Volume 4 | Number 2

ICRL 2 2021

ICRL

International Chemical Regulatory and Law Review

Articles

- The Revision of the Swiss Chemicals Ordinance
  Dag Kappes
- New Requirements on Safety Data Sheets in South Korea
  Dieter Drohmann, Jae-Seong Choi and Sun-Jong Park

Reports

- REACH Restriction Concerning the Use of Diisocyanates
  Paula Diaz
- China REACH Update (MEE Order No. 12): Difference with REACH
  Dandan Ge
- Borderline Products in the EU: Obstacles for Manufacturers and Importers
  Minetta Wunderskirchner

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Contents

Editorial 51
Dieter Drohmann

ARTICLES

The Revision of the Swiss Chemicals Ordinance 53
Dag Kappes

New Requirements on Safety Data Sheets in South Korea 61
Dieter Drohmann, Jae-Seong Choi and Sun-Jong Park

REPORTS

REACH Restriction Concerning the Use of Diisocyanates 68
Paula Diaz

Borderline Products in the EU: Obstacles for Manufacturers and Importers 72

China REACH Update (MEE Order No. 12): Difference with REACH 75
Dandan Ge

MISCELLANEOUS

Imprint II

Masthead III

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.

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For further information please contact
info@lexxion.eu
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This journal may be cited as [2021] ICRL.

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

ICRL

International Chemical Regulatory and Law Review

Editorial

As the world slowly emerges out the Covid-19 pandemic, the chemical industry can look back upon a difficult 18 months; and look forward to more uncertainty. Global restrictions on movement disrupted supply chains, the serve economic shock hit share prices and disturbances to markets reordered the global competitive order. In addition to these economic challenges, manufactures and suppliers must continue to keep abreast of the ever shifting legal and regulatory landscape. Since the last publication of ICRL, the European Chemicals Agency (ECHA) has started the process of updating its guidance on the information requirements and chemical safety assessment (IR&CSA) for nanoforms and the EFSA and ECHA have begun the review of renewal assessments of glyphosate, while the shape of the UK's post-Brexit regulatory regime still remains unclear. Keeping an eye on these developments, let me turn to our current issue.

In his article on the upcoming revision of the Swiss Chemicals Ordinance, Dag Kappes highlights two crucial changes. Firstly, in the future, the language of the place of supply will be decisive for the labelling of all chemicals including biocides, fertilisers and plant protection products. Secondly, manufacturers and importers will have to notify new substances, which are not listed on a static existing substances list, by submitting a data set to the notification authority before placing them on the market. All substances not registered in the EU, but placed on the market in Switzerland will be subject to notification.

In our article on developments in South Korea, my colleagues Jae-Seong Choi and Sun-Jong Park and I outline new requirements on safety data sheets. The existing regulation's low accuracy, abuse of 'trade secret' and unclear standards mean that a revised version was necessary. We detail all important changes made by the South Korean Ministry of Employment and Labor.

On 4 August 2020, a new regulatory restriction was adopted by European authorities under REACH. The new rules dictate that diisocyanates cannot be used as substances on their own, as constituents in other substances or in mixtures for industrial and professional use(s) after 24 August 2023, unless the concentration of diisocyanates individually and in combination is less than 0.1 % by weight, or certain training and labelling requirements are complied with. In her report, Paula Diaz examines this new regulation and highlights the need to improve the interface between REACH and OSH legislation.

In her report, Dandan Ge offers companies practical advice on how to export to the Chinese market following the implementation of Order No. 12 by the Chinese Ministry of Ecology and Environment (MEE). Although Order No. 12 has been called China REACH due to its similarity to Regulation (EC) No. 1907/2006 (EU REACH), there are some significant differences between the two regulations. Knowing these will be

crucial if you want to trade in China.

Rounding off the issue we have a report by Minetta Wunderskirchner on the obstacles faced by manufactures and importers of borderline products in the EU. Categorizing such products is difficult, but is crucial. As always, product compliance pays off in the long run so gaining a proper understanding of the regulation is worth your time.

Lastly, I would like to 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.

Dieter Drohmann
Managing Editor

The Revision of the Swiss Chemicals Ordinance

*Dag Kappes**

The Swiss Chemicals Ordinance will be revised, amending mainly two issues: Currently, the Chemicals Ordinance requires labelling of certain chemicals in at least two official languages. In consequence, products are legally on the market namely in the Italian-speaking parts of Switzerland not being labelled in Italian. With the planned revision, the language of the place of supply will be decisive for the labelling of all chemicals including biocides, fertilisers and plant protection products. Furthermore, manufacturers and importers have to notify new substances, which are not listed on a static existing substances list, by submitting a data set to the notification authority before placing them on the market. In future, all substances not registered in the EU, but placed on the market in Switzerland will be subject to notification. The public consultation on this revision project is open until 16 July 2021.

I. Introduction

1. Chemicals Legislation of a Small Country

The Swiss chemicals legislation aims to protect human beings and the environment against harmful effects arising from substances and preparations. At the same time, it should avoid barriers to trade.

Being too small to pursue a completely independent chemicals policy and operate a comprehensive risk-based chemicals regime, Switzerland bases its chemicals legislation largely on that of the European Union (EU), its largest trading partner.[1] Specifically, Switzerland has harmonised its chemicals legislation with that of the EU by introducing identical requirements to those in the EU REACH Regulation[2] (REACH) and the EU CLP Regulation[3] (CLP), particularly with regard to classification and labelling, restrictions and the authorisation system, as well as the safety data sheet. On a regular basis, the risk reduction measures adopted by the EU are autonomously introduced into Swiss chemical legislation, such as new restrictions in Annex XVII REACH or the Adaptations to Technical Progress (ATPs) of the Annexes I to VII of CLP.

2. The Chemicals Ordinance

The Chemicals Ordinance (ChemO; SR 813.11)[4] is one of the ordinances containing implementing provisions for the Swiss Chemicals Act (ChemA, SR 813.1), which entered into force on 1 August 2005. It is based, on the one hand, on the ChemA and on certain articles of the Environmental Protection Act (EPA; SR 814.01), the Water Protection Act (WPA; SR 814.20) and the Animal Welfare Act (AniWA; SR 455) and, on the other hand, on the Federal Act on Technical Barriers to Trade (THG; SR 946.51). The ChemO sets out the requirements for placing substances and preparations on the market. In particular, it regulates the:

* Dr. rer. nat. Dag Kappes, Dipl. Chem. is a scientific adviser in the REACH and Risk Management Section of the Chemical Products Division of the Swiss Federal Office of Public Health (FOPH). He is responsible for updating the Chemicals Ordinance. The author presents his personal opinion here. For correspondence: <dag.kappes@bag.admin.ch>

1 Dag Kappes, Olivier Depallens, Swiss Chemicals Legislation: An Overview [2018] ICRL 64.

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

3 Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 [2008], OJ L353/1.

4 The current Swiss legal texts can be consulted and downloaded free of charge on the internet in the classified collection of laws (CC) at <https://www.fedlex.admin.ch/en/cc> accessed 12 May 2021).

- Classification, labelling and packaging of substances and preparations, including the languages of labelling,
- Requirements for the safety data sheet and exposure scenarios,
- Registration and notification of new substances,
- Notification of substances and preparations,
- Supply of certain dangerous substances and preparations, and
- Use of substances of very high concern (SVHC).

In some articles, the ChemO refers directly to certain articles of REACH, CLPV and the EU Aerosol Directive.[5] As an example, Annex 2 Number 1 ChemO with the technical provisions for classification, labelling and packaging of substances and preparations refers to the Annexes I-VII CLP. Switzerland is not a member of the EU or the European Economic Area (EEA) and has no treaty in the area of chemical safety with the EU.[6] Therefore, Swiss chemicals legislation does not dynamically refer to EU legislation for reasons of sovereignty. In consequence, the ChemO indicates the version of the EU legislative enactment, which applies in Switzerland. In the case of the Annexes I – VII this would be presently the amendment by Regulation (EU) 2020/217.[7]

However, there are some areas in which Swiss chemicals legislation is not harmonised with that of the EU. These include, in particular, the registration or notification of substances and the obligation to report preparations, as well as the procedure for adopting risk reduction measures.

II. Need to Amend the ChemO

1. Language Requirements for Labelling

The official languages of Switzerland at federal level are German, French and Italian.[8] Until now, the minimum language requirements for labelling have been regulated differently in the various ordinances in the area of chemicals:

- ChemO: at least two official languages (Art. 10(3) let. b);
- Ordinance on Biocidal Products (OBP; SR 813.12): biocidal products in at least two official languages (Art. 38(2)); treated goods in the official language of the place where the goods are placed on the market (Art. 31*a*(2));
- Plant Protection Products Ordinance (PSMV; SR 916.161): At least two official languages, one of which is the official language of the region of sales (Art. 57(1)); for parallel imports at least one official language of the region of sales (Art. 57(2));
- Certain annexes to the Chemicals Risk Reduction Ordinance (ORRChem; SR 814.81): as a rule, at least two official languages;
- Fertiliser Ordinance (DüV; SR 916.171): at least one official language of the region of sale (Art. 23(4)).

Alternatively, for products that are not listed under the exceptions in Article 16*a*(2) THG,[9] labelling in the official language or languages of the place where the product is placed on the market is also possible (Art. 16*e*(2) THG).

The requirements in the ordinances that demand two official languages (ChemO, OBP and some annexes to the ORRChem) mean in practice that in the Italian-speaking parts of the country (these are the canton of Ticino and southern valleys of the canton of Graubünden) chemicals may be placed on the market that are not labelled in Italian. Therefore, in its statement of 4 March 2018 on the consultation on the revision of the OBP, the government council of the canton of Ticino requested that the requirements for labelling be adapted so that they must be in the official language of the place of supply.[10]

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5 Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers [1975], OJ L147/40.

6 The Agreement between the Swiss Confederation and the European Union on Mutual Recognition in relation to Conformity Assessment (MRA) comprises also one chapter each on Good Laboratory Practice (GLP) and biocidal products; available on the Internet in German, French and Italian at <https://www.admin.ch/opc/de/classified-compilation/19994644/index.html> accessed 12 May 2021.

7 OJ [2020] L44/1.

8 Cf. Art. 70(1) Federal Constitution of the Swiss Confederation (BV, CC 101)

9 a. Products that are subject to an authorisation requirement;
b. substances subject to notification under chemicals legislation;
c. Products that require prior import authorisation;
d. Products that are subject to an import ban;
e. products for which the Federal Council decides on an exemption in accordance with Article 4 paragraphs 3 and 4.

10 Available on the Internet at <https://fedlex.data.admin.ch/eli/dl/proj/6017/10/cons_1> accessed 12 May 2021.

2. Notification of New Substances

Like the former chemicals legislation of the European Economic Community (EEC), the ChemA distinguishes between old and new substances, whereby old substances may be placed on the market without the prior consent of the authorities[11] after self-regulation[12] has been carried out (Art. 5-6 ChemA), whereas new substances must be notified before being placed on the market (Art. 9 ChemA). The form and content of the notification (Art. 27 ChemO) have been adapted to the requirements of REACH so that the required data set corresponds to that of a REACH registration. With this data, sufficiently safe handling of the substance can be ensured.

