Volume 4 | Number 3

ICRL 3 2021

ICRL

International Chemical Regulatory and Law Review

Articles

Reports

The Legal Publisher
lexxion

CHEMSERVICE

Your global regulatory experts

www.lexxion.eu

You can focus on running your business – **we help you overcome the regulatory barriers**

www.chemservice-group.com • contact@chemservice-group.com

Contents

ICRL is hosted by:

CHEMSERVICE

Chemservice GmbH
Herrnsheimer Hauptstrasse 1b · 67550 Worms · Germany
Phone: +49 6241 95480 0 · Fax: +49 6241 95480 25
www.chemservice-group.com

ICRL is published by:

THE LEGAL PUBLISHER
lexxion

Lexxion Verlagsgesellschaft mbH
Güntzelstraße 63 · 10717 Berlin · Germany
Phone: +49 30/81 45 06-0 · Fax: +49 30/81 45 06-22
www.lexxion.eu

The digital version of the journal is open access, The printed version is available for 50,00 € for one issue and 120,00 € for four issues. Price includes postage and handling. In EU Member States, VAT will be added if applicable.

ICRL is supplied under our terms of sale and supply.
Copies of our terms and conditions are available upon request.
Lexxion Verlagsgesellschaft mbH. VAT Reg.No. DE 209981990.

For further information please contact
info@lexxion.eu
Tel.: +49 30/81 45 06-0 · Fax: +49 30/81 45 06-22

Contributions
are welcome and should be submitted according to the ICRL author guidelines. Any such contribution is accepted on the understanding that the author is responsible for the opinions expressed in it. More informations available at www.lexxion.eu/icrl.

Photocopying
All rights reserved. No part of this journal may be reproduced in any form whatsoever, e.g. by photo print, microfilm, or any other means, without prior permission of the publisher. This journal was carefully produced in all its parts. Nevertheless, authors, editors and publisher do not warrant the information contained therein to be free of errors. Readers are advised to keep in mind that statements, data, illustrations, procedural details or other items may inadvertently be inaccurate.

Ownership and shareholdings pursuant to Section 7 lit. a No. 2 and Section 2 No. 6 of the Berlin Press Act: Shareholder of Lexxion Verlagsgesellschaft mbH is Dr. Wolfgang Andreae, Publisher, Berlin.

This journal may be cited as [2021] ICRL.

ISSN (Print) 2566-834X · ISSN (Online) 2566-8412

ICRL

International Chemical Regulatory and Law Review

MANAGING EDITOR

Dieter Drohmann
Chemservice

COUNTRY CORRESPONDENTS

South Korea

Jae-Seong Choi
Chemservice Asia, Seoul

China

Yue Huang
Guangzhou University, Guangzhou

North America

Lynn L Bergeson
Bergeson & Campbell, Washington.

Turkey

Yaprak Yüzak Küçükvar
REACH Global Services S.A., Istanbul

EDITORIAL BOARD

Michael Cleuvers
Dr. Knoell Consult

E. Donald Elliott
Yale Law School

Ahmet Ecmel Yorganci
REACH Global Services

Andrew Fasey
ECHA

Kristian Fischer
SZA Schilling, Zutt & Anschütz

Lawrie McLaren
Burson-Marsteller

Jean-Philipp Montfort
Mayer Brown

Eléonore Mullier
Steptoe & Johnson LLP

Tobias Schulz
VCI Landesverband Nordost

Michael Raupach
BASF SE

Volker Soballa
Evonik Industries

Tade Spranger
Center for Life Sciences & Law, University Bonn;
Rittershaus law firm

Gooh Choo Ta
National University of Malaysia

EXECUTIVE EDITOR

Jakob McKernan
Lexxion Publisher, Berlin
mckernan@lexxion.eu

Editorial

Although they may not like to admit it, most Governments and policy makers do not make decisions in a vacuum. When drafting new laws and imposing regulations they must be aware of the context in which they operate: a globalised world with deeply interconnected economies. The push for wider and more significant harmonisation is particularly prevalent when it comes to the production, sale, import and export of chemicals. For instance, since its introduction nearly 15 years ago, the effect of EU REACH has been felt around the world with an increasing number of jurisdictions looking to implement similar (if not identical) regimes. In that regard, the United Kingdom's decision to introduce *greater* divergence between its chemical regulation regime and that of the European Union, stands out. Although the UK REACH is very similar to EU REACH, there are differences.

In the first article of this edition of ICRL, James Lloyd, Olena Krychevska and Adam Hedley discuss an area that has proven to be particularly problematic: the labelling and safety data sheet (SDS) aspects of REACH and CLP. To help various supply chain actors get ahead of the curve, the authors have outlined the obligations required to be compliant in both the EU and UK, and highlighted problems introduced by the UK's exit from the Union and present practical solutions to help achieve compliance, both complex and simple.

Addressing similar supply chain issues, my co-authors, Thomas Schaefer and Christopher Cohrs, and I outline the benefits of the OR-Trustee system. The EU REACH regulation and its counterparts KKDIK in Turkey, UK REACH in Great Britain and K-REACH in Korea, dictate that importers are subject to the obligation to register all imported chemical substances, unless substances are exempted from this obligation. Although importers can appoint an Only Representative (OR) to register substances for them, this may necessitate the disclosure of confidential business information. Using the example of EU REACH, our article demonstrates how the OR-Trustee systems can solve these problems.

To round off this issue, we have two reports: one from North America, and in a first for ICRL, one from India. In their contribution, Christy Leeper and Karina Kausch discuss the latest developments in the United States and in Canada. Covering the first months of the Biden Administration, the report covers a number of crucial developments. Offering a wider scope, Pramod Kumar, Prabhakar Maurya and Sarah Henly provide us not only with a comprehensive background of the regulation of chemicals in India but also detail the latest legislative developments. A must read for anyone looking to do business in India.

Lastly, I would like to once again point you in the direction of the upcoming Lexxion event on chemical regulation outside the European Union. The conference takes place in Frankfurt on 23 and 24 of September and I very much look forward to seeing you

there in person. As always, please feel welcome to submit your own contribution to the journal by reaching out to our Executive Editor, Jakob McKernan.

Dieter Drohmann
Managing Editor

Practical Solutions to Challenges Associated with Safety Data Sheets and Labelling in the EU-27 and the UK Following the UK Withdrawal from the EU

As a consequence of the UK withdrawing from the European Union, it is becoming more difficult to comply with the labelling and safety data sheet (SDS) aspects of REACH and CLP. Such difficulties have also begun to shine a light on compliance in those areas more widely across the EU – regardless of the impact of Brexit. Correspondingly, authorities are ramping up enforcement across the EU and ECHA's Enforcement Forum is undertaking an enforcement project currently focusing on this area. Fortunately for duty holders in the EU and UK, and those exporting into those jurisdictions, the majority of the obligations are the same. Primary differences are due to legal entity changes – downstream users becoming importers, and the subsequent change this requires in legal entity details on labels and in SDS. What follows is an introduction to this issue, an outline of the obligations required in each jurisdiction, problems encountered when attempting to achieve compliance, and practical solutions to these problems. We hope that this document can be used to support your continued market access and minimise the chance of enforcement action against your business, and that of your customers.

*James Lloyd, Olena Krychevska and Adam Hedley**

I. Introduction

The European Union's REACH[1] and CLP[2] regulations have long been intertwined. REACH relies heavily on CLP to determine how substances should be classified – arguably the most important step in compiling information to keep workers in the chemicals industry safe. CLP classifications are used to determine whether a safety data sheet (SDS) is required under REACH, and often the applicability of some exemptions and derogations such as those in REACH, Annex V. They also frequently form part of larger REACH processes to help determine whether:

- there is adequate risk to justify evaluation of substances and dossiers;
- a substance should be added to the Candidate List of Substances of Very High Concern (SVHC) in consideration for further regulatory action;
- a restriction is necessary to better protect consumers as well as workers in the chemicals industry.

CLP also has its own requirements in addition to classification. Once classified as possessing a chemical hazard, substances and mixtures must be labelled and packaged appropriately. There are specific criteria for clearly and accurately conveying hazard information on labels and packaging, including information relating to the supplier. More severe hazards, such as classification as a reproductive toxin, carcino-

* Author details: James Lloyd, Chemical Regulatory Consultant and Brexit Lead, H2 Compliance. For correspondence: j.lloyd@h2compliance.com. Olena Krychevska, Chemical Regulatory Consultant, H2 Compliance. For correspondence: o.krychevska@h2compliance.com. Adam Hedley, Partner, Reed Smith LLP. For correspondence: ahedley@reedsmith.com.

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 [2006] OJ L 396/1 (REACH).

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 [2008], OJ L353/1 (CLP).

gen, or mutagen, may also warrant a minimum classification that must always be adopted and applied on labels throughout the EU – harmonised classification and labelling.

As supply chains become increasingly complex and global, EU-based importers that provide onward supply must take on greater responsibility for accurate labelling and compilation of SDS. In many cases, they rely on labels and SDS generated by their non-EU suppliers. Often, it would appear that suppliers are not providing CLP-compliant labels, or sometimes even REACH-compliant SDS. This is becoming more prevalent with the increase in online sales of substances, especially where direct sales to smaller business through larger online marketplaces are concerned.

Online sale of products, often cross-border and via intermediary marketplace platforms, has become widespread and particularly challenging in terms of compliance. While the same regulatory framework applies, the traditional understanding of placing a product on the market is stretched and requirements for 'distance contracts', where a product can be purchased without first having sight of the label, come into play. Thus, for products sold online, any legally required warnings, information and labels should be indicated on the website and should be clearly visible in their entirety before the customer makes their purchase.[3]

Our experience in this area reflects a noticeable increase in enforcement action. Across the EU, authorities have often found the hazard information on the online marketplaces that offer hazardous products to be inadequate or lacking, and the rates of non-compliance high. Moreover, the location of the seller and the customer, and hence the supplier and language requirements for the hazard information on the label, are much more fluid and easily span across national borders.

EU Market Surveillance Regulation provides guidance on when the product sold online is considered to have been made available on the market – that is if the "sale offer is targeted at end users in the Union", which can be assessed based on such factors as the "geographical areas to which dispatch is possible, the languages available, used for the offer or for ordering, or means of payment".[4] The product should then be marketed and labelled in line with the Union law applicable to it. It therefore means that the label and SDS of a product should comply with the 'usual' requirements, have appropriate supplier information, and be written in the official language(s) of the Member State(s) where the substance or mixture is placed on the market, as stated in Article 17(2) of CLP.

The European Chemicals Agency (ECHA) and the national authorities have recognised that this is a growing concern to the extent that they are increasing enforcement action regarding labelling of products and provision of compliant SDS, in particular with regard to online sales. The national enforcement authorities have taken coordinated effort in controlling the internet sales first through the EU Enforcement Forum's pilot project on CLP and further – its major enforcement project REF-8 on CLP, REACH and BPR duties related to substances, mixtures and articles sold online.

The pilot project, report published in 2018, checked if the advertisements for the hazardous products mentioned the type(s) of hazard indicated on the label, as required in Article 48(2) of the CLP Regulation and found frequent non-compliance (82 % rate) where no information was provided on hazard statements and/or supplementary statements.[5] While the requirement can also be fulfilled by providing a clear picture of the product label, the pilot project's report points out that the label language requirements under Article 17(2) of CLP are to be "considered for the obligatory information in the advertisement" – an obvious challenge for the distant sales within the EEA.

Whilst this is relatively simple to enforce – label elements are either present or not - it remains somewhat difficult for businesses to comply depending on who in the supply chain takes responsibility. Moreover, those smaller businesses that go on to supply chemicals are less likely to be familiar with the legislation with which they are required to comply.

The UK's withdrawal from the EU introduces an extra degree of complexity in addition to the challenges relating to duplication of obligations and da-

3 Commission Notice 'The 'Blue Guide' on the implementation of EU products rules' [2016] OJ C 272/01 ('Blue Guide')

4 Regulation 2019/1020 (EU) on Market surveillance and compliance of products [2019] OJ L 169/1 (Market Surveillance Regulation)

5 European Chemicals Agency, 'Final report on the Forum Pilot Project on CLP focusing on control of internet sales' [2018] <https://echa.europa.eu/documents/10162/17088/forum_project_report_on_control_of_internet_sales_en.pdf/> accessed 16 August 2021

ta sharing under UK REACH, and further burdens relating to international trade as a whole. With products destined for both the UK and EU markets, a single EU- or UK-based distribution hub may no longer be sufficient. Problems arise concerning which address and contact details should be present on the label, and who is responsible for the content of those labels. International suppliers now find themselves faced with amending and duplicating labelling across all of their Europe-bound product lines, at a cost; or passing that burden onto their EU- and UK-based customers, potentially leading to loss of business.

II. Regulatory Overview

1. Obligations

Only legal entities established in the EU have obligations under the REACH and CLP regulations. Similarly, only legal entities established in Great Britain (GB) have obligations under the counterparts as retained in UK law.[6,7] As such, the non-UK and non-EU entities do not, and indeed cannot, have any obligations under these regulations.

The obligations placed upon various EU and UK actors in the supply chain change depending upon their role. As such, we limit our scope here to the role of *supplier of a substance or a mixture* (henceforth "supplier") as defined in REACH, since it is the supplier that has the obligation to provide SDS [REACH, Article 31(1)], and suppliers that have the obligation to label substances and mixtures [CLP, Article 4(4)].

The definition of a supplier is identical between the EU regulations and their retained UK counterparts:

"*any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture*"

The only relevant difference between the EU and UK definitions for each of those roles in the supply chain is that the role of manufacturer, importer, downstream user, or distributor is either defined as being established in the EU or the UK, respectively.

