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A Manual of Best Practice: A System of Chemicals Registration, Evaluation, Authorisation and Restriction

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1. Introduction

The European Union's (EU) Chemical, Biological, Radiological and Nuclear (CBRN) Risk Mitigation Centres of Excellence (CoE) Initiative aims to strengthen international and regional security by targeting the risks posed by CBRN materials. Its projects focus on legal, regulatory, enforcement and technical issues in 62 Partner Countries to strengthen their institutional capacity in CBRN risk mitigation.

EU CBRN CoE Project 61 (Project 61) was created to address outstanding chemical safety and security issues in areas of legislation/regulation, prevention, detection, preparedness and response in Southeast Asia.

The project's activities are divided in five work packages and carried out by a consortium, comprising of Sustainable Criminal Justice Solutions (SCJS), United Kingdom; the UK Health Security Agency (UKHSA); the International Security and Emergency Management Institute (ISEMI), Slovakia; the National Institute for Public Health and the Environment/Rijksinstituut voor Volksgezondheid en Milieu (RIVM), the Netherlands; and the Verification Research, Training and Information Centre (VERTIC), United Kingdom.

This manual has been compiled under Work Package 1 of Project 61, which focuses on the legislative aspects of chemicals management to support future efforts to strengthen national legal frameworks. It has been developed by VERTIC, with significant contributions from UKHSA, and final review by the Project 61 partner countries. Under Work Package 1, VERTIC and the Project 61 Partner Countries carry out extensive analyses of Partner Countries' legislation for the implementation of international instruments relating to the sound management of chemicals and chemical waste. The Partner Countries in question are Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, the Philippines and Viet Nam. Work Package 1 also focuses on the development of manuals and guidelines relating to chemicals management legislation, of which this report concerning best practices in the control of chemicals is one.

This manual seeks to identify approaches and best practices in the control of chemicals by analysing regional efforts in both ASEAN and the EU. In particular, it includes a thorough analysis of the EU's REACH system. On the basis of this analysis, the manual highlights a number of best practices that would be beneficial in establishing a suitable system for the registration, evaluation, authorisation and restriction of chemicals either at the national or regional level.

2. Approaches to Control Chemicals

2.1 ASEAN's Approach to Control Chemicals

At the regional level, the Association of Southeast Asian Nations (**ASEAN**) has committed itself to addressing chemicals and their waste.[1] This is set out in the ASEAN **Socio-Cultural Community (ASCC) Blueprint 2025** under the objectives C.1 on sustainability (conservation and sustainable management of biodiversity and natural resources) and D.2 on resilience (a safer ASEAN that is able to respond to all health-related hazards including biological, chemical, and radiological-nuclear, and emerging threats).[2] To achieve objective C.1, the implementation of relevant international agreements (such as those mentioned above) is noted as a strategic measure. Similarly, to achieve objective D.2, it is noted that regional standards should be promoted in order to ensure "enhance interoperability, ensure unity of action and strengthen collective resilience."

The ASEAN **Economic Community (AEC)**, which is responsible for achieving economic regional integration, has its own **Blueprint 2025**. This blueprint strives towards "effective, efficient, coherent and responsive regulations, and good regulatory practice"[3] given that regionally harmonised legislation is necessary to support a regionally integrated market. Moreover, the ASEAN **Economic Ministers (AEM)** have adopted the ASEAN **Good Regulatory Practice (GRP) Core Principles**, which have been endorsed by the AEC Council. These principles aim to foster ASEAN-wide regulatory cooperation.

While implementation of international agreements allows for harmonisation of regulatory measures across ASEAN countries, there is currently no regional regulatory scheme on chemicals in ASEAN. Chemicals are controlled through ASEAN Member States' national legal systems which may take international instruments into account. Under EU CBRN CoE Project 61, legislation of the Partner Countries related to the controlling of chemicals has been analysed against the requirements and guidelines of international instruments under Activity 2 of Work Package 1. As an example of efforts to improve regional regulatory harmonisation, the ASEAN Regulatory Cooperation Project sought to address differences in ASEAN Member States' chemicals laws by aiming towards regulatory harmonisation. This project was led by the American Chemistry Council, European Chemical Industry Council, Japan Chemical Industry Association, and the Singapore Chemical Industry Council.[4]

In addition, the AEM and the Japanese Ministry for International Trade and Industry (**AEM-METI**)'s Economic and Industrial Cooperation Committee (**AMEICC**) includes a Working Group on Chemical Industry, which has developed the **ASEAN - Japan Chemical Safety Database** (**AJCSD**). This database includes chemical regulatory information, GHS classification results, and risk and hazard information.