The ChemA (Art. 4(1) let. a) delegates the definition of the term "existing substance" to the Federal Council (i.e. ChemO) and stipulates that all other substances are considered new substances. The adoption of the EEC list of existing substances EINECS[10] (Art. 2(2) let. f ChemO) at the time prevented technical barriers to trade with the EU for the placing on the market of existing substances as such or in preparations. Existing substances could be placed on the market both in the EU and in Switzerland without the prior consent of the authorities, whereas new substances had to be notified before placing on the market both in an EU member state as well as in Switzerland.

In the EU, all substances subject to registration have been registered since 2018 and the EINECS has become obsolete. Therefore, it is time to reconsider the notification procedure for new substances in Switzerland. Substances not listed on EINECS may only be placed on the market in Switzerland after notification, even if they are registered in the EU, whereas EINECS substances may circulate freely in Switzerland, regardless of whether they are registered in the EU or not. The latter may result in insufficient data being available for the manufacturer to carry out self-regulation in accordance with Article 5 ChemO.

3. Divergences in the Reporting Obligation

Article 45(4) CLP provides for harmonisation of the requirements of information on emergency health care and preventive measures in the EU. The corresponding Annex VIII CLP was published in 2017 and revised twice in the meantime. [13,14,15] The harmonised requirements entered into force on 1 January 2021; the last transitional arrangements expire on 31.12.2024.

As the Swiss reporting obligation already existed before the harmonised requirements of the EU, the corresponding requirements of Articles 48 - 54 ChemO differ in many points from those of the notification according to Annex VIII CLPV.[16] This starts with the scope of the obligation: In Switzerland, all mixtures[17] that meet the criteria for the preparation of a safety data sheet must be reported. In the EU, only those that have been classified as hazardous due to their health or physical effects must be notified.

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11 According to the current definition of Art. 2(2) let. f ChemO, an existing substance is a substance listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) of 15 June 1990. This corresponded to the definition of an existing substance in the seventh amendment to EEC Directive 67/548/EEC, which has since been repealed (Art. 1 letter h of Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances; Official Journal [1992] L 154/1). 18 September 1981 was the deadline for the substance to be on the market; 15 June 1990 refers to the adoption of the list by the European Commission.

12 For self-regulation purposes, the manufacturer must assess whether substances or preparations may endanger human life or health or the environment. For this purpose, it must classify, package and label the substances and preparations in accordance with the provisions of this Ordinance and prepare exposure scenarios and a safety data sheet.

13 Commission Regulation (EU) 2017/542 of 22 March 2017 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures by adding an Annex on harmonised information for emergency health care. *OJ [2017] L78/1.*

14 Commission Delegated Regulation (EU) 2020/11 of 29 October 2019 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, as regards information for emergency health care; *OJ [2020] L6/8.*

15 Commission Delegated Regulation (EU) 2020/1677 of 31 August 2020 amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures in order to improve the practicability of information requirements in the context of emergency health care (Text with EEA relevance). *OJ [2020] L379/3.*

16 Samantha Doninelli, Dag Kappes, David Murmann, Die Meldepflicht, der UFI und das Produkteregister in der Schweiz; StoffR [2020] 171.

17 The Swiss ChemA uses the term "preparation".

In addition, CLP provides, among other things, the following two simplifications, which do not exist in the ChemO:

a. Bespoke Paints

Art. 25(8) CLP provides for an exemption from the notification obligation for bespoke paints under certain conditions. In Switzerland, these paints formulated on request are currently subject to the notification obligation. [18]

b. Generic Names of Perfumes and Colouring Agents

Annex VIII CLPV provides that perfumes (up to 5%) and colouring agents (up to 25 %) which are not classified for any health hazard may not be declared with their chemical name but with their function. Currently, the notification authority for chemicals already accepts the generic names "fragrance", "scent" or "perfume" with up to 5 % of the notified formulation, provided that a safety data sheet for the perfume is also submitted. There is currently no relief for colouring agents in Switzerland. These differences mean that companies importing preparations into Switzerland may not have the necessary data to fulfil the reporting requirement.

III. The Planned Amendments and Their Effects

1. Harmonisation of Language Requirements for Labelling

a. The Proposed Regulation

In order to harmonise the language requirements in the five ordinances mentioned above and to meet the demand of the government council of the canton of Ticino, the following regulation is proposed: Labelling should have to be in the official language or languages of the place where the substance or preparation is supplied to private or professional users. In the ChemO and OBP, the simplification for supply to professional users should be retained as well as introduced in the ChemRRV: In agreement with individual professional users, a substance or preparation may be labelled in another official language or in English for supply to them. (Art. 10(3), 2nd sub-sentence ChemO).

b. Impact Assessment of the Regulation

In order to assess the economic impact of these measure, a Regulatory Impact Assessment (RIA) was prepared.[19] The results of an RIA contribute to a good and fact-based basis for decision-making and better regulation. Within the framework of an RIA, five points regarding the measures are systematically examined. [20]

On the benefit side, the alignment with the requirements under the THG facilitates the placing on the market, especially for biocidal products and plant protection products, which only will have to be labelled in the official language of the place of supply. This is a particular relief for imports from neighbouring countries into the respective language region, e.g. import of products from Germany into German-speaking Switzerland, which are only labelled in German.

An additional expense arises for those products distributed throughout Switzerland that are supplied to private users and are labelled bilingually - but not in the official language of the place where they are placed on the market. According to the cantonal chemical authorities, this only occurs in practice in the Italian-speaking parts of Switzerland. The labelling of products for professional users does not have to be adapted because of the above-mentioned special provision.

Based on data collected by the Ticino Chemicals Agency, the initial costs of a changeover to the language(s) of the place of supply were estimated at 1.4 million Swiss Francs (CHF). Once the new system will have been introduced, the additional annual costs will be low at around CHF 36,000 compared to the current system. The costs are incurred by those responsible for labelling, in the case of the ChemO

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18 Commission Delegated Regulation (EU) 2020/1676 of 31 August 2020 amending Article 25 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, as regards paint formulated to order; *OJ [2020] L379/1*.

19 The RIA in German with a summary in English is available on the internet at <https://www.anmeldestelle.admin.ch/chem/de/home/themen/recht-wegleitungen/revisionen-des-chemikalienrechts/aenderung-der-chemikalienverordnung-chemv.html> accessed 12 May 2021.

20 The details on how to prepare a RIA are available in German and French on the internet at <https://www.seco.admin.ch/RFA> accessed 12 May 2021.

the manufacturers and importers, in the case of biocidal products the authorisation holder etc.

c. Transitional Provisions

Chemicals already on the market have to comply with the foreseen regulation until 31 December 2025. On the same day, the transitional period for the labelling with the UFI expires.

2. Modernisation of the Obligation to Notify New Substances

The revision is intended to ensure that safety-relevant data are available for all relevant substances that are placed on the market in Switzerland. This will enable the manufacturer or importer to conduct the self-regulation, i.e. to assess their risks and, if necessary, to mitigate them. All substances registered in the EU become "existing substances" within the meaning of Art. 2(2) let. f ChemO. Substances not being registered in the EU and placed on the market in Switzerland but falling under the scope of registration requirements in the EU become "new substances" in Switzerland and must be notified with a data set before being placed on the market.

a. Alignment of the Scope of Application

In order to harmonise the requirements for the notification obligation under ChemO with that of the REACH registration, the ChemO introduces the same exemptions as in REACH (Art. 2(7)), such as Annex IV with certain groups of substances that are not subject to registration. However, due to the provisions of the ChemA (Art. 6), a substance must be notified in Switzerland before it is placed on the market or imported (pre-marketing approach), whereas in the EU the registration obligation already begins with the manufacture or import (pre-manufacturing approach, Art. 5 REACH). In Switzerland, intermediates also remain exempt from the obligation to register, as was envisaged in the message on the ChemA. [21]

b. Equal Requirements for the Substance Dossiers

Annexes VI - XI REACH with the quantity-dependent requirements for the registration dossiers have been autonomously adopted and updated in Switzerland in Annex 4 of the ChemO - with the exception of the requirements for nanomaterials or nanoforms, as currently the definitions do not match.[22]

c. No Duplication of Dossiers

Switzerland is a small country that autonomously adopts the risk management measures from the EU. It makes no sense to take up again data in Switzerland that have already been deposited with the European Chemicals Agency (ECHA), reviewed and processed within the framework of ECHA's Integrated Regulatory Strategy, as the framework conditions regarding use and exposure are comparable in Switzerland and the EU. [23,24] Added value is created by the fact that Switzerland requires and checks notifications for substances that are placed on the market in Switzerland but are not registered in the EU. Non-confidential data on notified substances will be published like under REACH (art. 119).

d. Regulatory Impact Assessment

The RIA estimated the number of substances newly affected of the notification obligation on the basis of a survey of the relevant associations.[25] According to this, around 75 EINECS substances not registered in the EU are currently on the market in Switzerland in quantities of more than 1,000 kg/year that would fall under the registration obligation in the EU. These substances would have to be notified with a data set in Switzerland at the end of a transitional period. The

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21 Botschaft zum Bundesgesetz über den Schutz vor gefährlichen Stoffen und Zubereitungen (Chemikaliengesetz, ChemG) vom 24. November 1999 (99.090), BBl 2000 687- 99; available in German, French and Italian on the Internet at <https://www.fedlex.admin.ch/eli/fga/2000/195/de> accessed 12 May 2021.

22 The definition of "nanomaterials" in Switzerland is to be harmonised with that of the EU as soon as the EU has published the results of the review of the definition of nanomaterials and ensuring their coherent application in all legislation using legally binding mechanisms, as announced in the Chemicals Strategy for Sustainability towards a toxic-free environment for 2021.

23 See IRS Annual report 2020, available on the internet at <https://echa.europa.eu/documents/10162/27467748/irs_annual_report_2020_en.pdf/646c8559-360d-f6ab-bfb7-02120eab52fa> accessed 12 May 2021.

24 For a use (> 1t/a) not described in the safety data sheet an exposure scenario must be prepared (Art. 16(2) ChemO).

25 The RFA is available in German with a summary in English on the internet at <https://www.anmeldestelle.admin.ch/chem/de/home/themen/recht-wegleitungen/revisionen-des-chemikalienrechts/aenderung-der-chemikalienverordnung-chemv.html> accessed 12 May 2021.

notification of these 75 substances, including the compilation of the data, will cost manufacturers/importers a maximum of CHF 12 million on a one-off basis. With the change in the notification requirements, the number of notifications received annually will decline compared to the current system. The corresponding annual saving has been estimated at around CHF 1 million.

e. Transitional Provisions

The draft stipulates that, within 18 months of the revision coming into force, manufacturers/importers must pre-notify the notification authority of substances that are not registered in the EU and that they wish to continue to place on the market in Switzerland in quantities of more than 1 000 kg/year. This will ensure that testing on vertebrates is only carried out once for a substance in case that it has to been pre-notified by more than one company. Due to the small number of substances, the formal establishment of Substance Information Exchange Fora (SIEFS) as in REACH will not be necessary. After the pre-notification, 3.5 years are provided for carrying out the necessary studies.

