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International Chemical Regulatory and Law Review

Editorial

Given the continuous lockdown we have been in since the last publication of the ICRL it would be understandable to think that we have remained in a regulatory status quo. However, despite the global pandemic and ongoing restrictions on movement and social gatherings, the world of international chemical regulation, and the forces that move it, remain dynamic. As well as the continued uncertainty surrounding Brexit, January also saw the inauguration of a new US President who has already signalled his administration's plan to review regulatory changes which happened under his predecessor, including more than a dozen Environmental Protection Agency actions directly affecting commercial chemicals and the chemical industry. In Europe, the Commission's goal to phase out the non-essential uses of 'forever chemicals' PFAS has found recently support from member states. These issues will no doubt be covered in upcoming issues of the journal but for now let me turn to the present issues and the pressing issues discussed within.

Our articles section is focused on the topic of sustainability and in particular the European Commission's recently adopted Chemicals Strategy for Sustainability (CSS). As Lawrie McClaren, Roland Moore and Alexander Majer point out in their contribution, the CSS has potential to introduce radical change to the functioning of EU chemicals legislation. Although the Commission promises that that any legal proposals, including a revision of REACH will be achieved "in the most targeted way possible", and will be made "on the basis of public consultations and subject to comprehensive impact assessments", close scrutiny of this strategy is essential. Helpfully, this article maps out what areas merit particular attention and highlights how EU chemicals legislation may be impacted in the near and midterm. Focusing on the Chemicals Strategy for Sustainability's use of the 'essential use' concept to regulate the most harmful chemicals, Jean-Philippe Montfort's article reviews the possibilities and legal implications of the use of this concept within the current REACH Regulation.

Our reports section begins with Jeffrey Hafer's contribution on identifying polymers of low concern under REACH. Noting that the recent proposal by the European Commission to include polymers in the provisions on registration in Title II of REACH would present a monumental challenge in implementation, Haffer offers a number of pragmatic steps that can be taken to negate these. In addition, we have a report from my colleague Jaime Sales and myself concerning Restriction and Authorisation, REACH processes which are clearly driving replacement of substances of concern. Concluding the section we have an excellent overview of Serbian chemical regulation by Alja Livio Torkhani. The report provides not only a synopsis of the legislation but also highlights and analyses future developments, making it essential reading for any business looking to export to the Serbian market.

Rounding off the issue we have a Case Note by Eléonore Mullier and Andrea Bonavita on the recent judgement on Case C-471/18 P, which ended the SONC saga and the

question of what is the competent forum in the case of challenge against Statements of Non-Compliance.

As always, I would like to thank everyone who contributed to this issue and would encourage all of you to reach out, should you wish to contribute to one of the next issues or if you have questions about any of the contributions.

Dieter Drohmann
Managing Editor

The European Commission's Chemicals Strategy for Sustainability: The Challenge of Matching Political Aspirations with Workable Regulatory Outcomes

*Lawrie McLaren, Roland Moore and Alexander Majer**

I. Introduction

In October 2020, the European Commission published the long-awaited European Union Chemicals Strategy for Sustainability (CSS)[1], which had been announced in the European Green Deal and described as the first major EU strategy for chemicals since the adoption of the REACH Regulation.

Broken down into five priorities and announcing over 50 upcoming policy proposals, the CSS has the ambition to guide EU chemicals policy in a more sustainable and circular direction, while also making the regulatory process for chemicals simpler and more transparent, through initiatives aimed at securing a more coherent legal framework[2]

The Commission promises that any legal proposals, including a revision of REACH will be achieved "in the most targeted way possible", and will be made "on the basis of public consultations and subject to comprehensive impact assessments".

By adopting the CSS, the Commission has developed a policy strategy with the potential to introduce radical change to the functioning of EU chemicals legislation.

Because of the CSS's overall ambition, a reopening of REACH and CLP appears likely in the coming years. The scope of this reopening, as well as the exact procedure it will follow, remain to be seen.

What is certain is that the CSS – which itself looks to answer calls for a "Non-Toxic Environment Strategy" expressed in the Commission's 2013 7th Environmental Action Plan – is the beginning and not the end of a lengthy process of policy change for chemicals, which will require stakeholder collaboration, strong data, and accurate scientific analysis if it is to achieve workable regulatory outcomes.

II. Where the CSS Carries Most Impact

At the heart of the CSS are five priorities, defining the Commission's vision for EU chemicals policy as part of the European Green Deal:

1. Innovating for safe and sustainable EU chemicals
2. Stronger EU legal framework to address pressing environmental and health concerns
3. Simplification and consolidation of the legal framework
4. A comprehensive and transparent knowledge base on chemicals
5. A model inspiring chemicals management globally

Under these headline priorities, the action-heavy CSS Communication proposes over 50 new initiatives to promote the protection of health and the environment from hazardous chemicals, while encouraging the use of safer alternatives. Here, we examine some of the hardest-hitting actions in more detail.

1. The Toxic-Free Hierarchy

Using nomenclature that is reminiscent of the "Waste Hierarchy", which has become the operating framework for the EU Circular Economy, the CSS introduces a new "Toxic-Free Hierarchy" with the aim of "avoiding substances of concern for non-essential uses." Only where this is not possible does the hierar-

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1 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2020%3A667%3AFIN>

2 While some had hoped that it would also provide a framework for how chemicals can help deliver sustainability, this has not materialised.

About *CARACAL*
CARACAL gathers the competent authorities for REACH and CLP and acts as an expert group advising the European Commission and ECHA on the two regulations. It includes officials from Member States, representatives from EEA-EFTA countries, as well as observers from third countries and stakeholders (such as industry associations and NGOs). CARACAL meets roughly once per quarter. Contrary to the REACH Committee, it does not deliver votes on amendments to the REACH regulation, such as new REACH restrictions or inclusions on the Authorisation List. Since 2019, it acts as an advisory committee for new Adaptations to Technical Progress of the CLP regulation, under the Delegated Acts procedure.

chy suggest appropriate control measures to minimise exposure (i.e. risk management measures) or, only as a last resort, elimination and remediation. The CSS defines "substances of concern" as those "having a chronic effect for human health or the environment (Candidate list in REACH and Annex VI to the CLP Regulation) but also those which hamper recycling for safe and high quality secondary raw materials."

Unlike the waste hierarchy, which is enshrined in EU law in the Waste Framework Directive, it remains to be seen if and how a similar legal basis will be given to the Toxic-Free Hierarchy. Nevertheless, accompanied by a new EU definition of "essential use" criteria – currently under discussion by Commission and EU Member State representatives in the CARACAL committee – the Toxic-Free Hierarchy is likely to become a new point of reference for civil society and those regulators calling for more restrictive regulatory measures on substances considered to be "of concern".

2. Essential Use Criteria

In what could be described as a highly interventionist step, to accompany the Toxic-Free Hierarchy objective to avoid non-essential uses of substances of concern, the CSS proposes to define "criteria for essential uses", taking into account existing definitions under the Montreal Protocol. According to the Commission, criteria for essential uses will have to be properly defined to ensure coherent application across EU legislation and will in particular take into consideration the need to achieve the green and digital transitions. This issue is currently the object of intense discussion in CARACAL and it remains unclear how the Commission plans to define essential chemicals in practice and whether this definition will find a legal basis in EU legislation, for example through an amendment to REACH. It is also unclear to what extent essential use criteria could be used to support, rather than pre-empt, existing assessments conducted by ECHA's Socio-Economic Analysis Committee (SEAC). Introducing a definition of essential uses creates strong pressure on substances that may be identified as being "of concern" when they are used in applications that are not viewed as essential. This would be a particularly significant departure from the current system for REACH restrictions, which have historically targeted uses on the basis that these presented an "unacceptable risk" rather than on their essentiality.

3. Broader Use of Generic Risk Assessment

The Commission proposes to extend the role of generic risk assessment, an approach that entails automatic risk management measures, such as restrictions in sectoral legislation, for certain categories of chemicals. Generic risk assessment is currently used for carcinogens, mutagens and reprotoxicants (CMRs) in the Cosmetics Regulation, for example. The proposals in the CSS would broaden the application of generic risk assessment beyond its current use to include other concerns, such as endocrine disruption (ED), persistence and bioaccumulation.

Separately, the Commission plans to launch a comprehensive impact assessment to define modalities and timings for extending generic risk assessment to chemicals that affect the immune, neurological, or respiratory system, as well as chemicals toxic to specific organs.

Extending generic risk assessment will require changes to several pieces of legislation governing the use of substances in consumer products (e.g. cosmetics, toys, food contact materials) with impacts for a range of downstream users of substances. These will likely require their own impact assessments, but in

the meantime the Commission is already committing to prioritise the substance categories listed above for restrictions based on groupings.

If implemented across EU legislation, the extension of generic risk assessment – viewed by some as a shortcut for a more hazard-driven approach – will mean more automatic regulatory risk management measures in product legislation for CMRs and other substances, such as EDs, PBTs, immunotoxicants, and respiratory sensitisers.

For the Commission, a significant advantage of generic risk assessment is that it would speed up the implementation of risk management measures to address hazardous substances in key legislation.

4. Horizontal Identification of Endocrine Disruptors

Concluding the Commission's Fitness Check on EDs, the CSS proposes to establish legally binding hazard identification of EDs based on the WHO definition and building on the existing ED criteria for pesticides and biocides.

The Commission will formally introduce EDs as SVHCs under the REACH regulation, amending the current system which only offers the opportunity to list EDs as SVHCs based on "equivalent level of concern". This will create a more direct and obvious route for regulators aiming to identify substances as SVHCs due to ED properties. To date, eleven substances out of 211 SVHCs on the Candidate List have been listed based on ED properties through "equivalent level of concern"[3].

In the CSS, the Commission also promises to introduce new hazard classes for EDs under the CLP regulation. It is worth noting that major changes to hazard classes will require a reopening of key EU CLP articles and annexes, expected for 2021. Bringing EDs within scope of CLP would alter the functioning of the regulation by introducing harmonised classification for a mode of action, rather than simply adverse effects. This would create a precedent under GHS internationally, and open new avenues to regulate EDs at the European level.

5. A New Mixture Assessment Factor to Address Combination Effects

Responding to strong political pressures to address what are sometimes referred to as "cocktail effects", the Commission proposes to assess how best to introduce a Mixture Assessment Factor (MAF) in REACH to account for unintentional combination effects of chemicals. The CSS Annex indicates that the MAF will be introduced in REACH Annex 1 through comitology processes. If introduced, the MAF would bring an additional level of precaution to the assessment of chemicals by assuming combination effects, rather than conducting detailed assessments of potential interactions for each specific substance under review.

6. Environmental Concerns: New Rules on Persistent, Mobile and Toxic (PMT), Very Persistent and Very Mobile (vPvM) Substances, and PFAS

In another major change for the EU CLP regulation, the Commission proposes new hazard classes and criteria to address environmental toxicity, persistency, mobility and bioaccumulation in both EU CLP and the UN Globally Harmonized System (GHS) of classification and labelling of chemicals. Under REACH, it proposes new criteria to identify PMT/vPvM chemicals as Substances of Very High Concern (SVHC).

Hoping to address overwhelming pressure from Member States, civil society, and the European Parliament (as exemplified by a screening of the PFAS-themed film "Dark Waters" hosted by European parliamentarians[4]), the Commission also proposes what is likely to be the most ambitious set of actions ever adopted for a specific chemical family, specifically targeting PFAS. This is supported by a separate Staff Working Document attached to the CSS[5]. Headline initiatives include new REACH restrictions on all PFAS in firefighting foams and other uses, apart from where essential for society.

As with the changes envisaged for EDs, new environmental hazard classes in CLP will need to be introduced by reopening key articles and annexes in

3 <https://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2020_achievements_en.pdf/ea2249db-bf03-a3ed-e3dd-42a2dcce05db>

4 <https://eeb.org/hollywoods-mark-ruffalo-brings-chemical-warning-to-europe/>

5 <https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_PFAS.pdf>

the CLP legal text, following the EU's Ordinary Legislative Procedure involving the European Parliament and the Council of the EU.

New SVHC criteria for PMT/vPvM substances will also be difficult to achieve without reopening REACH Article 57 on SVHC listing. These changes are likely to be included in a broader legislative proposal to reopen REACH, expected in 2022.

By proposing these measures, the Commission offers new regulatory pathways for hazard classification and regulatory risk management of specific environmental concerns. While PMT/vPvM substances have already started to be listed as SVHCs through "equivalent level of concern" under REACH Article 57f, the CSS proposes to formalise this through targeted SVHC criteria.

7. Safe and Sustainable Products and Non-toxic Material Cycles

Linking the CSS to its Circular Economy ambitions, the Commission proposes to introduce new criteria for safe and sustainable by design when it comes to chemical content, including through upcoming legislative initiatives on sustainable products and ecodesign announced in the 2020 Circular Economy Action Plan. It proposes to minimise the presence of "substances of concern" in products, giving priority to textiles, packaging, furniture, electronics, construction and buildings. It remains to be seen how such initiatives will intersect with existing regulatory instruments aimed at addressing substances in products, such as REACH restrictions and the RoHS Directive.

When it comes to chemical content in waste, the Commission commits to limit as far as possible the use of derogations and authorisations for substances of concern in recycled materials – a promise that links in with ongoing challenges under REACH. Depending on how "safe and sustainable by design" criteria are defined, they may create opportunities for specific industries but threaten the licence to operate for others.

8. Polymer Registration

Responding to a long-time stated intention to consider extending REACH registration requirements to polymers, the Commission commits to propose registration of "certain polymers of concern", following up on ongoing debates on "polymers requiring registration" in the CARACAL group.

While discussions are still ongoing in CARACAL, introducing registration obligations for certain polymers is likely to require legislative changes under REACH – which currently exempts polymers from registration. Polymer registration, depending on its final scope, could increase regulatory pressure on industry and expose specific polymers to further regulation based on their size, their intrinsic properties or, potentially, monomer impurities.

9. Occupational Health and Safety: More OELs

In order to strengthen the protection of workers, the Commission commits to identify harmful substances for which it will propose new occupational exposure limits (OELs) following the established consultation process in the area of health and safety at work.

Binding OELs are defined at the EU level under occupational safety legislation, in consultation with social partners in the Advisory Committee on Safety and Health at Work, and following the Ordinary Legislative Procedure with the European Parliament and Council.

10. One Substance – One Assessment (OSOA)

As part of its efforts to improve the coherence of the EU policy framework for chemicals, the Commission proposes to use a single ECHA Public Activities Coordination Tool (PACT) to provide an overview of all planned and ongoing regulatory initiatives.

Under the OSOA headline, the CSS aims to review the allocation of assessments under chemicals legislation, strengthen ECHA's governance model, increase the use of grouping for chemicals with similar structures or functions, reform the REACH authorisation and restriction processes, and establish a working group to strengthen the coordination of Commission services and agencies. This has potential implications for sectoral expert committees such as the Scientific Committee on Consumer Safety in the cosmetics area, the responsibilities of which

could be transferred to ECHA as was recently done in the field of worker protection with the transfer of the SCOEL committee's work to RAC.

A potentially far-reaching change, which has not been broadly advertised as part of the CSS, is the Commission's proposal to grant itself the right to initiate harmonised classification dossiers under EU CLP, currently largely a prerogative of member states. Though easy to miss in the 50+ CSS actions, this is one of the proposals that will likely require a legislative reopening of CLP through the Ordinary Legislative Procedure.

Beyond creating CLP proposal rights for itself, it is currently unclear which changes the Commission will introduce to the current regulatory framework to implement the OSOA approach. It is notable, however, that ECHA's governance model is currently defined in the REACH Regulation, meaning significant changes may require a reopening of key articles. Important changes may also be proposed to reform REACH restriction and authorisation, which could require a reopening of key REACH titles.

In principle, OSOA offers an opportunity for the EU to implement a more consistent approach to assessments across various pieces of legislation. It is currently possible, for example, to observe inconsistencies between assessments conducted for the same chemicals under REACH or CLP and in food contact materials legislation or other product legislation.

11. International Action

Last but not least, the CSS confirms the Commission's long-standing ambition to lead in international fora on chemicals. This includes stepping up efforts to achieve the UN 2030 agenda as regards chemicals, adopt objectives and targets for international chemicals policy beyond 2020, introduce new hazard classes in GHS covering persistency, bioaccumulation, mobility and endocrine disruptors, and strengthen protection under international treaties such as the UN Stockholm Convention, where the EU already holds the title for most active Party in proposing new POPs for listing.

Changes in this area will largely not be achieved through EU legislation, but through concerted action by the EU under relevant UN Conventions and groups. An exception is GHS, where the Commission will attempt to shift the international agenda by first introducing new hazard classes at the EU level. Changes to international conventions require lengthy and complex negotiation processes. Nevertheless, as exemplified by Norway's recent proposal to introduce new requirements on plastic waste under the UN Basel Convention, these can be highly impactful.

III. Next steps: Outlook for EU chemicals legislation

The CSS takes the form of a Communication (i.e. a policy document and not a legislative proposal) and as such is itself not subject to amendments by the European Parliament or the Council of the EU. The Parliament had already issued a resolution on the CSS in July 2020, with many of its demands subsequently incorporated in the Commission's Communication. The Council has produced a number of conclusions on chemicals, most recently in June 2019, and held an orientation debate on CSS at the Environment Council in December 2020. New conclusions are expected to be adopted in the first half of 2021 under the Council's Portuguese Presidency.

The CSS is accompanied by an Action Plan and five staff working documents (SWD) detailing the Commission's approach and timeline for implementing the Strategy, respectively addressing endocrine disruptors, combination effects, PFAS, REACH Article 138, and summarising feedback received by stakeholders so far on the CSS.

Several of the actions in the CSS will require changes to EU legislation. This can happen via comitology (delegated acts, implementing acts, or the now outdated regulatory procedure with scrutiny, which still applies to REACH) when they cover technical aspects such as the various REACH annexes, but will require the Ordinary Legislative Procedure if they include changes to key articles in EU legislation. Major changes such as new SVHC criteria and polymer registration under REACH, in addition to new hazard classes and a right for the Commission to initiate CLH dossiers under CLP will fall in the latter category.

Under EU Better Regulation rules, the Commission is committing to conduct thorough impact assessments and stakeholder consultations in advance of any legislative proposals, which will in turn need to be jointly adopted by the European Parliament and Council, both of which will have the opportunity to

introduce amendments. The importance of gathering and submitting data to these processes is paramount.