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[1] ASEAN, Cooperation on Environment, https://asean.org/our-communities/asean-socio-cultural-community/environment/.
[2] ASEAN, Socio-Cultural Community (ASCC) Blueprint 2025, Objectives C.1 and D.2, https://asean.org/wp-content/uploads/2021/08/8.-March-2016-ASCC-Blueprint-2025.pdf.
[3] ASEAN, Economic Community (AEC) Blueprint 2025, Objective B.7, https://aseandse.org/wp-content/uploads/2021/02/AEC-Blueprint-2025-FINAL.pdf.
[4] ASEAN Regulatory Cooperation Project, https://scic.sg/asean/index.php.

2.2 The European Union's REACH Regime

The **Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)** regime is a Regulation of the European Union (EU) adopted in December 2006 and in force since June 2007.[5] Like any other Regulation of the EU, it is legally binding on EU Member States. It also applies to countries that are part of the European Economic Area (EEA).[6]

Other countries outside of the EU, such as the United Kingdom and the Republic of Korea, have adopted legislation similar to REACH. Moreover, given the EU's trade in chemicals[7] and the globalised nature of trade, including between the EU and ASEAN Member States, REACH can affect third countries.[8] For example, chemicals that are imported into the EEA market have to comply with REACH in the same way as those produced in the EU.[9] While it is the importer in the EEA that bears the responsibility to abide with REACH, the exporter of the chemicals may in practice also be affected as it needs to sell chemicals that the importer can accept.

REACH is a comprehensive, but also complex system that raises various challenges to its users. For example, it has been noted that users face substantive issues, such as interpretation challenges with regard to REACH's legal text, and practical challenges, for example, using ICT tools such as IUCLID correctly.[10] In this manual, however, the focus is on understanding the REACH regime and on the best practices that can be distilled from it.

The main aims of REACH are to ensure a high level of protection of human health and the environment from the risks of chemicals; to promote alternative methods for hazard assessment of substances; and to enhance competitiveness, innovation, and the free movement of substances, mixtures, and articles.[11]

The REACH regime is implemented through the **European Chemicals Agency (ECHA)**.[12] This agency is responsible for the management of registration, evaluation, authorisation and restriction processes in order to maintain consistency across the EU Member States.

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[5] 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 (hereafter "REACH").

[6] The EEA consists of all EU Member States and Iceland, Liechtenstein and Norway. Switzerland is not part of the EEA.

[7] The EU was the largest exporter and the second-largest importer (after the US) of chemical products in the world in 2019. See https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Production_and_international_trade_in_chemicals#Extra-EU_trade_in_chemicals_by_Member_State.

[8] Katja Biedenkopf, 'Global REACH? The Potential International Impact of EU Chemicals Regulation' (2009) p. 11.

[9] Katja Biedenkopf, 'Global REACH? The Potential International Impact of EU Chemicals Regulation' (2009) p. 12.

[10] For more information on the challenges impacting REACH, see In REACH Project, 25 Critical Issues impacting REACH Regulation implementation, http://www.inreachproject.eu/wordpress/wp-content/uploads/2015/07/Flyer_25_Critical_Issues.pdf.

[11] REACH, Article 1.

[12] REACH, Article 75.

REACH is not limited to a list of selected chemicals - it applies to *all* chemicals to ensure they do not adversely affect human health or the environment, unless they are exempt from all or certain aspects of REACH.[13] However, there is no obligation to register substances[14] that are manufactured or imported into the EEA in amounts below one tonne a year.[15] REACH establishes procedures for gathering and analysing information on these chemicals. Individuals and companies are required to register their chemicals, which ECHA evaluates for compliance with REACH.

