to see how these various elements will relate and interface with each other. Once again this makes effective contribution by others to the development of the legislation difficult. It is vital that the views and expertise of the many and varied stakeholders are fully taken into account and, if possible, a broad consensus is reached especially recognising the possibly diverging interests. It is not easy to see how this can work currently.

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One of the aims of the Green Deal is the circular economy. The reuse and recycling of chemicals and materials can reintroduce toxic substances into the supply chain. How do we balance the need to encourage the circular economy with the objectives of a toxic-free and zero pollution environment? The BfR says that the approach in the CSS to a 'toxic-free environment' could be considered misleading because what matters is "an environment free from chemical pollution and of exposure to hazardous chemicals at levels that are harmful to human health and the environment." The point here is not to challenge its laudable ambitions but to point out that currently the many and varied aims and objectives in the CSS (and the Green Deal) do not appear to be entirely coherent and consistent, and without greater clarity they will remain so.

Terms and concepts

Few contest the ambitious nature of the CSS or the need for urgent change. However, there are so many undefined terms and vague concepts that contributing to it in a meaningful way is difficult. For example, terms like 'zero pollution' and 'toxic free' (are all substances toxic in a sufficiently high dose?) are absolutes. Does this mean that the aim realistically is for zero emissions from every manufacturing site and every use whatever the substance and the use? As objectives they are of course laudable but the implications of this for the regulatory framework are huge and could be to the detriment of society as a whole.

Most would agree that individuals, animals or ecosystems should not be harmed by chemical use. But how should this be achieved in a way that balances societal interests with protection of human health and the environment? Many medicines are toxic and they or their toxic metabolites will be released to the environment as waste products. How will they be affected? One might assume that these would be essential uses but how does this square with the idea

of 'toxic free'? What account will be taken of toxins that are ubiquitous and/or produced by animals such as methane and ethylene oxide?

And there are many other terms which are not yet defined, such as 'critical' raw material, chemicals and hazard properties. What do they mean or what will this mean for chemicals management? And this does not touch on significant developments such as the 'mixture assessment factor' (MAF) which could have massive, and as yet, unforeseen consequences for the availability of products.

This article does not even discuss one of the most important aspects of the CSS to many, that is the phasing out the use of per- and polyfluoroalkyl substances (PFAS) in the EU, unless their use is essential. This takes us back to the concept of essentiality. This subject alone would deserve a separate article, indeed several.

The devil is in the detail …
The CSS, and in particular the revision of REACH and CLP, introduces new terms, concepts, criteria and definitions. Exactly how these are defined and implemented will have a huge bearing on what they mean for regulators, industry and other stakeholders. They include:

- new hazard categories due to be introduced for persistent (P), mobile (M) and toxic chemicals (PMT and vPvM);
- a new hazard category for, and the identification of, endocrine disruptors (EDCs);
- the introduction of new hazard categories in the Globally Harmonised System for classification and labelling (GHS);
- the data, methods and approaches used to address the criteria for new and existing hazard categories (for example, adverse effects mediated by an endocrine disrupting mode of action);
- the addition of new and existing hazard categories to new or existing regulatory processes (for example, authorisation and/or restriction or a combination of the two);
- a new approach to authorisation and restriction operate, including potentially a change of scope;
- the concept of 'one substance, one assessment' (OSOA) and how it will work in practice, taking into account the many existing regulatory approaches and the many inconsistencies between them;
- the development, and introduction, of criteria for the EU's safe and sustainable-by-design chemicals; and
- strengthening the EU's open strategic autonomy, while ensuring the implementation of the CSS and the Green Deal.

The CSS stresses the importance of guaranteeing the availability of chemicals used in health applications and for achieving the overall sustainability goals set in the Green Deal, including technologies for climate neutrality, such as batteries, wind turbines and photovoltaics. All these technologies require the use of hazardous chemicals (for example, lithium salts in batteries, heat transfer fluids in many 'essential' applications), some of which are already subject to risk management measures under the current REACH regime and would seem likely to be subject to regulatory action under the provisions of the REACH revision. How will the competing interests, for example, meeting Green Deal objectives and achieving a toxic-free environment, work in practice?

Resources

Another issue is how the new approach(es) will be resourced. Yes, processes have to be more efficient and effective than hitherto. But the implications of the CSS are that greater resources will be needed across the board. Where will these come from? Will the level of enforcement be increased so that there is a genuinely level playing field? Currently, an enduring complaint from many in industry is that the free riders and non-compliant are not being caught and if they are, the punishments are not sufficient to discourage non-compliance (or to incentivise compliance). There is a real risk that the demands placed on the various stakeholders will be so great that the resources, in terms of experts, will be stretched far too thinly meaning that many things may be done but little done well. Every decision on the risk management of chemicals has major implications for individual companies, and industry and society as a whole. It is vital that those that have an impact on the protection of human health and the environment, sustainability, use of alternatives among others are subject to rigorous scientific, legal and regulatory scrutiny and decision-making processes commensurate with the importance of the decisions in question.

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The BfR report considers that an opportunity has been missed. It says: "The CSS … clearly aims at improving the efficiency of the existing system. In light of the often painstakingly long time currently needed to achieve regulation of substances of concern, this initiative is highly welcome … however, it appears questionable whether proposed (pragmatic but less scientifically sound) regulatory approaches … can serve these purposes … this might do more harm than good … in most cases, the actual scientific risk assessment takes up only a minor fraction of the overall time needed. The major part is spent in time-consuming and bureaucratic procedures … the CSS largely fails to acknowledge this rather low-hanging fruit to improve efficiency."

Conclusion

The objectives of the CSS are laudable and rightly ambitious. However, there are many questions that need to be answered on how it will be turned into practice in a regulatory sense, and in a way that will be legally sound. Until we start to see answers, stakeholders can be forgiven for worrying about where we are heading. I was personally involved in the drafting of the Commission proposal for the REACH Regulation and we managed to come up with something, at the end of the trialogue process, that has largely stood the test of time. Many doubted that this could and would happen. However, the challenges ahead for the regulators in turning the CSS into a workable reality are, I would argue, massively greater. The regulators need to give all stakeholders the possibility to have meaningful, constructive and systematic input into the development of individual proposals but first and most importantly on the overall regulatory architecture and framework. Stakeholders' contribution should not be limited to having to frenetically track the many discussion documents and regulatory proposals and reacting to them one by one and in an ad hoc way.

The views expressed in this article are those of the author and are not necessarily shared by Chemical Watch. The author transparency statement can be seen here.