It is also important to note the role of the Only Representative (OR) in these supply chains. ORs are not recognised under CLP, and as such can have no obligations relating to labelling. However, they may be appointed under REACH to take on the obligations of the importer. Typically, these obligations do not extend to the provision of SDS. To that end the Only Representative Organisation (ORO), one of ECHA's Accredited Stakeholders, have a best-practice guide for OR practitioners that indicates which obligations should be assumed by the OR. Simply, "The Only Representative has no legal obligation to supply Safety Data Sheets for the hazardous substances or mixtures exported to the EU" by the appointing entity.[8]

2. Brexit Effect – What Has Changed as a Consequence of Brexit?

Fortunately, there are few significant content changes between the EU and UK versions of REACH and CLP, regarding SDS and labelling. The implementation of UK REACH and GB CLP via secondary legislation has ensured that there can be no fundamental policy changes made to retained EU law, unless there is a clear inoperability. Provisions pertaining to SDS and CLP labels remain completely operable.

The primary changes are related to the identified duty holders, and whether labels and SDS destined for one jurisdiction still remain valid in another. Chemical products being placed on the GB market from 1st January 2021 (IP Completion Date)[9] must be labelled in accordance with GB CLP. As such, products imported for onward sale in GB must bear the identity of the GB-based importer – the supplier. For example, prior to 1st January 2021 – the end of the Brexit transition period – a product label on a mixture imported into Germany would have been equally valid when subsequently supplied into GB for onward supply, provided the appropriate languages are

6 The REACH etc. (Amendment etc.) (EU Exit) Regulations 2020, SI 2020/1577 (UK REACH, GB REACH) <https://www.legislation.gov.uk/uksi/2020/1577/contents/made> accessed 15 August 2021

7 The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019, SI 2019/720 (UK CLP, GB CLP) <https://www.legislation.gov.uk/uksi/2019/720/contents/made> accessed 15 August 2021

8 Only Representatives Organisation, 'Best Practice Guide' [2014] <http://www.onlyrepresentative.org/images/download/oro/ORO%20Best%20Practice%20Guide%20v1_0%2014%20May%202014%20final.pdf> accessed 15 August 2021

9 'Implementation Period' completion day

present and no substantive changes to packaging or product are made.

From the beginning of 2021, the name, address and telephone number of that German supplier would no longer be relevant in GB. The product must contain the name, address and telephone number of the UK-based supplier in order to remain compliant. Hence, the question becomes who is responsible for this change in labelling? Or more specifically, whilst the duty holder may formally be in the UK, which actor in the supply shall chain bear the cost in time and resources for relabelling products?

For some companies serving both the EU and UK jurisdictions, the need to apply new labels and the ease of enforcement has highlighted a gap that needs to be filled. And possibly a gap that has long been present within the EU.

Importantly, it should be noted that where a product passes through multiple levels of a supply chain within a given jurisdiction – from importer to consumer via distributors - the labelling does not necessarily need to change.

3. Legal Entity Identity – is an EU-based Legal Entity Enough?

In the case of import of chemicals under EU REACH, the legal entity (LE) established in the EU, which is responsible for the import, should make the relevant registration.[10] The registration dossier must include general information for the identification of the registrant and the substance, which includes the LE's identity, address, and contact details.[11] Similarly, in GB, only a LE established in GB can be a registrant. The same obligations apply, and the dossier must contain information relating to the GB LE's identity, address, and contact details. Additionally, the same dual regime applies to provision of SDS, and content of labels as defined in CLP and GB CLP.

To be able to comply with the obligations with respect to providing the LE's address and contact details on labels, or with respect to provision of SDS, the LE defined as the supplier must have a legal presence in the relevant jurisdiction (EU or GB) in which the product is being supplied. Thus, the question arises as to what constitutes a legal presence, or "being established". Some companies supplying from outside a jurisdiction believe that simply creating a LE in the respective jurisdiction will solve the problem. However, this leads to multiple complications as the definition of LE varies nationally, as do the obligations that LE may have depending on the supply chain roles undertaken.

4. Legal Entity Definition

Under the ECHA Guidance on Registration, 'Legal Entity' (LE) is a term encompassing both natural and legal persons who can import chemicals in the EU.[12] What constitutes a legal or natural person depends on the national laws in individual EU Member States; the following principles generally guide the distinction:

1. 'Natural persons' are people, who are capable of entering and have the right to enter into contracts or other commercial transactions; and
2. 'Legal persons' tend to be companies, which have their independent legal personality.

In this article, any LE will be a legal person, unless stated otherwise.

As per the above, in the EU, the requirements for what constitutes LE are a matter of national law. Consequently, it is not possible to provide a single definition that applies across the EU and UK. Moreover, there are different rules for setting up a LE depending on its type.

By way of an illustration, the rules governing the incorporation of LE in the UK also vary depending on its type. The three most common types of LE are:
(1). private limited company (or a company);
(2). limited liability partnership (or an LLP); and
(3). public limited company (or a PLC).

A private limited company would be the best vehicle for the purposes of import of chemicals into GB because it provides a separate and distinct legal entity, as a result of which the shareholders are not liable for the debts and other obligations of the LE in most of the cases. Moreover, there is no requirement for minimum share capital – anything above £0 will suffice. However, to be able to successfully incorpo-

10 Section 2.1.2.4, European Chemicals Agency, 'Guidance on registration' [2021] <https://echa.europa.eu/documents/10162/2324906/registration_en.pdf/> accessed 16 August 2021 (ECHA Guidance on Registration)

11 Section 5.2.1, ECHA Guidance on Registration

12 Section 2.1.2.1, ECHA Guidance on Registration

rate a private limited company, it must have its registered office in GB, Articles of Association, and must comply with various filing requirements. Similar criteria exist for the establishment of legal entities in other jurisdictions, although as noted, the specific details required for each vary nationally.

As part of the UK, the same rules governing establishment and incorporation of a LE apply in Northern Ireland. However, as per the Protocol on Ireland/Northern Ireland (NI Protocol)[13], EU REACH and EU CLP will continue to apply to Northern Ireland for at least four years.

EU REACH and CLP define an 'Importer' as "any natural or legal person established within the Community who is responsible for import".[14] 'Import' is defined as "the physical introduction into the customs territory of the Community".[15] Neither of these definitions develops the concepts in detail and they do not explicitly state the minimum requirements for an importer. However, as the definitions under both CLP and EU REACH are the same, it is unlikely that an LE would be considered an importer under CLP, but not under EU REACH and vice-versa.

The ECHA guidance expands on the definitions and notes that the "responsibility for import depends on many factors such as who orders, who pays, who is dealing with the customs formalities, but this might not be conclusive on its own."[16] The same Guidance goes on to say: "For example, in the case of a 'sales agency' established in the EU and acting as an intermediary, i.e. transmitting an order from a buyer to a non-EU supplier (and being paid for that service) but taking no responsibility whatsoever on the goods or the payment for the goods and not having their ownership at any stage, then, the sales agency is not to be considered as the importer for the purposes of REACH. The sales agency is not responsible for the physical introduction of the goods."

This guidance confirms at least two things:

1. giving/receiving payment and/or holding title (albeit at what time is not made clear) are further indicators of who is the importer; and
2. if you do not do either of these things, or otherwise take any "responsibility...on the goods", you will not be considered an Importer.

Consequently, simply having a LE established in the EU does not guarantee compliance. If the newly-established LE is not an importer (or distributor), then they cannot be a supplier and cannot have obligations pertaining to labelling and SDS provision. That obligation would still fall upon the EU-based entities that fulfil the supply chain roles of importer and/or distributor. Therefore, the simple establishment of an LE that does not participate in the supply chain achieves nothing in relieving potential burden from EU-based duty holders.

Whilst no explicit guidance is given for the UK, the HSE has specified the continuing validity of ECHA guidance documents in GB, given the close alignment of the two regulatory frameworks.[17] As such, establishing a LE in GB, which is not itself a relevant duty holder, will not remove obligations on GB-based importers.

5. Complications in Case of Online Sales in the EU

The EU Blue Guide makes clear that the EU product laws (including EU REACH) apply to all forms of supply, including distance selling and online selling. Therefore, regardless of the selling technique, products intended to be made available on the Union market must comply with the applicable legislation.[18]

There is no specific guidance for distance sales with regard to EU REACH or EU CLP and the general guidance does not mention it. Therefore, it can be assumed that the same general regime applies to online sales. The only difference is a result of the role of fulfilment houses (FH), which is developed in detail below.

E-commerce gave rise to a new business model – FHs. To ensure swift delivery to consumers, products offered via online platforms can be stored in FHs. In addition to storage, FHs may also offer services such as packaging and shipping of products, or even returns. In any event, to fall under the definition of 'ful-

13 GOV.UK, The protocol on Ireland/Northern Ireland (2020) <https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/840230/Revised_Protocol_to_the_Withdrawal_Agreement.pdf> accessed 16 August 2021

14 Article 3(11), REACH; Article 2(17), CLP

15 Article 3(10), REACH; Article 2(16), CLP

16 Section 2.1.2.4, ECHA Guidance on Registration

17 UK Health and Safety Executive (HSE), 'EU REACH links' <https://www.hse.gov.uk/reach/eu-reach-links.htm> accessed 16 August 2021

18 'Blue Guide', p.16

filment service providers', the FHs must offer at least two of the following services: warehousing, packaging, addressing and dispatching, without having ownership of the products involved, excluding postal services, parcel delivery services and any other postal services or freight transport services.[19] FHs are often considered a separate LE which provide services to other LEs.

The EU Blue Guide confirms that FHs, which provide services beyond mere parcel service and transit, are considered importers under the relevant EU product laws (including EU REACH) and as such, must comply with the corresponding legal responsibilities.[20]

The Draft revision to the EU Blue Guide (which is not yet in force) adds that FHs must cooperate with Member State Authorities (MSA) to address issues of non-compliance with the products they handle, and the relevant MSA can take enforcement measures against them. Perhaps more importantly, if the relevant non-EU exporter of chemical products into the EU does not have presence in the EU, the FH become the responsible economic operator with regard to the chemicals. They may incur the obligations of the supplier (SDS provision, labelling), as well as the importer (registration, classification).

Essentially, the specific supply chain role conferred upon an entity by the REACH and CLP regulations e.g., importer, can apply regardless of whether a company sees themselves as simply a fulfilment house, or a distributor (in the general non-REACH context). It follows that the same would be equally true in the UK as it is in the EU, given that the legal text as retained is much the same. In one sense, the problem becomes simplified: does the LE fulfil the role of importer (or supplier), under REACH and CLP? The larger problem then becomes ensuring these entities are aware of what exactly their obligations are, and how they can comply with them.

III. Practical Difficulties in Compliance

The first time a product enters the EU, the entity importing is considered the importer. As such, if a product is shipped from a non-EU legal entity to multiple EU-based legal entities, in multiple EU countries, each one is considered an importer. Those complying with REACH are familiar with this concept, and the associated obligation to register if they import one tonne per annum. Similarly, where there is onward supply, *each of those importing legal entities* would be required to classify and label the product.

Where a CLP-compliant label is required, each individual importer further supplying to the EU is considered a *supplier* and must provide "the supplier's details" on the label. The identity, address and contact details of the non-EU legal entity exporting the products to the EU are not sufficient since that entity is not "established within the Community" and therefore does not qualify as a "supplier".

Before the UK's withdrawal from the EU, this appeared to present less of a problem. Depending on the point of entry into the EU, a single packaging roll detailing a single label with the details of the importing entity could have been sufficient – notwithstanding any amendments to the product or packaging that would result in a need to amend the label. This could apply across the EU and UK, with each supply chain actor beyond the importer being a distributor or downstream user able to rely on the existing details (if appropriate). This removes a significant obligation for each of those entities to conduct labelling themselves.

ECHA guidance on this topic clarifies that intermediate supply chain actors that do not modify the packaging or labelling do not have to add their contact details to the label nor replace the contact information of their supplier. This approach was agreed via HelpNet – ECHA's network of Member State Helpdesks – such that there is harmonisation of this approach across the EU.[21]

Since the end of the transition period, with GB being completely outside the jurisdiction of EU REACH and CLP, products coming from GB going to the EU and vice versa are unlikely to be immediately compliant in the destination jurisdiction. Products imported into the EU will need to contain details of the EU importer on the label and on the SDS. The same is true of products entering GB. As noted earlier, this creates a relabelling burden on the importing entity, who may decide that it is worth changing source to

19 Article 3(11), Market Surveillance Regulation

20 'Blue Guide', p.36

21 ECHA Q&A 0242, 'Is a supplier always required to provide their contact details on the label?' [2019] <https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/ids/0242> accessed 25 August 2021

one within the same jurisdiction (where possible), depending on the size of the compliance challenge.

The light being shed onto this issue as a consequence of the UK's withdrawal from the EU has also indicated that this may have been a lesser-known point of non-compliance throughout the EU. No doubt the results of ECHA's REF-8 Forum enforcement project will show the extent of this issue.

1. Old Stock

Specific issues arise for an existing stock in circulation. Anything supplied to the EU or UK markets prior to 1st January 2021 remains in compliance provided that it is not placed on the market again. REACH and CLP define "placing on the market" as "supplying or making avaialble...", and distinction is made in the legal text when specifically referring to placing on the market "for the first time".

This is different to how many people interpret the phrase "placing on the market", as it is frequently thought that once a product has been imported into the EU it has been "placed on the market" (which is true), and as such that operation is complete. In reality, whenever a product is supplied from one party to another in the EU, it is "placed on the market" for the purposes of REACH and CLP. This means compliance with those regulations is required at each point in the supply chain – not only the first time the product is imported into the EU. As a consequence, it becomes clear that there are no special considerations for stock imported prior to the end of the transition period, which is still sitting with distributors. Whilst such a "stockpiling" approach was a useful temporary solution for REACH registration purposes – both before the 2018 deadline, and in advance of the transition period ending – it is not beneficial with regard to labelling and provision of SDS.

Given that products placed on the market in GB must comply with GB REACH and GB CLP, the situation is identical. There are no transitional provisions in this arena. As such, it is likely that a relabelling operation is required for old stock, as well as new products, being placed on the market in the UK and EU – even if they have already been imported prior to 1st January 2021.

To be clear, where a label is required on a chemical product, it must be compliant with either GB CLP every time it is placed on the GB market, or EU CLP every time it is placed on the EU market; that is, every time a product passes from one party to another in that jurisdiction. To comply with EU CLP, the details of a GB-based company will not suffice, since a GB company can no longer be a supplier under EU CLP. Equally, the details of an EU-based company are no longer sufficient to achieve compliance with GB CLP.