3. Adjustments to the Reporting Obligation

a. Bespoke Paints

For reporting in Switzerland, the same simplifications shall apply for bespoke paints as in art. 25(8) of CLP.[26]

b. Generic Names of Perfumes and Colouring Agents

The reliefs for perfumes and colouring agents shall be introduced as in Annex VIII CLP. However, in Switzerland, the perfumes and colouring agents may not be substances on the SVHC candidate list (Annex 3 ChemO) and thus may not be vPvB, PBT substances or endocrine disruptors. A number of perfumes contain substances having such properties, e.g. the amber fragrance Karanal and nitromusks such as musk xylene.

c. Necessity of a RIA

Since Tox Info Suisse,[27] the Swiss information centre for poisonings, agrees with the changes and the effects are insignificant, a RIA for these measures was waived.

IV. The consultation procedure

The consultation procedure aims to involve the cantons, political parties and interested parties in the formation of opinion and decision-making by the Swiss Confederation. It is intended to provide information on the factual correctness, suitability for implementation and acceptance of a federal project. (Article 2 of the Consultation Act (VlG, SR 172.061)). Among other things, a consultation procedure must be carried out for ordinances and other projects that are of great political, financial, economic, ecological, social or cultural significance. (Art. 3(1) let. d VlG). This is particularly the case with regard to the harmonisation of language requirements and the modernisation of the notification procedure.

On 31 March 2021, the Federal Council has decided to open the consultation.[28] It will run until 16 July 2021, which means that all interested parties, including those from abroad, can submit comments on the draft amendment and the explanatory report until this date. The Federal Chancellery has published the documents on its website. [29]

Parallel to the consultation procedure, Switzerland has notified the World Trade Organisation (WTO) of the amendments.[30]

V. Further Procedure

The comments received during the consultation will be reviewed by the competent administrative unit

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26 Commission Delegated Regulation (EU) 2020/1676 of 31 August 2020 amending Article 25 of Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, as regards paint formulated to order; OJ [2020] L379/1.

27 Available on the internet at <https://www.toxinfo.ch> accessed 12 May 2021).

28 See media release of 31 March 2021, Der Umgang mit Chemikalien soll noch sicherer werden; available in German, French and Italian on the Internet at <https://www.admin.ch/gov/de/start/dokumentation/medienmitteilungen.msg-id-82922.html> accessed 12 Mai 2021.

29 Available on the Internet at <https://fedlex.data.admin.ch/eli/dl/proj/2021/14/cons_1> accessed 12 Mai 2021.

30 G/TBT/N/CHE/25...

and published on the website of the Federal Chancellery.[31,32] In addition, the competent administrative unit prepares a consultation report that summarises the comments. If necessary, individual groups of respondents are invited to an exchange of views in order to better understand their needs and find compromises, if possible.

Then the draft is adapted and goes through a number of internal administrative procedural steps, such as an internal consultation, which corresponds to the inter-service consultations in the EU Commission, before the Federal Council will decide on the adapted draft. According to current planning, this decision on the revision of the ChemO is scheduled in February 2022 for.

VI. Discussion

1. The Adaptation of the Language Requirements for the Labelling

In the run-up to the consultation, some industry and association representatives were critical of the adaptation of the language requirements; on the one hand, because of the costs that a change to three languages would entail for the nationwide marketing of products, and on the other hand because of the possible reduction in font size and thus poorer legibility of the labels.

In the end, the decision is likely to be a political one, which, in addition to economic and protection arguments, must also take into account the fact that Switzerland is a multilingual country in which the rights of minorities have traditionally been respected.

2. The Modernisation of the Obligation to Notify in Switzerland

Swiss companies have (co-)financed the registration data in the EU, either directly as manufacturers or indirectly as customers. According to scienceindustries statistics in 2020, 70% of chemical imports (excluding pharmaceuticals) came from the EU and around 50% of chemical exports went into the EU.[33] Exports are not subject to registration under the current premarketing approach in Switzerland. However, they must meet the requirements of the importing country.

Three countries, the United Kingdom (UK), Turkey and Switzerland, follow the EU chemicals legislation in the strict sense. However, they pursue different approaches. While the UK has adopted the acquis until 31.12.2020, it intends to adopt risk reduction measures independently of the EU (or not to adopt them in the sense of "deregulation") on the basis of its own registration data. [34] This divergent approach will lead to increased administrative burdens for industry and non-tariff barriers to trade on top of the new tariffs to be paid between the EU and UK. In contrast, Turkey has adopted the chemicals acquis with few exceptions and is updating the relevant annexes. [35,36] However, Turkey stipulates that all substances must be registered, regardless of whether they are already registered in the EU or not. This leads to a high administrative burden with little benefit, since Turkey adopts the EU's risk reduction measures anyway and cannot have any interest in non-tariff trade barriers due to its customs union with the EU.

Being much smaller than the UK and Turkey, Switzerland takes an efficient and pragmatic approach, relying even more on the EU. However, the revised system will also create new data for substances not registered in the EU.

VII Conclusion

Switzerland bases its chemicals legislation largely on that of the EU, as it is too small to pursue a completely independent chemicals policy and operate a comprehensive risk-based chemicals regime. Exceptions are the notification and reporting requirements, which are not harmonised with the registration requirements of REACH and Annex VIII CLPV.

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31 In the case of the ChemO, this is the FOPH, which involves experts from the Federal Office for the Environment and the State Secretariat for Economic Affairs as well as the Chemicals Notification Authority.

32 Available on the Internet at <https://fedlex.data.admin.ch/eli/dl/proj/2021/14/cons_1> accessed 12 Mai 2021.

33 Available on the Internet at https://www.scienceindustries.ch/services/aussenhandelszahlen (last accessed on 5.5.2021).

34 Hanna Widemann , Chemicals regulation in the UK after Brexit, StoffR [2021] ICRL 9, DOI: https://doi.org/10.21552/stoffr/2021/1/4.

35 Yaprak Yuzak Kucukvar, Pre-registration and Global Supply Chains: Compliance with KKDIK [2019] ICRL 70, DOI: https://doi.org/10.21552/icrl/2019/2/8.

36 Examples include the classification of boric acid and its salts in Annex VI of the CLP Regulation, which Turkey has not adopted, and the additional Annex 18 of KKDIK with the requirements for the preparers of a safety data sheet in Turkey, although the EU has not yet taken up this option.

With the planned amendment, the notification requirement will complement the EU registration regime. Two facilitations from Annex VIII CLPV are also to be introduced in Switzerland for the report of preparations. The language in which dangerous chemicals are to be labelled will be based on the language of the place of supply. The draft for this revision of the ChemO is in public consultation until 16 July 2021. All stakeholders or interested group or person are invited to comment it.

New Requirements on Safety Data Sheets in South Korea

*Dieter Drohmann, Jae-Seong Choi and Sun-Jong Park**

I. Introduction

The chemical industry in South Korea has grown steadily, with chemical sales in Korea now reaching the top 5 in the global chemical industry (ca. 127 billion EUR/year)[1]. It is also known that approximately more than 40 thousand of chemicals are manufactured, imported or distributed in this country, with continuously increasing trends of imported quantities of chemicals in this country – above 0.3 billion tons per year is imported.

Within this fast-growing industry, the Material Safety Data Sheets (MSDS)[2] has been an essential tool for preventing chemical accidents since the introduction of the Global Harmonized System (GHS) into this country. However, the existing regulation's low accuracy, abusing "trade secret" and uncleared standards have occurred many issues, and the issues have connected to the demands on the improvement of the relevant regulations. The Ministry of Employment and Labor ("MoEL"), the competent authority for the MSDS, therefore, introduced the full amendment of the K-OSHA[3] which came into force on 16 January 2021. With this amendment to the act, MoEL now aims to achieve safer use of hazardous chemicals for workers by adopting new requirements on MSDS distributed on the internal market.

This article will provide an overview of the newly adopted system – submission of MSDS with its process and the impacts on the "trade secret" in MSDS for non-Korean manufacturers who need to keep confidentiality of chemical substances.

II. Preparation for the New Regulation

1. Scope of Obligation

A chemical product consists of only non-classified substances is out of the scope of the MSDS-related obligations. Article 38 of the K-OSHA Presidential Decree defines the exclusion of the scope as described in the Table 2.

The guided exclusion list is mainly based on excluding products used in general consumer units (even in industrial sites, except for general industrial use) and products regulated by other laws in Korea. According to the amendment of the act, chemicals or mixture products containing chemical ingredients classified according to Article 104 of the K-OSHA and [Annex 18] of the K-OSHA Ministerial Decree are in scope. The recommended referencing source for defining hazard classification would be the NIER[4]'s classification list[5] on hazardous chemicals as well as global chemical inventories (e.g. EU CLP).

Chemicals for R&D uses are also being exempted from the MSDS submission obligation, but a simple notification to the authority is required when the substance identity should be protected. K-OSHA defines the R&D cases not only with the scientific researches, but also with the pilot productions of chemicals. Further details on the protection of substance identity for the R&D chemicals is described in the latter part of this article.

2. Exclusion from Cut-off value

Since the hazard classification of a mixture product differs depending on content of hazard classified ingredients, the "cut-off value" is also required to be

* Dieter Drohmann is CEO of the Chemservice Group. For Correspondence: <d.drohmann@chemservice-group.com>. Jae-Seong Choi is Branch Manager at Chemservice Asia. For Correspondence: <js.choi@chemservice-asia.com>. Sun-Jong Park is Regulatory Affairs Advisor at Chemservice Asia. For Correspondence: <sj.park@chemservice-asia.com>

1 Cefic – European Chemical Industry Council, Facts & Figure of the European chemical industry, 2020 (p.7)

2 "Material Safety Data Sheet" (MSDS) is the official terminology according to the K-OSHA, while "Safety Data Sheet" is generally used in other countries.

3 Korea Occupational Safety and Health Act (Act No. 17326)

4 National Institute of Environmental Research

5 Rules on Classification and Labelling, etc (NIER official gazette No. 2020-52)

Table 1: Major Changes on MSDS from the K-OSHA amendment

Subject	Before the amendment	After the amendment (as of 16 January 2021)
Responsible body	Distributor or Supplier of chemical product(s)	Manufacturer or Importer of chemical product(s)
Submission scheme	Not existed	Newly adopted – Art. 110 of the Act
Composition information	Full ingredient information	GHS classified substance only
CBI indication	Indicated as "Trade secret"	Indicated as Generic names via CBI claim to authority – Art. 112 of the Act
Only Representative system	Not existed	Newly adopted – Art. 113 of the Act

Table 2: Excluded from the MSDS-related obligation

Definition	Examples
Exempted substances (considering low-concerned about toxicity and explosiveness) according to Article 3 of MoEL official gazette (No. 2020-130) Chemicals or mixture products used by consumers as household goods other than as defined in other laws	Health functional foods Pesticides and active ingredients Narcotics Fertilizers Feed Source materials for radiation in the natural environment Household chemical products Consumer Chemical Products (Household goods) Foods and food additives and containers and packages Drugs and quasi-drugs Radioactive materials Hygiene products Medical devices and Biopharmaceuticals Explosives Wastes Cosmetics

considered for the determination of exclusion of the MSDS submission obligation. To be more specific, "1%" or "0.1%"[6] of the concentration limit as cut-off values shall be the criterion for determining classification of mixture product according to the rules[7] of the MSDS. In fact, the cut-off values have been applied before the K-OHSA amendment as well, but it became more important to be referred for the decision making for the MSDS submission of mixture products.