The CSS marks the beginning and not the end of a lengthy process of policy change for chemicals. Many of the political aspirations contained therein are yet to be defined and their applicability remains to be worked out. However, the CSS clearly represents the start of a period of major change for the EU regulatory system, one that can be expected to extend well into the next five to ten years.

The Concept of Essential Use to Regulate Chemicals: Legal Considerations

*Jean-Philippe Montfort**

The European Commission's chemicals strategy for sustainability contemplates using the concept of "essential use" to regulate the "most harmful chemicals" under REACH and other legislation. This article reviews the possibilities and legal implications of the use of this concept within the current REACH Regulation. Essentially, it may be possible to apply the "essential use" concept under the current legal framework as a qualifier to the socio-economic assessments which are conducted when considering a potential restriction or authorisation under REACH. However, the essential use concept cannot serve to extend the list of substances of very high concern nor to refuse authorisation to substances the risks of which are adequately controlled. It can also not serve to reverse the burden of proof that is on authorities to demonstrate under a REACH restriction that a given substance presents an unacceptable risk. In essence, it is the principle of proportionality that should guide authorities in introducing the essential use concept under REACH, which entails to ensure that any restriction is not more restrictive than necessary to serve the legitimate objectives pursued. For many substances of concern, this principle would not allow outright bans of uses only because they are not strictly necessary for safety, security and the functioning of society, as in the Montreal Protocol. This concept could however serve to streamline and speed up authorisation or exemptions from restrictions for essential and strategic uses of substances. But societal benefits in a much broader sense, also taking into account the quality of life, and the evolution of societal needs, would need to be considered in order to regulate other less strategic uses of chemicals of concern in a proportionate manner.

I. The Concept of Essential Use in the CSS and under Existing EU Regulations

1. The CSS

The European Commission's Chemicals Strategy for Sustainability (CSS)[1] was adopted on 14 October 2020 as a follow up to the European "Green Deal" published in December 2019.[2] The CSS contemplates using the concept of "essential uses" to regulate per- and polyfluoroalkyl substances (PFAS) and the "most harmful chemicals", i.e. to allow their use "where proven essential for society". It further specifies that "(t)he criteria for essential uses of these chemicals will have to be properly defined to ensure coherent application across EU legislation, and will in particular taken into account the needs for achieving the green and digital transition". As will be discussed later in this paper, this is important since the CSS makes a clear link between "essentiality" and these fundamental EU policy objectives.

When referring to PFAS, the CSS provides additional granularity to the essential use concept when specifying that "the very large number of uses of PFAS, including some critical for society (for example medical devices) show that some of their uses can bring high socio-economic benefits. Such bene-

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1 Communication from the Commission of 14 October 2020 (COM(2020) 667), Chemicals Strategy for Sustainability Towards a Toxic-Free Environment <https://ec.europa.eu/environment/pdf/chemicals/2020/10/Strate-gy.pdf>

2 Communication from the Commission of 11 December 2019 (COM(2019) 640), The European Green Deal <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1588580774040&uri=CELEX%3A52019DC0640>

fits should be compared with the socio-economic costs of the environmental contamination and of the adverse effects on human health. A concept that could be useful in this assessment, with the purpose of reducing emissions, is that of essential uses". Thus the CSS envisages to analyse essentiality as part of, or in connection with, their socio-economic assessment.

On 12 November 2020, the European Commission issued a first document on Essential Uses, a "thought starter" prepared for and presented to CARACAL (the "Caracal Paper 1")[3] which contains some initial considerations and questions designed to launch the discussion on the application of this concept under REACH in CARACAL. That document does not include any specific proposal.

It is striking to note, however, that the CSS does not define what those "most harmful chemicals" are that would justify the use of this concept[4], nor what criteria should be applied and what process should be followed to identify or select them. Similarly, this consideration is absent from the Caracal Paper 1.

2. The Montreal Protocol

As noted in the Caracal Paper 1, the concept of essential uses was first applied under the Montreal Protocol on Substances that Deplete the Ozone Layer (the "Montreal Protocol").[5] The Montreal Protocol is a global agreement agreed in 1987 in order to protect the earth's stratospheric ozone layer by phasing out the chemicals that deplete it. Since the publication of the CSS, the Montreal Protocol is commonly referred to as a forerunner in the development of the concept of essential use in the field of chemicals.

Initially, the essential use exemption was not part of the Montreal Protocol. It was integrated to the Protocol in 1992 through Decision IV/4[6] During their Fourth Meeting, the Parties to the Protocol chose to reconsider the absolute nature of the phasing-out and created an exemption mechanism in article 2 to the Protocol to permit production or consumption of the substances controlled by the Protocol when deemed necessary to satisfy uses agreed by the Parties to be essential.[7]

For the purpose of implementing article 2, the Parties adopted Decision IV/25 on Essential Uses in which they elaborated a dual set of exemption criteria to be met:

– Firstly, (i) that the use is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects), and (ii) that there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health[8][8].
– Secondly, (i) that all economically feasible steps have been taken to minimize the essential use and any associated emission of the controlled substance; and (ii) that the controlled substance is not available in sufficient quantity and quality from existing stocks of banked or recycled controlled substances, also bearing in mind the developing countries' need for controlled substances.[9]

Since the Parties have amended the Protocol to include the essential use exemption, they examine essential-use nominations during each Meetings of the Parties.[10] Those decisions show that a very limited number of sectors have been considered essential in the framework of that Protocol, i.e. medical uses, fire protection, crop protection, laboratory and analytical uses, process agents and aerospace applications.

In its Caracal Paper 1, the Commission was clearly inspired by the Montreal Protocol when defining an essential use as one that is "necessary for health,

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3 European Commission document on "Essential Uses" dated 12 November 2020 (CA/61/2020) presented at the 37th meeting of Competent Authorities for REACH and CLP (CARACAL) on 17-18 November 2020.

4 On Page 10 of the CSS, it is specified that the Commission will "extend the generic approach to risk management to ensure that consumer products (...) do not contain chemicals that cause cancers, gene mutations, affect the reproductive or the endocrine system, or are persistent and bioaccumulative." It also refers in that context of "further harmful chemicals, including those affecting the immune, neurological or respiratory systems and chemicals toxic to a specific organ", but no link is made between this listing and the reference to the "most harmful chemicals" as referred to in the same CSS in connection with the essential use concept.

5 Montreal Protocol on Substances that Deplete the Ozone Layer (1987) <https://ozone.unep.org/treaties/montreal-protocol/montreal-pro-tocol-substances-deplete-ozone-layer>

6 Amendment to the Montreal Protocol on Substances that Deplete the Ozone Layer, Copenhagen, 25 November 1992 <https://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=XXVII-2-c&chapter=27&clang=_en>

7 See Articles 2A 4), 2B 2), 2C 3), 2D 2), 2E 3), 2G, 2H 5), 2I, and 2J 5).

8 Decision IV/25 : Essential uses.

9 Ibid.

10 Handbook for the Montreal Protocol on Substances that Deplete the Ozone Layer. <https://ozone.unep.org/sites/default/files/MP_handbook-eng-lish-2018.pdf>

safety or is critical for functioning of society" and for which "there are no available technical and economically feasible alternatives".[11]

Importantly, the Montreal Protocol addresses a very limited number of substances with undisputed and irreversible environmental impacts, not the universe of substances like REACH, and therefore one would certainly have to be prudent when seeking to extrapolate requirements suitable for substances that deplete the ozone layer to other categories of substances. This refers us back to the unanswered question as to which chemical substances are the "most harmful". Also, as demonstrated below, the essential use concept, as developed in the context of the Montreal Protocol could not be used as such, as part of the socio-economic analysis required under the authorisation and restriction processes of REACH, as this would be contrary to the provisions of the REACH Regulation and to the principle of proportionality.

3. The EU Biocidal Products Regulation

In EU law, the test of essentiality for chemicals is not completely new. Under the Biocidal Product Regulation 528/2012 (the "BPR"), certain active substances cannot be approved under the ordinary procedure if they are classified under the CLP as CMR (carcinogens, mutagens and reproductive toxicants), or having endocrine-disrupting properties or meeting the PBT (persistent, bioaccumulative and toxic) or vPvB (very persistent and very bio-accumulative) criteria[12][12], thus substances that would otherwise qualify as substances of very high concern ("SVHC") under REACH.

Under the BPR, an applicant can benefit from an "essential [use]" exemption, if he can show that the active substance is "essential to prevent or control a serious danger to human health, animal health or the environment" or if he demonstrates that "not approving the active substance would have a disproportionate negative impact on society when compared with the risk to human health, animal health or the environment arising from the use of the substance".

This approach of essential use focuses on the environmental or health benefits for society completed by an alternative balance test[13], thus departing from the broader approach of the Montreal Protocol. In fact, the current text of article 5.2 (b) and (c) of Regulation 528/2012 is the third attempt at defining essential uses of a biocides, showing that the concept as defined in the Montreal Protocol is not universal and that it is a difficult concept to grasp. Its reference to proportionality is however very relevant as discussed below.

To the best of our knowledge, the Commission has issued five decisions under the legal regime applicable before the BPR[14] and eight since then[15]in which it considers this exemption. All of them were granted on the basis of a public health interest.

II. Key Considerations for the Possible Accommodation of the Concept of Essential Use Under Reach and the CLP Regulations

The REACH Regulation is the legal framework that applies today and probably the main target for the introduction of the essential use concept by the European Commission. It is also the legal framework under which a proposed restriction on PFAS is being considered for which the CSS refers explicitly to this concept.

As noted in the Caracal Paper 1, some references have already been made to the concept of essential use in the framework of two proposals for REACH restrictions on microplastics and PFHxA[16][16], respectively, in both cases to justify exemptions from the

11 CSS p. 10.

12 Regulation 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, Article 5

13 In order to perform this balance test, the Commission first evaluates the impact on society that non approving the active substance would entail (e.g. social and economic consequences) and then looks at the risks to human health, animal health or the environment that approval would generate. As part of the second branch of the analysis, the Commission takes account of the possibilities to mitigate the risks and compares the risks presented by other active substances that may be used instead. A conclusion is then drawn balancing both evaluations (see Commission Implementing Regulation (EU) 2019/637 of 23 April 2019 approving cholecalciferol as an active substance for use in biocidal products of product-type 14).

14 Commission Decision 2009/395, Commission Decision 2011/48, Commission Decision 2014/85, Commission Decision 2014/395 and Commission Decision 2014/459.

15 Commission Implementing Regulations 2017/1376, 2017/1377, 2017/1378, 2017/1379, 2017/1380, 2017/1381, 2017/1382, 2017/1383, 2019/637

16 See Caracal Paper, page 6

proposed restrictions. It is thus necessary to analyse to what extent the essential use concept can be accommodated within the REACH Regulation as it stands.

In the Caracal Paper 1, the Commission foresees the possibility to apply the concept of essential use either as an "interpretative principle for guidance or as an element to be used in implementing legislation", or as a "new element for decision making" to be included "in co-decision legislation" (see Caracal Paper 1, page 15, section 5, §1). The REACH Regulation is a very broad regulation that imposes various layers of requirements on most chemical substances manufactured or imported into the EU. Registration under REACH applies to all substances manufactured or imported into the EU at 1 ton or more per year, irrespective of their classification as hazardous.

As noted above, the CSS calls for the introduction of the essential use concept for "the most harmful substances" without defining them. "Harmful" does not mean "hazardous" and thus would seem to refer to the notion of "risk", as opposed to "hazard". Indeed, the concept of "hazard" is distinguished from that of "risk" which is defined as the likelihood of harm based on both hazard and exposure. The classification of hazardous substances is one of the purposes of the CLP Regulation, which is considered to be "hazard based". Under REACH, however, only the identification of SVHCs is hazard based, as described below. Other processes address substances of concern, which means that they represent not only a "hazard" but also a "risk". This is the case in particular of the "substance evaluation" and "restrictions" processes. The authorisation process also takes account of the risks of the substances submitted to that process, as discussed below.

As the substance evaluation process is an intermediate process leading to requesting additional information to clarify a concern before this concern is either removed or materialises in proposals triggering the authorisation or restriction process or harmonized classification and labelling ("CLH") decisions under the CLP, substance evaluation does not seem directly relevant for introduction of the essential use concept in the current framework.

We can also rule out the application of the essential concept in CLH decisions. Indeed, a substance will be classified or not on the basis of available data on its hazardous properties; while the CLP allows consideration of the form or physical state in which a substance is placed on the market or expected to be used, there is no scope for making a difference in classification depending upon the essentiality of its uses. By contrast, the REACH authorisation and restriction processes could potentially serve as possible anchors for the implementation of an essential use concept, as discussed below.

1. The Authorisation Process Under REACH

The Authorisation Process under REACH is triggered by the identification that a substance is a CMR or a PBT/vPvB or that it presents an "equivalent level of concern", such as endocrine disrupting chemicals. The legislator has thus predetermined that substances presenting such properties are "substances of very high concern" ("SVHC") and deserve a specific treatment, that is that they should be banned unless authorized, following the REACH authorization process.

This does not mean, however, that the authorisation process is "hazard based". If some categories of SVHCs are identified on the basis of hazard (CMRs and PBTs) others (vPvB) do not have intrinsic hazards. Also, authorities have agreed to first conduct a regulatory management option analysis ("RMOA"), which takes account of the best regulatory option to manage the risks which such hazards may entail. And that risk management option may be a REACH restriction for example. Finally, the authorisation process itself seeks to determine whether the "risks" are adequately controlled or the benefits outweigh the "risks".

One could however consider that SVHCs could be candidate for being among the "most harmful substances" referred to in the CSS for the introduction of the essential use concept. When an economic actor requests authorization for a given SVHC, this authorization is "use specific" and applies only to the applicant. If the applicant can satisfactorily demonstrate that the risks resulting from the use of the SVHC it applies for are "adequately controlled", Article 60.2 of REACH requires that such use "shall be authorized". For uses the risks of which cannot be demonstrated to be adequately controlled, which includes substances for which no thresholds of exposure can be established, such as substances with PBT or vPvB properties, an authorisation may still be

granted under Article 60.4 of REACH but only "if it can be shown that socio-economic benefits outweigh the risks to human health or the environment arisingfrom the use of the substance and if there are no suitable alternative substances or technologies".

It results from the above, that under the current authorization process, the concept of "essential use" could not serve to extend the scope of authorisation to cover other substances of concern, not meeting the criteria of Article 57 of REACH. Also, the concept of "essential use" could not serve to refuse authorisation of uses the risks of which would be demonstrated to be "adequately controlled", which is a mechanistic exercise for threshold substances. These uses indeed "shall" be authorized regardless of whether or not they are "essential" for society. Any deviation from this rule would be illegal.

For uses the risks of which are not adequately controlled, however, there may be scope for the essential use concept within the socio-economic analysis to be conducted as part of the "socio-economic route" for authorisation, as discussed below.

2. The Restriction Process Under REACH

The Restriction Process under REACH requires demonstration that a given chemical substance present "a Community-wide unacceptable risk to human health and the environment (...) which needs to be addressed on a Community-wide basis"[17].The burden of proof that a given substance presents "an unacceptable risk to human health and the environment" lies on authorities.

One could therefore anticipate that substances proved to present an unacceptable risk to human health and the environment would be among the "most harmful substances" considered for the introduction of the essential use concept. In that respect, Article 68 requires authorities to "take account of the socio-economic impact of the restriction, including the availability of alternatives" when deciding on a restriction and therefore the concept of essential use could potentially serve in that context, as discussed in section 3. below, to determine which derogations for particular uses could be granted if the benefits they bring are "essential" to society.

Importantly, however, the essential use concept could not serve to revert or change the fundamental elements of the restriction process, as described above. Thus, the use of a substance could not be restricted without a clear demonstration that the risks it presents are "unacceptable", even if the use is deemed non-essential, and that the adopted measure is proportionate to such risks, considering its benefits to society.

3. Socio-Economic Benefit Analysis

The concept of "socio-economic" benefits is referred to in both the authorisation and the restriction processes, though in different terms. While Article 60.4 allows authorising the use of an SVHC "if it is shown that socio-economic benefits outweigh the risk", Article 68 requires the EU authorities "to take into account the socio-economic impact of a restriction". In the first case, demonstrating socio-economic benefits is a condition of authorisation, while in the second case the socio-economic impact must be "taken into account". Importantly, as does the Montreal Protocol, both articles 60.4 and 68 of REACH also refer to the "availability of alternatives", negatively as a condition to grant an authorisation and positively as an element to take into account in considering a restriction. This is discussed in the Sections 6 below.

Coming back to the nature of the "socio-economic" element of the authorisation and restriction processes, Article 60.4 refers to socio-economic "benefits" outweighing the risks, while Article 68 refers to socio-economic "impact", without further explanation in the preamble or anywhere else.

Does this semantic difference matter? In both cases, a socio-economic analysis must be conducted and essentially allows measuring the "proportionality" of the proposed measure. In the authorisation context, one must compare (i) the risks (of the continued use "benefits" that such use bring to society. In the context of a Restriction, the situation is reversed, since authorities have to compare the benefits of a restriction to its socio-economic "impact".

The socio-economic analysis to be conducted in both the Authorisation and Restriction processes is generally similar as evidenced by Annex XVI of REACH which provides a single description of such analysis for both of these processes. Indeed, Annex

17 REACH Article 68

XVI "outlines the information that may be addressed by those submitting a socio-economic analysis (SEA) with an application for authorisation, as specified in Article 62(5)(a), or in connection with a proposed restriction, as specified in Article 69(6)(b)".

Also, the ECHA Guidance documents on "the preparation of socio-economic analysis as part of an application for authorisation"[18] and on "socio-economic analysis-restrictions"[19] contain generally similar language for the assessment of the economic and social impacts of the proposed measure.

Thus, while there is a difference on the process to be followed leading to the conduct of a socio-economic analysis in the Authorisation and Restriction processes, and on the consequences to be drawn from that analysis, it appears that the socio-economic analysis itself is generally similar, following the criteria of Annex XVI of REACH.