The REACH regime covers the following **actors** that are **based in the EU/EEA**:

1. **Manufacturers**: individuals and companies based in the EU/EEA that produce or extract chemicals;[16]
2. **Importers**: individuals and companies based in the EU/EEA that buy chemicals from outside the EU/EEA and bring them into the customs territory of the EU/EEA;[17]
3. **Downstream users**: individuals and companies based in the EU/EEA that use[18] chemicals;[19]
4. **Distributor**: individuals and companies based in the EU/EEA that store chemicals and then place them on the market for someone else.[20]

Individuals or companies **outside the EU/EEA**, including those in ASEAN Member States, are not bound by REACH. If they export products to the EU/EEA, it is the importer in the EU/EEA that has to ensure compliance with REACH. However, an individual or company outside the EU/EEA that manufactures a substance, mixture[21] or article that is being **imported** into the EU/EEA, may appoint its **Only Representative**, an individual or company based in the EU/EEA, which carries out the obligations that would usually be left to importers. This relieves importers of any obligations for importers under the regime, and they can be treated as downstream users for its purposes.[22]

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[13] REACH, Articles 1(1) and 2.

[14] REACH, Article 3(1) defines a 'substance' as "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition".

[15] REACH, Article 6(1).

[16] REACH, Article 3(9) defines a 'manufacturer' as "any natural or legal person established within the Community who manufactures a substance within the Community" and Article 3(8) defines 'manufacture' as "production or extraction of substances in the natural state".

[17] REACH, Article 3 (11) defines an 'importer' as "any natural or legal person established within the Community who is responsible for import" and Article 3(10) defines 'import' as "the physical introduction into the customs territory of the Community".

[18] REACH, Article 3(24) defines 'use' as "any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization".

[19] REACH, Article 3(13) defines a 'downstream user' as "means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user".

[20] REACH, Article 3(14) defines a 'distributor' as "any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a mixture, for third parties".

[21] REACH, Article 3(2) defines 'mixture' as "a mixture or solution composed of two or more substances".

[22] REACH, Article 8.

The actors mentioned under 1 to 4 form part of a supply chain. The REACH Regulation requires that suppliers of a substance or mixture[23] provide recipients (i.e. downstream users or distributer)[24] with a **Safety Data Sheet** (SDS) in cases where:

a) a substance or mixtures meets the criteria for classification as hazardous in the CLP (Classification, Labelling and Packaging) Regulation, which implements the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) in the EU, and with which the REACH regime is harmonised;
b) a substance is PBT (Persistent, Bio-accumulative and Toxic) or vPvB (very Persistent and very Bio-accumulative), (see part 1. Registration of chemicals below); or
c) a substance is of very high concern (SVHC), (see part 1. Registration of chemicals below).[25]

The Safety Data Sheet should include information about the properties of the substance (or mixture), its hazards, and instructions for handling, disposal, and transport as well as first-aid, fire-fighting, and exposure control measures. The content and format of an SDS[26] are defined in Annex II[27] and comprise a 16-section format in line with the hazard communication system of the GHS. Downstream users must follow the risk management advice in the Safety Data Sheet or demonstrate that the measures they have in place provide an equivalent or better level of control.

As is evident from its full title, REACH involves **four core activities**: the registration, evaluation, authorisation and restriction of chemicals.

1. Registration of chemicals

Registration of chemicals is based on the "**one substance, one registration**" principle. A substance is a chemical element and its compounds.[28] A manufacturer or importer of a substance (or a mixture, which is a solution composed of two or more substances)[29] must submit a registration.[30] Similarly, a producer or importer of an article[31] that contains a substance that is intended to be released has to submit a registration.[32] However, in both instances, the substance needs to be in quantities of one tonne or more per year for the registration requirement to apply.[33]

Registrants[34] will have to work jointly to submit a registration for each substance. This is done through a **Registration Dossier** which is prepared in IUCLID (International Uniform Chemical Information Database),[35] a software application to

[23] REACH, Article 3(32) defines 'supplier of a substance or a mixture' as "means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture, or a mixture".
[24] REACH, Article 3(34).
[25] REACH, Article 31(1).
[26] REACH, Article 31(6).
[27] REACH, Annex II 'Requirements for the compilation of Safety Data Sheets'.
[28] REACH, Article 3(1) defines 'substance' as "a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition."
[29] REACH, Article 3(2).
[30] REACH, Article 6(1).
[31] REACH, Article 7(1). Article 3(7) defines 'article' as "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition."
[32] REACH, Article 7(1).
[33] REACH, Articles 6(1) and 7(1).
[34] REACH, Article 3(7).
[35] REACH, Article 111; IUCLID, https://iuclid6.echa.europa.eu/project-iuclid-6.

store information on chemicals that is in line with the OECD Harmonised Templates, which in turn are standard data formats for reporting information on chemicals.[36]

The Registration Dossier consists of:

- a **Technical Dossier**; and
- a **Chemical Safety Report (CSR)** for substances manufactured or imported in quantities of 10 tonnes or more.