An example case is described in here to help to have a better understanding on how the cut-off values work. Although a chemical substance in a mixture is one of chemicals regulated under K-OSHA, the obligation of MSDS submission will be exempted only when the concentration of the regulated chemical is below the cut-off value. For a specific example, we can assume that chemical product "A" and "B" are imported into Korea. And if the product "A" contains 99.95 % of Water (CAS No. 7732-18-5) and 0.05% of substance "x" which is classified according to K-OSHA criteria. In this case, the MSDS of the product "A" does not need to be submitted under the control of K-OSHA because the concentration of the sole hazard ingredient, "x", does not exceed the cut-off value

6 Respiratory sensitization, Skin sensitization, Toxicity to reproduction (1A and 1B), Carcinogenic, Hazard to the ozone layer.

7 Official gazette No. 2020-130 – Ministry of Employment and Labor.

Table 3: Cut-off values of substance 'x' as example

Classification	Cut-off value	"A" contains 0.05 %	"B" contains 0.5 %
Acute Toxicity-Oral 3	1 %	Not exceeded	Not exceeded
Acute Toxicity-Dermal 3	1 %	Not exceeded	Not exceeded
Acute Toxicity-Inhalation 3	1 %	Not exceeded	Not exceeded
Skin corrosive/ irritation 2	1 %	Not exceeded	Not exceeded
Skin sensitization 1	0.1 %	Not exceeded	Exceeded
Carcinogenic 1	0.1 %	Not exceeded	Exceeded

(0.1%). On the other hand, if the product "B" contains 99.95 % of Water (CAS No. 7732-18-5) and 0.5% of substance "x", the mixture product "B" shall be classified as skin sensitize and carcinogenic due to the exceeding cut-off value of "x", then the MSDS of the product "B" shall be submitted, accordingly.

III. Procedure and Requirement

1. Composition Verification

The verification of composition information is the one of the priority actions to take, that enable MoEL to check the suitability of the indication of composition information and non-disclosure of confidential information when the MSDS is submitted.

Before the amendment of K-OSHA act, the obligation to indicate the composition information was not clearly defined for the non-hazardous classified chemicals.

In accordance with this amendment, it is defined that the only hazardous classified chemicals are mandated to the indication of MSDS, while the other chemicals (i.e. the non-hazardous classified chemicals, or the hazardous chemicals in lower than the threshold limit in mixture) are not disclosed on the MSDS. In the case of the non-disclosure of the non-hazardous classified chemicals, a separate method from the MSDS is required to report the full composition information which is to justify the correctness of the submitted MSDS.

If a chemical product is sourced for a formulation, then is delivered to Korea, the full composition information of the final product could not be clarified by the final exporter who would be the principal of the OR. In this case, the obligation of composition verification can be substituted by submitting the Letter of Confirmation (the "LoC") which guarantees that the ingredients excluded from the reporting of composition verification are composed only with the substances as non-hazardous classified.

2. Confidential Business Information (CBI) Claim

Only marking as "trade secret" on the section 3 of MSDS used to be widely applied in the Korean industry. It is now regarded as the conduct of misuse and abuse of the "Trade Secret" and is disallowed.

It is necessary to identify substances that cannot be applied for CBI Claim under Article 16 of MoEL official gazette (No. 2020-130). These substances are usually regulated chemical substances such as prohibited chemicals, chemicals subject to authorization, or hazardous chemicals regulated under K-REACH regulation[8]. Except these regulated substances, hazardous classified chemicals are applicable to apply for the non-disclosure assessment (the

8 Korean REACH: Act on Registration, Evaluation, etc. of Chemicals (Act No. 17326).

Table 4: Examples of generic names for CBI Claim.

Chemical name (IUPAC)	Generic name	Description
Chlorobenzene	**substituted** benzene	'substituted' replaces Chlorine substituent
1,4-dihydroxybenzene	**phenol derivatives**	It is chosen in Chemical handbook

"CBI claim"). The CBI claim shall be submitted in substance unit basis before the MSDS submission process in order to secure the confidentiality. Then the alternative chemical name (i.e. generic name) and content range[9] (up to +-20%) can be applied in the MSDS for the submission of the MSDS.

For the authority's assessment on the CBI claim, proper evidence to prove the confidentiality of the substance identity shall be provided. According to a confidentiality-related legislation[10], the term "trade secret" is defined as information including a production method, sale method, useful technical or business information for business activities, which is not disclosed to public under management as confidential information with having independent economic value. The details are as follows:

- Statement of CBI (not required for R&D): Non-disclosure, confidentiality, economic value
- Substance identity
- Generic name & alternative content range
- Others: MSDS, full composition information, etc.

As the result of the CBI claim, the chemical name will be indicated as a generic name of the substance rather to be hidden as "trade secret". There is also a rule[11] to define the generic name and the Table 4 shows simple examples how to define them according to the rule.

MoEL will examine the submitted CBI claim and the result comes out after 28 official working days. There will also be a possibility to claim objection against the rejection of the CBI claim. Under the MoEL's approval, an alternative name (i.e. generic name) may be applied in the MSDS for the submission.

3. MSDS submission

The submission of MSDS to the authority via a dedicated online platform[12] must be done before the expiration of the grace-period[13] depending on the annual volume of products. When getting ready for the MSDS submission, the most painstaking task as a non-Korean company will be preparing Korean version MSDS since the authority only accepts MSDS in Korean language. However, the authority will not review every single MSDS into details and the inspection will be conducted randomly. Therefore, maintaining current procedure or method to prepare Korean MSDS will still be sufficient to deal with the new obligations, but it would worth checking particular sections in the MSDS which are related to the composition, hazard classification (i.e. GHS pictogram, H-codes and P-codes), hazard properties (i.e. physico-chemical properties, toxicological and ecotoxicological) and regulatory information to secure the accuracy of the submitted MSDS.

The dedicated online platform for the MSDS submission is recently opened in January 2021, with limited function which allows single product submission only (for both MSDS submission and CBI claim). Therefore, the submissions can be done product by product until the system allows an improved function for the bulk submission which is planned to be implemented in several months.

For mixture product, it is allowed to consolidate family products into one submission of MSDS only when the components of mixture are identical, and the concentration change of each component is less than 10%. For specific products which contain pig-

9 Without CBI Claim, the range shall be present up to ± 5 %, while it could be wider up to ± 10 to 20 % depending on content after CBI Claim approval.

10 Unfair Competition Prevention and Trade Secret Protection Act (Act No. 16204).

11 Regulations on application and management of the data protection (MoE official gazette No. 2018-237).

12 K-OSHA MSDS IT system (https://msds.kosha.or.kr).

13 Manufacturer and/or importer can use existing MSDSs without submission during the grace-period. The grace-period is applicable only for products which have already been placed in Korean market before 16 January 2021.

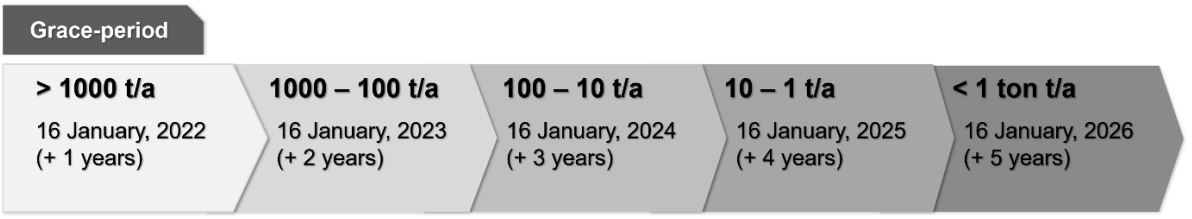

Figure 1. K-OSHA MSDS submission Grace-period (Source: Chemservice Asia, 2021).

ments or fragrant materials could consolidate several MSDS of its family products even though the substances of pigments or fragrant materials are changed, only when the concentration of pigment or fragrant material is less than 5%, and the hazard profile of the product is very similar. This exception would decrease difficulties for paint and fragrance industries when a group of products has widely subdivided segments within small changes of ingredients or the case of product mixing proportion needs to be frequently modified. However, when a single MSDS, as a representing MSDS, covers its family products, the MSDS shall indicate the list of all relevant products which are consolidated.

After the submission of the MSDS, a unique serial number (e.g. AA0000-00-00000000) shall be issued to each submitted MSDS by the system automatically. This submission number will be the only evidence of the MSDS submission which shall be indicated on the first page of the MSDS when it is updated for the distribution to Korean importers. By indicating it, the recipient of the updated MSDS will be able to check their coverage of the K-OSHA compliance which leads to avoid unnecessarily duplicated MSDS submission for a single product.

4. Further Requirements for the MSDS submission

Besides of the preparation of MSDS for the submission, there will be further requirements about the full composition information and the use category selection.

Regarding the full composition information, non-classified substances can be excluded from the MSDS but then the composition information shall be submitted during the MSDS submission. As prescribed at chapter III.1 of this article, LoC can replace the full composition information to ensure that all of the hazard classified substances are well indicated on the MSDS.

On the other hand, use category shall also be verified by considering every relevant use information of chemical product. The list of the use categories under K-OSHA is similar to the K-REACH use categories[14], but was designed in accordance with the National Chemical Classification and Indication System Integration Standard[15] which consists 48 use categories with sub-categories. The selection of this use category is recommended to be marked on the updated MSDS together with the submission number when the updated MSDS shall be provided to the Korean importers.

The revision date of the MSDS is another one to be reported to the system, so it is recommended to update the revision version and the date properly before every submission (i.e. initial and updating submission) of the MSDS.

5. Only Representative

To enable non-Korean manufacturers or producers secure confidentiality of the composition information from the MSDS submission and CBI application obligations, the Only Representative ("OR") system was newly implemented in the K-OSHA.

The concept of OR under K-OSHA is very similar to the K-REACH OR, but the difference is that the OR appointment is company basis rather to be substance or product basis, and the appointment validity is limited up to 5 years. Therefore, a list of products for the

14 55 Use Categories, [Annex 2] of K-REACH Presidential Decree

15 Co-legislated by MoEL, MoE, and 9 other government departments, 23rd Sep 2019.

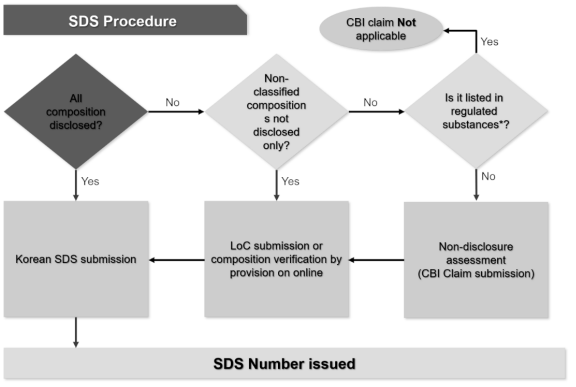

Figure 2. Procedures depending on cases (Source: Chemservice Asia, 2021)

OR appointment shall be managed separately by the contract between principal and the OR. And the renewal of the appointment validity will be required at least in every 5 years.

Due to the limited function of the online platform, so called K-OSHA MSDS IT system, the application of the OR appointment is required to be submitted to the local office of MoEL via fax or post to receive the approval of the OR appointment.