4. Essentiality as Part of a Socio-Economic Benefit Analysis

The next question is whether the concept of essentiality can be accommodated as part of the socio-economic analysis under the REACH authorisation or restriction processes. As noted in the Caracal Paper 1, "currently, socioeconomic assessment in SEAC does not necessarily take into account the concept of essentiality in the sense of criterion 1a of the Montreal protocol (thus the fact that a use is necessary for health or safety or is critical for the functioning of society). Therefore, socio-economic benefits may outweigh the risk also in cases of non-essential uses."[20]

This may be true, but that does not mean that such concept could not find its place as part of a socio-economic analysis. The health and safety and the need to ensure uses that are critical to the functioning of society, can be seen as part of the "social" benefits that must be assessed, to the extent that they have not been covered by the analysis of the "human health and environmental impacts" and "economic impacts" of the measure. The ECHA Guidance Documents on "socio-economic analysis" indeed define "social impacts" as those which may affect workers, consumers and the general public "other than those analysed under the human health and environmental impacts and economic impacts."[21] The ECHA Guidance Documents then specify that these will mainly be impact on employment, employment conditions but also "quality of life (such as change in availability and quality of consumer products)".[22]

Essentiality could therefore fit within such social benefit analysis. However, what is essential remains to be determined and there is an obvious gap between the concept of a used being "critical to the functioning of society" as found in the Montreal Protocol and that of the "quality of life", as referred to in the ECHA Guidance. The Caracal Paper 1 refers the sectors that have consistently been considered "essential" under the Montreal protocol, thus medical uses, fire-fighting, plant/crop protection, aerospace applications, laboratory and analytical uses and process agent uses.[23]

This list is of course far away from encompassing everything that ensures the quality of life, which certainly would include e.g. cosmetics, toys, decorative products, etc. These products may be less "essential" to the "functioning" of society, strictly speaking, but they meet essential societal needs. In fact the Montreal Protocol itself also refers to "cultural and intellectual aspects" as being criterial for the functioning of society, which would clearly go beyond the limited number of sectors mentioned above as being essential. Many industrial products used in other sectors are critical to serve EU strategic objectives such as mobility or digital autonomy and should thus be considered essential.

If products such as cosmetics, toys, or decorative products may be less essential that some medicinal products, they are certainly not worth sacrificing "in bloc", outside of a proper and broad "cost-benefit" analysis that takes account of the specific risks posed by the continued use of substance of concerns in such uses and the loss of quality of life that their ban or restriction would cause.

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18 Guidance on the preparation of socio-economic analysis as part of an application for authorisation, January 2011 <https://echa.europa.eu/documents/10162/23036412/sea_authori-sation_en.pdf/aadf96ec-fbfa-4bc7-9740-a3f6ceb68e6e>

19 Guidance on Socio-Economic Analysis – Restrictions, May 2008 <https://echa.europa.eu/documents/10162/23036412/sea_restric-tions_en.pdf/2d7c8e06-b5dd-40fc-b646-3467b5082a9d>

20 Caracal Paper 1, page 11

21 Guidance on Socio-Economic Analysis – Restrictions, May 2008, p. 16; Guidance on the preparation of socio-economic analysis as part of an application for authorisation, January 2011, p.18

22 Guidance on the preparation of socio-economic analysis as part of an application for authorisation, January 2011, p.82

23 Caracal Paper 1, page 9

To conclude, taking into account the "socio-economic consequences" of a restriction (or the socio-economic benefits of an authorisation) could indeed include measurable consequences in terms of job creation or losses, but also loss of availability of products to serve societal needs, including the "quality of life", and thus the importance of such needs. In this context, a concept that would seek to define in which conditions a use or a product is "essential" versus "convenient" - or a "must have" as opposed to a "nice to have" - may find its place. But this can only be considered in comparison of the specific risks that this particular use or product raises, throughout its life cycle, and after an assessment of the possible alternatives is made which is as rigorous as that applied to the potentially restricted substances.

5. Essentiality in the Cousins Paper

Significant efforts have been made by a series of academic authors, led by Ian Cousins, from the Stockholm University, to express their concern over PFAS, to review their uses, and even propose risk management measures to address these alleged concerns, notably based on the concepts of grouping and essential use.[24]

As regards the concept of "essential use", Cousins et al have proposed to set up three categories of essential uses "to aid phase out of non-essential uses of chemicals of concern, exemplified with PFAS uses". These categories are:

(1) Non-essential uses, defined as "uses that are not essential for health and safety, and the functioning of society";
(2) Substitutable uses, defined as "uses that have come to be regarded as essential because they perform important functions, but where alternatives to the substances have now been developed that have equivalent functionality and adequate performance, which makes those uses of the substances no longer essential";
(3) Essential uses, defined as "uses considered essential because they are necessary for health or safety or other highly important purposes and for which alternatives are not yet established".[25]

In doing so Cousins et al. are directly inspired from the Montreal Protocol to arrive at conclusions/proposals that could however not be accommodated as such within the current REACH framework. Indeed, it would not be legally possible under REACH today nor proportionate to determine at the outset that any use of a substance of concern that is not "necessary for the betterment of society in terms of health, safety and functioning"[26] should be banned, irrespective of the availability of suitable alternatives or not. Also, it would be very difficult, if not impossible, to reach a societal or political agreement as to what "betterment for society" concretely means.

The author submits that, under REACH, the use of a substance of concern in a product that serves the quality of life and has no substitute should not be automatically banned or refused authorisation. If it can be demonstrated that the benefits of such product outweigh the risks involved, that use should be authorised as per Article 60.4 of REACH. Otherwise, the ban would be in breach of the REACH Regulation and subject to annulment by the European Courts.

In a restriction, it is for authorities to demonstrate that the impact of the ban of such product will not be disproportionate considering the benefits that the ban would entail in terms of the risks to human health and the environment. Here again an automatic ban of products deemed in advance not to be "necessary for the betterment of society in terms of health, safety and functioning" would also be contrary to Article 68 of REACH and thus illegal.

For example, the Cousins et al. Paper refers to "dental floss, water-repellent surfer shorts and ski waxes" as non-essential uses of PFAS that should be banned[27]. Similarly, the Commission refers in the CSS to the use of PFAS to provide water and oil repellence to textiles, for which a high level of worker protection may be considered essential until suitable alternatives are available, while for consumer uses, "oil repellence could be considered convenient but not essential"[28].

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24 Cousins, Ian T. et al., "The concept of essential use for determining when uses of PFASs can be phased out", Environmental Science :Processes & Impacts 21.11 (2019): 1803-1815 <https://pubs.rsc.org/en/content/articlelanding/2019/em/c9em00163h#!divAbstract>

25 Cousins, Ian T. et al, p. 1805

26 Ibid. p. 1804

27 Ibid. p. 1805

28 European Commission Staff Working Document on Poly- and perfluoroalkyl substances (PFAS) accompanying the Communication from the Commission of 14 October 2020 (COM(2020) 667), Chemicals Strategy for Sustainability Towards a Toxic-Free Environment, p. 9 <https://ec.europa.eu/environment/pdf/chemicals/2020/10/SWD_PFAS.pdf>

We submit that it would not be legal under REACH nor proportionate to ban or refuse authorisation to groups of PFAS substances used in any potentially "non-essential" applications, without a proper socio-economic analysis that takes into account all elements discussed above, including the risks involved with the use of PFAS in those specific applications, the risk management measures taken to control such risks, the socio-economic benefits of such uses, including their impact on the quality of life, and the availability of suitable alternatives.

It should also be considered whether banning such uses for the general public may cause companies to no longer be able to produce in economically viable conditions the equivalent professional products and thus lead to the loss of these products as well, though deemed essential. This also should be part of the analysis of the proportionality of the measure as discussed in Section 7 below.

6. Essentiality and the Need to Analyse Available Alternatives

The Montreal Protocol allows a use to qualify as "essential" if it is necessary for the health, safety or is critical for the functioning of society and "if there are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health"[29].

As regards this second condition, Article 68 of REACH is more laconic as it only refers to the need to take into account the socio-economic impact of the restriction, "including the availability of substitutes". As regards Article 60.4 of REACH it refers to "suitable alternative substance or technologies", a concept that is further qualified in Article 60.5 of REACH as follows:

"When assessing whether suitable alternative substances or technologies are available, all relevant aspects shall be taken into account by the Commission, including:

(a) Whether the transfer to alternatives would result in reduced overall risks to human health and the environment, taking into account the appropriate

ness and effectiveness of risk management measures;

(b) The technical and economic feasibility of alternatives for the applicant".

In the authorisation context therefore, a qualified alternative must be proved to (1) be "technically and economically feasible for the applicant", and (2) reduce the overall risks to human health and the environment (compared with the substance subject to authorization). It is important to note that the technical and economic feasibility must be assessed on the basis of the conditions applicable "to the applicant" and thus it must be possible (proportionate) for that applicant, technically and economically, to switch to the alternative. This second condition is also fundamental, otherwise this would lead to what is referred to as "regrettable substitutions".

The same conditions should also apply in the context of a restriction under REACH in particular if the "socio-economic" impact to be conducted in that framework is broadened to also take account of a concept of essentiality. Thus, key to the application of the essential use principle will be that a process as rigorous as that used to demonstrated the "concern" of the substances considered for a ban or a restriction be used to determine whether the potential alternative substances or technologies indeed have a better profile in addition to being technically and economically feasible.

7. Essentiality and Proportionality, One of The Main Legal Principles of EU Law

Any decision by the Commission under Article 64.8 of REACH to ban or authorise a substance following the authorisation process or in a restriction adopteunder Article 73 of REACH would be subject to the control of the legality of such measure by the European Courts. In their review, the European Courts would not only rule on the legality of decisions taken on the basis of the essential use concept, with the provisions of the REACH Regulation but also with the Treaty on the Functioning of the European Union (TFEU) and the essential principles of EU Law, enshrined in such Treaty, such as the principles of

29 Decision IV/25 : Essential uses. <https://ozone.unep.org/treaties/montreal-protocol/meet-ings/fourth-meeting-parties/decisions/decision-iv25-essential-us-es?q=es/meetings/fourth-meeting-parties-montreal-protocol/deci-sions/decision-iv25-usos-esenciales>

proportionality, non-discrimination, legal certainty and foresee-ability, legitimate expectations, good administration, etc.

It is beyond the scope of this article to make an extensive review of the possible application of all the EU principles of law to the possible introduction of the essential use concept in the application of Article 60.4 and 68 of REACH. But we review below how the principle of proportionality must be taken into consideration and may invalidate decisions taken on the basis of the essential use concept if applied without due consideration of such principle.

The principle of proportionality requires that measures adopted by EU authorities do not exceed the limits of what is appropriate and necessary in order to attain the objectives legitimately pursued by REACH[30]. In the context of REACH, those objectives include, according to Article 1 of REACH, primarily the protection of human health and of the environment, but also the free circulation of substances on the internal market.

Article 68 of REACH when referring to the need to take into account the socio-economic impact of a restriction, including the availability of alternative, in the restriction process, is clearly underpinned by the principle of proportionality and such principle can then be used to guide the Commission in making its restriction decisions.

As regards Article 60.4 of REACH, it is also inspired from that principle but the REACH text is somewhat more specific in that it imposes upon the authorities to grant an authorisation if the socio-economic benefits of a use outweigh the risks and if there are no suitable alternatives. As described above, on that basis, the simple translation of the Montreal Protocol or of the three categories proposed by Cousins et al. in the implementation of these articles would be contrary to both the REACH text and the principle of proportionality for most uses.

More generally, the principle of proportionality requires that each specific use be analysed and the benefits of its ban or restriction compared with the risks that such specific use represent, thus requiring a case-by-case, use-by-use analysis. For example, it would be disproportionate to ban a use, even if non-essential, of a substance presenting a concern for the environment, if that use would represent virtually no environmental exposure; Indeed, such ban would bring no environmental benefits and thus be disproportionate.

Also, to be proportionate, this analysis must take account of the specificity of each chemical substance being considered. There cannot be a one size fits all restriction that picks up on the characteristics of one chemical to extrapolate it to all other chemicals in a group without positive demonstration of their harmful criteria. Most PFAS for example, are claimed to be persistent or very persistent, and some may be bioaccumulative, but not all. REACH includes criteria for substances that are PBTs or vPvBs showing that it is the addition of persistency and bioaccumulation and/or toxicity which is of concern. It remains to be demonstrated that each and every PFAS meets such criteria of concern or other criteria of concern, provided that these are determined and defined in full transparency and legality.

Otherwise, a ban or restriction will inevitably breach the principle of proportionality, that is the fundamental basis of Articles 60.4 and 68 of REACH, and is an overarching essential principle of EU Law. Importantly also, these essential principles apply not only to decisions taken by the Commission or ECHA in matters of their competence, as specified by the EU legislator in EU legislation such as the REACH Regulation, but these principles also apply to the EU legislator itself.

Indeed, though the Court of Justice has recognized that a certain discretion must be allowed to the legislature when making political, economic and social policy choices that require to carry out complex assessment[31], there is no general exemption with regards to the respect of the general principles of EU law by the legislator. Article 263 TFEU indeed makes clear that "(t)he Court of Justice of the European Union shall review the legality of legislative acts" notably on the ground of "infringement of the Treaties or any rule of law relating to their application"[32]. The EU legislator engaged in a revision of REACH would thus also be required to take due account of all the above considerations as regards the proportionality of the introduction of the essential use concept in a revised EU REACH or other EU legislation.

30 See CJUE, Etimine SA v. Secretary of State, 21 July 2011, §124

31 See CJCE, 12 November 1996, C-84/94, §58, United Kingdom v. Council of the European Union, See also CJCE, 14 December 2004, Swedish Match v. Secretary of State for Health, §48

32 See CJ Stauder v. City of Ulm, 12 November 1969, C-29/69, §7

8. Essentiality Under WTO Rules

The Agreement on Technical Barriers to Trade (TBT Agreement) prohibits technical regulations that are discriminatory or which create unnecessary obstacles to trade. The TBT Agreement leaves however to WTO Members a certain leeway on which legitimate objective (e.g. the protection of human health) they want to pursue providing the technical barrier can pass the necessity test, which is essentially a "proportionality" test.

Under the TBT Agreement, a technical regulation survives the necessity test when it is not more trade-restrictive than necessary to fulfil a legitimate objective. This test has been clarified by the Appellate Body of the WTO through a three prong test which includes:

(a) the degree of contribution made by the measure to the legitimate objective at issue;
(b) the trade-restrictiveness of the measure;
(c) the nature of the risks at issue and the gravity of consequences that would arise from nonfulfillment of the objective(s) pursued by the Member through the measure[33].

The author submits that essentiality as such should not be a "legitimate objective" on its own under the TBT Agreement, and, therefore, EU measure incorporating the concept of essentiality, including specific bans or restrictions on substances for non-essential uses, would need to not be more trade-restrictive than necessary in order to fulfil another objective, such as the protection of human health.

The TBT may thus not easily accommodate a strict view on essential use which would consist in banning all non-essential uses of an harmful substance on the basis of its hazard only, without demonstrating the necessity of such measure to achieve the desired objective.

III. Practical Suggestions for the Introduction of the Concept Under Reach

From the above, the author concludes that it should be possible to introduce the concept of essential use within the socio-economic analysis that is being conducted in the framework of the authorisation and restriction processes of REACH while ensuring that this is done as part of a robust analysis of the proportionality of the proposed measure. This section now addresses some issues related to the concrete implementation of such concept in such socio-economic analysis:

1. Developing Criteria of Essentiality

In the Caracal Paper 1, the European Commission has raised a series of broad questions on existing uses of the essential use concept, examples of essential and non-essential uses, whether decisions should be based on pre-defined criteria or case-by-case assessments, and other substantive and procedural questions. The responses received from the EU Member States and other stakeholders, as summarized in a second document produced by the European Commission for the 38th meeting of CARACAL (the "Caracal Paper 2")[34], show that it will be very difficult to find a consensus on how to approach this issue.

While Member States generally support the introduction of the concept, and the need to define criteria, they also seem to agree that some degree of case-by-case review will be needed. However, beyond that, the initial responses diverge significantly, going from proposing that the concept should be fed at the level of product development so that only products proved to be essential should be marketed[35] to more reasonable suggestions to fit some level of essentiality in the current REACH system[36].

It is beyond the scope of this paper to elaborate a possible definition or criteria for the introduction of the essential use concept under REACH. Neverthe-

33 Report of the Appellate Body – United States – Measures concerning the Importation, Marketing and Sale of Tuna and Tuna Products, WT/DS381/AB/R, 16 May 2012, §322 <https://www.wto.org/english/tratop_e/dispu_e/381abr_e.pdf>

34 European Commission document on "Essential Uses – A possible concept for REACH (Summary of and response to comments to CA/61/2020)" dated 1 March 2021 (CA/14/2021) presented at the 38th meeting of Competent Authorities for REACH and CLP (CARACAL) on 3-4 November 2021.

35 Essential Uses Doc Ca/61/2020, Questions To Caracal, REACH FR competent authority (ministry for the ecological transition) preliminary thoughts, page 2.

36 In the Caracal Paper 2 (page 2), the Commission indicates that it will "develop a working paper on the concept" of essential use and that it is "considering launching a study to continue, amongst other, the legal analysis, assess possible criteria, the scope of application and policy options which will determine the decision making process". At the time of finalizing this article, these working paper and study were not yet available.

less, it is important to stress that the introduction of an essential use concept will need to allow space for science and technology to evolve and new uses to emerge. It will also need to take into account that society and the needs of society are in constant evolution, including in terms of quality of life. An essential use concept should therefore allow for the dynamic adaptation of its scope and assessment criteria as a function of changing societal need and future innovation.

It will therefore be very difficult to arrive at a comprehensive set of criteria that can simply be applied and case-by-case review will certainly be needed, which may make existing procedures even more complex and lengthy, thus far away from the objectives of streamlining the authorization and restriction processes. In that respect, indeed, the Commission indicates in the Caracal Paper as the first advantage of the use of the concept that "some authorisations and restrictions under REACH may be processed faster"[37].

2. Use of Presumptions to Fast Track Essential Uses

One possible way to streamline these processes would be to use "presumptions" as do the (now old) "new approach directives."[38] These Directives establish "essential requirements" and allow EU Standards to be elaborated to demonstrate compliance with such requirements. Products that comply with EU standards are "deemed" in compliance with the essential requirements, but compliance can be also demonstrated by other means.

The proposal would therefore be to agree on a set of rules to define at the outset what products and applications should be "deemed essential" and could be fast tracked for rapid decision making. Possibly rules could also be set up at the outset to define which products are "deemed not to be essential". In both cases, rules would also be set up to reverse these presumptions, also specifying who has the burden of proof to do so.

Products subject to such presumptions, while undergoing a case-by-case analysis, would nevertheless be fast tracked when considering a request for authorisation or a proposal for a restriction, as part of the socio-economic analysis. This may lead to the authorisation of such uses, to their being excluded from the scope of the proposed restriction or exempted from the later.