Important to note is that, for the time being, the hazard classification criteria remain identical between both implementations of CLP.

CLP (and therefore GB CLP) does not specify the details of which supplier in the supply chain must be present, nor take precedence. Indeed, the contact details of each entity in an international supply chain could be present, although this is ill-advised as it is likely to cause confusion. Nonetheless, a label containing clearly legible information regarding both UK and EU suppliers can be a compliant solution in some circumstances, since it should be noted that multiple addresses can be present on a label to simplify compliance. While this goes some way to solving the problem introduced by Brexit, it does nothing to address the potential underlying problem which still remains – where there are multiple points of entry into the EU (or indeed the UK), each one may become a supplier in their own right and require their details on a label.

IV. Solutions

In our experience, a common industry suggestion is to set up a LE in the relevant jurisdiction and simply use that for the contact details which must be present on labels and SDS. As discussed above, beyond what actually constitutes a LE, this is not necessarily a valid solution. The details of the entity that appear on labels and SDS must be those of a LE with an obligation e.g., to label as per Article 4 of CLP. Put simply, they must be a *supplier*, and therefore a:

- Manufacturer (unlikely in this scenario where we are mostly considering import)
- Importer
- Distributor
- Downstream user

As previously discussed, the requirements for establishing a LE in various jurisdictions in the EU are a

matter of national law. Not only do the requirements vary per state, but they also vary per type of LE. When investigating the ideal member state in which to establish presence, businesses should bear in mind the following factors:

1. Does the new LE need to have a physical address? Is a PO box enough?
2. Does the new LE need to have employees?
3. Could the new LE be merely an extension of an existing business? For example, the current official ECHA *Guidance on registration*, which is the main guidance on this topic, confirms that an LE can operate via subsidiaries in the EU, which have separate legal personality and qualify as a LE for the purposes of EU REACH.[22]
4. Does the new LE need to have directors or someone legally responsible? An extension on this may be consideration of whether the new LE will be separately responsible for any debts/legal responsibility. Also, do such directors need to be physically located within the country of establishment of the LE?
5. Are there any filing requirements? If so, how onerous they are?
6. What standard documents must be prepared before the new LE is incorporated?
7. Is there an obligation for minimum share capital?

These considerations as well as practical considerations such as language of engagement, are important when determining in which country a LE should be established, as well as the type of entity to be established (regardless of jurisdiction). However, underpinning all of this is that whichever entity is established, in any relevant country, that LE must be a duty holder in order to offer any meaningful solution to the problems outlined above.

1. Intra-group arrangements – an interesting solution

A possible solution for REACH registration compliance with respect to the necessary presence of a LE in both the EU and GB markets for import of REACH chemicals is putting in place intra-group REACH importer arrangements. While this approach is not perhaps widely used in the market, it is possible to enter into an intra-group service agreement designating one group entity (holding the relevant REACH registration) as REACH importer for a payment of a modest consideration to the REACH importing entity. While there would be internal logging of REACH transactions including imports, there would be no direct relationship between the REACH importer entity and the customer.

2. Options available to companies wanting to access the EU and UK markets

1. Establish a LE in the appropriate jurisdiction of supply that can formally take on the role of *supplier* under REACH and CLP (i.e., actually have a duty to label products correctly) – an importer or distributor.
   - As discussed, this entity must "take responsibility" for the goods at some point in the supply chain. For example, they must be responsible for import, and/or process orders and payments via this entity.
   - Only by being a duty holder under (UK) REACH or (UK) CLP would the identity and contact details be relevant to the LE being established.
   - This places the largest burden upon the exporter, whilst removing many obligations that would otherwise fall upon customers. It would not be unreasonable for a modest product cost increase to arise to account for the establishment, maintenance and supply chain modifications.
   - In the case of online and distance sales, this role of supplier is likely to be taken on by the fulfilment house.
2. Depending on the relationship between the exporting company and importing entities, a similar solution could be to specify an existing importer as a "preferred importer". This importer would act as the single-entry point into the relevant jurisdiction, before onward distribution to other entities.
   - In such a scenario, there would be no need to establish a new LE. A LE is already both established in the jurisdiction, and has a relevant supply chain role (importer).
   - The obligations for labelling and SDS provision could be undertaken by this preferred importer.

22 Section 2.1.2.1, ECHA Guidance on registration

Provided no changes to packaging content or formulations are made further downstream, there would be no obligation upon those downstream users and distributors to relabel.
   - One potential issue would be rearrangement of the supply chain – in some cases it may not be possible.
   - Another could be finding an existing importer with which an appropriate business relationship could be established, whilst avoiding pitfalls relating to anti-competitive practise.
3. To remove the burden from EU- and UK-based customers completely, the exporting company could opt to provide bespoke labelling and SDS content per importing entity. The result would be the importer receiving goods which are already labelled with the correct details of the supplier (themselves), having worked with the exporter to ensure their obligations are met. The same information could also be applied to an SDS.
   - This has the advantage of reducing the barrier to entry for customers wishing to access those products.
   - There may be additional cost to the exporting entity in the modification of labelling systems to allow for product runs specific to a given importer.
   - Such an approach becomes less feasible with increasing numbers of importing entities seeking a bespoke labelling solution. Although where there already exists an EU- and UK-based fulfilment house, this may allow that FH to minimise the work required on-site to meet their obligations.
4. Finally, an option could be to place the burden of compliance almost entirely on the duty holder based in the UK or EU; they must label the product appropriately. This could have multiple levels, from each importer having to generate their own CLP-compliant labels and REACH-compliant SDS from the classification data provided to them – at significant time and cost; to providing labels and SDS containing correct hazard information, and an instruction to add a "stick-on" label containing the relevant identity and contact details.
   - Such an approach minimises the cost to the exporter based outside of the relevant jurisdiction, although it could impart a barrier to sales due to the manual intervention required to achieve complaince.
   - This is another solution that may not scale well, particularly where there are larger volumes of products in physically smaller packaging. A significant manual operation is required on the part of the importing entity to apply labels.

V. Conclusions

The increasing complexity of international supply chains and rapid digital progression have led to novel ways of conducting business and entities with new roles in those supply chains. As the lines between those responsible for import and those responsible for transit are blurred, gaps in compliance are likely to grow and increase in frequency. Especially regarding obligations that can be difficult to identify and easy to enforce, such as CLP-compliant labels and REACH-compliant SDS.

ECHA has identified this and have responded accordingly with an investigation and increase in enforcement activity. This will help ensure that workers in those supply chains are adequately protected. The results of that project will shed light on the scale of the problem and will likely lead to more robust guidance; with enforcement action resulting in better self-management in the supply chain in the longer term.

To help various supply chain actors get ahead of the curve, we have outlined above the obligations required to be compliant in both the EU and UK, and highlighted problems introduced by the UK's exit from the Union. We then presented practical solutions to help achieve compliance, both complex and simple, from those that are favourable for EU- and UK-based businesses, to those that more directly benefit the exporting entities. It is hoped that this guidance can be used to minimise the chance of enforcement action against your business, and that of your customers.

Compliance in Complex Supply Chains: A Unique Solution for Multi-Stage Supply Chains Under REACH, Turkey-REACH (KKDIK), UK REACH and Korean REACH (K-REACH)

*Dieter Drohmann, Thomas Schaefer and Christopher Cohrs**

*According to the European **REACH** regulation[1] and its counterparts **KKDIK**[2] in Turkey, **UK REACH**[3] in Great Britain and **K-REACH**[4] in Korea, importers are subject to the obligation to register all imported chemical substances, unless substances are exempted from this obligation. To enable importers to be exempted from these registration obligations, the respective regulations provide that non-domestic manufacturers and formulators can appoint a so-called **Only Representative** (OR), who registers the respective substances on behalf of the manufacturer/formulator and thus makes the respective importers so-called **Downstream Users** (DU). For this purpose, the OR must keep records of the respective importers as well as their annual imported substance quantities, which leads to problems in complex and multi-stage non-domestic supply chains, since indirect customers and suppliers as well as compositions of formulations are not known in many cases. Compliance with the OR's record keeping obligation would therefore only be possible by disclosing **Confidential Business Information** (CBI) in the supply chains, which may even be contrary to competition law rules if the OR is a related legal entity of the manufacturer/formulator. Therefore, in these cases, neither the manufacturers/formulators (represented by ORs) nor the importers can fulfil their obligations without disclosing such CBI and also risking loss of business. In the following article, a solution to this problem is presented using the **example of EU REACH**, which is also used in Turkey and Great Britain and works very well there. In Korea, the system is used in a slightly modified form.*

I. Introduction

In multi-stage non-EU supply chains, substance manufacturers usually do not know through which channels and in which products their substances are imported into the EU. Thus, the non-EU manufacturers usually do not know the importers and their individual imported substance quantities. In most cases, the EU importers also do not know the exact product compositions or the respective substance manufacturers.

In addition, exact product compositions as well as information about suppliers and customers are a major trade secret of formulators and distributors. On top of that, competition/antitrust law must be respected. As a result, neither the non-EU manufacturer (represented by its OR) can exempt the importers from their obligations, nor can the EU importers comply with their registration and compliance duties without communication of CBI within the supply chains, which in turn may lead to loss of business and violation of competition and antitrust regulations.

* Dr Dieter Drohmann, CEO Chemservice Group, Email: d.drohmann@chemservice-group.com; Thomas Schaefer, Director Data & System Services, Chemservice S.A., Email: t.schaefer@chemservice-group.com; Christopher Cohrs, Team Leader Supply Chain Compliance, Chemservice S.A., Email: c.cohrs@chemservice-group.com.

1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

2 Turkish Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals, 23 June 2017.

3 UK Registration, Evaluation, Authorisation & Restriction of Chemicals (REACH).

4 K-REACH: Act on Registration, Evaluation, etc. of Chemicals (Act No. 17326).

II. The Role of the Only Representative

All substances placed on the EU market in quantities of one tonne or more are subject to registration unless they are considered exempt under REACH. Since REACH is an EU regulation, it does not impose compliance obligations on non-EU manufacturers. Therefore, REACH shifts the registration obligation to the EU importers[5] who place the substances on the EU market. This can lead to a very large cost burden for importers, as each importer must register all imported substances himself. For this reason, importers will predominantly purchase only registered chemicals. If there is no registration, the non-EU manufacturer is at an enormous competitive disadvantage, as he can only export his substances to the EU through those importers who have their own substance registrations, which in turn makes him dependent on these importers. For this reason, REACH provides that any non-EU manufacturer or non-EU formulator can appoint a so-called Only Representative[6] (OR). The OR must be an EU-based natural or legal person who legally represents the non-EU manufacturer in the EU (or more precisely in the European Economic Area (EEA)). The aim is to relieve EU importers of their obligation to register substances and to allow non-EU manufacturers to supply any EU importer with only one substance registration. However, the appointment of an OR does not automatically mean that the OR must register certain substances. This obligation remains with the EU importers, unless they obtain written confirmation from one or possibly even more ORs that their imported quantities of certain products are 100% covered by registrations or exemptions from ORs of non-EU manufacturers. It is therefore up to the non-EU manufacturer to decide which EU importers in his supply chain he wants to exempt from their registration obligations by informing them of the appointment of the OR and having the OR confirm to them in writing that their imports are indeed covered. These confirmations allow the EU importers to maintain clear documentation, as they would otherwise remain responsible for non-confirmed imports and therefore cannot be considered as so-called Downstream Users[7] (DU). By issuing such confirmations to importers, the OR assumes the obligation to maintain up-to-date records of covered and supplied importers and their imported substances. Figures 1 and 2 show a simple example of the material flow and the difficulties associated with the required information flow.

The black/white arrows in Figure 2 represent a dead end for the respective actors, as they do not know whom to contact for appropriate REACH support due to confidentiality. Even in the case of direct communication (black arrows), it is often impossible to get help because the respective supplier either does not want to disclose his product composition or cannot do so because he does not know it himself in detail.

III. Problems and Possible Solutions

Which possibilities does the EU importer have to ensure his REACH compliance and to prove this to the enforcement authorities? To this end, supply chain actors are adopting various approaches that lead many EU importers to believe that they are indeed REACH compliant and do not need to take any action. However, most approaches are associated with several problems that make watertight compliance impossible.