6. Recommendation on procedures

Recommended procedures to achieve K-OSHA regulatory compliance can differ from cases to cases. However, a general way of preparing and handling submissions can be summarized as follows.

First, Check the section 3 (composition information) at the MSDS with the product's full composition information if any of ingredient(s) need to be undisclosed. Then look over the list of regulated chemicals under K-OSHA (refer to the chapter III. 3 of this article) to sort out the ingredients which are mandated to be indicated on the MSDS. Afterwards, one of below options could be chosen to proceed the following up actions which are also described in Figure 2.

- If all chemicals are present on Section 3 in the MSDS, only MSDS submission is needed.
- If Chemicals that fall under the K-OSHA classification standards are disclosed and non-classified compositions are not disclosed, enclosing LoC of those non-classified composition is needed along with MSDS submission.
- If Chemicals that fall under the K-OSHA classification standards need to be undisclosed and are not listed in those regulated substances (under Article 16 of MoEL official gazette (No. 2020-130)), prepare non-disclosure assessment and submit it on the K-OSHA online platform. After MOEL's approval, revise the Korean MSDS including the alternative information for CBI Claim approved substances. And submit the revised Korean MSDS on the K-OSHA online platform. Then, we receive the MSDS number for the MSDS.

IV. Follow-up actions of the MSDS submission

1. Updating MSDS

As prescribed at chapter III. 3, an updated MSDS shall be prepared after the MSDS submission. Although composition information and CBI application are the most important part to be accurately applied, the new factors to be included only in the Korean MSDS are the submission number and the selected use categories. Companies who are providing MSDS to Korean importers, should make sure to check internally or with the SDS service provider if an indication of the new factors specifically for the Korean MSDS is possible, so that the updated MSDS can be delivered properly to their importers and downstream users.

2. MSDS provision to importers or downstream users

If the MSDS submission is done by the OR, the obligation to provide the updated MSDS to the importer is on the OR. However, it is not necessary to involve the OR into the communication with the importer. That is, distributing the newly updated MSDS can be done by the non-Korean companies themselves, but then the OR will need to be ensured for the completion of the provision. There can also be another option of providing the MSDS via the online platform which can be a formal way to record a history of provision in the official system.

In case of products with various uses, the MSDS submission shall combine all relevant use categories

collectively. But for the provision of the MSDS to importers, it is also possible to divide the MSDS by each use category or use information with using the same MSDS submission number, so that each importer could refer to only the applicable use information for their business.

V. Conclusion

As the number of distributed chemical products in the market has been being exponentially grown in Korean industry, the implementation of the scheme of the MSDS submission seems not easy to be operated. Moreover, there are various information sources to be considered which are widely dispersed through the laws and regulations. Furthermore, most of the information under Korean legislation is not formally translated into English. Consequently, local assistance in the interpretation of relevant clauses or legal texts would be required in ensuring that non-Korean companies properly understand the obligation.

Nonetheless, MoEL is aiming to develop a new direction in the chemical safety management by adopting the new MSDS management system through the K-OSHA amendment. However, industries may also be confused with huge difficulties in fulfilling the new type of compliance within complex and diverse supply chain routes. On the other hand, the obligations of submitting MSDS could be more stringent to well-known chemicals due to extensive information on its hazardous. So the irony of <“no data, no market” turning into “no data, no problem”> could even bring retrogression of safety management in this country.

Therefore, improving regulations and monitoring consequences shall be continued by the authority with rigorous analysis of global regulatory interactions and the impact to industries, in order to operate this new type of regulation according to its fundamentally aimed purpose.

Reports

REACH Restriction Concerning the Use of Diisocyanates

*Paula Diaz**

I. Introduction

The main goal of the REACH Regulation (Regulation EC/1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals) is to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances while enhancing innovation and competitiveness of the EU chemicals industry.

The Restriction of chemicals (together with the Registration, Authorisation and Evaluation) is one of the four processes foreseen in REACH to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions may limit or ban the placing on the market or use of a substance. Conditions for the placing on the market of substances can apply to both, domestic production and imports as well as for substances in articles.

On 4 August 2020, a new regulatory restriction adopted by European authorities under REACH was published in the Official Journal of the European Union (OJ)[1]. The restriction established that diisocyanates cannot be used as substances on their own, as constituents in other substances or in mixtures for industrial and professional use(s) after 24 August 2023, unless the concentration of diisocyanates individually and in combination is less than 0.1 % by weight, or certain training and labelling requirements are complied with.

All diisocyanates are known as sensitisers and are classified as Resp. Sens. 1, either as a harmonised classification or as self-classification by the suppliers.

This restriction on diisocyanates requires training prior to use for adhesives and sealants containing polyurethane. The restriction established that, as of 24 August 2023, successfully completed training will be required for all professional and industrial users of products with a total monomeric diisocyanate concentration of > 0.1%. The training does not amend existing health and safety requirements but is additional to them. The restriction also dictates that certain labelling and information requirements have to be complied with.

The new regulation applies only to professionals and industry; a separate restriction for consumer use came into force several years ago. Methylene diphenyl diisocyanate (MDI)[2] and some of its isomers have not been able to be placed on the market since 27 December 2010, as a constituent of mixtures in concentrations equal to or greater than 0.1 % by weight of MDI for supply to the general public, unless suppliers shall ensure before the placing on the market that the packaging contains protective gloves and is marked visibly, legibly and indelibly to inform consumers about sensitisation, dermal and inhalation risks.[3]

The restriction covers all these diisocyanates, as well as other substances which contain residual diisocyanates. This includes prepolymers, oligomers and polymers of diisocyanates which still contain more than 0.1 % free diisocyanates.

II. What are Diisocyanates and How are They Used?

Diisocyanates are basic components of polyurethane (PU), used in the manufacture of many different products including adhesives and sealants. Polyurethane

* Paula Diaz, Regulatory Affairs Manager, FEICA - Association of the European Adhesive & Sealant Industry. For Correspondence: <p.diaz@feica.eu>

1 COMMISSION REGULATION (EU) 2020/1149 of 3 August 2020 amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards diisocyanates

2 MDI: Methylene diphenyl diisocyanate

3 Commission Regulation (EC) No 552/2009 of 22 June 2009 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annex XVII

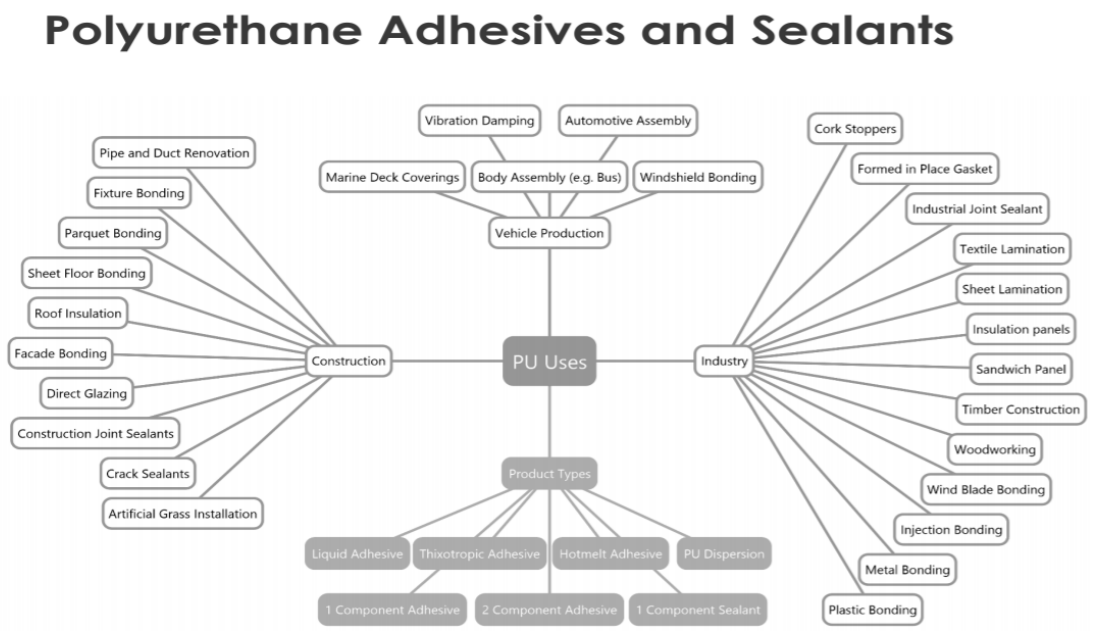

Fig 1. Uses of PUR Adhesives and Sealants (Source: FEICA PU restriction and OELs Taskforce)

adhesives and sealants, in turn, are versatile, innovative and safe. They are used in a wide variety of applications: construction, packaging, automotive, furniture, engineering, marine, transportation and many more. Diisocyanates are a group of chemicals containing two isocyanate functional groups (R–N=C=O) in otherwise varied structures. Due to the functional groups, all diisocyanates induce similar health effects, and are potent skin and respiratory tract sensitisers.

Diisocyanates are widely used in different applications in industry, most notably in the manufacturing of polyurethanes (that are used for various purposes) and as hardeners in industrial paints, glues, varnishes and resins. Moreover, diisocyanates are used in adhesives and sealants across a diverse set of markets and applications as a result of the performance advantages they bring, as illustrated in the graph.

Diisocyanate-containing products are in many of the above examples the only, or the preferred, products for their applications. Polyurethanes cannot be produced without aromatic or aliphatic diisocyanates. Therefore, there is currently no commercially viable alternative to MDI, TDI[4], HDI[5], IPDI[6] or H12MDI[7] and others. Competitive technologies have not been found to be able to reproduce polyurethane properties in most of the respective articles.

As is the case with any substance, the use of diisocyanates is safe when chemicals are handled according to relevant risk management and safety measures. It is also important to stress that no diisocyanates can be found in finished articles. Diisocyanates are used only as reactive chemicals; they react with the polyol to form the PU product and are used up during the reaction.

The diisocyanates restriction is targeted at avoiding the unsafe handling of diisocyanates, not at restricting product availability. Because of their unique properties in many applications, polyurethane adhesives and sealants will remain widely available.

III. Requirements

1. Labelling and Information Provision

As of 24 February 2022, PU products intended to be used in industrial or professional settings with a to-

4 TDI: Toluene diisocyanate

5 HDI: Hexamethylene diisocyanate

6 IPDI: Isophorone diisocyanate

7 H12MDI: 4,4′-Dicyclohexylmethane diisocyanate

tal monomeric diisocyanate concentration of > 0.1% shall include the following phrase on their packaging: 'As of 24 August 2023, adequate training is required before industrial or professional use of this product'. The legal text does not provide further information on the labelling requirements, such as size or location, language requirements, inner/outer packaging rules, small containers, etc.

Since labelling changes need to be implemented in advance, FEICA, the Association of the European Adhesive & Sealant Industry, strongly urges its membership to start adapting labels immediately to comply with the mentioned requirement.

Furthermore, end users of polyurethane products should be provided with information on the training on the safe use of diisocyanates. However, instructions on how suppliers must provide end users with information are not provided in the restriction text. To facilitate adhesive and sealant companies to comply with the information provision requirement, a FEICA information webpage has been created to provide users with additional information on the training and will be updated regularly. The link to this webpage (or the QR code) can be added to adhesives and sealants labels. Once training materials are available, a link to the training platform will be added to the webpage. This will allow end users of adhesives and sealants to stay informed about the training development and access the training when it is available.