The Technical Dossier[37] is required to include, among other things, the registrant's details; the identity of the substance; its physicochemical, toxicological, and ecotoxicological data; outline of testing methods in case any gaps in data have been identified that need to be filled; and information on the classification and labelling of the substance in accordance with the CLP Regulation.[38] The Technical Dossier also needs to include guidance on safe use in line with Safety Data Sheets (SDS), another feature of the GHS and hence the CLP Regulation.[39]

For substances manufactured or imported in quantities of 10 tonnes or more,[40] a **Chemical Safety Report (CSR)**[41] is also required as part of the Registration Dossier. The CSR contains the registrant's **Chemical Safety Assessment (CSA)**.

The Chemical Safety Assessment (CSA) consists of a Hazard Assessment, and under certain circumstances, an Exposure Assessment and Risk Characterisation.

The **Hazard Assessment**[42] contains four different assessments:

- a human health hazard assessment;[43]
- a physicochemical hazard assessment;[44]
- an environmental hazard assessment;[45] and
- a PBT (Persistent, Bio-accumulative and Toxic) and vPvB (very Persistent and very Bio-accumulative) assessment.[46]

The first three assessments listed above seek to decide on the classification and labelling of the substance. The **human health hazard assessment** also seeks to determine the substance's safe levels of exposure for humans, while the **environmental hazard assessment** does the same for the substance's effects on the environment. The **PBT/vPvB assessment** seeks to determine if the substance qualifies as a PBT or vPvB. On a related note, these are chemicals that are relevant under the Stockholm Convention on Persistent Organic Pollutants, which covers chemicals that persist in the environment and accumulate in living organisms.

If the substance is PBT or vPvB, or if the substance otherwise falls into a specified hazard class or category of Annex I of the CLP Regulation,[47] then an Exposure

[36] OECD Harmonised Templates, https://www.oecd.org/ehs/templates/introduction.htm.
[37] REACH, Article 10(a).
[38] REACH, Article 10(a)(iv); Annex VI, section 4 refers to the CLP Regulation (No 1272/2008).
[39] REACH, Article 10(a)(v); Annex VI, section 5 refers to Safety Data Sheets.
[40] REACH, Article 14(1).
[41] REACH, Article 10(b).
[42] REACH, Annex I, section 0.6.1.
[43] REACH, Article 14(3)(a); Annex I, section 1.
[44] REACH, Article 14(3)(b); Annex I, section 2.
[45] REACH, Article 14(3)(c); Annex I, section 3.
[46] REACH, Article 14(3)(d); Annex I, section 4.
[47] The classes or categories are specified in REACH, Article 14(4) and Annex I, section 0.6.3.

Assessment and Risk Characterisation are necessary components of the Chemical Safety Assessment. An **Exposure Assessment** seeks to determine the dose or concentration of the substance to which humans or the environment are or may be exposed.[48] A **Risk Characterisation** outlines the risks involved in manufacturing/importing the substance in question.[49]

Once the registration has been submitted and checked for completeness,[50] a registrant will be assigned a registration number.[51] The registrant may start or continue manufacture or import of the substance if there is no indication to the contrary from the ECHA within 3 weeks of the submission date.[52] Registrants remain responsible for updating their registration if they gain new information.[53]

2. Evaluation of chemicals

REACH contains provisions allowing ECHA to check whether registrations are in compliance with the requirements of REACH. The purpose is to ensure that substances that can adversely affect human health or the environment do not appear on the EU market.

The evaluation of a Registration Dossier consists of:

- a Dossier Evaluation; and
- a Substance Evaluation.