In that framework, essentiality could be assessed starting with the EU strategic objectives and the determination of the product needed to achieve those objectives. Substances of concern necessary for the functionality of such strategic products would be deemed essential and fast tracked for authorization or exemption from proposed restrictions, unless suitable alternatives would be demonstrated to exist.

For example, chemical substances needed to ensure the functioning of batteries for electric vehicles that are key to ensure the EU green mobility, a strategic EU objective, would be "deemed essential" and thus authorized or exempt from restriction under REACH if such substances would come to be subject to such processes (like some Lithium compounds)[39], unless and until alternative substances or technologies presenting less health or environmental risks would be developed that become economically and technically feasible.

Essential products so authorized could still be subject to risk management measures to limit exposure to the extent possible during production, use and at the end of their life. The process could for example facilitate authorization for products produced in sites that comply with EU Eco-Management and Audit Scheme (EMAS)[40] or that meet the future sustainability by design requirements.

This would be a pragmatic way to ensure that not only the protection of human health and the environment but also the strategic objectives of the EU, including those in the Green Deal, are met and that the processes are streamlined to that effect. By contrast, in the past years, antagonistic goals, pursued by different parts of the European Commission, have driven in different directions, with industry having to defend under REACH processes products that are deemed essential to meet EU strategic goals.

For other products that are not "strategic", the normal REACH process would apply with a proportional analysis of the socio-economic impact of the pro-

37 Caracal Paper 1, Page 7.

38 See the Guide to implementation of Community harmonization directives based on the new approach and the global approach, October 1994 <https://op.europa.eu/en/publication-detail/-/publica-tion/3d49c4e8-03de-4a9a-ab41-5d18721eea8a/language-en/for-mat-PDF/source-search>

39 lithium carbonate; lithium chloride; lithium... - Registry of CLH intentions until outcome - ECHA (europa.eu)

40 EMAS – Environment - European Commission (europa.eu).

posed measure, taking into account societal needs and leaving the door open for the satisfaction of future needs.

Finally, for categories of products that could be "deemed not to be essential", the bar would be set higher, in accordance with the principle of proportionality, for producers and users to demonstrate that the use of substances of concern remains beneficial, possibly also following a fast-track system leading to their ban or restriction unless these stricter conditions can be demonstrated to be met.

It will remain to be determined how far can the European Commission lawfully go in developing criteria that could allow fast tracking the review of essential or non-essential uses under the current REACH Regulation processes and whether this could be done in the form of guidance, or via an implementing regulation or whether an amendment to the REACH Regulation would be needed. Provided that the decisions taken in the authorization and restrictions processes duly follow the establish processes and maintain a case-by-case review that respect the conditions set forth in the legislation and the principle of proportionality, a guidance on essential uses could be elaborated to serve in the socio-economic assessment that is required under REACH. The criteria for socio-economic assessment of Annex XVI of REACH would seem sufficiently flexible to accommodate this, even if a reference to the essential use concept via an amendment of such Annex would provide useful additional legal support.

IV. Conclusion

The question of "essentiality" is not limited to chemical regulation. It is also a concept that is largely referred to in the context of the Covid-19 pandemic. And everyone could observe with the different answers given in the different countries to the very same questions, how relative and diverse are the perceptions that one has on which human activities are essential or less essential in that context.

The author submits that the concept of essential use could be legally applied under REACH but only under the REACH authorization and restriction processes for substances of concern that present an unacceptable risk and are not adequately controlled and that are today subject to a socio-economic analysis and an analysis of alternatives.

Great care should however be taken by authorities to avoid products being banned on the basis of subjective judgements of what is good or bad for society. Indeed, banning the use of substances in products on the basis of subjective judgements would lead to arbitrary, discriminatory and/or disproportionate decisions that breach essential EU legal principles and could thus be legally challenged.

Reports

REACH Registration of Polymers: Identifying Polymers of Low Concern

*Jeffrey Hafer**

I. Introduction

Polymers are currently excluded from the provisions on registration in Title II of REACH[1] (Registration, Evaluation, Authorisation and Restriction of Chemicals, (Article 2(9)). The European Commission (the Commission) has proposed that polymers now be included within the scope of the regulation. A study[2] (Wood-PFA) published in 2020 estimated that there are over 200,000 polymers in commerce in countries under REACH jurisdiction, and that approximately 33,000 could require registration, representing roughly 11,000 'unique polymers'. This diminution recognizes the fact that, unlike discrete chemical names, a polymer name represents a group of substances that cannot be defined by a single molecular formula or structure. In order to rationalize the universe of 200,000 polymers down to 33,000 polymers requiring registration (PRRs), Wood-PFA proposed a method of classification and grouping. The proposal included the concept of Polymers of Low Concern (PLCs) and recommended that registration of PLCs should not be required. But the report did not explicitly identify any systematic method for identifying PLCs. Recently, the Commission suggested using the Canadian criteria to identify PLCs.[3]

In 2005, Canada revised its New Substance Notification (NSN) requirements under the Canadian Environmental Protection Act (CEPA) to include a new Reduced Regulatory Requirement (RRR) polymer[4] category recognizing polymers that meet the criteria for low concern. Thus, RRR polymers are subject to fewer data requirements for evaluation and, if warranted, are approved for inclusion on the Canada Domestic Substances List (DSL) as an RRR polymer.[5] But Canada's NSN paradigm was not the first regulatory system to identify PLCs.

II. PLC Origin

In 1973 Japan was the first country to establish an inventory-based industrial chemical control law as we know them today. It included the concept of 'existing' substances (those listed on the established substance inventory) and 'new' substances (those not listed and thus requiring notification to the authorities prior to commercialization). Although the regulation did not include an explicit exemption for specific polymers, the original Existing and New Chemical Substances (ENCS) inventory had many 'group' listings that de facto covered a large number of polymers not individually listed by Ministry of Economy, Trade and Industry (METI) numbers.[6] For instance, ENCS 6-186 is associated with the group 'Alkyl acrylate-Alkyl methacrylate-Styrene copolymer'. Theoretically, this listing might apply to hundreds of poten-

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1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency [2006] OJ L396/1.

2 Wood-PFA, 'Scientific and technical support for the development of criteria to identify and group polymers for Registration/Evaluation under REACH and their impact assessment' (Doc Ref. 40867-WOOD-XX-XX-RP-OP-0002_53_P03.5, June 2020)

3 Background Document for the CASG-polymers meeting 16 December 2020, Brussels (08/12/2020).

4 *New Substances Notification Regulations (Chemicals and Polymers)* SOR/2005-247.

5 RRR polymers are added to the DSL with a P flag, indicating that in order to take advantage of that DSL listing, a polymer must meet the RRR criteria.

6 METI numbers are used as identifiers on the ENCS list. Some, but not all, numbers are cross-referenced to Chemical Abstracts Service Registry Numbers (CASRNs).

tial polymer compositions.[7] Currently, ENCS 6-186 is cross-referenced to 32 individual Chemical Abstracts Service Registry Numbers (CASRNs). These group listings introduced the idea that the inherent risk from exposure to certain categories of polymers was low enough that notification to and evaluation by regulatory authorities prior to commercialization was not necessary.

In 1976 the United States (US) Toxic Substances Control Act (TSCA) was enacted without specific guidance for polymers, or even a statutory polymer definition vis-à-vis inventory listing. The requirement to submit premanufacture notices (PMNs) for new chemical substances to the US Environmental Protection Agency (USEPA, the Agency) prior to commercialization became effective on July 1, 1979, 30 days after the publication of the initial TSCA inventory. After review of 4000 PMNs (1200 for new polymers), a final rule establishing an exemption for certain polymers was promulgated in 1984. The Federal Register (Fed Reg) notice for the rule[8] included a polymer definition, as well as the criteria to identify PLCs eligible for the exemption and the rationale for their adoption. Eligible polymers still required notification to the Agency prior to commercialization, but with reduced data requirements and an expedited review (21 days versus 90 for a full PMN). Substances that successfully passed the review were added to the inventory after receipt of a notice of commencement of manufacture or import. However, unlike discreet chemical PMN substances that were generally added to the inventory without specific physical property restrictions, exempt polymer inventory listings were limited to polymers that met the applicable exemption conditions including the weight percent of the residual reactants and low molecular weight (MW) species reported in the notice or, in the case of an exempt polyester, use of allowed reactants.[9] If anyone other than the original PMN submitter wants to use an exempt polymer listing to demonstrate compliance with TSCA inventory requirements, they have to contact the Agency to determine whether their polymer meets the conditions of the original submission.

Under Article 13(2) of the seventh amendment of the Dangerous Substances Directive (DSD)[10] that preceded REACH, polymers were considered as notified (i.e., were excluded from the need to be notified) unless their composition included 2% or more of any substances that were not listed on the European Inventory of Existing Commercial Chemical Substances (EINECS). For polymers that were not excluded, a 1993 Commission Directive[11] delineated the base-set testing requirements. Annex VII D allowed for the testing of representatives of families of polymers, rather than all polymers of a given family. It also established criteria to identify high-MW polymers for which a reduced test package (RTP) would be sufficient. Many of the RTP requirements are similar to the PLC criteria in use in the US, Australia, and Canada.

After review of over 10,000 more polymer PMN submissions and an additional 2000 polymer exemption notices between 1984 and 1995, a revised exemption was enacted by USEPA.[12] It maintained some components of the 1984 exemption, but it expanded and refined the criteria for PLCs. In addition, other than a one-time communication of the number of new exempt polymers commercialized for the first time in the prior year, no notification to the Agency is required and the polymer is not added to the inventory.

In 1997 Australia established a PLC category with criteria essentially identical to the TSCA exemption,[13] but these PLC polymers still required an application for assessment with reduced data requirements prior to commercialization, and were eventually included on the Australian Inventory of Chemical Substances (AICS).

The 2005 Canada RRR criteria are closely aligned with the PLC requirements in the US and Australia. In 2014, the Canadian government published a system for identifying polymers requiring different levels of assessment under their Chemicals Manage-

7 ENCS 6-186 includes the stipulation that the listing is limited to polymers insoluble in water, acid and alkali, and to those where the content of oligomers having a molecular weight (MW) less than 1000 Da is 1% or less.

8 Premanufacture notification exemptions; exemption for polymers, 49 Fed Reg 46,066 (Nov 21, 1984).

9 Indicated by a Y1 or Y2 flag on the inventory listing.

10 Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [1967] OJ L196/1.

11 Commission Directive 93/105/EC of 25 November 1993 laying down Annex VII D, containing information required for the technical dossier referred to in Article 12 of the seventh amendment of Council Directive 67/548/EEC [1993] OJ L294/31.

12 60 Fed Reg 16,316 (Mar 29, 1995).

13 *Industrial Chemicals (Notification and Assessment) Act 1989* (July 1990 as amended in 1997).

ment Plan.[14] In 2018, it published a 'second phase of polymer rapid screening' document which 1) provided explicit criteria for identifying PLCs and 2) used identification as a PLC to eliminate the need for further evaluation in the screening process.[15]

Based on the recommendation of the Commission, the first step to determine if a polymer might require registration under REACH would be to determine if it meets the RRR criteria.

III. PLC Criteria

At the most basic level, the PLC criteria for Canada, Australia, and the US incorporate the following components:

- A polymer definition
- Compositional limitations (elements, metals)
- Stability (polymer must not readily degrade or decompose)
- Exclusion of certain polymer categories (e.g., cationic[16])
- Number Average Molecular Weight (Mn) thresholds and corresponding limits on oligomer content with MWs < 1000 and < 500 daltons (Da)
- Reactive Functional Group (RFG) limitations dependent on MW

These criteria rely heavily on physical-chemical properties that affect bioavailability. The Organisation for Economic Co-operation and Development (OECD) Task Force on New Chemicals Notification and Assessment conducted an Expert Group Meeting on polymers and recommended that a scientific examination of the PLC concept be performed by analysis of polymer data submitted to OECD regulatory authorities. Data for 205 polymers classified under two categories (PLCs and non-PLCs) using US criteria were reviewed with the aim of identifying correlations between polymer characteristics and potential health or ecotoxicological concerns.[17] Despite the use of some conservative assumptions, 87.8% of polymers classified as PLCs showed low health and/or low ecotoxicological concern.[18] Overall, the analysis supported the notion that using PLC criteria to exclude polymers from the need for regulatory review is sound.

IV. PLC Evolution

While the OECD study validated the PLC criteria extant in 2009, these criteria are not static. The 1995 TSCA exemption revised, added, and eliminated[19] components of the 1984 exemption. For example, the exemption now excluded water-absorbing polymers[20] with a Mn greater than 10,000. This restriction is based on an assumed mechanism for lung damage by high-MW water-absorbing polymers, which involves a failure of the lungs to clear particles of these materials. The Agency concluded that exposure to respirable fractions of these polymers might present an unreasonable risk to human health. In 2010 USEPA revised the 1995 polymer exemption to specifically exclude certain fluoropolymers.[21]

In 2020 Australia adopted a new Australian Industrial Chemicals Introduction Scheme (AICIS).[22] The scheme includes six categories of new substance introduction with different regulatory requirements proportionate to the likely level of risk. PLCs are eligible for self-assessment (no notification to the regulatory authorities required) and will not be added to the inventory. The 'Exempted Introductions' category for polymers largely incorporates the prior PLC criteria with some notable revisions. For example, based on human health and ecotoxicological concerns, substances (polymer and non-polymer) that have certain ranges of fully fluorinated carbon atoms are not eligible for an exempted introduction. It is also noteworthy that, based on human health concerns, a poly-

14 Environment Canada and Health Canada, *Approach under the* Canadian Environmental Protection Act, 1999 *to Address Polymers on the* Domestic Substances List *that were identified as priorities during categorization* (December 2014).

15 Environment and Climate Change Canada and Health Canada, *Second Phase of Polymer Rapid Screening: Results of the Screening Assessment* (April 2018).

16 Not excluded if solid, neither water soluble nor dispersible, or only used in the solid phase.

17 OECD, 'Data analysis of the identification of correlations between polymer characteristics and potential for health or ecotoxicological concern', ENV/JM/MONO(2009)1.

18 In the report, the term 'concern' is based on the intrinsic properties of the polymers not considering exposure or risk.

19 Exclusion of 1) polymers containing less than 32% carbon, 2) polymers manufactured from reactants containing halogen atoms or cyano groups, and 3) biopolymers.

20 A polymer capable of absorbing its own weight of water. Water-soluble and water-dispersible (that is, self-dispersing or already dispersed) polymers are not considered to be water-absorbing substances. Only water-insoluble, non-dispersible water-absorbing polymers are excluded.

21 75 Fed Reg 4295 (Jan 27, 2010).

22 *Industrial Chemicals Act 2019*.

mer with a Mn greater than 70,000 Da is not eligible if it is 1) insoluble in water and 2) intended for use in aerosol cosmetics. Thus, like the 1995 TSCA exemption, this exclusion incorporates physical-chemical property criteria and a specific route of exposure.

For Canada's polymer rapid screening assessment, the RRR criteria were utilized to broadly screen the 334 polymers to be evaluated. Meeting the RRR requirements was considered sufficient to conclude that a polymer does not meet the criteria in section 64 of CEPA,[23] and the polymers that qualified were excluded from further assessment. Polymers not meeting the RRR criteria were subject to a second phase of evaluation that included additional hazard and exposure criteria.

As an example, the ecotoxicological component of the second phase included a threshold for annual volume (1000 kg/year) and water extractability (greater than 2% by weight). The final step of the screening for ecotoxicological considerations involved use of release scenarios to estimate environmental exposure. For human health, the exposure bands in Table 1[24] were developed to prioritize the need for further evaluation based on exposure potential.

If a polymer was used in multiple applications and could fall into more than one exposure band, the higher band was used to determine the need for further evaluation and/or support its classification as toxic according to CEPA.

V. Economic Impact

REACH excluded polymers from registration obligations, but required polymer manufacturers and importers to register monomers and relevant reactants used in the manufacture of the polymer at greater than 2% when the volume based on polymer weight exceeded 1000 kg/year. Assuming PLC criteria are used as the initial screen to determine whether derogation from registration is warranted, these companies would then need to expend funds to generate the required data if it does not currently exist. If a polymer does not meet PLC criteria and requires registration, these companies are likely to be liable for significant expenses related to additional data generation and registration. In that case, since they have already incurred the cost to register the constituent monomers and other relevant reactants, it would seem equitable to devise a mechanism for restitution as long as the company did not and does not manufacture or import those substances.

VI. Conclusion

Revoking the exclusion for polymers under REACH presents a monumental challenge in implementation. As mentioned, it is estimated that approximately 33,000 polymers could require registration, representing roughly 11,000 unique polymers. Certainly any approach needs to have as its goal the protection of human health and the environment, but it must also be pragmatic. Adoption of the Canadian PLC criteria (essentially the same as those used in Australia and the US) as an initial screen to identify polymers that should not require registration seems a logical choice based on the following:

- The 2009 OECD study demonstrated that the vast majority of polymers classified as PLCs under the US criteria showed low health and/or low ecotoxicological concern.
- The PLC criteria have been in use in the US since 1995, Australia since 1997, and Canada since 2005 without observations of negative effects to human health or the environment.
- While Canada continues to review RRR polymers prior to commercialization, the TSCA exemption and the Australia exempted introduction for polymers do not require any notice to or evaluation by the regulatory authorities (they are 'self-actuated').

This approach to prioritization for registration is promising, but it is not without challenges.

- It is unlikely that all polymer manufacturers and importers have the data necessary to establish PLC status, and in some cases it may not be possible to generate it.
- Agreement on substance identity has been difficult for many discrete chemicals. Agreement on substance identity for polymeric substances will likely present a new set of issues.

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23 Section 64 of CEPA defines a substance as 'toxic' if it is entering or may enter the environment in a quantity or concentration or under conditions that 1) have or may have an immediate or long-term harmful effect on the environment or its biological diversity, 2) constitute or may constitute a danger to the environment on which life depends, or 3) constitute or may constitute a danger in Canada to human life or health.

24 Second Phase of Polymer Rapid Screening, page 19.

Human Health Exposure Band Classification

Band	Criteria
3	A polymer in products available to consumers that are intended to be consumed (e.g., foods, drugs, and natural health products) or intentionally applied directly to the body (e.g., cosmetics)
2	A polymer with consumer use in household products that are not intended to be applied directly to the body or consumed (e.g., cleaning products, house paint, and motor oil); or A polymer with industrial use and a reported single-company import, manufacture or use quantity > 1,000,000 kg with a water extractability ≤ 2% by weight % or > 100,000 kg with water extractability > 2% by weight
1	A polymer used in manufactured articles where it is reacted into or contained within the finished product (e.g., disposable cutlery); or A polymer with industrial use and a reported single-company import, manufacture or use quantity ≤ 1 000 000 kg with a water extractability ≤ 2% by weight or ≤ 100 000 kg with a water extractability > 2% by weight

– Obtaining confidential information from suppliers in order to make a PLC evaluation is certain to be a barrier for some non-manufacturing importers.
– As new evidence becomes available, PLC criteria can change over time, introducing complexity and uncertainty into the process.