1. Simple Communication of Registration Numbers

A common approach is the simple communication of registration numbers, in the form of general REACH compliance statements or in the Safety Data Sheet (SDS), issued by non-EU manufacturers and further communicated to the EU importers. First of all, this approach is very dependent on the successful communication between several downstream suppliers (formulators, distributors, etc.). This is very error-prone as registration numbers can be altered or even be lost on their way to importers. Even if this transmission takes place successfully, the registration numbers received cannot necessarily be checked for validity, even though registration numbers allow substances to be identified via the ECHA website. In addition, there is no control of the actual supply chains and quantities of substances supplied, which allows so-called "free-riding" on registrations of third

5 Importer - ECHA (europa.eu).

6 Only Representative - ECHA (europa.eu). See REACH Article 8.

7 Downstream User - ECHA (europa.eu).

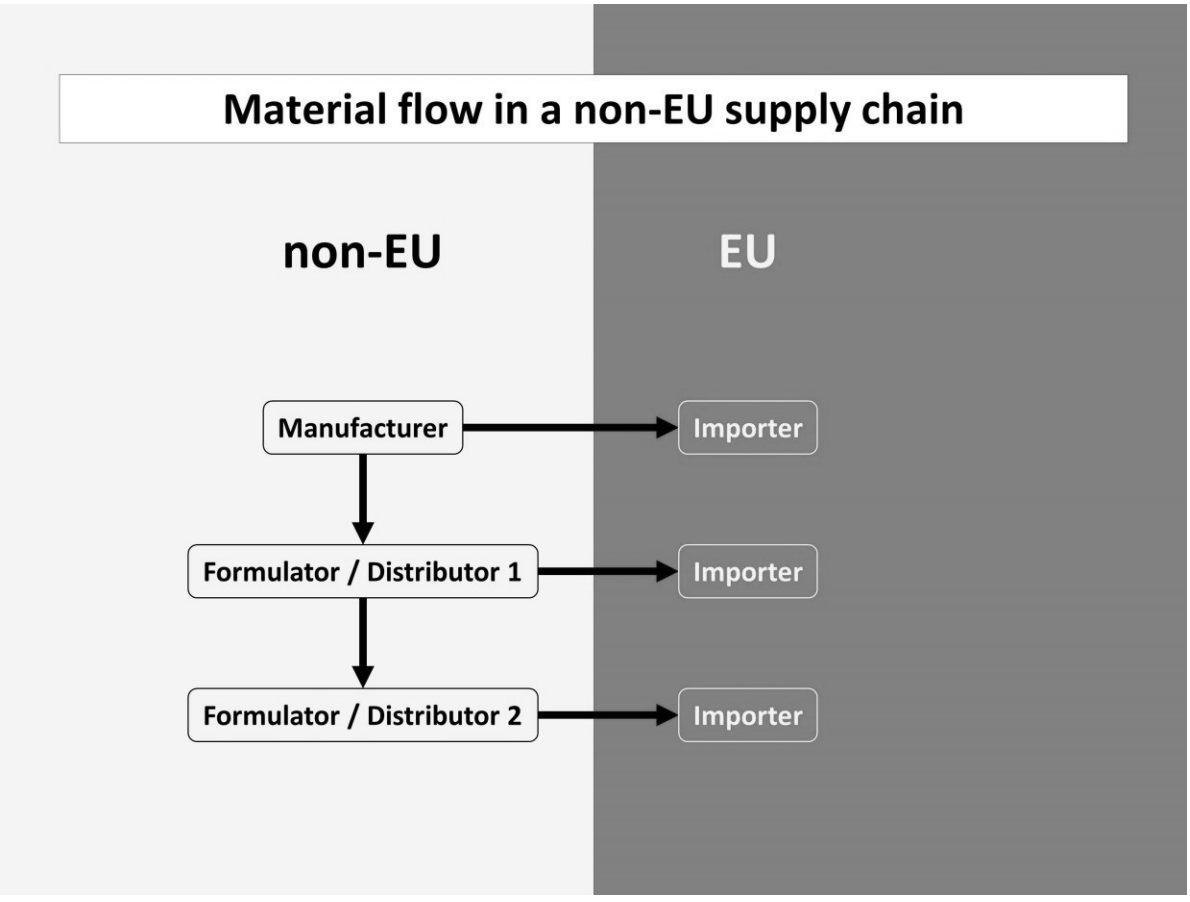


Figure 1: Material flow in a non-EU supply chain (Source: Chemservice, 2021)

parties. No registration numbers are assigned to substances that are exempt from registration, but they can still be contained in imported products. Importers have no chance of checking whether they have actually received all the registration numbers of the substances contained in their products with unidentified compositions. The main problem, however, is that there is no communication between ORs and EU importers regarding the imported substances and quantities. Thus, the ORs cannot fulfil their tracking obligations regarding the importers and their imported substance quantities. Consequently, EU importers are not covered by the registrations of the ORs and are therefore still subject to the registration obligations for their imported substances.

Furthermore, the full disclosure of all registration numbers of a product allows the downstream supplier/user to identify detailed product compositions. The presence of a registration number does not automatically mean that an imported substance is REACH compliant (e.g. if the total annual quantity imported exceeds the registered tonnage band). Relying solely on the communication of registration numbers via Safety Data Sheets (SDS) makes the situation even worse, as SDSs only need to be provided for hazardous products and just the hazardous ingredients need to be disclosed. Moreover, a hazardous substance might not have a registration number yet (because it is included in the supplied formulation <1 tonne/year, for example), but still be REACH compliant. Even wrong registration numbers (copied from others) have occurred frequently. The importer has no chance of verifying this, nor can he submit reliable information to the authorities.

However, the main problem remains that in these cases there is no communication between ORs and EU importers regarding imported substances and quantities.

– The ORs cannot fulfil their tracking obligations on importers and substance quantities.

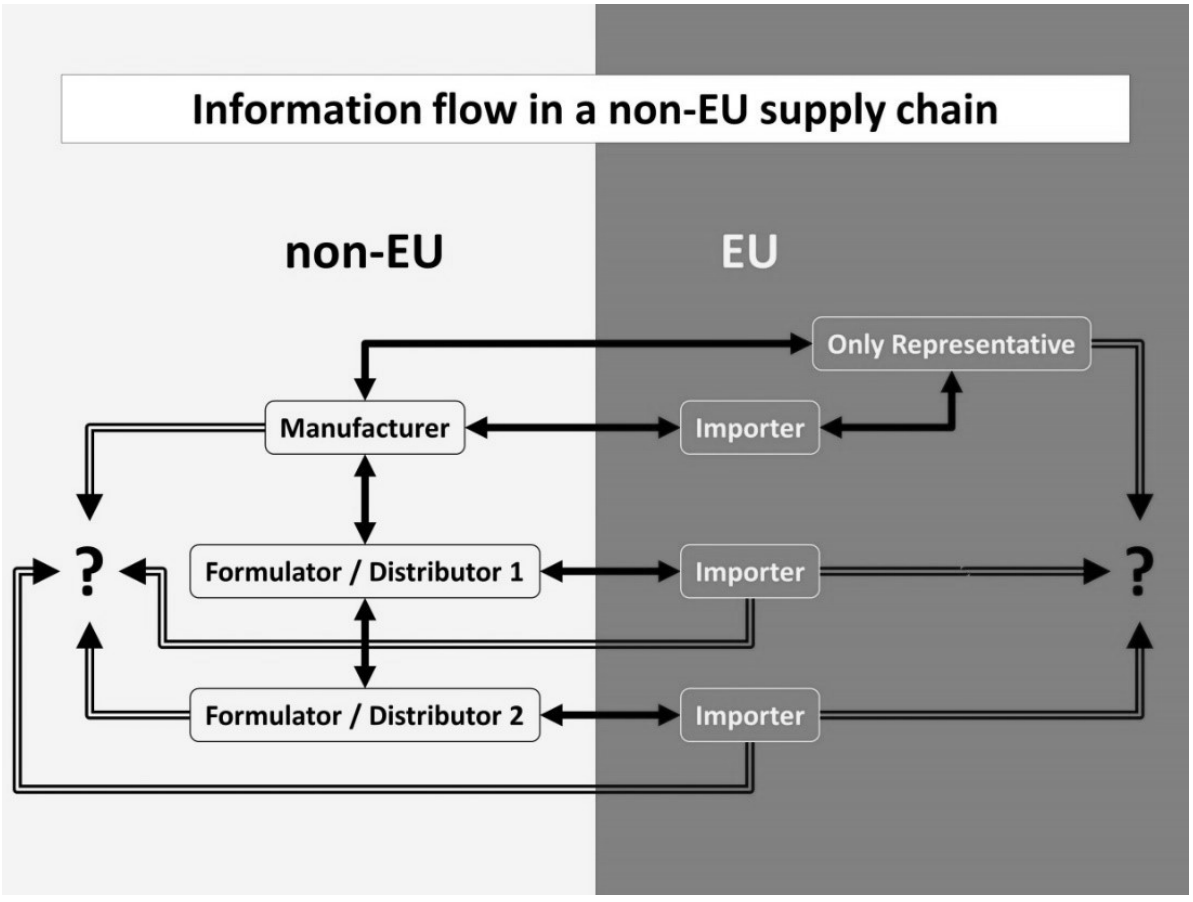


Figure 2: Information flow in a non-EU supply chain (Source: Chemservice, 2021).

- Consequently, EU importers are not covered by registrations of the ORs.
- Thus, EU importers remain responsible for their registration obligations.
- Finally, EU importers without their own registrations are importing illegally.

2. Bi-directional Distribution of REACH Compliance Declarations Within the Different Supply Chains

A well-considered approach to exempt importers from their registration obligations is the bi-directional distribution of REACH compliance declarations within the different supply chains. In this case, non-EU manufacturers issue REACH compliance declarations (including information on the OR(s)) confirming REACH compliance of the products supplied to direct non-EU customers. In the next step, the respective customer is expected to prepare his own compliance declarations for his own products (which may include additional substances) and to add additional OR information, if necessary. These new compliance declarations are based on all declarations received and must then be processed and forwarded by all downstream customers according to the same system until finally the EU import takes place. Subsequently, EU importers are expected to report their annual imported product quantities back to their direct suppliers in the supply chain. These suppliers then have to "split" the received volume information into the respective tonnages of the product components and subsequently pass on this new information (including information about the importers!) to the corresponding suppliers of their own product components. This continues up the supply chains until the relevant information reaches the corresponding non-EU manufacturers, so that the ORs of the non-EU manufacturers can record the information

about EU importers and their imported substance quantities. In this model, the ORs of the non-EU manufacturers can only ensure that all substances are in the correct tonnage bands once all EU imported substance quantities have been reported back through all supply chains. But this is a problem for the OR, as he cannot know if there will be further responses. Importers are not able to prove to the REACH enforcement authorities that their imports are indeed 100% REACH compliant until all relevant ORs have finally confirmed this in writing, which – for the aforementioned reasons – is very difficult.

This system relies completely on all actors in the respective supply chains to correctly calculate all component quantities and to communicate this information completely and correctly down and up all supply chains involved. Due to the complexity of supply chains as well as product compositions, it is highly probable that the final reported product quantities are incorrect or incomplete. Even if all calculations are accurate, importers do not know if and when they have legally compliant documentation. Another problem is that there is no control of the product quantities supplied. Thus, formulators or distributors may be able to obtain the same product, for which they have received a valid REACH compliance declaration from other non-REACH compliant sources, and use the existing declarations for "free-riding" to supply such non-compliant material into the EU.

In the end, it may even happen that a higher product volume is reported back to the non-EU manufacturer than the latter ever delivered to its customers. In such a case, the supply chains would have to be fully checked again. It must be noted that this system requires passing information about EU importers openly through the supply chain. This may result in loss of business and/or competition law issues for some actors in the supply chain. In addition, the system is very labour-intensive and therefore costly.

IV. The Trustee System

The web-based Chemservice OR-Trustee system[8] replaces the previous REACH-Code-Model system[9], which was developed back in 2008 as a unique solution for REACH and has since been used by leading companies in the chemical industry worldwide, including their downstream supply chains with several hundred participants.

1. Objective

The model aims to address all of the aforementioned problems and weaknesses of the various approaches and to provide the EU importer with immediate legally compliant documentation that places him in the status of a DU under REACH. In the Trustee system, for example, an independent OR acts as a trustee for non-EU manufacturers, formulators, distributors and importers, and their respective substances and formulations, to ensure confidentiality at all stages of the supply chains. To exchange the relevant supplier, customer, product and volume information between the supply chain participants and the trustee, a database-driven system is applied, which follows the supply chains in terms of information flow. The system generates unique time and quantity limited confirmations for all supply chain participants and makes them available to the respective actors in the supply chain. This is done for all product supplies that contain material from a non-EU manufacturer and which are intended to be imported in whole or in part into the EU. Using a database, the trustee tracks, among other things, all information on suppliers, customers and importers, as well as the relevant product information and quantities, and ultimately issues Import Certificates (Figure 3) to EU importers regarding the covered imported products and quantities.

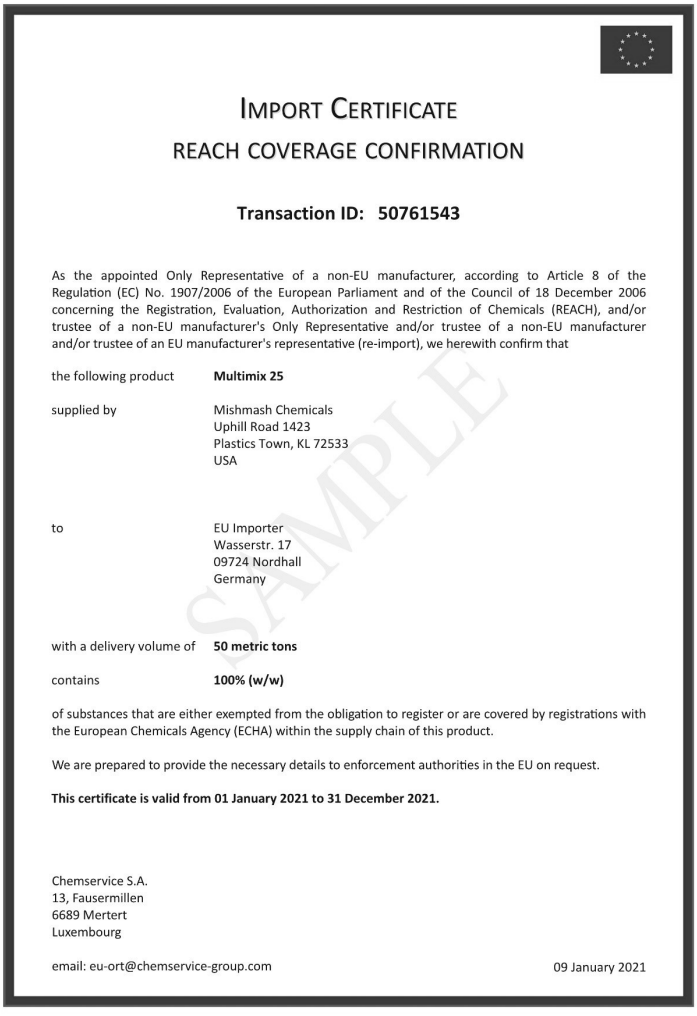
This ensures that all parties involved can continue their business without having to exchange CBI with each other and enables all stakeholders to fulfil their REACH obligations.

2. Benefits

The benefits of the Trustee system are as follows:
- The system is a self-service portal, eliminating unnecessary waiting time by filling out Word forms, email communications, etc.
- Information on the exact composition of raw materials is stored exclusively in a separate offline

8 OR-Trustee – Chemservice (chemservice-group.com).

9 REACH-Code-Model – Chemservice (chemservice-group.com).



IMPORT CERTIFICATE

REACH COVERAGE CONFIRMATION

Transaction ID: 50761543

As the appointed Only Representative of a non-EU manufacturer, according to Article 8 of the Regulation (EC) No. 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), and/or trustee of a non-EU manufacturer's Only Representative and/or trustee of a non-EU manufacturer and/or trustee of an EU manufacturer's representative (re-import), we herewith confirm that

the following product	**Multimix 25**
supplied by	Mishmash Chemicals Uphill Road 1423 Plastics Town, KL 72533 USA
to	EU Importer Wasserstr. 17 09724 Nordhall Germany
with a delivery volume of	**50 metric tons**
contains	**100% (w/w)**

of substances that are either exempted from the obligation to register or are covered by registrations with the European Chemicals Agency (ECHA) within the supply chain of this product.