The purposes of the **Dossier Evaluation** are to examine any testing proposals in the Registration Dossier and to determine whether the Registration Dossier contains the required information.[54] Such a **Compliance Check** can be done at any time.[55] Not all Registration Dossiers are selected for a Compliance Check, but a selection is made based on specified criteria.[56]

The main purpose of the **Substance Evaluation** is to evaluate substances to clarify whether they pose a risk to human health or the environment. ECHA is responsible for coordinating the Substance Evaluation process.[57] In cooperation with the EU Member States, ECHA defines risk-based criteria[58] and then selects the substances that are to be evaluated. These are listed in the Community Rolling Action Plan (**CoRAP**).[59] The Substance Evaluation process assesses all Registration Dossiers from all registrants specific to the same substance.

Each substance listed in the CoRAP is assigned to a Member State for evaluation.[60] After evaluation, the Member State either asks for more information[61] or prepares a

[48] REACH, Annex I, sections 0.6.2 and 5.
[49] REACH, Annex I, sections 0.6.2 and 6.
[50] REACH, Article 20(2).
[51] REACH, Article 20(3).
[52] REACH, Article 21(1).
[53] The type of new information is specified in REACH, Article 22.
[54] REACH, Article 40. ECHA seeks to ensure that every testing proposal addresses the actual information needed and avoids unnecessary testing, particularly when testing involves the use of vertebrate animals.
[55] REACH, Article 41(1).
[56] The criteria can be found in REACH, Article 41(5).
[57] REACH, Article 45.
[58] REACH, Article 44(1).
[59] REACH, Article 44(2).
[60] REACH, Article 45.
[61] REACH, Article 46.

conclusion on whether or how the obtained information will be used for the purposes of identifying **substances of very high concern** (see part 3. Authorisation of chemicals below) or imposing **restrictions** (see part 4. Restriction of chemicals below).[62]

3. Authorisation of chemicals

The authorisation process aims to ensure that **substances of very high concern (SVHCs)** are progressively replaced by less dangerous substances or technologies where economically and technically viable.[63]

The following substances may be identified as SVHCs:

- Substances meeting the criteria for classification as "carcinogenic, mutagenic or toxic for reproduction" (CMR) category 1A or 1B in accordance with the CLP Regulation;[64]
- Substances which are PBT or vPvB according to REACH Annex XIII; [65]
- Substances on a case-by-case basis, that cause an equivalent level of concern as CMR or PBT/vPvB substances.[66]

EU Member States or ECHA may propose inclusion of a substance as an SVHC by preparing a dossier in line with Annex XV.[67] Following a consultation process, the substance can be added to the **Candidate List**.[68]

The inclusion in the Candidate List brings immediate obligations for suppliers of the substance. These include providing a Safety Data Sheet to recipients of the substance[69] and providing information on the substance to recipients[70] and, upon their request, consumers[71] of an article[72] containing a certain concentration of the substance in order to allow for safe use of the article. Producers or importers of such articles also have to notify ECHA.[73]

A separate decision will be taken whether to include a substance in the list in Annex XIV, which is known as the **Authorisation List**.[74] Manufacturers, importers and downstream users that want to continue using a substance included in the Authorisation List need to apply for authorisation.[75] An authorisation is granted if the risk to human health or the environment from the use of such a substance is adequately controlled.[76] An exception to this is if it is shown that socio-economic

[62] REACH, Article 48.
[63] REACH, Article 55.
[64] REACH, Article 57(a)-(c).
[65] REACH, Article 57(d)-(e).
[66] REACH, Article 57(f).
[67] REACH, Article 59(2). See here for a registry of current proposals: https://echa.europa.eu/registry-of-svhc-intentions.
[68] REACH, Article 59(1). See the updated list here: https://echa.europa.eu/candidate-list-table.
[69] REACH, Article 31(1)(c).
[70] REACH, Article 33(1).
[71] REACH, Article 33(2).
[72] REACH, Article 3(3) defines 'article' as "an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition".
[73] REACH, Article 7(2); REACH Article 3(4) defines 'producer of an article' as "any natural or legal person who makes or assembles an article within the Community".
[74] REACH, Article 58(1); Annex XIV 'List of substances subject to authorisation'. See here for the updated Authorisation List: https://echa.europa.eu/authorisation-list.
[75] REACH, Article 62(2).
[76] REACH, Article 60(2).

benefits outweigh these risks and if there is no suitable alternative substance or technology.[77]