Acknowledging the challenges, use of the Canada RRR criteria as an initial screen to exclude PLCs from registration requirements provides a practical tool to 1) eliminate substances of low concern and 2) allow the regulatory process to focus on registration of polymeric substances that might potentially pose risk to humans or the environment.

REACH Restriction and Authorisation are Driving Replacement of Harmful Chemicals

Know Your Substances Before It Is Too Late

*Jaime Sales and Dieter Drohmann**

I. Introduction

The REACH Regulation[1] has introduced significant challenges for the European chemical industry. Some of those challenges relate to technical and administrative obligations, mainly focused on the registration process, such as filling data gaps, performing physico-chemical, toxicological and ecotoxicological studies, development of (and compliance with) exposure scenarios, or payment of fees to the European Chemicals Agency (ECHA) and data owners. However, other regulatory procedures triggered by REACH may have a stronger impact in the business of chemical companies, because they may require even more burdensome actions to ensure the continued use of certain chemical substances in the EU, which may come with stringent conditions in terms of risk management measures or operating conditions to be implemented. Ultimately, in certain cases the use of some substances could be simply banned or severely restricted. Furthermore, following the implementation and development of REACH in the past years, the EU has taken the lead in triggering complex regulatory processes for industrial chemicals. Therefore, it is to be expected that such processes may be taken up in other jurisdictions, because many countries are following closely what happens in Europe in terms of regulating chemicals. So, it may be the case that regulatory pressure on a chemical could travel worldwide, hence impacting companies on a global scale.

The scope of the REACH Regulation is to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry; in the long run, it is expected that the most hazardous substances should be substituted with less dangerous ones. This second objective highlights the threat for companies that market or operate with those substances regarded as being "of concern". Under REACH, the substances that will be subject to more stringent regulatory procedures are called Substances of Very High Concern (SVHC). These are substances that meet certain criteria related to their hazardous properties, mainly (but not only) in relation to their classification and labelling as per the EU CLP Regulation[2]. However, before a substance is included in the SVHC list (also known as the Candidate List for authorisation[3]), certain steps are taken by the EU regulators to verify such condition. Since the implementation of REACH close to 15 years ago, the process to regulate such chemicals has been progressively refined, reaching a somewhat standardized system that helps to provide some predictability. Furthermore, it should also be recognized that issues identified under EU REACH will likely travel globally, resulting in scrutiny of chemicals and potential restriction under other regulatory jurisdictions. Some examples can be found under Korea-REACH[4] and the Turkish KKDIK[5].

II. Integrated Regulatory Strategy

The Integrated Regulatory Strategy (IRS)[6] was developed by ECHA based on the experience gained through the early years of implementation of REACH

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1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals.

2 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

3 See, <https://echa.europa.eu/candidate-list-table>

4 See, <https://elaw.klri.re.kr/kor_service/lawView.do?hseq=31605&lang=ENG>

5 See, <https://www.resmigazete.gov.tr/eskiler/2017/06/20170623M1-18.htm>

6 See, <https://echa.europa.eu/documents/10162/27467748/irs_annual_report_2019_en.pdf/bd23e8cb-a55a-24af-4be3-7a29828ebb09>

and CLP. The IRS was implemented in 2016, continuing previous initiatives from ECHA (e.g., the SVHC Roadmap). It brings together the various regulatory processes in order to provide a clear and coherent basis for achieving the aims of the Regulation. The main objectives of the IRS are:

- To efficiently select substances, or groups of substances, that raise potential concern.
- To identify the most suitable regulatory risk management measures by generating additional information.
- To ensure appropriate and timely intervention by all actors; ECHA, Member States, the European Commission and industry.
- To ensure that registrants meet REACH information requirements promoting communication on safe uses in the supply chain.
- To promote collaboration between authorities to ensure effective implementation of REACH and CLP processes.
- To ensure transparency and predictability of regulatory activities.

The following diagram shows the main processes and relations established between them in the IRS. It is to be noted that the diagram should be used for orientation purposes, as a substance may enter any regulatory process at any given time, without necessarily following the flow described in it (ECHA, 2020).

III. Regulatory Management Option Analysis

When evaluating chemicals, the starting point for regulators is the registration dossier, which is usually the main source of information, however other data sets (e.g., notifications to the classification and labelling inventory) may also be used. It is to be noted that certain substances that are exempted from registration may be impacted by other regulatory processes in REACH. In such cases, obtaining reliable data may pose a challenge. The next step is to perform a Regulatory Management Option Analysis (RMOA)[7] based on the information available. An RMOA intends to help authorities to clarify whether regulatory action is needed for a substance, and to identify the most appropriate measure to address a concern. While the RMOA is not present in the REACH legal text and their conclusions are not mandatory, RMOAs have proven to be a valuable tool to decide the regulatory path for substances of concern. The outcome of an RMOA will identify the most appropriate option for the substance, which could include the need to generate further information or assessment (via the Evaluation process under REACH). If the data available is deemed sufficient to establish a conclusion, there are different possibilities that can be laid out for the chemical under scrutiny. This could be the need for further regulatory risk management under REACH (e.g., restriction, SVHC listing followed by authorisation) or CLP (Harmonised Classification and Labelling), or under different regulatory schemes, such as the Chemical Agents Directive[8], Water Framework Directive[9], Industrial Emissions Directive[10], Waste Framework Directive[11], or others. Obviously, another possible conclusion is that no further regulatory action is required on the substance.

In the present paper we will focus on the REACH regulatory management options that are deemed more demanding for chemical companies marketing substances in the EU – authorisation (via prior inclusion in the Candidate List) and restriction.

IV. SVHC - Authorisation

The Roadmap for SVHC Identification and Implementation of REACH Risk Management Measures[12] established a goal for the EU to have all relevant known SVHC substances included in the Candidate List by 2020. A Member State of the European Union, or ECHA at request of the European Commission, may propose a substance to be identified as a Substance of Very High Concern (SVHC). According to

7 See, <https://echa.europa.eu/es/understandng-rmoa>

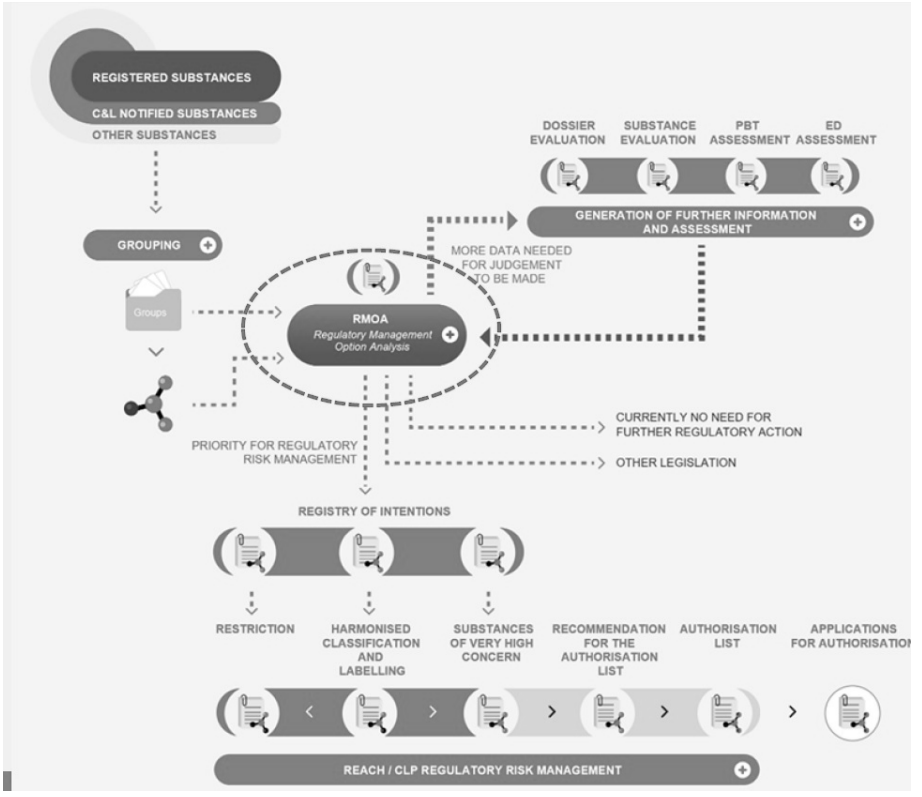
8 Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work.

9 Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy.

10 Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control).

11 Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives

12 See, <https://echa.europa.eu/svhc-roadmap-to-2020-implementation>.



Picture 1: Figure 1: Diagram of Integrated Regulatory Strategy

REACH, substances that fall under the following categories may be appointed as SVHCs:

- Carcinogenic, Mutagenic or toxic for reproduction Category 1A or 1B (CMR) according to CLP.
- Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) according to REACH Annex XIII.
- Substances that provide an equivalent level of concern, such as endocrine disrupters, or skin and respiratory sensitisers.

The inclusion of a substance in the Candidate List can be regarded in itself as an RMO. Indeed, there are certain obligations for suppliers of SVHC substances, essentially related to:

- Reporting the presence of the SVHC substance above 0.1% (w/w) in extended Safety Data Sheets provided to customers.
- Communication in the supply chain (e.g., indications on safe use in reply to customer requests).
- Notifications to ECHA if the SVHC substance is present in articles above 0.1% (w/w), if the overall volume of manufacture or import is above 1 tonne per year.

However, at present time there is no mechanism in REACH to ensure that a substance will remain in the Candidate List without further regulatory action, nor there is any official system established to remove a substance from such list if, for example, new scientific evidence would demonstrate that the classification that led to its consideration as SVHC is not fully warranted. In addition to new scientific data, delisting would likely require a Member State CLH Proposal[13], endorsement by RAC and removal by the Commission. Therefore, there is always the possibility for an SVHC substance to be eventually moved to Annex XIV of REACH – the Authorisation List.

The main objective of authorisation under REACH is to ensure that SVHC substances are progressively

13 See, <https://echa.europa.eu/es/registry-of-clh-intentions-until-outcome>

replaced by less dangerous substances or technologies, where technically and economically feasible alternatives are available. Under authorisation, the ultimate goal for EU authorities is to phase out the use of SVHCs in Europe; if this is not possible, the risk of the continued use must be adequately controlled. Where this is not fully possible (e.g., in the case of substances for which a safety threshold cannot be established), it must be demonstrated that the socio-economic benefits of the continued use of the substance for the European society outweighs the remaining risks, which in any case must be minimised. It is to be noted that between the inclusion of a substance in the Candidate List as an SVHC, and the selection of the substance for authorisation, there is an additional step known as prioritisation, by which ECHA periodically recommends a selection of SVHC substances to be included in REACH Annex XIV. It is eventually the European Commission that takes the final decision, based on the opinion from the Member States Committee.

Whereas the obligation to register chemical substances under REACH lies with the manufacturers or importers, the requirements of the authorisation process impact all users of a substance. So, downstream users under REACH who may have had a limited involvement with the regulation will be fully impacted if they use a substance that is placed in the Authorisation List. Certain uses are exempted from authorisation, for example substances that can be defined as intermediate substances under the definition of REACH; still, companies relying on an authorisation exemption need to be careful, since there is currently an intense debate on-going in the EU related to the specific conditions under which a substance can be considered to be used as an intermediate.

Companies that wish to obtain an authorisation from the European Commission to continue with their use need to be covered by an Application for Authorisation (AfA)[14]. This AfA will include the following elements:

- Chemical Safety Report (CSR), providing proof that the risk derived from the use of the substance is adequately controlled. Applicants need to demonstrate that each use is adequately described, while providing sufficient detail to ascertain that a thorough risk assessment has been performed.
- Socio-Economic Analysis (SEA), demonstrating that the socio-economic benefit of use outweighs the residual risk. For substances that have a safety threshold, the SEA is optional (but highly recommendable). The global impact of the substance in the EU has to be evaluated, comparing the cases in which the use is continued against a non-use scenario. This needs to include all potential cost aspects (e.g., potential cancer treatment of identified number of potential cases, if the SVHC is a carcinogen), and benefits from developing possible alternatives, in addition to direct economic impact for the applicant or EU industry.
- Analysis of Alternatives (AoA), describing if there are *suitable alternatives* to the SVHC for each one of its uses. The term *suitable alternative* needs to be evaluated carefully. An increasing concern by regulators comes from regrettable substitution (replacing a chemical by another one which in the end will exhibit the same hazard properties as the one it is intended to replace). The key characteristics to consider an alternative as viable are:
- It delivers similar technical performance; this may not always be easy to proof – or challenge.
- It is available in sufficient quantity, at reasonable cost and in time (it may not be available today, but it could be reasonably expected that it will be in a few years). It has to be noted that an alternative may be regarded as viable by authorities if it is considered to be a Suitable Alternative Generally Available (SAGA) even if a particular user may not be fully prepared to implement it, for whatever reason.
- It results in reduced overall risk compared to the SVHC.

In terms of timing, two dates are relevant when a substance is included in the Authorisation List:

- Latest Application Date (LAD): it is the last date to submit an AfA after inclusion the substance in Annex XIV (typically between 18 and 30 months).
- Sunset date: this is the date from which a substance in Annex XIV cannot be used without an authorisation granted by the European Commission for that use (generally this is 18 months after the LAD).

Combined with the relatively tight deadlines described above, the particularities of the authorisation

14 See, <https://echa.europa.eu/applications-for-authorisation-consultation>

process with regards to supply chain organization may give rise to significant complexities for industry to coordinate, build and manage an AfA. Unlike registration, under authorisation companies involved in the same uses of a substance may decide to pursue authorisation on an individual basis, although joint submission is possible. Furthermore, manufacturers and importers may apply on behalf of their downstream users, or the users may apply directly for their own uses. Users need to remind that if they rely on a supplier applying on their behalf, they become tied to that supplier (i.e., they can only source the substance from the supplier(s) that have covered them in their AfA). Therefore, there are a number of key strategic factors for companies to evaluate, when deciding their strategy on how to face their obligations under authorisation – with limited time to take such decisions and implementing the agreed strategy.

Following opinions from the RAC[15] and SEAC[16] committees of ECHA, the European Commission may decide to reject or to grant an authorisation. Even if granted, this is not forever. An authorisation will be granted under a certain review period, which is the time until the company will need to reapply again for the same use. Standard review period is 7 years, although periods of 4 or 12 years are also possible (in cases where users have identified alternatives but those cannot yet be implemented, applicants may request a specific review period covering the time in which they consider that implementation will be possible). The review period will essentially depend on the opinion of the committees which will be based on the quality of the AfA. The key quality parameter to consider is uncertainty; the higher the uncertainty, the lower the review period. In general, very broad AfAs intended to cover a large number of different uses or situations are in larger risk to present higher uncertainty, resulting in more chances of getting a reduced review period. Longer review periods than 12 years may be possible for specific cases of uses deemed to be critical in which no substitution is possible. This is why ensuring that the use is adequately described and providing high quality information AfA is crucial. At the end of the review period, a new AfA needs to be submitted, which should be focused on the efforts performed during the review period to find a viable alternative to the SVHC.

Even if an authorisation is granted, the European Commission may impose additional technical conditions that perhaps the applicant was not expecting. In addition, there are fees to be paid to ECHA, per substance, use and legal entity. All of these features render authorisation under REACH a significant challenge to industry; companies dealing with SVHCs, or substances that meet the criteria to be identified as SVHCs at one point in time, will need to plan ahead of time what their strategy will be, as there could be significant business impacts for a substance placed in the Authorisation List.

V. Restriction

The aim of the restriction process under REACH is to limit or ban the manufacture, placing on the market and/or use of certain substances, when it has been established that they pose an unacceptable risk to human health and/or the environment at Community level. Restricted substances are listed in REACH Annex XVII. Unlike authorisation, the responsibility to put together a restriction dossier lies on authorities (Member States or ECHA). Ultimately, it is expected that safe uses of substances would be allowed to continue, while those posing an excessive risk will be banned.

A restriction may include derogations on specific cases or conditions under which a use may be continued, as well as timelines until the restriction becomes mandatory for all or a selection of uses. It may cover issues related to imported articles that contain SVHCs (a case which is not covered by the authorisation process), and it also involves the opinions from RAC and SEAC, which have fixed deadlines to provide such opinions from the date that the restriction proposal is put forward. Public consultations allowing for stakeholders (industry, other authorities or NGOs) will be launched during the process.

Although typically restriction is regarded as a more flexible tool compared to authorisation by industry, companies need to be aware of how the restriction proposal is put forward, as it may also introduce unexpected conditions, which could result in challenges for companies to continue their use.

15 See, <https://echa.europa.eu/about-us/who-we-are/committee-for-risk-assessment>

16 See, <https://echa.europa.eu/about-us/who-we-are/committee-for-socio-economic-analysis>

While the fact that it is the responsibility of authorities to put forward restriction dossiers may remove some burden from industry, there is also a negative factor in that industry loses control of the content of the dossier, or of how this is presented. It is to be noted that a restriction dossier needs to include risk assessments and socio-economic evaluations, as in the case of an AfA.

Although conceptually different, authorisation and restriction aim for the same objective, which is the replacement of substances or applications that generate a situation of concern in relation to human health or the environment with safer alternatives. In fact, a recent document published by ECHA it was concluded that to this date, restriction is perceived as a stronger incentive for substitution by the chemical industry.

VI. Impact on suppliers and users of chemicals

The previous sections have described, in a highly summarized way, the key features of the more stringent regulatory procedures under REACH, and how some of them may be interconnected. Those procedures may result in significant challenges for industry, which could face severe impacts in terms of business performance and strategy, particularly related to forecasting market access and market trends in Europe for the long term. While the pressure to replace substances of concern by viable alternatives, companies will need to place effort to avoid regrettable substitution. It is therefore important that companies plan the different options that they may take ahead of time, when facing such challenges. The following reflections aim at offering a starting point with questions that may help in the process of making managerial decisions, in relation with different regulatory processes.