We are prepared to provide the necessary details to enforcement authorities in the EU on request.

This certificate is valid from 01 January 2021 to 31 December 2021.

Chemservice S.A.
13, Fausermillen
6689 Mertert
Luxembourg

email: eu-ort@chemservice-group.com 09 January 2021

This document was issued electronically and is therefore valid without a signature.

SAMPLE

Figure 3: Sample of a coverage confirmation resp. EU Import Certificate (Source: Chemservice, 2021).

system to which only the respective ORs have access.
- Only information that is already known is exchanged between suppliers and customers. The trustee uses the data exclusively in communication with the enforcement authorities; it is not passed on to participants in the supply chain.
- The certification process follows the supply chains step by step, from manufacturers/formulators to importers, automatically checking all data entered for plausibility and thus preventing unnecessary errors.
- The Trustee system controls the covered product quantities along the supply chain to prevent inadmissible use.
- The ORs of the manufacturers/formulators remain responsible for the accuracy of the information that is submitted and certified by the system.
- All confirmations are valid immediately without having to wait for feedback from importers about their imported substance quantities first.
- The OR-Trustee system allows to provide compliance information to authorities in a simple, quick and safe manner.

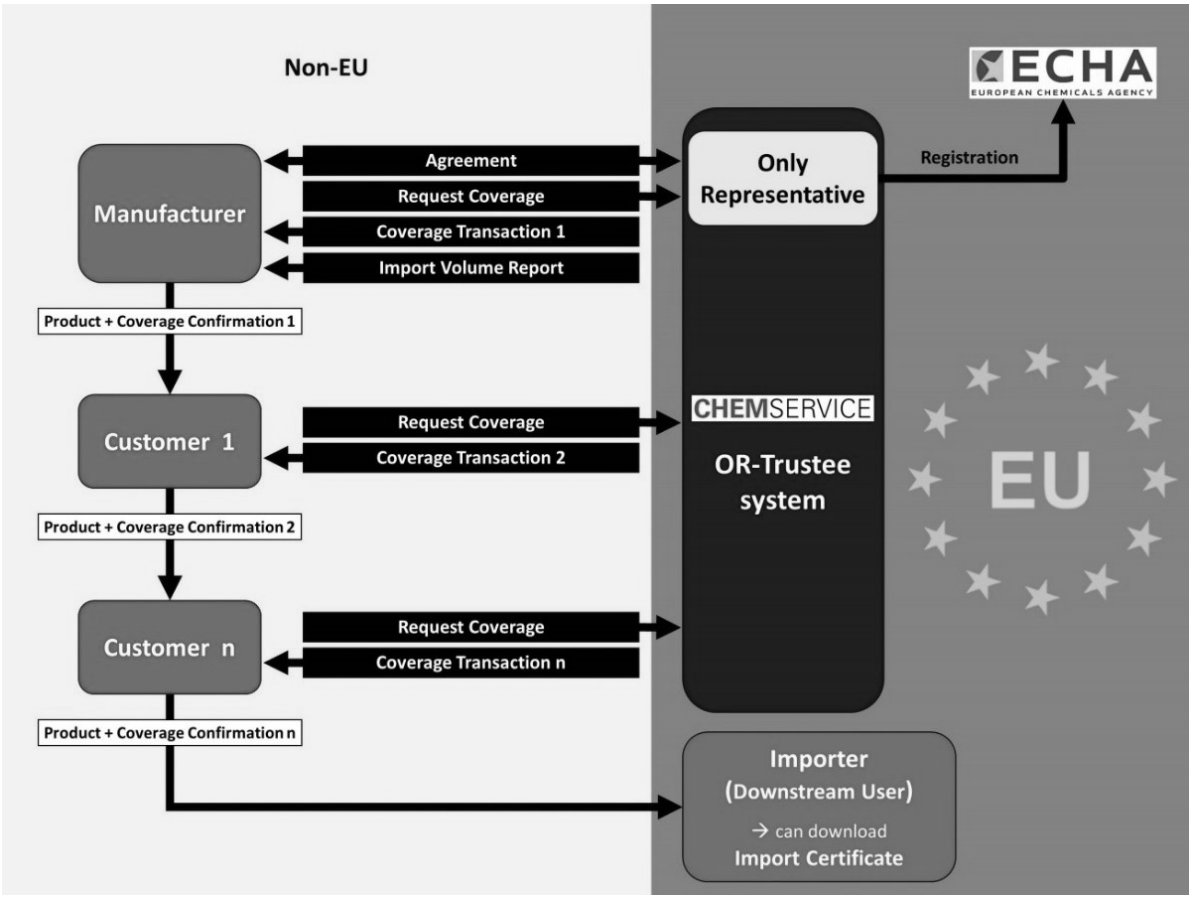


Figure 4: Flow chart of the Trustee system (Source: Chemservice, 2020).

– No need for individual contracts between DUs and Chemservice.

Figure 4 shows a schematic diagram of the process.

V. Conclusion

The OR-Trustee system is an uncomplicated and simple procedure to ensure REACH compliance along the product flows and avoid double registrations, saving resources and costs. The overall control of the coverage confirmations (e.g. verification of covered product quantities, validity of certificates, etc.) is performed centrally and database-driven, thus preventing accidental or even deliberate manipulations. The system is applicable even in case of re-imported substances, where it is relevant that no more material is re-imported into the EU than was previously exported from the EU. Combinations of the different scenarios and multiple supply chains are also easy to implement. The administrative efforts and costs are very low for all parties involved.

Due to the great demand to cover indirect imports, especially in complex multi-stage supply chains with imports to the UK as well as Turkey and in the course of the registration obligations of chemicals in the respective countries, the system was also introduced in these regions. In Korea, a slightly modified model was implemented due to the legal requirements. The system has been facilitated because the respective REACH-like chemical control legislations established the institution of the OR. Without the "OR function", indirect imports could not be adequately reflected.

Finally, it should be noted that this system will be made available to all ORs in the EU, UK and Turkey so that supply chains can be fully mapped and traced with a unified database-driven system.

Reports

Regulatory Framework on Chemicals in India: Latest Developments and Challenges

*Pramod Kumar, Prabhakar Maurya and Sarah Henly**

I. Introduction

Over the past few decades India has introduced widespread industrial reforms through which it has progressively transformed from an agro-based economy into an industry-based economy. Constituting a highly diversified industry covering over 80,000 commercial products, the Indian chemical sector accounts for 3% of the global chemical market and has played a pivotal role in this economic transformation. It is currently valued at USD 163 billion and expected to rise to USD 304 billion by 2025. India ranks 14th in exports and 8th in imports of chemicals (excluding pharmaceutical products) globally.[1] As per World Integrated Trade Solution (WITS) database, India's imports of chemicals were USD 47.56 billion in 2019, and out of which 11.48% (USD 9.29 billion) were imported from Europe and Central Asia.[2]

The Indian chemical industry is a mix of public sector undertakings and private organisations (including multinational companies) and comprises a wide range of small scale as well as large scale manufacturing units. The categories of chemical manufacturing industries have been segmented as follows: Alkali Chemicals, Inorganic Chemicals, Organic Chemicals, Pesticides, Dyes & Pigments, Basic Major Chemicals, Synthetic Fibres, Polymers, Elastomers (S. Rubber) Synthetic, Detergent Intermediates, Performance Plastics.[1]

Currently, India has a complex legislative framework for the management of chemicals and hazardous chemical waste. The Environment (Protection) Act, 1986 acts as an umbrella legislation and covers the Manufacture, Storage, and Import of Hazardous Chemicals (MSIHC) Rules, 1989 (as amended in 1994 and 2000), and the Chemical Accidents (Emergency Planning, Preparedness and Response) (CAEPPR) Rules, 1996. However, there are multiple other rules which governs chemicals management in India, such as Ozone Depleting Substances (Regulation and Control) Rules, 2000; Insecticides Act, 1968 and Insecticides Rules, 1971; Public Liability Insurance Act, 1991; Chemical Weapons Convention Act, 2000; Motor Vehicles Act, 1988 and Central Motor Vehicles Rules, 1989; Explosives Act, 1884 and Explosives Rules, 2008; Disaster Management Act, 2005; Factory Act, 1948; Hazardous and Other Wastes (Management and Transboundary Movement) Rules, 2016; E-Waste (Management) Rules, 2016; Plastic Waste Management Rules, 2016; Batteries (Management and Handling) Rules, 2001.

The Ministry of Environment, Forest, and Climate Change is the nodal Ministry responsible for the implementation of the Environment (Protection) Act, 1986. Some of the other important ministries and departments that regulate chemicals include the Ministry of Commerce and Industry, the Ministry of Labour, the Department of Chemicals and Petrochemicals under the Ministry of Chemicals and Fertilizers, the Ministry of Agriculture, the Ministry of Petroleum and Natural Gas, the Central Pollution Control Board, the State Pollution Control Boards and the National Disaster Management Authority. [1]

An overview of the chemical sector as provided above shows that there is a robust system in place to regulate the sector as a whole. However, the existing framework has many ambiguities and gaps, which pose challenges to the chemical sector and does not

* Pramod Kumar, Director, CEHTRA Chemical Consultants Private Limited, India. For correspondence: <pramod.kumar@cehtra.com>. Prabhakar Maurya, Toxicologist, CEHTRA Chemical Consultants Private Limited, India. For correspondence: <prabhakar.maurya@cehtra.com>. Sarah Henly, Manager, CEHTRA Limited, United Kingdom. For correspondence: <sarah.henly@cehtra.com>.

1 National Law School of Indian University, Handbook on Chemicals and Hazardous Waste Management and Handling in India (2019).

2 World Integrated Trade Solution (WITS) database <https://wits.worldbank.org/> accessed 5 August 2021.

adequately cater for industry-specific requirements. The multiplicity of rules leads to excessive paperwork and management protocols that need to be followed. The involvement of different ministries and government bodies leads to ineffective implementation and enforcement of these regulations. In the absence of the requisite legislative umbrella infrastructure, it poses a serious problem for the chemical products manufactured in India to be compliant with international regulations like European Union's REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals). Thus, there is an urgent need for a harmonized approach and the incorporation of a single-window system for chemical regulation.

II. Draft Chemicals (Management and Safety) Rules, 2020

In 2010, the Ministry of Commerce and the Basic Chemicals, Cosmetics & Dyes Export Promotion Council, popularly known as CHEMEXCIL, proposed a roadmap for the development of new chemical regulations in India. With the inputs from the Department of Chemicals and Petrochemicals, a National Chemical Policy was drafted. However, no progress was made for almost a decade. In May 2019, a technical committee was formed to draft the Chemicals (Management & Safety) Rules (CMSR) in India. In August 2020, the committee had circulated the fifth draft of the CMSR within the industrial bodies for comments.[3] It should be stated here that the implementation date and content of the final version or the CMSR are not yet known, but it is useful to consider the details of the current draft version.

The fifth draft of CMSR is mainly divided into six Chapters, 37 Rules, and 19 Schedules. It provides the regulatory framework for notification, registration and restrictions, or prohibitions, as well as labelling and packaging requirements, and applies to all substances (including substances in mixtures, intermediates and articles with some specific criteria) that are manufactured, imported, placed or intended to be placed on the market in the Indian territory. These rules also provide safety procedures for the manufacture, handling, and import of hazardous chemicals, and preparedness and management of accidents related to hazardous chemicals.

'Hazardous Chemicals' are defined as substances which satisfies the criteria of toxic, flammable, or explosive as per Part I of Schedule X, or substances which are listed in Part II of Schedule X (currently covers 669 chemicals) or column 2 of Schedule XI (currently covers 30 chemicals or categories) and Schedule XII (currently covers 179 chemicals).

The draft CMSR also defines 'Priority Substances' as chemicals classified under Category 1 or 2 of Carcinogenicity, Germ Cell Mutagenicity, Reproductive Toxicity, and/or Specific Target Organ Toxicity (repeated exposure or single exposure) as per the eighth revision of the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS Rev. 8), or fulfils the criteria of Persistent, Bioaccumulative and Toxic or very Persistent or very Bioaccumulative, as set out in Schedule I of CMSR, or any substance listed in Schedule II (currently covers 750 chemicals).

For the purpose of implementation, a National Chemical Authority, consisting of the Steering Committee, the Scientific Committee, Risk Assessment Committee and the Chemical Regulatory Division is proposed to be set up in accordance with CMSR.

1. Notification

The CMSR rules provides an Initial Notification Period of 180 days which shall commence one year from the date of enforcement of the rules and during which all manufacturers or importers (or Authorised Representatives acting on behalf of foreign entities) are obliged to notify the Chemical Regulatory Division of all 'Existing Substances' that they have placed in Indian territory in quantities greater than 1 tonne per annum. All 'New Substances' (and 'Existing Substances' after the expiry of the initial notification period) have to be notified at least 60 days prior to the date on which they are placed in Indian territory in quantities more than 1 tonne per annum.

The information required to be provided for notification are listed in Schedule V of the draft CMSR and must be based on test reports from National Accreditation Board for Testing and Calibration Laboratories (NABL) accredited labs, or GLP labs, or any

3 CHEMEXCIL, Draft Chemicals (Management and Safety) Rules, 20xx' (New Draft OCR 24 Aug 2020) <https://chemexcil.in/uploads/files/NEWOCRdraft_07092020.pdf> accessed 26 July 2021.

other published authentic study report. All data submitted by the Notifier to any foreign regulator in other jurisdictions for the purpose of registration of the same Substance shall be acceptable to the extent possible.

All notifiers of a substance or an intermediate listed in Schedule II, or a Hazardous Chemical, are also required to submit an up-to-date Safety Data Sheet in the format set out in Schedule IX and share such Safety Data Sheet with the Downstream Users of the substance.