4. Restriction of chemicals

For chemicals that pose an unacceptable risk to human health or the environment, restrictions apply.[78] A restriction means a condition for, or prohibition of, the manufacture, use or placing on the market[79] of a substance on its own, in a mixture or in an article.[80] The **list of restricted substances**, mixtures and articles can be found in Annex XVII[81] and cannot be manufactured, placed on the market[82] or used, unless that is done in line with conditions for that restriction.[83]

An EU Member State[84], or ECHA, at the request of the European Commission,[85] can start the restriction procedure when they are concerned that a certain substance poses an unacceptable risk to human health or the environment. A dossier in line with Annex XV needs to be prepared.[86] ECHA can also propose a restriction on articles containing substances that are on the Authorisation List (Annex XIV).[87]

Upon receiving the dossier, ECHA's Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC) check whether the proposal conforms to the requirements of Annex XV.[88] If it does, the dossier will be made publicly available for consultation.[89] Based on the dossier and the consultation, these two committees will give their opinion on whether the restriction is appropriate in reducing the risk to human health and/or the environment.[90]

The European Commission then decides whether to prepare a draft amendment to Annex XVII on the basis of these two opinions.[91] A final decision is taken with the involvement of the EU Member States and the European Parliament.[92]

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[77] REACH, Article 60(4).
[78] REACH, Article 68(1).
[79] REACH, Article 3(31).
[80] REACH, Article 67(1).
[81] REACH, Annex XVII 'Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles'. See here for the updated version: https://echa.europa.eu/substances-restricted-under-reach.
[82] REACH, Article 3(12) defines 'placing on the market' as "supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market".
[83] REACH, Article 67(1).
[84] REACH, Article 69(4).
[85] REACH, Article 69(1).
[86] REACH, Article 69(1); Annex XV 'Dossiers'.
[87] REACH, Article 69(2).
[88] REACH, Article 69(4).
[89] REACH, Article 69(5).
[90] REACH, Articles 70 and 71.
[91] REACH, Article 73(1).
[92] REACH, Article 73(2).

3. Best Practices to Control Chemicals

From the analysis of efforts to control chemicals above, a number of best practices can be identified that could be replicated in both national and regional legislative and regulatory frameworks for chemicals.

3.1 Sharing of Responsibility at the National Level

Adopting a legislative framework for chemicals that places greater responsibility on individuals and companies is a useful practice, as it makes a better use of the capabilities of both a state's regulatory authority and the private sector involved in chemicals.

The companies that directly deal with chemicals, for example by producing them, could be required to provide information on the chemicals to the regulatory authority, instead of requiring the regulatory authority of a country to have the necessary knowledge and resources on each chemical.[93] Those in the chemical industry are best placed and therefore made responsible for identifying and managing the risks that are associated with the chemical.

3.2 Sharing of Tasks at the Regional Level

One benefit of increased cooperation at the regional level is the option to share tasks among member states. When certain governance activities are done within a regional framework rather than the national one, it allows for the division of tasks while including procedures for all national states to have a say.

For example, as seen above in the REACH regime's evaluation phase, it is only one EU Member State that carries out the evaluation of a chemical on behalf of all other EU Member States. Its draft decision on the matter is adopted unless other EU Member States make amendments, in which case a Member State Committee is responsible for resolving differences of opinions concerning evaluation.[94] This approach is less labour intensive for states' regulatory authorities as the evaluation of characteristics of chemicals is shared with other countries. Moreover, a mechanism that allows input and decision making by all states still allows for every state's experience or knowledge of the chemical to be included.[95]

ASEAN could consider setting up a structure at the regional level. Such an organisation could act as a hub and clearing house for information on ASEAN Member States' chemicals legislation or have responsibilities assigned to it that are more of a task-sharing character, for example in terms of assessment of chemicals.

Finally, increased cooperation at the regional level also encourages the free circulation of substances, mixtures, and articles within a region, allowing for increased competition and innovation.

[93] Katja Biedenkopf, 'Global REACH? The Potential International Impact of EU Chemicals Regulation' (2009) p. 5.
[94] REACH, Articles 52, 51(4) and 76(e).
[95] Katja Biedenkopf, 'EU Chemicals Regulation: Extending Its Experimentalist REACH' (2015) p. 112.