1. Know your Substance

- Do you supply or use substances included in the Candidate List, or that meet the criteria to make them eligible to be identified as SVHC in the future?
- Is the substance critical for your business? How would your company react in front of potential market restrictions due to regulatory developments?
- Is your use critical for your supplier of the substance? If so, you should ensure that you would get support in e.g., AfA (this does not necessarily mean that your supplier would apply for authorisation on your behalf, but that they will support you to ensure that your use will be adequately covered in an AfA, which may be submitted by your company).
- Are there suitable alternatives available, that would allow you to replace the substance that you use, or that would allow your customer to substitute the substance that you supply for their use?
- Is it expected that alternatives will become available in the future? Companies need to be aware of R&D initiatives, not only internal ones, but also from other stakeholders. This may of course not always be easy, but it needs to be considered that in the authorisation process, AoAs will be made public, offering stakeholders (e.g., companies focused on developing alternatives to SVHCs) the opportunity to comment and eventually challenge conclusions stating that no alternatives are available.
- Are you using or supplying a substance that is chemically similar to an SVHC, but not yet included in the Candidate List, or classified with the same hazard properties?
- Ultimately, remember to ensure that the registration dataset and strategy (e.g., read-across) is solid, or review it if regulatory challenges can be anticipated; follow-up on external initiatives, e.g., divergent classifications via the C&L inventory.

2. Be Alert on Regulatory Initiatives

- Despite efforts by ECHA (e.g., with the IRS), it is still uncertain to anticipate when regulators may initiate action on a given chemical. Be prepared and plan possible future impacts with sufficient time.
- Authorities are not always clear in terms of why one substance is picked and not the other, or when actions may be started, however this is improving via the standardisation of the RMOA procedure or the focus on groups of chemicals.
- Timing of regulatory processes is always a challenge, especially when discussions are required

within the supply chain. Organisation of AfAs involving various actors in the supply chain may be a significant effort, therefore communications need to be efficient. For this reason, potential roadblocks (e.g., sharing of Confidential Business Information) need to be identified and managed.
– Beware of regrettable substitution. The trend from regulators is to look more at groups of similar chemicals, or chemicals that have a similar function. So, companies need to be aware of developments for "similar" chemicals to the ones they handle.
– Replacing a chemical with a "less regulated alternative" instead of a "lower risk alternative" may generate future problems (e.g., investing in a substitute which may proof to be unacceptable in the mid-term).

3. Build up your Case

– Authorisation may reshape business strategies for the whole supply chain, e.g., applicants may focus on uses that are critical for their business, due to high costs of AfAs; be ready to defend your case, highlighting the reasons why you believe that your use is critical for the wellbeing of the European society.
– Be proactive and engage with your supply chains (suppliers, customers, industry associations) to coordinate actions if a chemical of interest is under scrutiny e.g., providing input into RMOAs or SEAs. Do this in the earliest stages of the regulatory processes, or even before they are started.
– Solid scientific arguments are necessary, but adequate advocacy actions to defend proportionate regulatory management options will likely be essential as well.
– Consider that there may be a need to "sacrifice" something, e.g., a use with higher exposure, or a more toxic substance within a group of chemicals.
– Collect accurate exposure data and make sure that demonstration of controlled/minimum risk is possible. As a general principle, data coming from real measured exposure (workplace monitoring, emissions to the environment) are preferred against modelled data, which can be used but with verification of reliability.
– Feedback from users is generally more valuable than that from manufacturers, as it can provide a broader picture of the importance of the continued use of a substance for the European society.
– Evaluate global impacts of a potential ban on a given substance, taking into consideration how key EU strategies like the Green Deal, Chemical Strategy for Sustainability, Climate objectives (e.g., decarbonization) could be impacted.
– An SEA must evaluate not only damage to industry (or one company), but overall impacts for the EU, for example, the benefits in terms of savings due to reduced health or environmental impacts coming from the ban of a substance, or opportunities for business development if alternatives can be implemented.
– While it is essential to provide accurate estimations of potential economic and labour impact, consequences of potential loss of employment should not be overestimated; workers may find other jobs (differences on employment evolution within different countries in the EU should be considered), and alternative technologies may emerge that could absorb lost labour force for one banned chemical.

VII. Conclusions

Chemical companies that are (or that may be in the future) impacted by REACH beyond the registration process should take actions in order to ensure that their regulatory affairs departments are closely linked with the company's business strategy and key departments (commercial, operations, R&D), because the regulatory developments may have significant influence in defining where and how a company can operate or sell.

Being aware of potential regulatory risks derived from the chemicals that a company handles, by following initiatives from regulators, and engaging with the supply chain in order to be informed on their plans in case a substance is placed on the regulatory radar should be continued actions that every company handling substances of potential concern should undertake on a regular basis. Also, ensuring that reliable data is available in order to define the continued use of that substance (in terms of exposure, socio-economic importance or alternatives) should be a top priority. Special attention should be placed in avoiding overconfidence derived from the use of chemicals that may be regarded as 'safe', when similar sub-

stances are pushed into the regulatory processes. This could lead to a situation of regrettable substitution, which may damage the company's reputation but also result in significant economic damage due to substitution efforts being placed on adapting the process to a solution that is not sustainable in the future.

Chemical Legislation in Serbia: An Overview

*Alja Livio Torkhani**

I. Introduction

At the proposal of the Ministry of European Integration, the Government of the Republic of Serbia adopted the 3rd revised version of the National Program for the Adoption of the Acquis Communautaire (NPAA, Nacionalni program za usvajanje pravnih tekovina Europske unije) at its session on 1st March 2018.

The NPAA is the most important and comprehensive document in the process of the European integration of Serbia, considering that in addition to harmonizing the entire domestic legislation with EU law, it also envisages the obligation to strengthen administrative capacities during accession negotiations with the EU, as well as long-term financial planning and responsible budget planning.

According to the NPAA, it is planned to fully harmonize the legislation with EU law by the end of 2021, followed by a period of monitoring the implementation of regulations until accession.[1] One of the chapters related to current Serbian negotiations with the European Union is Part 27, which is focused on adopting EU Legislation in the field of environmental protection, including management of chemicals.

II. Legal Background

In Serbia the competent authority for safe management of chemicals is the Serbian Ministry of Agriculture and Environmental Protection with its Department of Chemicals as the central administration. The Republic of Serbia passed in 2009 the Law on Chemicals (Zakon o hemikalijama).[2] This law regulates integrated management of chemicals, classification, packaging and labeling of chemicals, integrated register of chemicals and register of chemicals placed on the market, restrictions and prohibitions on production, placing on the market and use of chemicals, import and export of certain hazardous chemicals, licenses, marketing authorizations for the use of particularly hazardous chemicals, placing on the market of detergents, systematic monitoring of chemicals, availability of data, supervision and other issues of importance for the management of chemicals.

Another important act in Serbia concerning chemical control is the Law on biocidal products (Zakon o biocidnim proizvodima).[3] The public debate on the draft legislation was held in the period from 25th October until 23rd November 2018 and was conducted by the Ministry of Environmental Protection according to the Public Hearing Program.[4] The draft text was posted on the Ministry's website[5], and remarks, proposals and suggestions were submitted to the Ministry.

Bylaws based on both above mentioned regulations can be found in the List of regulations issued by the Serbian Ministry of Agriculture and Environmental Protection and its Department of Chemicals.[6]

Important part of Serbian legislative framework concerning chemicals is also the Law on General Use Items (Zakon o predmetima opšte upotrebe).[7]

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1 Ministry of European Integration, Government of the Republic of Serbia, Ministarstvo za evropske integracije Republike Srbije, see < mei.gov.rs/srl/vesti/1295/189/335/detaljnije/usvojena-treca-revidirana-verzija-nacionalnih-programa-za-usvajanje-pravnih-tekovina-eu/9 >accessed 25th November 2020;

2 Law on chemicals, Official Gazette 36/2009, 88/2010, 92/2011, 93/2012, Zakon o hemikalijama, Službeni glasnik 36/2009, 88/2010, 92/2011, 93/2012, see < pravno-informacioni-sistem.rs/SlGlasnikPortal/eli/rep/sgrs/skupstina/zakon/2009/36/5/reg >, accessed 25th November 2020;

3 Law on biocidal products, Official Gazette of the Republic of Serbia, 36/2009, 88/2010, 92/2011, and 25/2015, Zakon o biocidnim proizvodima, Službeni glasnik 36/2009, 88/2010, 92/2011, i 25/2015, see < pravno-informacioni-sistem.rs/SlGlasnikPortal/eli/rep/sgrs/skupstina/zakon/2009/36/6/reg > accessed 23rd November 2020

4 Izveštaj sa javne rasprave o Nacrtu zakona o biocidnim proizvodima, 2018, see < ekologija.gov.rs/izvestaj- sa-javne-rasprave-o-nacrtu-zakona-o-biocidnim-proizvodima > accessed 11th November 2020;

5 Izveštaj sa javne rasprave o Nacrtu zakona o biocidnim proizvodima (Note 5);

6 List of regulations in the field of environmental protection in the Republic of Serbia, 2017, page 13 and 14, see < ekologija.gov.rs/wp-content/uploads/inspekcija/List_of_regulations.pdf > accessed 19th November 2020;

7 Law on General Use Items, Official Gazette 25/2019, Zakon o predmetima opšte upotrebe, Službeni glasnik, 25/2019, see < paragraf.rs/propisi/zakon-o-predmetima opste-upotrebe.html > , accessed 25th November 2020;

1. Serbian Law on Chemicals

Serbian Law on Chemicals is composed of 15 chapters. The following subjects are dealt with in this regulation:
- Chemical Inventory,
- Classification, Packaging and Labeling of Chemicals,
- Restrictions and Prohibitions on the Production, Placing on the Market and Use of Chemicals;
- Import and Export of Certain Dangerous Chemicals;
- Permits for Performing Trade Activities and Permits for the Use of Certain Dangerous Chemicals;
- Integrated Chemical Management;
- Placing on the Market of Detergents;
- Obligations of Chemical Advisors;
- Systematic Monitoring of Chemicals;
- Availability of Data;
- Supervision and other Issues of Importance for the Management of Chemicals.

a. Definitions of terms with respect to the Serbian Law on Chemicals

According to Article 3 the below mentioned terms are defined. Below only those are referenced, which are used as well under EU REACH (Regulation (EC) No 1907/2006).[8]
- Downstream User:

  A legal entity or entrepreneur based in the territory of the Republic of Serbia, which is not a manufacturer or an importer of the substance, and who uses the substance or substance contained in the mixture for industrial or professional purposes, including the person producing the mixture. The distributor and consumer are not considered downstream users.
- Distributor:

  A legal entity or entrepreneur based in the territory of the Republic of Serbia, which stores and places chemicals on the market.
- Scientific Research and Development:

  The scientific experimentation, analysis or research of chemicals carried out under controlled conditions.
- Article:

  An object which during production has been given a certain shape or design which determines its function more than its chemical composition.
- Manufacturing:

  Production or extraction of substances in their natural form.
- Manufacturer:

  A legal entity or an entrepreneur who manufactures a substance.
- Placing on the Market:

  The supply or making available of chemicals to third parties in the territory of the Republic of Serbia, either with or without compensation, whereby import is also considered to be placing on the market.
- Substance:

  A chemical element and its compounds in the natural state or obtained in the manufacturing process including additives necessary to maintain its stability and impurities arising from the applied process, excluding solvent which can be separated so as not to affect the stability of the substance or change its composition.
- Preparation:

  A mixture or solution of two or more substances.
- Exposure Scenario:

  Set of risk-management conditions and measures, including workplace conditions, which describe how a substance is produced or used during its life cycle, how the manufacturer or importer can control it, and which recommend to the downstream user how to to control the substance when people and the environment are exposed to it, provided that the recommendation may relate to one specific process or method of use or several processes or methods of use of the substance.
- Supplier of a substance or a preparation:

  A legal entity or entrepreneur who is a manufacturer, importer, distributor or downstream user, who places chemicals on the market.

The Serbian law on chemicals defines some terms that are not mentioned in REACH:
- **Detergent** is defined as a substance or mixture that contains soaps or other surfactants and is used for washing and cleaning. Detergents also include

8 Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals-REACH, 2006, see < eur-lex.europa.eu/legal-content/EN/PDF/TXT/?uri=CELEX:32006R1907&from=EN > accessed 19th November, 2020;

auxiliary washing mixtures (pre-washing, rinsing or bleaching of clothes), fabric softeners, mixtures for other cleaning and the like. European authorities have on the other hand clarified in Questions and agreed answers concerning the correct implementation of Regulation (EC) No 648/2004 on detergents that cleaning products without soaps and surfactants can also be subjected to regulations on detergents.[9]

- **Good Laboratory Practice (GLP)** is laboratory practice that is carried out in accordance with the principles (guidelines) prescribed by the law governing drugs and medical devices.[10]
- **Revocation** is any activity or measure that enables the return of a chemical or product which the manufacturer or distributor has already delivered or made available to consumers or downstream users.
- **Withdrawal** is any activity or measure that prevents further supply and making available of chemicals or products placed on the market.
- **Complete aerobic biodegradability** is such a level of biodegradability that the surfactant is completely decomposed into carbon dioxide, water and mineral salts with the help of microorganisms in the presence of oxygen (mineralization).
- **Washing** is the cleaning of laundry, dishes and hard surfaces.
- **Primary biodegradability** is a structural change (transformation) of a surfactant under the action of microorganisms, which loses its surface active ability due to the degradation of its structure.
- **Handling** is the production, processing, packaging, storage, trade, transport and use of chemicals or any other activity related to chemicals.
- **Surfactant** is any organic substance or mixture having surface active properties and containing one or more hydrophilic and hydrophobic groups capable of reducing the surface tension of water by forming a spread or adsorbing monolayer at the water-air contact and forming an emulsion or microemulsion or micelles, as and to be adsorbed on the water-solid surface contact.
- **Chemical name** according to the IUPAC nomenclature is the name of the chemical identified in the nomenclature of the International Union of Pure and Applied Chemistry (IUPAC).
- **A chemical** is a substance and a mixture.
- **Chemical and product intended for general use** is a subject of general use in terms of the law governing the safety of general use objects.[11]
- **Cleaning** is the definition of this term from the standard SRPS ISO 862.[12] This differs from the EU regulation. Reference to the ISO 862 definition was removed from the Regulation 648/2004/EC on Detergents by amendment by (EU)259/2012.[13, 14]

b. Application of the Serbian Law on chemicals

The legislation does not apply to:

- radioactive chemicals,
- chemicals in transit,
- transport of dangerous chemicals,
- chemicals which are considered waste in terms of the provisions of the law governing waste management;[15]
- chemicals which are under customs control in a customs warehouse or free zone for re-export or transit if the chemicals are not processed or processed there.

The provisions of the Law on chemicals relating to the entry of chemicals in the Register (Inventory) of Chemicals and to the entry of substances of concern in the Register of Chemicals shall not apply to chemicals that are placed on the market in final form as:

- Biocidal Products,
- Plant Protection Products,
- Medicines and Medical Devices used in human and veterinary medicine,
- Cosmetic products,
- Food, Food Additives and Flavors,
- Animal Feed and Food Additives.

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9 Questions and agreed answers concerning the correct implementation of Regulation (EC) No 648/2004 on detergents, see < file:///C:/Users/windows/Downloads/2018-12-19_Detergents%20FAQ_clean.pdf >, accessed 5th February 2021

10 Law on Drugs and Medical Devices, Official Gazette 30/2010, 107/2012, 113/2017 and 105/2017, Zakon o lekovima i medicinskim sredstvima, Službeni glasnik 30/2010, 107/2012, 113/2017 i 105/2017;

11 Law on General Use Items (Note 8);

12 Serbian Institute for Standardisation, Institut za standardizaciju Srbije, Surfactants SRPS ISO 862:1994;

13 Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents

14 REGULATION (EU) No 259/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 14 March 2012 amending Regulation (EC) No 648/2004 as regards the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents

15 Law on Waste Management, Official Gazette of the Republic of Serbia 36/2009, 88/2010, 14/2016, 95/2018, Zakon o upravljanju otpadom, Službeni glasnik 36/2009, 88/2010, 14/2016, 95/2018;

The provisions of this law relating to the classification, packaging and labeling of chemicals do not apply to the following categories of chemicals:
– which are used for scientific research and development and which are not placed on the market, but are used under controlled conditions where exposure is reduced;
– which are placed on the market in the final form as:
– Medicines and Medical Devices used in human and veterinary medicine,
– Cosmetic Products,
– Food, Food Additives and Flavorings,
– Animal Feed and Food Additives.

The provisions of this Law from Chapter VIII relating to the import and export of certain hazardous chemicals shall not apply to:
– Chemical Weapons and Precursors for Chemical Weapons;
– Precursors of Narcotic Drugs and Psychotropic Substances;
– Food and Food Additives;
– Animal Feed and Food Additives;
– Medicines used in human and veterinary medicine;

- Chemicals used for Scientific Research and Development in an amount that does not affect human health and the environment, and does not exceed 10 kg for each chemical at each import.[16]

c. Classification, packaging and labeling of chemicals

Chapter IV regulates classification, packaging and labeling of chemicals. Further details are set in the Rulebook on classification, packaging, labeling and advertising of chemicals and certain products.[17] Article 9 states that the manufacturer, importer or downstream user who places chemicals and certain products on the market is obliged to classify them, and the supplier of chemicals to label and package them in accordance with this law and regulations adopted on the basis thereof. The exporter is obliged to package and label the exported chemical in accordance with this law and regulations adopted on the basis thereof, unless it is necessary to package and label the chemical in a different way, in accordance with international standards, required by the country to which the chemical is exported.

A dangerous chemical is defined as a chemical that can be classified into at least one of the hazard classes. Within hazard classes, chemicals can be further classified based on the route of human or environmental exposure to the chemical or on the nature of the effects.

A substance is classified in accordance with the classification of a substance with the same chemical composition from the List of Classified Substances.[18]

If a substance is not on the List of Classified Substances or listed in the respective hazard classes, the classification of that substance is based on existing data on the properties of that substance.

The classification of a mixture is performed by assessing the hazard of the mixture on the basis of data on the properties of the substances contained in the mixture or by direct experimental tests of properties of the mixture.

When classifying a chemical, data from epidemiological studies, statistical data on occupational diseases, as well as data obtained by other internationally accepted methods for determining the properties of chemicals can be used.

Evidence of chemical hazards obtained from animal studies shall be used for classification, regardless of the shortcomings of the findings related to effects on humans.

The properties of a chemical for the purpose of its classification are determined on the basis of the form or physical condition in which the chemical is placed on the market, and in special cases on the basis of the form or physical condition in which the chemical is used.