Once all required information regarding a Notification has been submitted to the satisfaction of the Chemistry Unit, the Substance shall be entered into the Register of Notified Substances, and a notification number shall be assigned to the Notifier for such Substance and notification certificate in the form set out in Schedule XVIII shall be granted to the Notifier.

The submitted information needs to be updated annually, no later than 60 days after the end of each calendar year.

In accordance with Schedule XIX to CMSR and depending on the enterprise category and tonnage bands, the fees for Notification ranges from 10,000 to 600,000 (~€100 to €7000) and fees for updating tonnage band ranges from 20,000 to 575,000 (~€225 to €6500).

2. Registration

All 'Priority Substances' listed in Schedule II (currently covers 750 chemicals) which are placed or are intended to be placed in Indian territory in quantities greater than 1 tonne per annum must be registered by their manufacturers, importers and authorised representatives (in the case of foreign manufacturers) within one and half years from the date of inclusion of the Substance in Schedule II. Registration may be required for Priority Substances placed in Indian Territory in quantities lower than 1 tonne per annum, if and when recommended by the Scientific Committee and the Division.

Registration shall be done by submitting a Technical Dossier, as set out in Schedule VII. Additionally, an 'Exposure Scenario' shall be submitted at the time of Registration of Priority Substances which are placed or are intended to be placed in Indian territory in quantities less than or equal to 10 tonnes but more than 1 tonne per annum. Moreover, a 'Chemical Safety Report' in the format prescribed in Schedule VIII shall be submitted at the time of Notification or Registration of Priority Substances which are placed or are intended to be placed in Indian territory in quantities greater than 10 tonnes per annum.

For Substances already registered with any foreign regulator in other jurisdictions, the data submitted on the same Substance to that regulator for the purpose of registration shall be acceptable to the extent possible. Like EU REACH Regulation, potential registrants of same substance may jointly register the substance, provided however that such joint registration follows all such obligations applicable to an individual Registration under these Rules. Also, a request may be submitted that trade secrets, proprietary business information, and other intellectual property related data and information shared by the Notifier or the Registrant be kept confidential and not be disseminated publicly.

Upon the receipt of a Registration, a preliminary check for the dossier completeness and receipt of prescribed fees shall be done by the Toxicology Unit. If the Registration is incomplete, the Division may require the Registrant to submit additional information for completing the dossier within 60 days. If the Registration is complete, a registration number shall be assigned to the registrant of such substance and a registration certificate in the form set out in Schedule XVIII shall also be granted to the registrant.

To reflect any change or revision in the information submitted that affects hazard and risk management, the technical dossier needs to be updated, not later than 60 days after the manufacturer, importer or authorised representatives has become aware of such change or revision.

In accordance with Schedule XIX to CMSR and depending on the enterprise category and tonnage bands, the fees for Registration ranges from 15,000 to 900,000 ~€170 to €10,000) and fees for updating tonnage band ranges from 20,000 to 575,000 (~€225 to €6500).

3. Evaluation, Authorisation, and Restriction

The Chemistry and Toxicology Units of the Division shall evaluate the Technical Dossier within one year

of its submission. Based on the evaluation, the unit may request additional test data which must be submitted within 120 days of being informed (or within 210 days if an extension of 90 days is granted). If the Registrant is unable to supply the required information within the deadline, the registration of the substance shall be suspended and the registrant shall not place the substance in Indian territory. Upon submission of the pending information to the satisfaction of Division, the suspension under sub-rule (4) shall be withdrawn.

The Priority Substance Unit of the Division shall evaluate the available data to assess if the registered substance poses an unacceptable risk to human safety or the environment during various uses in India. If the risk posed by the use of the Registered Substance is substantial, it may propose the Risk Assessment Committee to Restrict the use of such Substance or Prohibit such Substance. Once a Restriction on a Priority Substance has been notified, a request for authorization for use of a Restricted Substance may be submitted by a Manufacturer, Importer or Authorized Representative to the Division along with the fees of 1000,000 (~€11000). The Division may grant permission for authorised Use of Substances restricted under sub-rule (4) for an initial period of no more than 4 years. The Division may further extend such permission for a maximum additional period of 4 years on re-application by the Registrant.

An appeal may be filed to the Steering Committee by any person aggrieved by a decision of the Division in writing within 90 days of being notified of the decision of the Division. The Steering Committee must decide the appeal within 60 days from the date on which the appeal is filed. In accordance with Schedule XIX to CMSR and depending on the enterprise category, the fees for filing an appeal ranges from 10,000 to 100,000 (~€100 to €1100).

4. Safety and Accident Preparedness

Hazardous Chemicals shall be transported in a properly labelled vehicle enabled with tracking and communication systems, and in accordance with GHS Rev. 8 and rules under the CMSR and the Motor Vehicles Act, 1988. In case of transportation to or transit through other states, prior notice shall be given to the concerned State Pollution Control Board.

While handling a Hazardous Chemical in an industry, a site safety report in the format set out in Part II of Schedule XIV needs to be provided to the concerned authority with respect to identification and prevention of Chemical Accident hazards and to limit its impact on persons and the environment. This report shall be submitted within 30 days of commencement of any industrial activity or within 30 days of coming into force of CMSR, whichever is later, and an acknowledgement has to be obtained from the authority within 60 days of submission, failing which the activity shall not be continued.

When an industrial activity or isolated storage involving a quantity of a Hazardous Chemical equal to more than the threshold quantity specified in column 3 of respective Schedule XII or XI, a notification in the format set out in Part I of Schedule XIV shall be submitted.

For a new industrial activity, the notification and site safety report shall be submitted at least 90 days before commencing that activity. Provisionally, for industrial activity existing at the date of coming into force of CMSR or a new activity started within 90 days after CMSR enforcement, the notification and site safety report shall be provided within 120 days of the date of coming into force of CMSR.

When an industrial activity involved a quantity of Hazardous Chemical equal to more than the threshold quantity specified in column 4 of Schedules XI or XII, an independent safety audit of the Industrial Activity shall be carried out by an accredited expert agency empowered by the Steering Committee, at least once every 2 years, and a copy of the auditor's report shall be submitted to the Concerned Authority within 30 days after the completion of such audit. At least one Safety Audit Report shall be submitted within 180 days from the date of coming into force of CMSR. Moreover, an up-to-date Emergency plan as per Part III of Schedule IV shall be submitted to the concerned Authority, within 90 days of coming into force of the CMSR for an existing activity or within 30 days of commencement of new industrial activity.

Where a Chemical Accident (including a Major Chemical Accident for the purpose of CMSR) occurs on-site or off-site, it shall be notified to the Concerned Authority within 24 hours and a Chemical Accident report, in the format set out in Schedule XVI, shall be submitted within 72 hours of the accident.

5. Import of Priority Substances or Hazardous Chemicals

Upon completion of the relevant Registration and Notification requirements, import of Priority Substances or Hazardous Chemicals in India shall be informed to the Concerned Authority, at least 15 days before importation of such substance in quantities greater than the lowest of any of the following: 1 tonne or the quantity specified in column 3 of Schedule XI or Schedule XII.

6. Labelling and Packaging

All Priority Substances, Hazardous Chemicals and mixtures containing more than 10% (w/w) of any Priority Substance or Hazardous Chemicals shall be labelled as per Schedule XVII and packaged in accordance with Rule 34, before being placed in the Indian Territory. All product identifiers, hazard statements and pictograms, signal words, and precautionary statements used in the labels shall be in accordance with the GHS Rev.8.

III. Issues and Challenges for CMSR

The CMSR seems to be drafted based on the framework of international chemical regulations like REGULATION (EC) No 1907/2006 of the European Parliament (i.e. REACH Regulation). The REACH Regulation identifies four tonnage bands for standard registrations (1-10 tonnes a year, 10-100 tonnes a year, 100-1000 tonnes a year, and more than 1000 tonnes a year). The registration timelines and data requirements in the technical dossiers varies with the tonnage band. In the lowest tonnage band, less data is required and more than ten years were given for the registration since the first publication of REACH laws in 2006. However, the CMSR doesn't make such a differentiation and all registrants are subject to the same technical dossier requirements and all need to notify and register the chemicals within a short timeline of one and half year from the date of enforcement of the rules. It is impractical to expect the highly unorganised and not well-financed micro, small, and medium enterprises (MSMEs) of the chemical sector to fulfil the regulatory obligations within such a short timeline.

The notification process requires the submission of hazard classification of the substance or safety data sheet according to the eight revision of UN-GHS. India has released a draft of its Dangerous Goods (Classification, Packaging and Labelling) Rules, 2013, but it has never officially been adopted.[4] Without having a proper Government training programme in place, it would be very challenging for the Indian chemical industry to directly adopt the eight version of UN-GHS.

The registration process requires the submission of a technical dossier with 'Robust study summaries'. However, details are missing in the draft CMSR regarding the endpoints for which these 'Robust study summaries' are required. Also, details and codes regarding the 'Use category' are not provided. It requires the submission of 'Chemical Safety Report' but doesn't provide the details on the process to calculate the exposure and risk levels. It suggests to limit the animal testing but doesn't confirm the acceptance of in vitro testing methods. Also, the draft CMSR doesn't elaborate the process of 'Joint Submission' and how to handle data-sharing disputes.

Moreover, the draft CMSR requires 'Site Safety report' and/or 'Safety Audit report' for industrial activities handling hazardous chemicals. However, more details are needed for effective implementation of these rules.

Furthermore, the draft CMSR mandates the appointment of 'Appointed Representative (AR)' for any foreign entity who wishes to place a substance, mixture or article in Indian territory. However, the situation is not clear about who can provide such services and what penalties may apply in the case of non-compliance.

IV. Conclusion

The CMSR is definitely a giant leap towards harmonizing the chemical regulatory framework in India. Establishment of a National Chemical Authority will provide a single-window system to the chemical industry and should help for an effective implementation and enforcement of the CMSR. However, con-

4 Government of India, Ministry of Environment and Forests, Draft Dangerous Goods (Classification, Packaging and Labelling) Rules, 2013 <https://www.mpcb.gov.in/sites/default/files/hazardous-waste/rules/DGCPL_Rules2013.pdf> accessed 6 August 2021.

sidering the current structure of the fifth draft of CMSR, it is likely to carry forward the ambiguities prevailing with the MSIHC and the CAEPPR Rules. Currently, the Indian Government is drafting the CMSR within a closed-door consultation with limited stakeholders only. As the CMSR will impact all the stakeholders of the Indian chemical industry, including non-Indian manufactures of chemicals, it is anticipated that the drafting committee will organise an open public comment phase to invite the suggestions from all stakeholders, and furthermore to organise robust training programmes to educate and prepare the MSMEs before the implementation of these rules.

Outline and Summary of Current Regulatory Developments in the USA and in Canada

*Christy Leeper and Karina Kausch**

The following report intends to provide a summary and an overview of current developments related to chemical control activities in the USA and in Canada.

I. PFAS – US EPA and FDA Stance

Per- and polyfluoroalkyl substances (PFAS) are synthetic chemicals used in a wide range of consumer and industrial products since the 1940s. PFAS are considered PBT substances (Persistent, Bioaccumulative, and Toxic) meaning they are persistent in the environment (forever chemicals), bioaccumulate in people/wildlife, and are toxic.

Certain PFAS are authorized by the FDA for limited use in cookware, food packaging, and food processing equipment. As of February 2021, the FDA has indicated PFAS will continue to be monitored as additional science/data emerges. They do acknowledge evidence to date suggests PFAS may cause serious health conditions. In 2016, the FDA revoked the food contact regulations authorizing the use of long-chain PFAS in food packaging but has not yet updated regulations around the short-chain PFAS.

As of June 2021, 38 out of 50 states have acted on PFAS by either implementing their own policies or adopting those of other states. The majority of current PFAS policy relates to drinking water standards and/or elimination from food packaging materials. In addition to state level policies, retail and food service industry companies are joining in to remove PFAS from their approved packaging materials. With 76% of states taking actions against PFAS, it is only a matter of time before the FDA and/or EPA take additional actions. On June 10, 2021, the EPA announced three actions to better protect all communities from pollution.

1. Proposed rule requiring all manufacturers/imports of PFAS in any year since 2011 to report the following information:
   a. Chemical identity
   b. Categories of use
   c. Volumes manufactured/processed
   d. Biproducts
   e. Environmental and health effects
   f. Worker exposure
   g. Disposal
2. Withdrawal of EPAs compliance guide, published in January 2021, on PFAS Significant New Use Rule (SNUR) for the following reasons:
   a. It weakened the July 2020 SNUR by altering the definition of a surface coating; the July 2020 SNUR prohibits importing certain long-chain PFAS as part of a surface coating without prior EPA approval.
   b. The guide was finalized without considering or addressing public comments.
3. Implemented NDAA (National Defense Authorization Act) requirements to report PFAS to TRI (Toxics Release Inventory)
   a. NDAA automatically added 3 new PFAS to TRI because they are subject to a SNUR under TSCA.
   b. PFAS will be added to TRI on an annual basis per the framework provided by NDAA.

II. Biden-Harris Administration - Environmental Accomplishments in the first 100 Days

President Biden promised to take aggressive action to tackle climate change by rejoining the Paris Agreement and issued a list of more than 100 environmental actions planned for review that protect air, water, and communities. Below are some highlights of the Environmental Protection Agency (EPA) accomplishments in the first 100 days of the Biden-Harris Administration:

1. Combat Climate Change

EPA restored California's waiver to enforce stringent greenhouse gas pollution standards for vehicles. EPA

* Christy Leeper is Managing Director of Chemservice Americas. For Correspondence: c.leeper@chemservice-group.com. Karina Kausch is Regulatory Affairs Advisor for Chemservice Americas. For Correspondence: k.kausch@chemservice-group.com.

also awarded approximately $10.5 million USD to replace older diesel school buses with cleaner buses, including alternative fuel and electric buses, through its Diesel Emissions Reduction Act (DERA) funding. Additionally, EPA relaunched the Agency's climate change website.