2. Training

By 24 August 2023, users shall have successfully completed training on the safe use of diisocyanates prior to the use of the substances or mixtures. In line with the requirements laid down in the restriction, the training content will vary depending on the application's risk.

There are three levels of training corresponding to levels of risk. The *first level* of training concerns staff involved in professional uses. In this case, training entails a host of subjects including, for example, risks of exposure (e.g., dermal contact and inhalation), safety (e.g., personal protective equipment and ventilation), and proper handling (e.g., critical handling stages, and cleaning and leakages). The *second level* concerns staff involved in industrial applications at room temperature. Here there will be additional training for, for example, management of change, and risk in relation to the application process used. The *third level* of training, then, concerns staff involved in applications at high speed or over 45 °C. This additional training concerns, for example, open handling of hot or warm formulations (> 45 °C). It should be noted that managers will also have to be trained.

A consortium comprised of the diisocyanates manufacturers, the European Diisocyanate & Polyol Producers Association (ISOPA)[8] and the European Aliphatic Isocyanates Producer Association (ALIPA)[9], as well as several downstream user associations including FEICA, are planning to make training available online for easy usability. Additionally, the training material will be available for individual classroom training. Training material for use by FEICA members and by adhesive or sealant users will become available by mid of 2022 in all official EU languages.

Holding a certification to prove attendance at the training, including passing a final exam, will be mandatory for all professional and industrial users of the product. The training must be renewed every five years. The adopted legal text requires the training to be provided by an expert in Occupational Health & Safety. Employers must keep records of the training provided to their employees.

The diisocyanates restriction legal text does not require Member States to implement any additional measures. However, it states that the training shall comply with the provisions (existing or new) set by the Member State in which the industrial or professional user operates.

IV. Conclusion

Industry experience already shows that training is the most effective Risk Management Measure to reduce the already low number of occupational asthma cases from exposure to diisocyanates. This restriction including training obligations will be particularly important to raise awareness among workers of the sensitisation risks from both inhalation and dermal exposure to diisocyanates. The restriction will

8 See, <https://www.isopa.org/>

9 See, <https://www.alipa.org/>

complement existing efforts to protect workers from exposure to diisocyanates under OSH legislation and provide a level playing field for industry across Europe.

The established mandatory certification system will reduce the administrative burden of checks and inspections to be carried out by Member State authorities. Harmonised training will be fully monitorable and enforceable.

Finally, the implementation of the diisocyanates restriction highlights the need to improve the interface between REACH and OSH legislation[10]. Industry sees diisocyanates as a good opportunity to put this objective into practice. Restrictions based on training obligations could also be the most appropriate Risk Management Measure for other substances. The upcoming revision of REACH as foreseen in the Chemical Strategy for Sustainability could be a unique opportunity to consider this matter.

It should be noted as well, that the restriction is a much more proportionate regulatory management option compared to the REACH Authorisation process, because it achieves the objective to protect human health and the environment without establishing a fairly burdensome process for downstream users, and their suppliers.

Additional information on the safe use of diisocyanates can be found on the FEICA website.[11]

10 OSH = Occupational Safety & Health

11 See, <https://www.feica.eu/our-priorities/safe-use-diisocyanates>

Borderline Products in the EU: Obstacles for Manufacturers and Importers

Minetta Wunderskirchner*

I. Introduction

In order to be compliant with the regulatory requirements for a specific product in the EU market, one crucial preliminary step is to identify and categorise a given product and determine to which regulatory framework it belongs. This can be a quite challenging task since there are products that lie between two categories consequently being affected by different regulatory frameworks. The term borderline product is used when a product lies on the edge of one product category and verges on another. Criteria which can lead to a product being regarded a borderline product are for example, its purpose (or intended use) and its function, in case they overlap with those of other product categories. Other relevant criteria are the product claim and the product composition (e.g. active substances) as they may advertise qualities of other product categories. Finally, the overall presentation of a product has also to be taken into account. A misleading presentation of the claim, i.e. its prominence or relevance may result in the consumer assuming that the product belongs to a certain product category, which may fall under a more stringent regulatory framework. The decision on a product's categorization must be confirmed on a case-by-case basis, considering all characteristics of the product.

Some borderline products may fall within the scope of two (or more) regulations or directives. In such a case, one of the following three options is applicable:

i. The product is regulated under both/all regulatory frameworks within scope
ii. The product is regulated under the most stringent regulatory framework
iii. A commission and/or court decision categorized the product and decided if i. or ii. applies

In the following sections examples of typical borderline products and their characteristics are presented.

II. Cosmetic and Biocidal Functions: Hand Cleaners

Article 2(1)(a) of the EU Cosmetic Product Regulation[1] describes the main purpose of cosmetic products as keeping the external parts of the human body, the teeth and the mucous membranes of the oral cavity in a clean and good condition. Due to the diversity of areas of application and wide range of product types, cosmetic products are prone to overlap with other product categories. The same applies to biocidal products. According to Article 3(1)(a) of the EU Biocidal Products Regulation[2], the main purpose of biocidal products is to destroy or control the effect of harmful organisms by any means other than mere physical or mechanical action. Although the features described do not sound similar at first glance, cosmetic products often claim functions or characteristics of biocidal products and vice versa.

In context of the current COVID-19 pandemic, the number of hygienic products placed on the EU market increased. Hand cleaners in form of gels or wipes often contain alcohol as active substance and claim both cleaning and antibacterial or antiviral functions. In order to determine whether a hand cleaner falls within the scope of the EU Cosmetic Products Regulation or the EU Biocidal Products Regulation, the primary purposes of the product is critical.

According to the borderline products manual[3] published by the working group on cosmetic products (chaired by the European Commission), prod-

* Dr. Minetta Wunderskirchner is a Regulatory Affairs Manager at knoell Germany GmbH, responsible for chemical and cosmetics regulatory consulting worldwide with a special focus on EU REACH and EU Cosmetics Products Regulation. Before joining knoell, she held a position as Research Scientist in in the cosmetics industry. For correspondence: mwunderskirchner@knoell.com

1 Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (EU Cosmetics Products Regulation) [2009] OJ L 342/1

2 Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (EU Biocidal Products Regulation) [2012] OJ L 167/1

3 Manual of the working group on cosmetic products (sub-group in borderline products) on the scope of application of the Cosmetics Regulation (EC) No 1223/2009 (Art. 2(1)(a)) [September 2020, version 5.2]

ucts with a primary cosmetic purpose and a secondary non-cosmetic purpose are most likely subject to the EU Cosmetic Products Regulation. This means, the main purpose of the product must be to cleanse or clean the skin.

However, it can be difficult to distinguish between a primary and a secondary purpose in case both claims seem to be equally strong or no main purpose is declared. Therefore, in 2020, two additional guidance documents were published in order to a) assist member states and industry in determining the applicable legislation for leave-on hand cleaners and hand disinfectants[4], and b) to illustrate which claims would not support the classification of leave-on hydro alcoholic hand gels as cosmetic products[5]. According to those documents, products containing a biocidal active substance marketed with any claims of biocidal activity or specific effects of reducing cross contamination would be subject to the EU Biocidal Products Regulation.

III. Cosmetic and Biocidal Functions: Sunscreen Products with Insect Repellent

Sunscreen products with insect repellent function also are typical borderline products. They protect the skin from damage caused by the sun, which is a cosmetic function. They also repel insects, which is a biocidal function. Thus, they may fall within scope of both the EU Cosmetic Products Regulation and the EU Biocidal Products Regulation. Usually, products with a primary cosmetic function and a secondary biocidal function are regulated under the EU Cosmetic Products Regulation only.

However, in case of insect repellents, the biocidal function is normally considered a primary function.

If the cosmetic function is secondary, the product will be regulated under the EU Biocidal Products Regulation only. It should be noted that Article 19(9) of the EU Biocidal Products Regulation requires that biocidal products intended for the direct application to the external parts of the human body, the teeth or the mucous membranes of the oral cavity shall not contain any non-active ingredients that may not be included in a cosmetic product pursuant to the EU Cosmetic Products Regulation.

If both the cosmetic and the biocidal purposes are of relevance then both regulations need to be taken into consideration. As mentioned before, the EU Biocidal Products Regulation shall not apply to biocidal products that are within the scope of the EU Cosmetic Products Regulation. Nonetheless, the European Commission published a note for guidance[6], which contradicts this view. According to the notes of guidance, sunscreen products with insect repellent function have to comply with both regulations. The same criteria apply to sunscreen products with repellent effects for jellyfish or other harmful organisms.

IV. Medical and Biocidal Functions: Insect Repellents

Some insect repellents claim to have a medical function, such as the prevention of diseases that might be transmitted by certain insects. This raises the question whether they fall within the scope of the EU Biocidal Products Regulation or rather of the medical legislation. Article 1(2) of the EU Medicinal Product Regulation[7] describes medicinal products as substances or combinations of substances, which have (amongst others) properties for treating or preventing disease in human beings. According to Article 2(1) of the EU Medical Devices Regulation[8], medical devices can also serve the purpose of disease prevention.

Thus, the manual[9] on borderline and classification on the community regulatory framework for medical devices discusses the case of an insect repellent, which claims to prevent diseases transferred by mos-

4 Guidance on the applicable legislation for leave-on hand cleaners and hand disinfectants (gel, solution, etc.) [2020]

5 Technical document on the scope of application of the Cosmetics Regulation (EC) No 1223/2009 (Art. 2(1)(a)), product claims of leave-on hydro alcoholic hand gels in the context of COVID-19 pandemic agreed by the Sub-Working Group on Borderline Products [2020]

6 European Commission note for guidance on borderline between the legislation for cosmetics and biocides [2013] CA-Jul13-Doc.5.1.h

7 Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (EU Medicinal Products Directive) [2001] OJ L 311/1

8 Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (EU Medical Devices Regulation) [2017] OJ L 117/1

9 Manual on borderline and classification on the community regulatory framework for medical devices [2018] Version 1.19

quitoes, and is intended for the use on human skin. The manual concludes that the product's primary purpose is to repel insects, which is a biocidal function. Furthermore, the product does not have an effect on the human body, but on the insects. Therefore, the product falls within the scope of the EU Biocidal Products Regulation. As mentioned earlier, for biocidal products intended for the direct application to the human skin, restrictions on certain ingredients defined by the EU Cosmetic Products Regulation must be considered. Please note however that, when defining the claim of a biocidal product it should be considered that its purpose is to protect humans, animals, materials or articles against harmful organisms, by the action of the active substances contained in the biocidal product and not the prevention of diseases as such. Therefore such claims can be considered misleading.

V. Medical and Cosmetic Functions: Skin Discolouration

Other borderline products sit on the fence between the EU Medicinal Products Regulations and the EU Cosmetics Regulation. Besides treating or preventing diseases, medicinal products also restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action (Article 1(2) of the EU Medicinal Products Regulations). Many medicinal products are applied directly to the human skin in form of lotions, creams or ointments and thus, resemble many common types of cosmetic products. Furthermore, medicinal products may advertise cosmetic functions, such as moisturizing the skin. Cosmetic products on the other hand sometimes claim functions, which may be regarded of medicinal nature, such as soothing skin irritations.