In addition the Environmental Ministry shall issue legislation, which is regulating the procedures of classification, packaging, labeling and advertising of chemicals and certain products in accordance with the Globally Harmonized System (UN GHS).[19]

16 Law on Chemicals (Note 3);

17 Rulebook on classification, packaging, labeling and advertising of chemicals and certain products, Official Gazette 105/2013, 52/2017, 21/2019, Pravilnik o klasifikaciji, pakovanju, obeležavanju i oglašavanju hemikalije i određenog proizvoda;

18 Rulebook regarding list of classified substances, Official Gazette 22/2020, Pravilnik o spisku klasifikovanih substanci, Službeni glasnik 22/2020;

19 Globally Harmonised UN Classification and Labeling System, 2019;

d. Chemical Advisor

Part V describes the role of the adviser for chemicals. It requires that suppliers of hazardous chemicals are obliged to appoint a person who takes care of the proper management of these chemicals (hereinafter: chemical advisor). However, certain suppliers are not obliged to appoint

a chemical advisor. Environmental Ministry still needs to define in detail which sectors shall nominate the advisor.

The chemical advisor must have appropriate qualifications and have passed the Chemical Advisor Exam. The knowledge of chemical advisors is checked every six years. The Ministry defines the education, training program and the testing of knowledge of chemical advisors.

Training and testing of knowledge of chemical advisors according to the defined programs is performed by a legal entity or an entrepreneur who meets the requirements in terms of professional staff, premises and technical equipment for conducting the training. The Ministry shall issue an approval to a legal entity or entrepreneur who has met the conditions for appropriate training.

In order to manage hazardous chemicals in a way that reduces the risk and minimizes the harmful effects of these chemicals on human health and the environment and ensures the application of preventive measures, the chemical advisor shall ensure that the Law on chemicals and regulations adopted on its basis are properly applied.

e. Integrated register of chemicals

The Republic of Serbia introduced an integrated register of chemicals (Inventory), which is outlined in Part VI. Detailed information regarding the integrated register of chemicals is described in the Rulebook on the Register of Chemicals.[20]

Article 38 provides information on what kinds of chemicals are included in the Register. The Integrated Register consists of the Register of Chemicals and the Register of Biocidal Products as well as data on Plant Protection Products (PPPs).

Data on PPPs are general data on the trade names, names and properties of active substances, permitted uses, the person who places them on the market and the quantities placed on the market that the body responsible for plant protection received during registration procedure on the basis of the law governing PPPs.

The body responsible for plant protection shall submit to the Environmental Ministry the required data once a year, but no later than 31st March of the current year for PPPs placed on the market in the previous year.

The Environmental Ministry also maintains the Integrated Register of Chemicals as an electronic database for the purpose of data exchange and integrated management of chemicals. Chemicals that are produced or imported to the Serbian market are entered in the Register. Chemicals that have certain properties or are used for certain purposes are not entered in the Register, and they are placed on the market in quantities that are below the defined lower limit on an annual level. The Ministry does define certain chemicals that are not entered in the Register, as well as the lower volume limits of a chemical of certain properties and manner of use, below which that chemical is not entered in the Register.

Artlicle 40 requires that the manufacturer, importer or downstream user (the person who registers chemicals) is obliged to submit an application for entry of chemicals in the Register to the Environmental Ministry by March 31st of the current year for chemicals produced or imported in the previous year.

Confidential data required for the entry in the Register may be submitted by the foreign manufacturer directly or through an eligible representative.

The application shall contain: name and address, tax identification number, type of activity and name of the responsible person in the company (chemical advisor) who is obliged to present document that he/she is qualified in this field.

Along with the application a dossier on each chemical and for some chemicals also Safety Data Sheet shall be submitted. The chemical dossier shall contain in particular:

- Trade name of the chemical and other identification of the chemical,
- Data on the quantity of the chemical placed on the market,
- Data on each manner of use of the chemical,
- Data on chemical composition.

20 Rulebook on the Register of Chemicals, Official Gazette 16/2016, 06/2017, 117/2017, 44/2018, 7/2019 and 93/2019, Pravilnik o registru hemikalija, Službeni glasnik 16/2016, 06/2017, 117/2017, 44/2018, 7/2019 i 93/2019;

The Ministry shall define in detail the content of the chemical dossier. The electronic portal for integral register of chemicals, e-IRH portal, operates since 1st January 2019, when the legal obligation to report chemicals in the Register was put in place.

f. Other Parts

Other parts of the regulation include the following subjects:
- Restrictions and Prohibitions on the Production, Placing on the Market and Use of Chemicals (part VII),
- Import and Export of Certain Hazardous Chemicals (part VIII),
- Licenses for performing Traffic Activities and Licenses for the Use of Especially, Hazardous Chemicals (part IX),
- Detergents (part X),
- Systematic Monitoring of Chemicals (part XI),
- Data Availability (part XII),
- Control (part XIII),
- Penalties (part XIV) and
- Transitional and final provisions (part XV).

2. Classification of chemicals according to the Rulebook on Classification, Packaging, Labeling and Advertising of Chemicals and Specific Products and its Interconnection with the Law on Chemicals

Basic provisions regarding packaging, labeling and advertising of chemicals are set in the Articles 16 to 19 of the Law on Chemicals. An additional relevant document concernig classification, labeling and packaging of chemicals is the Rulebook on Classification, Packaging, Labeling and Advertising of Chemicals and Certain Products.

The packaging of a dangerous chemical and a specific product must correspond to the properties, purpose and manner of use of the chemical or product and must be marked in the described manner.

Packaging of a dangerous chemical, a certain product and a certain mixture that is not dangerous, but contains at least one substance classified as dangerous, must be disclosed so that it contains the trade name of the chemical, names of certain dangerous substances contained in the mixture, name and address of the chemical supplier, the amount of chemical in the packaging as well as graphic elements, labels and text indicating the hazardous properties of the chemical.

The packaging of a chemical and a certain product must be referenced in the Serbian language.

The method of labeling and packaging of a hazardous chemical depends on whether the chemical is packaged in both inner and outer packaging.

The Environmental Ministry has yet to further clarify in more detail the procedures and types of packaging and labeling of a chemical and a certain product.

The supplier of a dangerous chemical and a certain mixture that is not dangerous, but contains at least one substance that is classified as dangerous, is obliged to emphasize its dangerous properties in the advertisement and to advertise it in such a way that its users are not misled about the dangerous properties of the chemical.

A substance may be classified differently from a classification of a substance of the same chemical composition, which is included in the EU Classification and Labeling Inventory.[21] In that case, when entering the substance in the Register of Chemicals, together with the dossier on the chemical, an explanation for such differing classification shall be submitted.

In general, a substance shall be classified in accordance with the classification of a substance of the same chemical composition which is included in the EU Inventory of Classification and Labeling if the classification is the same and if it is included in the List of Classified Substances.

Article 19 also states that the supplier is obliged to keep records on chemicals, which in particular contain data on the identity of the chemical, distributors or downstream users and the quantities of chemicals delivered to them, as well as on the total quantities of chemicals sold to consumers in a calendar year. The supplier is obliged to collect all data on chemicals related to classification and labeling as well as other data necessary for the implementation of this law. The supplier is obliged to keep the records referred to in paragraph 1 of this Article and the data

21 EU Classification and Labeling Inventory, see < echa.europa.eu/information-on-chemicals/cl-inventory-database >, accessed 16.1.2021;

for at least 10 years after the last production, placing on the market and use of the chemical and to submit them to the Environmental Ministry upon request. If the supplier has ceased his business or divested part of his business to a third party, the obligation to keep and retain data and information passes to that person, and if the responsible person of the supplier has stopped working, he is obliged to submit the data to the Ministry immediately after termination.

III. Safety Data Sheet Content in the Republic of Serbia and Labels for Serbian Market

1. Safety Data Sheets

The Safety Data Sheet content is set in the Rulebook Concerning the Content of the Safety Data Sheet.[22]

The supplier is obliged to submit a Safety Data Sheet when placing on the market a dangerous chemical, a chemical containing substances identified as persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative. (vPvB) and other chemicals that have very high concerning properties to any other distributor or downstream user in the supply chain free of charge, in printed or electronic form and in Serbian language.

The Serbian exporter of a chemical is obliged to submit the Safety Data Sheet to the non-Serbian importer, and if possible the Safety Data Sheet should be in the language of the country to which it is exported.

The supplier is obliged to deliver the Safety Data Sheet to any other distributor or downstream user in the supply chain at their request, when they procure a mixture that is not classified as hazardous and contains:

- at least one dangerous substance, based on the danger that the substance poses to human health and the environment, in the amount of at least 1% by weight of the non-gaseous mixture, or at least 0.2% of the volume of the gaseous mixture;
- at least one substance, in the amount of at least 0.1% by weight of a mixture that meets the criteria for identification as PBT or vPvB or other substances that have the properties referred to in Article 43, paragraph 3 of the Law on chemicals;
- a substance for which occupational exposure limits (OEL) exist.

A Safety Data Sheet must contain the issuing date. The content is divided into 16 Chapters according to the REACH format.

1) Identification of the chemical and data on the person who places the chemical on the market (supplier);
2) Hazard Identification,
3) Data on the Ingredients in the Mixture,
4) First Aid Measures,
5) Fire Protection Measures,
6) Measures in Case of a Chemical Accident,
7) Handling and Storage,
8) Exposure Controls and Personal Protection,
9) Physical and Chemical Properties,
10) Stability and Reactivity,
11) Toxicological Data,
12) Ecotoxicological Data,
13) Waste Treatment and Disposal,
14) Transport Data,
15) Regulatory Data,
16) Other information.

The chapter on identification of chemical and data concerning supplier who places the chemical on the market is described in the Article 3 of the Rulebook Concerning the Content of the Safety Data Sheet and must contain following information:

1) the name of the chemical which must be identical to the name on the label of the individual package and in accordance with the regulations governing the classification, packaging and labeling of chemicals;
2) data on all known ways of using the chemical, and when the chemical can be used in more ways, only the most important or common uses are given, as well as a brief description of the chemical's action (e.g. antioxidant, antifreeze, etc.);
3) data on the legal or natural person who places the chemical on the market, as follows:

a) the name of the legal or natural person who places the chemical on the market;
b) whether that person is a manufacturer, importer or distributor;
c) address and telephone number;
d) e-mail address of the person in charge of preparing the Safety Data Sheet, and if that person is not located in the Republic of Serbia, the contact de-

22 Rulebook concerning the content of the Safety Data Sheet, Official Gazette 100/2011, Pravilnik o sadržaju bezbednosnog lista, Službeni glasnik 100/2011;

tails of the person in charge of submitting the safety data sheet with residence in the Republic of Serbia (telephone number and full address);

e) emergency telephone number of the legal or natural person who places the chemical on the market, that is, the telephone number of the Poison Control Center, with an indication

f) time at which the telephone number is available (eg twenty-four hours or only during working hours, etc.).

Sections of the Safety Data Sheet are subdivided. Detailed descripition regarding compulsory data for each subsection can be found in articles 7 to 25 of the Rulebook Concerning the Content of the Safety Data Sheet. If one Safety Data Sheet in all chapters contains information that is relevant for two or more chemicals, one Safety Data Sheet may be provided for those chemicals, provided that Chapter 1 provides identification for all chemicals.

The issuing date must be indicated on the first page of the Safety Data Sheet.

If the safety data sheet has been amended or supplemented the following must be stated on the first page: issuing date of the revised document, revision number and the date of the previous version.

All pages, including annexes, must be numbered and have an indication of the total number of pages (for example page 1 of 3) or an indication that the next page exists or that this page is the last (example end of Safety Data Sheet). It must not contain blank subsections.

The emergency telephone number from subsection 1.4 shall indicate the information on the services providing emergency information and the telephone number of the Serbian Poison Control Center (The Military Medical Academy, Vojnomedicinska akademija), indicating the time at which the service is available (example only during working hours) or the type of information provided by the service. The Military Medical Academy provides 24 hour medical assistance.[23]

2. Labels

The packaging of a substance or mixture classified as dangerous contains a label with following elements:

- Name, address and telephone number of the supplier,
- The nominal quantity of the substance or mixture in the package intended for general use, unless this quantity is indicated elsewhere on the packaging,
- Product identifier referred to in Article 19 of the Rulebook on classification, packaging, labeling and advertising of chemicals and specific products,
- Pictogram of danger from Article 20 of the Rulebook mentioned in point 3, if it can be applied;
- The word of warning referred to in Article 21 of the Rulebook mentioned in point 3, if it can be applied;
- Notifications on danger referred to in Article 22 of this Rulebook, if applicable;
- Notifications on precautionary measures referred to in Article 23 of the Rulebook from point 3, if applicable;
- Part for additional infor 3mation from Article 26 of the Rulebook from point, if it can be applied.

The information on the labels must be in Serbian language. The label may be written in several languages, provided that the information given in all the languages used is the same.

Label placement and appearance is described in article 32 of the Rulebook on Packaging, Classification and Labeling. Details are explained in Appendix 1, chapter 1.2.

Hazard pictograms are square in shape, placed diagonally, horizontally or vertically in relation to the pages of the label.

The hazard pictograms given in Appendix 3 of the Rulebook on Classification, Packaging and Labeling shall have a black pictorial symbol on a white background with a red frame of sufficient width to be clearly visible.

Each hazard pictogram shall occupy at least one-fifteenth of the surface of the label containing the information referred to in Article 18 of the rulebook mentioned in the last paragraph. The minimum area of each hazard pictogram is 1 cm2.

The below Table 1 provides information on minimum dimensions of hazard labels and pictograms.

When the packaging of a substance or mixture is of such a shape or is so small that it is impossible to satisfy the general rules for the application of the label than information on labels can be displayed in one of following ways:

23 The Military Medical Academy, see <http://www.vma.mod.gov.rs/sr-lat/specijalnosti/centri/nacionalni-centar-za-kontrolu-trovanja>, accessed 5th February 2021;

Table 1: Minimum dimensions of labels and pictograms.

Packaging capacity	Label dimensions (in mm)	Pictogram dimensions (in mm)
Does not exceed 3 liters	if possible at least 52 x 74	at least 10 x 10 if it's possible 16 x 16
Between 3 and 50 liters	at least 74 x 105	at least 23 x 23
Between 50 and 500 liters	at least 105 x 148	at least 32 x 32
More than 500 liters	at least 148 x 210	at least 46 x 46

– On folded labels or,
– On an attached plate or label or
– On the outer packaging.

The label on the inner packaging shall contain the pictogram of the hazard, the product identifier and the name and telephone number of the supplier of the substance or mixture.

Article 18 further outlines some exceptions to the application of the labeling elements.

When substances or mixtures, on the basis of classification, correspond to more than one hazard pictogram, the principles of precedence shall apply in order to reduce the number of hazard pictograms on the label.

Where a substance or mixture, according to the classification, corresponds to more than one hazard pictogram for the same hazard class, the label shall indicate the hazard pictogram corresponding to the most severe hazard category for each relevant hazard class.

The label of substances that are included in the list of classified substances and classified in accordance with the Rulebook on Classification, Labeling and Packaging of Chemicals in hazard classes that are not given in that list, shall indicate the hazard pictogram corresponding to the most severe hazard category for each relevant hazard clases.

IV. Implementation of GHS in the Republic of Serbia

In 2015 Serbia started a Partnership Project sponsored by the Eupean and Serbia. The Project was concluded in 2018 with the help of the Slovenian Bureau for Chemicals and the Austrian Agency for Environment in order to support the transition of EU Chemical Legislation into Serbian Chemical Laws. Since Serbia is in the process of becoming a member of the European Union it has to integrate European legislation into national regulations. Domestic legislation is in line with the EU since the seventh ATP (Adaptation to Technical Progress) of CLP.[24]

V. Trade with certain chemicals and international concessions

Chemicals are imported or exported in accordance with the Ratification of the Rotterdam Convention on the Procedure for Giving Consent on the Basis of Prior Notification for Certain Dangerous Chemicals and Pesticides in International Trade (hereinafter the Rotterdam Convention)[25], as amended.

In order to improve the division of responsibilities and cooperation in international trade with hazardous chemicals in accordance with the Rotterdam Convention for the Import and Export of Certain Substances,Restrictions and Prohibition of Production, Placing on the Market and Use, as well as certain mixtures and products containing these substances, the procedure of prior notification (PIC procedure) has

24 Commission Regulation (EU) 2015/1221 amending Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures, for the purposes of its adaptation to technical and scientific progress;

25 The Law on Ratification of the Rotterdam Convention on the Procedure for Giving Consent on the Basis of Prior Notification for Certain Dangerous Chemicals and Pesticides in International Trade, 1998

to be followed in Serbia. The responsible competent authority is the Environmental Ministry.

VI. Implementation of GHS and CLP in the Republic of Serbia

National legislation implementing the GHS was adopted on 29th June 2010. It was published in the Official Gazette of the Republic of Serbia on 10th September 2010. Serbia implemented a transitional period for re-classification and re-labeling according to GHS for substances until 2011 and for mixtures until 2015. If mixtures were placed on the market before June 1st 2015, the supplier has to re-label them from June 1st 2017 onwards.

Following building blocks are implemented into Serbian Rulebook on classification of substances:

- Unstable explosives, explosives division 1.1, 1.2, 1.3, 1.4, 1.5, 1.6,
- Flammable gases category 1 and 2, and chemical unstable gases category A and B,
- Aerosol category 1, 2 and 3,
- Oxidizing gases category 1,
- Gases under pressure: compressed gas, liquidfied gas, refrigerated liquid gas, dissolved gas,
- Flammable liquids category 1, 2 and 3,
- Flammable solid substances and mixtures category 1 and 2,
- Selfreactive substances and mixtures type A, B, C, D, E, F and G,
- Pyrophoric liquids category 1,
- Pyrophoric solid substances and mixtures category 1,
- Self-heating substances and mixtures category 1 and 2,
- Substances and mixtures, which in contact with water, emit flammable gases category 1, 2 and 3,
- Oxidizing liquids category 1, 2 and 3,
- Oxidizing solid substances and mixtures category 1, 2 and 3,
- Organic peroxides type A, B, C, D, E, F and G,
- Substances and mixtures corrosive to metals category 1,
- Acute toxicity category 1, 2, 3 and 4,
- Skin corrosion /irritation 1, 1A, 1B, 1C, 2,
- Serious eye damage/irritation, eye damage 1, eye irritation 2,
- Respiratory sensitization / skin sensitization, respiratory sensitisation 1, 1A, 1B, skin sensitisation 1, 1A, 1B,
- Germ Cell Mutagenicity 1A, 1B and 2,
- Carcinogenicity 1A, 1B and 2,
- Reproductive toxicity 1A, 1B, 2,
- Reproductive toxicity lactation,
- Specific target organ toxicity, single exposure category 1, 2 and 3,
- Specific target organ toxicity, repeated exposure category 1 and 2,
- Aspiration hazard category 1,
- Acute hazard to aquatic environment category 1 acute toxity, category 1, 2, 3 and 4 long-term toxicity,
- Hazard to the ozone layer category 1.