2. Restored Scientific Integrity

EPA Administrator Regan issued a scientific integrity directive to all employees. He also reset key science advisory boards, the Science Advisory Board (SAB) and the Clean Air Scientific Advisory Committee (CASAC) to return to the standard process of incorporating a balanced group of expert advisors. Additionally, EPA is in the process of vacating the prior Administration's exclusionary science rule, which placed inappropriate restrictions on the types of scientific studies that EPA could consider in its regulatory processes.

3. Advanced Environmental Justice

After meeting with leaders from the National Environmental Justice Advisory Council, Administrator Regan issued an agency-wide message directing EPA offices to take specific actions to ensure environmental justice is incorporated across the Agency's work in communities overburdened by pollution. These directives include: strengthening enforcement of environmental laws, increasing engagement, building environmental justice considerations into regulations, and incorporating President Biden's Justice 40 directive[1] to consider and prioritize direct and indirect benefits to underserved communities.

4. Funded Job-Creating Water Infrastructure

EPA has closed more than $1.3 billion USD in job-creating Water Infrastructure Finance and Innovation Act (WIFIA) loans to multiple communities. These investments will generate nearly 9,000 jobs and improve water quality and safety for nearly 4 million people. Additionally, EPA announced the availability of $6.5 billion USD in water infrastructure funding under the WIFIA and state infrastructure financing authority WIFIA (SWIFIA) program, which is estimated to create an additional 40,000 jobs. EPA also announced the availability of $2.7 billion USD for State Revolving Funds (SRFs) to assists states, Tribes, and territories.

5. Address PFAS Contamination

Administrator Regan issued a memorandum to EPA's senior leadership creating a new council charged with building on the agency's ongoing work to better understand and reduce the potential risks caused by these chemicals and to present recommendations to the Administrator within 100 days. EPA is also moving forward to establish a drinking water standard for perfluorooctanoic acid (PFOA) and perfluorooctanesulfonic acid (PFOS) and reissued the final Human Health Toxicity assessment for Perfluorobutane Sulfonic Acid (PFBS).

III. EPA Updated List of Alternative Test Methods to Animal Testing

The Toxic Substances Control Act (TSCA), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, directs the U.S. Environmental Protection Agency (EPA) to:

- Reduce and replace, to the extent practicable and scientifically justified, the use of vertebrate animals in the testing of chemical substances or mixtures; and
- Promote the development and timely incorporation of alternative test methods or strategies that do not require new vertebrate animal testing.

TSCA also requires EPA to develop a strategic plan on this topic and provide a progress report on the implementation of the plan to Congress every five years since the date of the enactment of the Lautenberg Chemical Safety Act, i.e., beginning in 2021.

In 2018, EPA published its Strategic Plan to Promote the Development and Implementation of Alternative Test Methods within the TSCA Program. The

1 40% of the benefits from federal climate action go to disadvantaged communities to offer clean energy and energy efficiency, public transit, and affordable and sustainable housing.

Strategic Plan incorporated input from two public meetings and written comments submitted on the draft strategic plan.

The Strategic Plan[2] has three core components: (1) identifying, developing, and integrating New Approach Methodologies (NAMs) for TSCA decisions; (2) building confidence that the NAMs are scientifically reliable and relevant for TSCA decisions; and (3) implementing the reliable and relevant NAMs for TSCA decisions.

The definition of NAMs has evolved over time. Currently, it is broadly descriptive reference to any non-animal technology, methodology, approach, or combination thereof that can be used to provide information on chemical hazard and risk assessment. NAMs are functionally equivalent to "alternatives" to animal testing.

In September 2019, Administrator Wheeler directed the Agency, and specifically the Office of Chemical Safety and Pollution Prevention (OCSPP) and the Office of Research and Development (ORD), to prioritize efforts and resources towards activities that will demonstrate measurable impacts in the reduction of animal testing while ensuring protection of human health and the environment.

In summary, the goals laid out in the Administrator's directive for the Agency are to:

- Reduce its requests for, and funding of, mammalian studies by 30% by 2025;
- Eliminate all mammalian study requests and funding by 2035; and
- Exclude from its approval processes (as much as possible) any reliance on mammalian studies conducted after January 1, 2035, including those performed by third parties.[3]

The OCSPP and the ORD experts were tasked with developing the New Approach Methods (NAMs) work plan[4] to set the objective and strategies for using NAMs that will reduce the use of animal testing while continuing to protect human health and the environment.

The Work Plan includes the following objectives:

- Evaluate Regulatory Flexibility for Accommodating NAMs
- Develop Baselines and Metrics for Assessing Progress
- Establish Scientific Confidence and Demonstrate Application
- Develop NAMs that Fill Critical Information Gaps
- Engage and Communicate with Stakeholders

In February 2021, the EPA published its second update to the list of alternative test methods or strategies (New Approach Methodologies or NAMs) that do not require new vertebrate animal testing. This action helps meet the requirements of the Toxic Substances Control Act to reduce and replace, to the extent practicable and scientifically justified, the use of vertebrate animals in the testing of chemical substances or mixtures. No new Organization for Economic Cooperation and Development (OECD) Test Guidelines (TG) were adopted in 2021.

The updated list[5] incorporates the following changes from the 2019 List:

- One new test guideline specific for endocrine active substances was added to the List of Test Guidelines for Human Health Effects.
- Incorporated two additional EPA guidance documents that reduce the use of animal testing,
  1. EPA's *Draft Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Technical Chemicals & Supporting Retrospective Analysis,* which was released in September 2020.
  2. The link for the *Final Guidance for Waiving Sub-Acute Avian Dietary Tests for Pesticide Registration & Supporting Retrospective.*
- OncoLogic™ version 9.0 of the organic chemicals' module was added to the List of Other NAMs Used for TSCA. OncoLogic™ is a system that that uses mechanistic and structure-activity relationship information to predict the carcinogenicity of organic chemicals (Version 9.0) and fibers, metals, and polymers (Version 8.0).

The EPA will review any potential NAM that it receives and determine the merits/relevance of the information. The EPA encourages all stakeholders to consult with them on the development and/or use of NAMs.

2 See, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/strategic-plan-reduce-use-vertebrate-animals-chemical>

3 Subject to applicable legal requirements, including the Administrative Procedure Act.

4 See, < https://www.epa.gov/chemical-research/epa-new-approach-methods-work-plan-reducing-use-animals-chemical-testing>

5 The Second Update to the List replaces the First Update to the List published on December 5, 2019.

IV. TSCA New Chemical Reviews

The U.S. Environmental Protection Agency (EPA) announced a major change in its approach to reviewing new chemical submissions. This will likely lead to the vast majority of premanufacture notification (PMN) submissions receiving orders from EPA under Section 5 of the Toxic Substances Control Act (TSCA). Chemical manufacturers and their downstream users should be prepared for these changes.

EPA's announcement identified two specific changes that will overhaul how EPA reviews, approves, and regulates new chemicals.

1. EPA will issue orders when they *lack sufficient information* to determine whether a new chemical is likely to present an unreasonable risk and when a new chemical *may present an unreasonable risk*. EPA will no longer rely on proposed Significant New Use Rules (SNURs) as a basis to conclude that these uses are not likely to present unreasonable risks, thereby rendering orders unnecessary. EPA had previously deployed non-order SNURs when the PMN submitter lacked information on reasonably foreseen conditions of use and could not include data to support a "not likely" determination on these uses. Because EPA is likely to take an wide interpretation of "reasonably foreseen," submitters should anticipate that EPA will consider *any conceivable use* of a chemical to be "reasonably foreseen." Combining this broad interpretation of "reasonably foreseen" with EPA's intention to use orders when it lacks sufficient information, it is safe to say that there will be a shift in the quantity of orders that EPA will issue.
2. EPA will no longer assume that companies will protect their workers with the appropriate personal protective equipment (PPE)—even if the submitter already uses such PPE and failure to do so would violate the Occupational Safety and Health Administration's regulations.

   This means that if EPA determines that a new chemical would present an unreasonable risk to workers in the absence of PPE, EPA will now issue an order requiring the submitter to provide prescribed levels of PPE to its workers and subsequently will promulgate a SNUR to apply to all other entities that manufacture or use the chemical. Therefore, EPA's new assumption—that companies might not adequately protect their workers, regardless of whether they actually provide the requisite PPE—will increase the number of orders even more.

It is important to keep in mind EPA's desire and ability to issue unilateral orders if submitters are not willing sign consent orders within the statutory 90-day deadline for EPA to make a final determination. If unilateral orders become more common, submitters may be left with no other recourse than filing lawsuits to challenge EPA's determinations under TSCA Section 5.

V. Proposed Fee Updates

U.S. EPA had proposed the following risk evaluation fee increases based on projected costs per chemical to conduct a risk evaluation:

- $2,560,000 paid jointly by manufacturers and importers for EPA-initiated chemical risk evaluations. Current fee amount is $1,350,000 per chemical.
- A company requesting a risk evaluation of a TSCA workplan chemical would make two payments of $945,000 plus an additional final payment to cover any remaining costs to cover 50% of actual costs. Current fee amount is $1,250,000 plus an additional payment to recover 50% of actual costs.
- A company requesting a risk evaluation of a chemical not included on the TSCA workplan would make two payments of $1,890,000 with a final payment to cover any remaining (100%) of actual costs. Current fee amount is one payment of $2,500,000 with an additional payment for any remaining actual costs.

EPA is not proposing an increase for the PMN (premanufacture notice) filing fee, set at $16,000. EPA proposes an increase for other fees associated with new chemical review, as follows:

- Companies would pay $500 to a bona fide notice of intent to manufacture or import. Currently no fee is required.
- Companies would pay $500 to file a notice of commencement after PMN review. Currently, no fee is required.

EPA also proposes changes to timing for fee payment. For EPA-initiated risk evaluations, payment is collected over two installments, with the first payment of

50% due 180 days after EPA publishes the final scope of a chemical risk evaluation. The second payment is due not later than 545 days after EPA publishes the final scope of a risk evaluation. Currently, payment is due in one payment 120 days after publication of the final scope. The timeline for manufacturer-requested risk evaluations is also extended to 180 days after providing EPA with notification for the first payment of three installments.

In its 2022 budget proposal, the EPA signaled it intends to re-propose the fee updates to expand focus based on public comments to date. Comments have not been supportive with the majority of chemical manufacturers opposing the proposal for reasons including: difficulty and resources needed for reporting, exposure of confidential production information based on ability to back-calculate, and an undue financial burden falling upon small businesses. A revised fee rule will likely not be adopted until Fiscal Year 2022, with implementation in FY 2023.

VI. Food and Drug Administration (FDA) Amendments

Upon assumption of control over the Executive Branch, the Biden-Harris Administration ordered a regulatory freeze of new or pending rules. However, several legislative actions have been enacted by Congress in late 2020 and early 2021, as they are outside of the regulatory freeze.

- National Centers of Excellence in Continuous Pharmaceutical Manufacturing Act (H.R. 4866)

This bill addresses the potential need for continuous manufacturing in pharmaceuticals in the United States. It calls upon the FDA to name National Centers of Excellence in Continuous Manufacturing (NCEs) to be leaders in this field.

- Making Objective Drug Evidence Revision for New (MODERN) Labeling Act (H.R. 5668)

Generic drug labels are required to have the same label as its RLD (reference listed drug). RLDs may be revised throughout the drug life cycle, but no mechanism exists to prompt a revision of the corresponding generic drug label. H.R. 5668 Provides the FDA with express authority to require generic drug manufacturers to update their labels based on new scientific evidence pertaining to the generic drug, labeling no longer meeting current legal and regulatory requirements, or when relevant accepted use is not listed on the drugs approved labeling.

- Safeguarding Therapeutics Act (H.R. 5663)

Since the onset of COVID-19, the presence of unapproved or counterfeit sanitizer and PPE in the market has increased drastically. The Safeguarding Therapeutics Act gives the FDA the authority to seize and destroy counterfeit medical devices refused admission at the border if they are valued at less than $2500. The Act also added is the definition of "counterfeit device" which aligns to the definition of "counterfeit drug".

- The Food Allergy Safety, Treatment, Education, and Research (FASTER) Act of 2019 (H.R. 2117)

Expands the current CDC allergen list to include sesame as a major allergen. Provides the FDA with the authority to add other foods to the list of major allergens based on new scientific research or evidence.

VII. Canada and U.S. Alignment with GHS Revision 7

On December 19, 2020, the Government of Canada published Canada Gazette, Part I, *Volume 154, Number 51*[6] containing Health Canada's proposed amendments to the Hazardous Products Regulations (HPR). These latest amendments seek to align Canada's Workplace Hazardous Materials Information System (WHMIS) with the seventh revised edition of the UN's Globally Harmonized System for Classification and Labeling of Chemicals (GHS).

Earlier this year, the U.S. Department of Labor's Occupational Safety and Health Administration (OSHA) published in the *Federal Register* a notice of proposed rulemaking to update its Hazard Communication Standard (HCS) with GHS Revision 7[7].

By aligning with Revision 7 of the GHS, the two nations are set for further progress toward achieving US – Canada Regulatory Cooperation Council's (RCC) Joint Forward Plan goals by ensuring proactive alignment of labelling and SDS requirements for workplace hazardous products in the US and Canada.

6 https://gazette.gc.ca/rp-pr/p1/2020/2020-12-19/html/reg4-eng.html

7 https://www.federalregister.gov/documents/2021/02/16/2020-28987/hazard-communication-standard

1. Notable Changes for Canada Workers

The proposed amendments include changes to several definitions listed in the HPR, the adoption of a new hazard category for non-flammable aerosols and new subcategories for flammable gases, the addition of a new test procedure for Oxidizing Solids, and modifications to Schedule 1 of the HPR to update the hazard information elements required on SDSs and supplier labels.