Often the mode of action of a product is crucial for the decision whether the product falls under the scope of a certain regulation or is excluded from the scope. For example, products that lighten the colour of dark circles under the eyes can operate in different ways. Make-up products cover dark circles in order to hide them. Such products do not exert any pharmacological, immunological or metabolic action and fall within the scope of the EU Cosmetic Products Regulation. Other products reduce the dark circles by acting on the cause of the discolouration. Such products are regulated under the EU Medicinal Products Regulations as they penetrate the skin layers and restore, correct or modify physiological functions.

According to the borderline products manual[3] published by the working group on cosmetic products, skin-whitening products fall within the scope of the EU Cosmetic Products Regulation as long as the purpose of the product is not associated with the treatment of pigmentation disorders. Skin conditions such as melasma, chloasma and lentigo are considered medical conditions. Therefore, products treating pigmentation disorders are regulated under the EU Medicinal Products Regulation.

VI. Conclusion

Categorizing a product can be challenging but is essential. Determining the product category, identifying the regulatory requirements that apply, rectifying the claims, if required, and registering or notifying the product under the correct regulation or directive will ensure product compliance and pay off in the long run. Falsely categorizing or wrongly claiming and presenting a product may lead to unnecessary costs in product registration or notification and a delay in placing the product on the market. In case a product is placed on the market but is registered or notified under the wrong regulatory framework, authorities might request a product recall and impose sanctions against the product manufacturer or the person responsible for marketing the product.

The European Commission has published several manuals and guidelines addressing borderline product cases in a variety of different legislations. It is highly recommended to consult such documents and stay informed about the developments in the regulatory world.

China REACH Update (MEE Order No. 12): Difference with REACH

*Dandan Ge**

I. China REACH Update - Replacement of MEP Order No. 7 by MEE Order No. 12 as of 01/01/2021

1. Definition, Application and Exemptions

On 15 October 2010 the Chinese **M**inistry of **E**nvironmental **P**rotection (MEP) released the revised version of the Measures on Environmental Administration of New Chemical Substance (MEP Order No.7). Ten years later, in 2020, the Chinese **M**inistry of **E**cology and **E**nvironment (MEE) issued Order No. 12, which replaced MEP Order No. 7 and has already come into force on 1st January 2021[1].

Under MEE Order No. 12 chemical substances are divided into existing and new substances. The new measures require different registration types for:

(a) New substances, which refer to the substances that are not listed in the **I**nventory of **E**xisting **C**hemical **S**ubstances of **C**hina (IECSC); and
(b) Substances, which have been listed in IECSC but are used for industrial applications other than permitted uses (i.e. subject to new usage environmental management, similar to Significant New Use Rules of Toxic Substances Control Act in the USA),

irrespective of annual tonnage before they can be researched, manufactured, imported, processed and used in the territory of the People's Republic of China (PRC). The registration shall be submitted to the Chinese competent authority - **S**olid Waste and **C**hemical Management **C**enter (SCC) of MEE.

New substance (in form: as such or in mixtures or in articles which is intended to be released under normal or reasonably foreseeable conditions of use) shall be registered, mixture/article itself not. Variable component substances, complex reaction products which have no unique and uncertain molecular structure, once they are new substances, also fall within the scope of registration. Polymers are not exempt from registration. Even if all monomers are listed in IECSC, registration is required, when polymer itself is a new substance.

MEE Order No.12 shall not apply for:
- Pharmaceuticals (including active pharmaceutical ingredients), pesticides (including pesticide technical materials), veterinary drugs (including veterinary drug substances), cosmetics, food, food additives, feed, feed additives, fertilizers, etc. and
- Radioactive substances.

Categories of exemption from registration cover:
- Naturally occurring substances;
- Non-commercial or non-intentionally produced substances (impurities, by-products);
- Other special categories:
- Materials (e.g. glass, ceramic, steel etc.);
- Alloys;
- Non-isolated intermediates;
- Articles;
- Non-artificial substance which is produced by chemical reaction when a product or mixture achieve its specific function by manufacturing or import or for sale;
- Mixture which is artificially mixed by existing substances and does not produce new substances;
- Substance in anhydrous form and its hydrate, one of which has been listed in IECSC.

New substances, which are imported and temporarily stored in a special customs supervision area, subsequently exported without any processing, shall be exempted from registration as well.

2. China's Existing Chemical Substance Inventory: IECSC

IECSC contains all existing substances manufactured, processed, sold, used or imported in China between 01/01/1992 and 15/10/2003 and new substances

* Dandan Ge is managing director at GEELIO Umwelttechnologie GmbH, technical director at Shanghai GEELIO Business Consulting Co. Ltd. responsible for chemical regulatory consulting with focus on EU REACH, UK REACH and China REACH. For correspondence: <dandan.ge@geelio.com>

1 MEE Order No. 12 full legal text (Chinese): https://www.mee.gov.cn/xxgk2018/xxgk/xxgk02/202005/t20200507_777913.html

Table 1: IECSC and the Supplements

Publication Date	Number of New Substances
01/2013	45,612
10/03/2016 (1. supplement)	31
22/11/2018 (2. supplement)	45
14/01/2019 (3. supplement)	28
03/01/2020 (4. supplement)	47
06/05/2020 (5. supplement)	156
15/10/2020 (6. supplement)	28
21/12/2020 (7. supplement)	238
16/04/2021 (8. supplement)	204
21/04/2021 (9. supplement)	115
18/06/2021 (10.supplement)	255
Total (effective 18/06/2021)	46,759

which were notified according to MEP Order No. 7 previously and five years have passed since their first manufacture or import. IECSC (version January 2013) included 45,612 existing substances, in which 3,270 substances were marked as confidential. Up to now it has been supplemented 9 times, illustrated in Table 1, and currently there are 46,759 substances in the inventory[2].

IECSC consists of two parts: the public part and the confidential part, which contains more than 3,000 substances. These substances are not publically accessible for reasons of confidentiality. In order to avoid unnecessary registration, before a substance is registered, it is recommended: (a) to check whether a substance is in IECSC (the public part); (b) to check whether a substance is exempted from registration; (c) to submit a formal enquiry to the authority SCC for a full IECSC search under uncertainty.

At present 3,000 CNY per substance will be charged by SCC for verifying whether a substance is identified as new substance[3]. Once all required data for an enquiry is available (e.g. substance name, CAS number, structural formula etc.), SCC will present the result normally within 14 days.

3. Applicant

Applicants for registration are:
- Manufacturers or importers (enterprises or public institutions registered within the territory of PRC who bear independent legal liabilities) of new substances in PRC;
- Non-Chinese companies (manufacturer or distributor) who export new substances to PRC;
- Companies (processing user) who intend to apply for new uses registration or to change the registered uses of the products managed by other laws and regulations to other industrial uses.

A non-Chinese company (manufacturer or distributor) who plans to export a new substance to PRC has two options to complete the registration: (a) request Chinese importer to register it; or (b) appoint a local qualified Chinese agent (enterprise or public institution registered within the territory of PRC who bears independent legal liabilities) by mutual agreement to register the substance. The role of the local Chinese agent is similar to the role of "Only Representative" under EU REACH. Non-Chinese company shall jointly perform the registration and bear liabilities according to MEE Order No.12.

Only an applicant can be holder of registration certificate. In case that a non-Chinese company appoints a local Chinese agent to complete the registration, the non-Chinese company holds the registration certificate, not the agent.

II. Registration Requirements

1. Registration Types

Subject to different purposes and quantities of the substance, there are three registration types under

2 IECSC and its supplements: https://www.mee.gov.cn/ywgz/gtfwyhxpgl/hxphjgl/wzml/

3 SCC official notice on 30/09/2017: https://www.meescc.cn/zhxx/tzgg/201709/t20170930_450420.shtml

Table 2: Registration Type and Application Materials

Registration Type	Record Notification	Simplified Registration	Regular Registration
Scope of Application	Q < 1 t/a; Polymer containing < 2% of monomer/reactant which is identified as new substance; Polymer of low concern (PLC)	1 t/a ≤ Q <10 t/a	Q ≥ 10 t/a
Application Materials			
Application form	×	×	×
Appendixes to the application form	×	×	×
Legal person certificate/business license, representation contract/agreement, authorization letter	×	×	×
List of monomers/reactants, plot of molecular weight distribution, mechanism of polymerization, materials illustrating that substances in question are not polymers which are subject to regular or simplified registration	× (for Polymer containing < 2% of monomer/reactant which is identified as new substance; PLC)		
Other known information on the characteristics of environmental and health hazards and environmental risks of new substances	×	×	×
Testing report or data/materials		×	×
Qualification certificate of the testing institutions		×	×
Materials stating the necessity of information protection		×	×
Letter of commitment for implementing/transmitting risk control measures and environmental management requirements		×	×
Conclusions incl. basis on the persistence, bioaccumulation and toxicity of new substance		×	
Environmental risk assessment report			×
Socio-economic benefit analysis report (for highly hazardous new chemicals[4])			×

Q = Quantities; × = required

MEE Order No.12: Regular Registration, Simplified Registration and Record Notification. Table 2 shows definitions of each registration type and the corresponding required materials for application.

2. Special Form of Regular and Simplified Registration

Other than individual registration (usual form), there are two special forms available, both for regular and simplified registration: Series Registration and Joint Registration.

Series Registration: A same applicant submits registration for multiple new substances which have similar molecular structure, identical/similar uses or similar testing data as a series.

Number of applicants: one; Number of substances in each series: < 6; Quantities: total volume of each substance.

Joint Registration: Same new substance is registered by two or more applicants at the same time.

Number of applicants: more than one; Number of substances: one; Quantities: total volume of each applicant.

3. Data Requirements

Compared to MEP Order No.7, the guidance to MEE Order No.12 published by MEE on 17/11/2020[4] contains some significant data requirement changes for the registration and focuses on the management of persistent (P), bioaccumulative (B) and toxic (T) substance. The key changes are for example: physicochemical properties test data generated in non-Chinese laboratories will be acceptable as soon as such test facilities meet the management requirements of the competent authority of the country where they are located or meet the requirement of internationally accepted Good Laboratory Practice (GLP) management norms; in-vitro data for skin corrosion/irritation and eye irritation will be accepted if the results are conclusive; the toxicity data requirement for Reg-

4 MEE Announcement (2020) No.51: ww.mee.gov.cn/xxgk2018/xxgk/xxgk01/202011/t20201119_808843.html

Table 3: Data requirement: Physicochemical Properties

Physico-chemical Properties	Test Method OECD TG	Simplified Registration (1 t/a ≤ Q < 10 t/a)			Regular Registration (Q ≥ 10 t/a)		
		Gas	Liquid	Solid	Gas	Liquid	Solid
Spectrogram		×	×	×	×	×	×
Melting point/ Freezing point	102		×	×		×	×
Boiling point	103		×			×	
Density	109		×	×		×	×
Vapor pressure	104		×			×	
Water solubility	105	×	×	×	×	×	×
n-octanol/water partition coefficient	107		×	×		×	×
pH			×			×	
Granulometry	110			×			×
Surface tension	115		×			×	
Critical point		×			×		
Dissociation constant (pKa)	112					×	×
Henry's law constant					×	×	×

× = required

Table 4: Data requirement: Ecotoxicology (Simplified Registration)

Ecotoxicology	Test Method OECD TG	Basic Simplified Data (non-P and non-B; P or B)	Special Simplified Data (P and B)
Algal growth inhibition toxicity	201	×	×
Daphnia acute toxicity	202	×	×
Fish acute toxicity / Fish short-term toxicity test on embryo yolk-sac absorption stages	203	*	*
Activated sludge respiration inhibition toxicity	209		
Adsorption/desorption	121/106		
Degradability	301/310	*	*
Earthworm acute toxicity test	207		
Daphnia reproduction test	211		×
Bioaccumulation	305	*	*
Fish chronic toxicity test	210/212/215		*

× = required; * = mandatory test in China; P = persistence; B = bioaccumulation

ular Registration is classified in three categories based on P and/or B potential of the substance.