From 1st June 2015, the relevant chapters of the Safety Data Sheet concerning hazard classification must provide information on classification of the substance or mixture according to the Rulebook.[26]

The last update of the Rulebook regarding the list of classified substances was in 2020.[27]

The following building blocks have been implemented:

- Unstable explosives, explosives division 1.1, 1.2, 1.3, 1.4, 1.5, 1.6,
- Flammable gases category 1 and 2, and chemical unstable gases category A and B,
- Aerosol category 1, 2 and 3,
- Oxidizing gases category 1,
- Gases under pressure category 1,
- Flammable liquids category 1, 2 and 3,
- Flammable solid substances and mixtures category 1 and 2,
- Selfreactive substances and mixtures type A, B, C, D, E, F and G,
- Pyrophoric liquids category 1,
- Pyrophoric solid substances and mixtures category 1,
- Self-heating substances and mixtures category 1 and 2,
- Substances and mixtures, which in contact with water, emit flammable gases category 1, 2 and 3,
- Oxidizing liquids category 1, 2 and 3,
- Oxidizing solid substances and mixtures category 1, 2 and 3,
- Organic peroxides type A, B, C, D, E, F and G,

26 Rulebook on classification, packaging, labeling and advertising of chemicals and certain products (note 13);

27 Rulebook regarding list of classified substances (note 19);

- Substances and mixtures corrosive to metals category 1,
- Acute toxicity category 1, 2, 3 and 4,
- Skin corrosion /irritation 1, 1A, 1B, 1C, 2,
- Serious eye damage/irritation, eye damage 1, eye irritation 2,
- Respiratory sensitization / skin sensitization, respiratory sensitisation 1, 1A, 1B, skin sensitisation 1, 1A, 1B,
- Germ Cell Mutagenicity 1A, 1B and 2,
- Carcinogenicity 1A, 1B and 2,
- Reproductive toxicity 1A, 1B, 2,
- Reproductive toxicity lactation,
- Specific target organ toxicity, single exposure category 1, 2 and 3,
- Specific target organ toxicity, repeated exposure category 1 and 2,
- Aspiration hazard category 1,
- Acute hazard to aquatic environment category 1 acute toxity, category 1, 2, 3 and 4 long-term toxicity,
- Hazard to the ozone layer category 1.

A lot of GHS capacity building activities were undertaken through activities within the project "Chemicals Risk Management in Serbia" with the Swedish Chemicals Agency (KEMI) and the project ″Assistance in Implementation of Chemical Management System in Serbia″ in order to establish effective implementation and enforcement of the new legislation.[28]

VI. Conclusions and Outlook

This paper tries to give an overall summary of the status of chemical legislation in Serbia and the situation on implementation of EU chemical legislation into Serbian law.

Serbia has already a high level of alignment with the EU chemical legislation. In 2019, Serbia opened an online platform for registering biocidal products. The goal of the Government is for Serbia to be technically fully ready for EU membership by the end of 2021, regardless of the date of the formal closing of the accession negotiations and the acquisition of full membership.

In 2019, Serbia started new projects related to ″Further Development of the Framework for Harmonization with EU legislation in the Field of Air, Chemicals and Horizontal Legislation" (EAS 3 project).[29] Furthermore, Serbia needs to boost its administrative capacity to implement legislation in these areas, and to ensure proper monitoring of persistent organic pollutants (POPs).[30]

Further alignment is needed as EU regulations are further updated. As of 1st September 2019 the new Rules on Product Classification, Packaging and Labelling according to CLP/GHS, entered into force. The change harmonised the requirements with EU legislation and comprises several amendments of the Regulation (EC)1272/2008(CLP).[31]

Legislation concerning classification, packaging, labeling and advertising of chemicals of the Law on Chemicals, shall be issued by the Environmental Ministry in accordance with EU Regulations.

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28 Projects Chemical Risk Management in Serbia and Assistance in Implementation of Chemical Management System in Serbia, 2010, see < unece.org/trans/danger/publi/ghs/implementation_e.htm#c25868 > accessed 25th November, 2020;

29 EAS 3 Project, 2016, see < eas.europa.rs > accessed 16th January 2021;

30 EU Report concerning Chapter 27 Negotiations EU Serbia, Pregovaračka grupa 27, 2019, see < pregovaračkagrupa27.gov.rs/?wpfb_dl=163&lang=lat >, accessed 10th November 2020

31 Regulation (EC) No 1227/2008 on classification, labelling and packaging of substances and mixtures (CLP Regulation) (Note 22);

Case Note

The Case Notes section will identify and analyse important judgements of courts around the world that shape the interpretation and application of chemical law and regulation.

The End of the "SONC" Saga: Judgment of the Court of Justice of 21 January 2021 in Case C-471/18 P, Federal Republic of Germany v ECHA

*Eléonore Mullier and Andrea Bonavita**

I. Introduction

On 21 January 2021, the Court of Justice of the European Union dismissed the appeal brought by Germany, supported by France and the Netherlands, against the General Court's judgment in Case T-283/15, *Esso Raffinage v ECHA* ("the First Instance Judgment"). This marks the end of a long judicial saga concerning ECHA's and Member States' respective powers when following up on a compliance check decision adopted under REACH[1] through so-called Statements of Non-Compliance ("SONCs"). The facts can be traced back to November 2012, when the European Chemicals Agency ("ECHA") issued a compliance check decision on the registration dossier submitted by company Esso Raffinage ("the Registrant").

The compliance check decision was issued by ECHA in light of the prerogatives granted to ECHA by the legislature through the provision of REACH, which include under its Title VI the power to conduct compliance checks of registration dossiers to verify that they contain the information required under REACH. If this assessment reveals that information required by REACH is missing, ECHA may prepare a draft decision requiring the concerned registrant to submit additional information to bring the dossier in compliance.[2] The adoption process for this type of decisions involves both (i) the opportunity for the registrant targeted by the decision to be heard in the course of the procedure by submitting comments, and (ii) consultation of Member States.[3] If the Member States Committee reaches unanimous agreement, the final decision may be adopted by ECHA. If no agreement is reached, the Commission may prepare a decision to be adopted by comitology[4].

In 2012, ECHA adopted a final compliance check decision on the Registrant's registration dossier. The decision concluded that additional information had to be submitted by a certain deadline, including a prenatal developmental toxicity study in rabbits by the oral route. The Registrant updated its registration dossier with additional information. When it comes to the prenatal developmental toxicity study in rabbits, the Registrant did not submit that study but submitted alternative information which did not involve the sacrifice of vertebrate animals.

In 2015, ECHA assessed the additional information submitted by the Registrant and issued a SONC. That letter, addressed to the enforcement authority

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1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, *OJ L 396, 30.12.2006, p. 1–849*, as amended.

2 Article 41 of REACH.

3 Article 51 of REACH.

4 Recital (67) and Article 51 paragraph 7 REACH.

of the Registrant (in this case, France), stated that ECHA had *"examined the information"* submitted by the Registrant and concluded that:

1. The updated registration dossier did not contain *"all of the information requested"* in ECHA's compliance check decision and therefore the Registrant "*has not met the obligations following from the compliance check decision issued by ECHA*"[5];
2. The registration dossier is not in compliance with Article 5 REACH; and
3. The Registrant was in breach of Article 41 paragraph 4 REACH.

ECHA attached an analysis of the reasons for this conclusion and asked the French enforcement authority to *"address the non-compliance"* by means of enforcement.[6]

The Registrant brought an action for annulment against this SONC. By judgment of 8 May 2018, the General Court annulled the SONC ("the First Instance Judgment"). It is that judgment which Germany appealed before the Court of Justice, leading to the Judgment of 21 January 2021.

Over the course of these successive steps and challenges, a number of important issues have been argued and discussed. We highlight and discuss some of those issues below.

II. Which forum is competent in the case of a challenge against a SONC?

SONCs are not regulatory acts which are foreseen or even mentioned in the REACH Regulation. When the first legal challenges arose against these acts, it was unclear whether they could be challenged before the ECHA Board of Appeal or before the General Court. The rule under the REACH Regulation is that the Board of Appeal is competent to rule on appeals against acts exhaustively listed in Article 91 of the REACH Regulation, and the General Court is competent to rule on actions for annulment against those acts adopted under the REACH Regulation but not falling within those listed under Article 91 above.[7] Determining which fora was competent thus involved a determination of the legal basis for the adoption of SONCs by ECHA.

Challenges were introduced before both the Board of Appeal and the General Court. In a unique turn of events, both fora declared that they were competent due to the legal basis for SONCs:

- The Board of Appeal in its *Solutia* decision[8] ruled that the legal basis for the adoption of SONCs should have been Article 42(1) of the REACH Regulation following the procedure laid down in Articles 50 and 51, for which the Board of Appeal is competent. Despite ECHA not having applied this legal basis, the Board of Appeal found that it was competent to rule against SONCs as acts which should be adopted pursuant to Article 42(1) and the procedure laid down in Articles 50 and 51;[9]
- The General Court in the First Instance Judgment also found that the SONCs should have been adopted following the procedure laid down in Article 51 of the REACH Regulation, which would have opened a route to the Board of Appeal. However, since ECHA had not applied this legal basis, the General Court found that the SONC was not covered by Article 91(1) listing the acts open to challenge before the Board of Appeal and declared itself competent to rule on the action for annulment in accordance with Article 94(1).[10]

Going forward, it is now clear that ECHA must apply the procedure laid down in Article 51 when adopting follow-up decisions to compliance checks under Article 42(1) and that, as a result, appeals may be brought before the Board of Appeal. It remains noteworthy that both fora declared themselves competent. This prevented challenges being ruled inadmissible at a time when it was no longer possible to bring a challenge before the other forum and is to be welcomed, in the authors' view, considering the uncertainty created at the time by these acts which were not foreseen by the REACH Regulation.

III. Is an action for annulment against a SONC admissible?

A large part of the grounds of appeal put forward by Germany against the First Instance Judgment fo-

5 As quoted at paragraph 30 of the Judgment.

6 *Ibidem*.

7 Article 94(1) of the REACH Regulation.

8 Decision of the ECHA Board of Appeal dated 29 July 2015 in Case A-019-2013 *Solutia Europe sprl/bvba*.

9 Paragraph 97 of the *Solutia* decision.

10 Paragraphs 36 and 37 of the First Instance Judgment.

cused on the admissibility of the action for annulment against the SONC. Germany argued, in essence, that a SONC is not a legally binding decision but a mere "opinion" of ECHA based on the so-called advisory tasks set forth under Article 77 REACH, without any legal effects separate from those of the initial compliance check decision. According to Germany, it is for national competent authorities alone to decide on the consequences of a registrant's failure to submit the information requested in a compliance check decision.

These arguments were dismissed by the Court of Justice. The Judgment confirms that SONCs are acts intended to produce legal effects not only as regards registrants, but also binding "automatically"[11] on national competent authorities who are invited to consider enforcement action. ECHA is confirmed as exclusively competent under the REACH Regulation for the evaluation of the compliance of registration dossiers. The Judgment upholds the General Court's finding that the REACH provisions *"do not confer on the Member States any competence to assess the compliance of registration dossiers, and that the Member States are empowered, under Articles 125 and 126 of the REACH Regulation, only to carry out checks and impose penalties in order to ensure compliance with declarations of non-compliance and findings that provisions of that regulation have been infringed previously made by ECHA"*.[12]

Member States, despite their involvement in the decision-making process through the Member State Committee, are not competent to declare that information submitted in relation to a compliance check is not compliant with either the compliance check decision or the REACH Regulation. They may only exercise their enforcement powers following a decision by ECHA and consequent notification that provisions of REACH have been infringed.

IV. What are ECHA's powers and limitations in a follow-up to a compliance check?

The Judgment confirms that ECHA (or the Commission, as the case may be) has the exclusive competence and even the obligation[13] to review information submitted in response to an initial compliance check decision, including adaptations to the requested standard study. This review involves a new assessment and is therefore not limited to a confirmation of the prior compliance check decision.[14]

There are, however, limits to this competence. In a follow-up to a compliance check, ECHA is required to follow the procedure provided by Articles 50 and 51 of REACH, as already ruled by both the First Instance Judgment[15] and ECHA's Board of Appeal.[16] After all, Article 42(1) does require explicitly ECHA to draft any appropriate follow-up decisions in accordance with Articles 40 or 41, which in turn refer to Articles 50 and 51 of REACH as regards the decision-making procedure. It has now also been confirmed by the Court of Justice that ECHA must follow this procedure, including the right for registrants to make their views known on the draft measure, meaning that cannot simply issue letters or statements without following any process provided by REACH.[17]

It remains that Article 42(1) of REACH only requires ECHA to adopt a decision *"if necessary"*. In the First Instance Judgment, the General Court interpreted these terms as meaning that a new decision adopted following the procedure in Articles 50 and 51 of REACH is not necessary where the information submitted in response to a compliance check is *"manifestly unreasonable [...] constituting therefore an abuse of process are equivalent to the complete failure to respond to the first decision"*.[18] In such scenarios, the General Court found that ECHA may find that the dossier is not compliant *"by means of a simple information to the Member State concerned and the interested party"*.[19] As this entails less procedural guarantees for the registrants than a new decision adopted following the procedure set out in Articles 50 and 51 of REACH, companies responding to a compliance check decisions by means other than the standard information requirement would be well advised to ensure that appropriate justification is provided to avoid being considered as an abuse of process.

11 Paragraph 111 of the Judgment.

12 Paragraph 73 of the Judgment.

13 Paragraph 78 of the Judgment.

14 Paragraphs 97 to 100 of the Judgment.

15 Paragraph 109 of the First Instance Judgment.

16 Paragraph 91 of the Board of Appeal's decision in Case A-019-2013 *Solutia Europe sprl/bvba*.

17 Paragraph 137 of the Judgment.

18 Paragraph 112 of the First Instance Judgment.

19 *Ibidem*.

An important and not yet fully answered question concerns the mandatory content of an ECHA decision adopted pursuant to Article 42(1) of REACH. The Judgment states that ECHA is (exclusively) competent, when applying Article 42(1) of REACH, to find that the information provided in response to the initial compliance check does not comply with the applicable requirements and to decide that the registrant has thereby infringed certain of its obligations.[20] This focus on competence rather than mandatory content is the consequence of the grounds of appeal as formulated by Germany in this case, which focused on the repartition of competences between ECHA and Member States. The Court of Justice was not called upon to assess the content of an ECHA follow-up decision adopted in accordance with Article 42(1) (which was not the case of the SONC subject to, and annulled by, this litigation).

In particular, when discussing what the terms *"any appropriate decisions"* mean under Article 42(1) of REACH, the Court of Justice did not go into the wording of Article 41(3) of REACH –applicable as confirmed by the General Court[21] – which requires any decision drafted by ECHA under Article 41 to set a deadline for the submission of the information requested.

This can be seen as a missed opportunity as, separately from any possible enforcement measures, registrants would benefit from a clear indication of how and by when to update their registration dossier after an adaptation to the standard information requested in a compliance check decision is rejected by ECHA. This is all the more important considering that, as confirmed by the Court of Justice, replying to a compliance check decision by way of an adaptation in accordance with Annex XI of REACH and/or the specific rules for adaptation in the Annexes of REACH is lawful and even mandatory in certain cases where vertebrate animal testing is involved.[22]

V. Conclusion

With the Judgment, the Court of Justice has clarified the repartition of competences between ECHA and Member States when it comes to verifying the compliance of registration dossiers with the REACH Regulation and with prior compliance check decisions adopted by ECHA or the Commission. The Court of Justice confirmed that ECHA is solely competent to assess such compliance and that any enforcement measures by Member States may only come after, and in accordance with, a finding of non-compliance adopted by ECHA or the Commission in accordance with Article 42 of REACH.

It is not the first time that Germany seeks a legal interpretation granting Member States more power under REACH. In Case T-755/17, Germany had challenged an ECHA Board of Appeal decision partially annulling a substance evaluation decision.[23] Germany alleged, *inter alia*, that ECHA's Board of Appeal was not competent to review that legality of the substantive assessments in a substance evaluation decision due to the important role of Member States in the steps leading to the adoption of a substance evaluation decision. As in the Judgment, these arguments supporting a wide reading of Member States' competence under REACH were rejected by the General Court.

The Judgment relates to facts dating back almost ten years. In the meantime, ECHA has further changed its practice regarding follow-ups to compliance check decisions, at least when it comes to the procedure followed. SONCs, which did not follow any procedure provided by REACH, have been replaced since the first quarter of 2019 by "failure to respond" notifications to registrants or, in typical REACH acronym fashion, "FTRs". Nevertheless, the case-law on SONCs is relevant as it is rich with important teachings as set out in this case review. Among those, this case-law confirms that acts adopted by ECHA pursuant to Article 42(1) of REACH are intended to produce binding legal effects and are

20 See paragraphs 86 and 141 of the Judgment.

21 See paragraph 108 of the First Instance Judgment. The General Court did not exclude the application of the first sentence of Article 41(3) of REACH when applying Article 42(1), as recently argued by ECHA's Board of Appeal.

22 Paragraphs 127 and following of the Judgment. In particular, having regard to the wording and the context of REACH, paragraph 132 of the Judgment clearly states that "*It follows from those general provisions, which are to be construed in the light of recital 47 of the REACH Regulation, according to which 'it is necessary to replace, reduce or refine testing on vertebrate animals', that a registrant has, generally and therefore especially where ECHA issues it with a decision asking it to complete its registration dossier with a study involving animal testing, not simply the possibility but the obligation to generate information obtained by means other than animal testing 'whenever possible' and to undertake such testing 'only as a last resort'.*".

23 Case T-755/17 *Germany v ECHA*, ECLI:EU:T:2019:647.

open to challenge. This is particularly relevant in light of the recent cases of the Board of Appeal with regard to the interpretation of the requirements for long term toxicity testing under Annex IX.[24] As such, the Judgment may mark the end of the SONC saga but not, it is expected, the end of litigation cases concerning follow-ups to compliance checks under REACH.

24 By way of reference and example, see cases A-009-2018, A-010-2018 and A-011-2018.

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