The proposed HPR amendments are expected to provide the following benefits and protections for Canadian workers:

- Changes to hazard classification procedures for amended hazard classes will help ensure products are being classified to better reflect the true hazards they pose (e.g. water-activated toxicants, flammable gases and pyrophoric gases);
- Amended hazard classes and categories/subcategories will include more detailed precautionary statements on product labels and SDSs to provide workers with a greater understanding of product hazards;
- The adoption of a new hazard category, hazard communication elements (signal word, hazard statement and precautionary statements) and other health and safety information will be required on labels and SDSs for non-flammable aerosols. These hazards are not covered in the current HPR, yet still pose a potential hazard because containers may burst if heated;
- New hazard subcategories will be adopted to better distinguish between extremely flammable gases, extremely flammable gases that are pyrophoric, extremely flammable gases that are chemically unstable, highly flammable gases and other flammable gases. The adoption of these new subcategories, along with corresponding hazard statements and precautionary statements, help better protect workers from the hazards associated with these products;
- Alignment of the HPR with GHS revision 7 will provide more comprehensive and detailed health and safety information on product labels and safety data sheets for the benefit of workers; and
- The HPR amendments will also clarify several provisions to better reflect their original intent and provide clearer health and safety information that will be easier for workers to understand.

2. Notable Changes for U.S. Manufacturers

Under the HCS, chemical manufacturers or importers must classify and provide information regarding the hazards of chemicals they produce or import. OSHA's proposal includes significant revisions to these rules. Proposed revisions applicable to chemical manufacturers or importers include revised criteria and new categories for the classification of certain health and physical hazards, revised requirements for labeling small containers and relabeling chemicals released for shipment, new rules regarding the disclosure of concentrations claimed as trade secrets, and changes to the required contents of SDSs.

3. Notable Changes for U.S. Employers

The HCS requires employers to provide information to employees about hazardous chemicals to which they are exposed in the workplace. Employers provide this information through a hazard communication program, labeling and other forms of warning, SDSs, and training. Although the rules applicable to hazard classification and labeling are intended towards chemical manufacturers and importers, employers should review proposed changes to these rules for any updates that will have an impact on their hazard communication and training requirements.

With modifications to existing hazard classifications and the addition of new hazard classes, hazardous product manufacturers, importers and distributors in the U.S. will need to re-evaluate the hazards of the products they sell or import into the country to ensure product hazards are classified according to GHS Revision 7 hazard classification criteria.

As a result, many SDSs and shipped container labels for chemicals affected by the proposed changes will need to be re-authored to reflect changes in chemical hazard classification or information and ensure compliance with updated requirements. Specific industry sectors identified by OSHA within the proposal including chemical manufacturing, oil and gas extraction, and plastics and rubber products manufacturing will be more significantly affected by these classification changes.

Downstream users will also need to assess whether they have chemicals affected by the revised classifi-

cations (e.g., aerosols, desensitized explosives, flammable gases) and prepare to manage the influx of updated SDSs as they enter the workplace. If they have chemicals affected by the proposed rule, they would also need to revise their written HazCom Plans and HazCom training to account for new classifications and new hazard and precautionary statements.

It is important to note that the Canadian and U.S. regulatory proposals are not final. Health Canada is currently developing the *Canada Gazette*, Part II regulatory submission which, when published, will be the final version of the Regulations Amending the *Hazardous Products Regulations* (GHS, Seventh Revised Edition) and Order Amending Schedule 2 to the *Hazardous Products Act*. U.S. OSHA's amendments to the HCS will become final when the Final Rule is published in the Federal Register.

VIII. State Developments

1. California

The state of California maintains Proposition 65 (Prop 65), which requires a warning label be placed on any consumer product which contains chemicals suspected by the state of causing cancer or reproductive harm. Prop 65 provides specific guidance for each of its listed chemicals, along with detailed warning requirements.

A Prop 65 warning is considered a "safe harbor", indicating use of the warning deems the product to not violate the regulation. There are two safe harbor warnings within Prop 65 which are commonly referred to as the "long form" and "short form".

In January 2021, the following revisions to the short form warning were proposed:

- Short form warning may only be used if:
- Total surface area of the product label is 5 square inches or less.
- Package shape or size cannot accommodate the long form warning.
- Short form warning will not longer be permitted on websites/catalogs/other print materials.
- Short form warning must include at least one chemical present in the product suspected of causing cancer or reproductive harm.

Public comments were accepted through March 29, 2021. It is anticipated the updated short form warning will go into effect in 2022, triggering widespread label and website updates.

IX. Canada Regulatory Developments

1. Toxic Substances Warning Label Act Introduced

The Toxic Substances Warning Label Act (C-266) was introduced and completed its first reading in the House of Commons in February of this year. The bill would prohibit the sale, importation, and advertisement of any product that contains a toxic substance or produces a toxic substance when used, unless that product has a label warning of the potential exposure to the toxic substance affixed on one or more surfaces of its packaging.

The bill sets out, in lists established by the California EPA, the U.S. National Toxicology Program and the European Chemicals Agency, the toxic substances to be banned in Canada unless they are clearly labelled. The Bill, which was developed in collaboration with Toxic Free Canada, Environmental Defence and Option consommateurs in Quebec is the newest push for hazard-based labelling in Canada.

The bill focuses on the hazard of a substance (the inherent ability of something to cause harm such as an ingredient) and does not consider the exposure (route of exposure, how much and how often), which does not provide sufficient information about the safety or risk of a substance. However, this bill is not expected to go far in Parliament.

2. Canada Rolling Workplan for Performance Measurement Evaluations of Toxic Substances

Canada conducts performance measurement evaluations to provide Canadians with information on the effectiveness of risk management actions for substances found to be toxic under the Canadian Environmental Protection Act, 1999 (CEPA). Canada methodically evaluates the risk management, human health, and environmental objectives using robust data and expert analysis.

The following table provides a high- level rolling workplan of performance measurement evaluations of risk management strategies for certain substances

Table 1: Proposition 65 – Safe harbor warnings

Harbor Type	Requirements
Safe Harbor 1 – the long form	Warning symbol "Warning" in bold, capital letters Detailed language of the potential exposure Name of at least one chemical present in the product on the Prop 65 list
Safe Harbor 2 – the short form	Warning symbol "Warning" in bold, capital letters Brief language of the potential exposure and reference to web link

Table 2: Evaluation Strategy for toxic substances

Timing	Substances	Targeted Component of the Evaluation
Evaluations in progress	Bis(2-ethylhexyl) phthalate (DEHP)	Health
	Inorganic arsenic compounds	Health
	Benzene	Health
	Dichloromethane	Health
	Dioxins and furans	Health
	Polychlorinated biphenyls (PCB)	Health
Upcoming evaluations (to be initiated in 2021/22 through 2022/23)	Inorganic arsenic compounds	Ecological
	Inorganic cadmium compounds	Health and Ecological
	Ethylene oxide	Health
	Nonylphenol and its ethoxylates	Ecological
	Polycyclic aromatic hydrocarbons (PAH)	Health and Ecological
	Octamethylcyclotetrasiloxane (D4)	Ecological
	Dioxins and furans	Ecological
	Perfluorooctane sulfonate (PFOS), its salts, and its precursors	Ecological

in progress or to be initiated over the next four years. Substances were selected as set out in the Performance Measurement Evaluation Strategy for toxic substances. Note that the substances and timeframes listed in the Table 2 below may be subject to change.

3. Strengthening Environmental Protection for a Healthier Canada Act

Commonly referred to as the CEPA (Canadian Environmental Protection Act) Modernization Bill, Bill C-28, Strengthening Environmental Protection for a Healthier Canada Act was introduced and completed its first reading in the House of Commons in April 2021. This is the first major proposal for updates to the legislation since it was enacted in 1999. The bill proposes amendments intended to address criticism of CEPA being ineffective in regulating newly discovered toxic substances and being inadequate in protection of vulnerable communities.

The bill seeks to recognize the right of every individual in Canada to a healthy environment to the extent provided for under the Act. The bill does not fully define this proposal and requires an "implementation framework" be established within two years of when the legislation becomes effective. The framework shall expand upon the ideas of environmental justice, including disproportionate impact of vulnerable populations, how data will support the protection of the right, and the balance of social, economic, health, scientific, etc. factors as related to the right to a healthy environment.

The bill also proposes updates in how toxic substances are controlled. A Plan of Chemicals Management Priorities will be required which includes prioritization for review of toxic/potentially toxic chemicals and a plan for management of risks to the environment or human health. A Watch List of substances capable of becoming toxic would also be implemented. The Minister of Environments power of authority would be extended to products containing a toxic substance or where a toxic substance may be released. Assessments would include details regarding a vulnerable population in relation to the substance, including cumulative effects due to exposure.

Upcoming Events 2021

THE LEGAL PUBLISHER
lexxion

	September	
■	29 – 1.10.	Irregularities and Fraud in EU Funds and Public Procurement | Amsterdam & Online
	October	
■	04	Subsidy Control: Changes and Challenges of the New UK Regime | Online Course
■	06 – 08	Strengthen your Risk Management and the Anti-Fraud and Corruption Cycle within EU Funds | Venice
■	07 – 08	Fundamentals of Public Procurement | Nice & Online
■	13 – 14	State Aid Requirements for ESI Funds | Venice & Online
■	20 – 21	State Aid for Energy and Environment | Lisbon & Online
■	20 – 22	Financial Management, Control and Audit of ESI Funds: Transition Towards 2021-2027 | Rome & Online
■	21 – 22	How to Best Prepare for Closure of ESI Funds and AMIF/ISF/BMVI 2014-2020 | Rome & Online
	November	
■	03 – 05	How to Effectively Manage, Verify and Audit Migration & Security Funds | Barcelona & Online
■	08 – 09	Public Procurement Requirements for ESI Funds | Málaga & Online
■	09 – 10	State Aid for Research, Development and Innovation Projects | Amsterdam & Online
■	16	State Aid for Tax Measures | Brussels & Online
■	24 – 26	Indicators, Monitoring and Evaluation in ESI Funds and Migration & Security Funds | Florence & Online
■	25 – 26	How to Most Effectively Use TA for ESI Funds and Migration & Security Funds | Florence & Online
■	25 – 26	EStALI Autumn Conference on European State Aid Law | Berlin & Online
	December	
■	02 – 03	EU Funds 2021-2027: Implementing the New Regulations | Barcelona & Online
■	08 – 10	Simplified Cost Options for ESI Funds and Migration & Security Funds | Vienna & Online
■	09 – 10	Innovation in Public Procurement | Vienna & Online
■	09 – 10	Winter Master Class: „State Aid Uncovered" with Prof. Dr. Phedon Nicolaides | Madrid
■	14 – 15	Essentials of State Aid Law | Brussels & Online

■ European State Aid Law — EStAL

■ European Structural and Investment Funds — EStIF

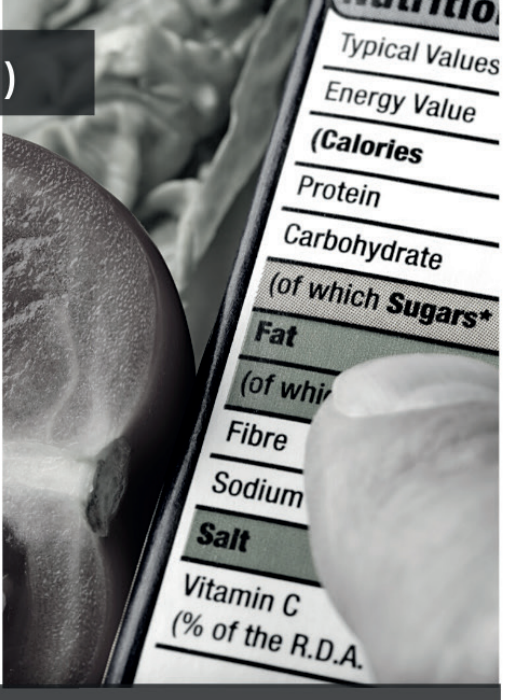
■ European Procurement and Public Private Partnership Law — EPPPL

For more information and registration please visit our website

www.lexxion.eu

Tickets starting from: € 645,- (excl. VAT)

Brussels & Online



15TH EUROPEAN FOOD AND FEED LAW CONFERENCE

21 - 22 October 2021

The EFFL Conference is an established annual event organised under the auspices of the European Food and Feed Law Review, bringing together experts from both public and private sectors.

This year we will discuss following topics , among many other topics:

- actions of the EU against food waste
- the new food labelling information system
- supply chain law
- transparency regulations
- learnings from the industry on the ban of titandioxide
- biocides in the food production
- the Brexit experiences and developments regarding the marketing of food

Renowned experts from the public authorities, food industry, private practice and academia will provide you with in-depth knowledge on European Food and Feed Law.

Hosted by
Prof. Andreas Meisterernst,
Partner at Meisterernst Rechtsanwälte

THE LEGAL PUBLISHER
lexxion

UK REACH

Chemical Regulations post-Brexit in Great Britain

Also available as E-Book

Since EU REACH entered into force in 2007, jurisdictions around the globe have sought to align their regulatory frame-works governing the chemical sector accordingly. By contrast, the United Kingdom, following its withdrawal from the European Union, may choose a path of regulatory divergence.

While the Northern Ireland Protocol has ensured that EU REACH will con-tinue to apply in Northern Ireland, the rules governing the manu-facture, sale and distribution of chemicals in Great Britain have been significantly altered.

To help chemical experts, manufac-turers, distributors, lawyers and consultants navigate these new rules, this book offers the first consolidated version of UK REACH.

Highlighting the sections of EU REACH that have been altered, this text is essential reading for anyone interested in placing chemical products on the UK market.

Order now

https://books.lexxion.eu/books/index

UK REACH
Berlin-2021; 112 Pages
Publication Print 2021: 39,80€
ISBN: 978-3-86965-377-8 (Book)
ISBN: 978-3-86965-378-5 (E-Book)

THE LEGAL PUBLISHER
lexxion

INTERNATIONAL CHEMICAL REGULATORY LAW REVIEW

Although it has been 10 years since the ground breaking REACH regulation came into force and fundamentally changed the way chemical substances are regulated, evaluated and authorised, this dynamic and ever changing policy area merits continuous scrutiny and analysis, including in Europe, Asia and North America. The International Chemical Regulatory and Law Review (ICRL) provides a forum to identify and analyse important legal and regulatory developments in this field on the national, EU and international level. The journal allows experts to report on and discuss important processes that shape the interpretation and application of chemical regulation, in particular those related to biocide law, chemical registration and licenses and the protection of human health and the environment.

ISSN: 2566–834X