For **Record Notifications** only known risk/hazard data need to be submitted. No test is required.

For **Simplified Registrations**, applicants need to provide physicochemical properties and data for ecotoxicity, based on persistent, bioaccumulative and toxic (PBT) properties of the substance. Toxicity data is not required.

For **Regular Registrations**, physicochemical properties, toxicity and ecotoxicity data will be required, depending on the hazardous properties of the substance. Tables 3, 4, 5 and 6 illustrate the detailed data requirements for different registration types.

The data required for registration can be generated by experimental testing (preferred) or by surrogate method, such as QSAR, read-across and literature data etc. General principles for data quality are authenticity, reliability, scientific, correlation and well balanced. The detailed requirement for testing facilities in respect of physicochemical properties, toxicology and ecotoxicology data are present in Table 7.

The Chinese test method, such as Guideline for the Testing of Chemicals (HJ/T153), relevant national standards of chemicals test can be used for diverse testing. The testing can also be performed according to OECD or other international accepted methods.

4. Post-registration Obligations

After successful registration a certificate will be issued. The registration certificate contains: (a) Type of the registration certificate; (b) Name of the applicant, and the agent (if relevant); (c) Identification of

Table 5: Data requirement: Toxicology (Regular Registration)

Toxicology	Test Method OECD TG	Basic data (non-P and non-B)	Special Data 1 (P or B)	Special Data 2 (P and B)
Acute toxicity (oral + dermal + inhalation)	423, 402, 403	×	×	×
Skin corrosion/ irritation	404 (in-vitro/in-vivo)	×	×	×
Eye irritation	405 (in-vitro/in-vivo)	×	×	×
Skin sensitization	406/429 (in-vitro/in-vivo)	×	×	×
Mutagenicity	471, 473/487, 476 (in-vitro/in-vivo)	×	×	×
Repeated dose toxicity (oral/dermal/inhalation, 28days/90days)	407/410/412 (28 days); 408/409, 411, 413 (90 days)	× (28 days)	× (90 days)	× (90 days)
Reproductive/ developmental toxicity	421/422	×	×	×
Toxicokinetics	417			×
Chronic toxicity	452			×
Carcinogenicity	451/453		×	×
Other		×	×	×

× = required; P = persistence; B = bioaccumulation

Table 6: Data requirement: Ecotoxicology (Regular Registration)

Ecotoxicology	Test Method OECD TG	Basic Data (non-P and non-B)	Special Simplified Data (P or B)
Algal growth inhibition toxicity	201	×	×
Daphnia acute toxicity	202	×	×
Fish acute toxicity / Fish short-term toxicity test on embryo yolk-sac absorption stages	203	*	*
Activated sludge respiration inhibition toxicity	209	*	*
Adsorption/desorption	121/106	×	×
Degradability	301/310	*	*
Earthworm acute toxicity test	207	×	×
Daphnia reproduction test	211	×	×
Bioaccumulation	305	*	*
Fish chronic toxicity test	210/212/215	*	*
Seed germination and root elongation test or Terrestrial plants growth test			×
Enchytraeid reproduction test or Earthworm reproduction test			×
Benthos chronic toxicity			×

× = required; * = mandatory test in China; P = persistence; B = bioaccumulation

the substance; (d) Registered use(s); (e) Registered volume; (f) Type of activities; (g) Control measures for environmental risks; (h) For highly hazardous substances (PBT/vPvB etc.) or PB/PT/BT substances & Regular Registration: Limited emission amount or concentration/ Requirements for the implementation of environmental management of new use(s) when they are listed in IECSC/ Submission of annual report/other environment management requirements.

The certificate holder needs to fulfill different post-registration obligations depending on the registration type. The post-registration obligations can be seen in Table 8.

Annual report is required only for those new substances meeting PB or PT or BT or highly hazardous criteria. Such requirement will be specified in the registration certificate. The deadline for submitting an annual report is 30th April each year.

Table 7: Requirement for Testing Facilities

Endpoints	Chinese Testing Facilities	Non-Chinese Testing Facilities
Physicochemical properties	Comply with relevant laws and regulations and the requirements of relevant national authorities.	Meet the management requirements of the competent authority of the country where the testing facility is located or meet the requirements of internationally accepted GLP management norms.
Toxicology	Comply with relevant laws and regulations and the requirements of relevant national authorities and one of the following testing facilities: - Passed GLP certification management of the State Food and Drug Administration; - Passed the quality assessment of the Chinese Center for Disease Control and Prevention; - Pesticide registration test unit announced by the Ministry of Agriculture and Rural Affairs; - Passed GLP evaluation approved by the China National Certification and Accreditation Administration.	Meet the requirements of internationally accepted GLP management norms.
Ecotoxicology	Comply with GLP and accept the supervision and random inspection of its testing conditions and conditions by the competent department of ecological environment of the State Council.	Meet the requirements of internationally accepted GLP management norms.

5. Information Protection Arrangements

Applicants of a regular registration can apply for protection of identification information of chemical substances for at most 5 years after issue of the registration certificate. The applicant needs to submit data which show the necessity of such information protection.

The identification information protection of substances which were registered under MEP Order No. 7, as well as substances which were included in IECSC under MEP Order No. 7 and already subject to identification information protection, will cease no later than 31st December 2025 and the protection cannot be extended.

Substances of Simplified Registration and Record Notification cannot be included into IECSC and will remain as new substances. The extension of identification information protection of highly hazardous chemicals or chemical substances which pose a high potential for environmental or health risk could cause an impact on environmental and/or public health.

6. Significant Difference compared to EU REACH

Although MEE Order No. 12 (also MEP Order No. 7 previously) is called China REACH due to its similarity to Regulation (EC) No. 1907/2006 (EU REACH), some significant differences between the two regulations are shown in Table 9.

7. MEE Order No.12 (China REACH) Compliance Strategy

Following recommendations for non-Chinese companies might be helpful before they place a substance onto the Chinese market:

- List all substances that you will export to China;
- Make sure which substance is identified as new substance according to China REACH (working with the latest IECSC);
- Assess which registration type needs to be done (quantities shall be determined based on actual market demand);
- Seek support from partner(s): does the Chinese import register the substance for you? Do you have a subsidiary in China who can register the substance as importer? Does it make sense that you appoint a local agency?
- Create an effective test strategy based on data gap analyse (if a non-Chinese company is data owner or has legal access to data, e.g. as per Letter of Access issued by data owner for the purpose of China REACH, the cost for a registration could be reduced significantly);
- Enrich your knowledge on China REACH.

Table 8: Post-registration Obligations

Post-registration obligations	Record Notification	Simplified Registration	Regular Registration
Information transfer in the supply chain (e.g. registration certification number, registered uses, hazard characteristics, risk control measures, environment management requirements)	×	×	×
Establish new substance activity situation record system	×	×	×
Keep documents on file for years	× at least 3 years	× at least 10 years	× at least 10 years
Submit update(s) if new hazards or risks arise and take measures to eliminate or reduce the risks	×	×	×
Submit first-activity report		×	×
Disclose the implementation situations of the environmental risks control measures and environmental management requirements			×
Annual report		× (PB/PT/BT/highly hazardous substance)	×

× = required

Table 9: Significant Difference between China REACH and EU REACH

Main difference	MEE Order No. 12 (China REACH)	Regulation (EC) No. 1907/2006 (EU REACH)
Substance to be registered	Substance not listed in IECSC, regardless its manufactured/imported quantities in PRC	Substance manufactured/imported in the EU/EEA
Polymer	Registration requirement for polymer as well, as long as it is defined as new substance.	Polymer itself is exempted from registration.
Only Representative (OR)	Non-Chinese company (incl. distributor) who exports new substances to PRC can appoint OR.	Only non-EU/EEA manufacturer or formulator or article producer can appoint OR.
Registration Type/Form	Record Notification, Simplified Registration and Regular Registration / Individual Registration, Series Registration, and Joint Registration.	Standard (Full) Registration and reduced Registration (intermediate) / Joint Submission and Individual Submission.
Data Sharing	No SIEF. Substance information exchange and/or data sharing are not mandatory.	SIEF. Testing on vertebrate animals as last resort. It is necessary to take measures limiting duplication of other tests.
Data Requirements for Registration	Physicochemical properties, toxicity and ecotoxicity data requirement depend on 2 tonnage levels (1-10 t/a, over 10 t/a); No test requirement for Record Notification (Q < 1 t/a, polymer with NM<2%, PLC); additional data requirement for highly hazardous substances (e.g. PBT/vPvB) and PB/PT/BT substances; some ecotoxicological tests must be performed by using local test organism (e.g. Gobiocypris rarus, activated sludge) in PRC.	Physicochemical properties, toxicity and ecotoxicity data requirement depend on 4 tonnage levels (1-10 t/a, 10-100 t/a, 100-1000 t/a, over 1000 t/a)
GLP Qualification	Because of not being OECD member, China GLP test data is not accepted as international GLP data under EU REACH and other non-Chinese chemical regulations.	Toxicity and ecotoxicity test shall be performed according to internationally accepted GLP Norm.
Language	Predominantly Chinese, test report in English possible, but Chinese translation for summary must be provided.	English
Software	No specific software, submission by using SCC's online registration system	IUCLID, submission to ECHA through REACH-IT
Registration Fee to Authority	No registration fee required by SCC. Enquiry for full IECSC check by SCC: currently 3,000 CNY per substance.	Commission Implementing Regulation (EU) 2015/864

Upcoming Events
Summer/Autumn 2021

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July

07 – 09	Simplified Cost Options for ESI Funds and AMIF/ISF/BMVI | Online Course
13 – 15	Financial Management, Control and Audit of ESI Funds: Transition Towards 2021-2027 | Online Course
26 – 28	Summer Course: Public Procurement from A to Z | Online Course

August

24 – 27	Summer Course: State Aid – Concept, Principles, Exemptions & Guidelines | Rome & Online
25– 27	On-the-spot Visits: How to Detect and Combat Irregularities & Fraud in EU Funds | Maastricht

September

13 – 14	Fraud and Corruption in Public Procurement | Athens & Online
13 - 14	State Aid Requirements for SGEI | Milan & Online
23	State Aid Temporary Framework | Brussels & Online
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 Conference | Berlin & Online

European State Aid Law — EStAL

European Structural and Investment Funds — EStIF

European Procurement and Public Private Partnership Law — EPPPL

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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