3.3 Use of a Global Database and Global Format

The harmonisation of chemical control practices at the global level can aid the transfer and trade of chemicals.[96] At the global level, there is already agreement on chemical safety data. However, there is no corresponding global platform to host this data.[97]

ASEAN has its ASEAN - Japan Chemical Safety Database (AJCSD), which includes chemical regulatory information, GHS classification results, and risk and hazard information. The REACH system of the EU uses IUCLID, a software programme to record data on chemicals developed by ECHA and the OECD. The information collected through the REACH regime is captured in IUCLID and "forms the largest regulatory database on chemicals in the world."[98] IUCLID could be used globally, however, which would mean only needing to update a single database for any chemical, thereby reducing the regulatory burden for countries and companies across the world.

Even without it being a global platform (yet), IUCLID can be used by any country. The software is made freely available on the IUCLID website and can be customised to suit a country's need and regulatory measures.[99]

3.4 Authorising Chemicals

In the REACH system, the concept of authorisation allows for the use of certain very hazardous chemicals on the basis of their advantages outweighing the risks.

This concept has proven useful and could be replicated by other countries wishing to ensure that the benefits can be utilised by industry and society in general, while risks are acknowledged and managed in a responsible manner.

Research conducted by ECHA estimates that the authorisation requirement in REACH for certain very hazardous chemicals (that have not yet been replaced by other chemicals) leads to benefits that are 20 times greater than their human health risks.[100] The authorisation requirement has also incentivised companies to replace such chemicals. Of the 54 chemicals that are subject to authorisation, it is estimated that the use of almost half has stopped in the EU.[101]

3.5 Restricting Chemicals

Similar to the authorisation requirement above, the concept of restriction of certain chemicals that pose an unacceptable amount of risk has proven successful and such a concept is used in many countries' regulatory systems. For example, many ASEAN

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[96] https://www.oecd.org/chemicalsafety/risk-assessment/electronictoolsfordatasubmissionevaluationandexchangeintheoecdcooperativechemicalsassessmentprogramme.htm.

[97] https://newsletter.echa.europa.eu/home/-/newsletter/entry/working-towards-one-global-iuclid.

[98] https://newsletter.echa.europa.eu/home/-/newsletter/entry/working-towards-one-global-iuclid.

[99] IUCLID Software Download, https://iuclid6.echa.europa.eu/view-article/-/journal_content/title/iuclid-6-is-availab-1;
OECD, Customisation Opportunities of IUCLID for the Management of Chemical Data, https://www.oecd.org/chemicalsafety/risk-assessment/customisation-opportunities-of-iuclid-for-the-management-of-chemical-data.pdf, p. 11.

[100] ECHA, https://echa.europa.eu/-/reach-authorisation-has-positive-health-and-environmental-impacts.

[101] ECHA, https://echa.europa.eu/-/reach-authorisation-has-positive-health-and-environmental-impacts.

Member States' laws include chemicals that are prohibited or restricted with certain conditions attached to their use.

Research conducted by ECHA estimates that restriction of chemicals that pose an unacceptable risk results in both health and environment benefits. With regard to health, while the cost of restricting chemicals is half a billion euros a year, the health benefits are worth more than two billion euros a year. The health benefits of restricting certain chemicals are therefore four times greater than the costs of restricting the chemicals.[102]

3.6 Encouragement of Innovation

A regulatory framework that requires individuals and companies to substitute chemicals where possible will act as an incentive for innovation and safer substitutes. As these alternatives are likely to become legally binding in the future, their development and use is encouraged. In addition, the use of testing proposals reduces animal testing and promotes the development of alternative methods for assessment of the hazards of substances. Finally, a control framework that deals with all chemicals, whether existing or new, in the same way does not promote continuation of the use of existing chemicals over the new ones.[103] That way, certain chemicals can be phased out and replaced with newer and safer alternatives. Data from ECHA shows that the registration of new substances has increased overall since the beginning of REACH's operation. In 2014, over 100 new chemicals were registered, while in 2020 the number was 346.[104]

[102] ECHA, https://echa.europa.eu/-/restricting-hazardous-chemicals-protects-millions-of-europeans-from-serious-diseases.

[103] Katja Biedenkopf, 'Global REACH? The Potential International Impact of EU Chemicals Regulation' (2009) p. 5.

[104] ECHA, Report on the operation of REACH and CLP 2021, https://echa.europa.eu/documents/10162/13634/operation_reach_clp_2021_en.pdf/e271b3c8-137a-48ad-30ad-499249235ee5, p. 33.

4. Conclusion

Any regulatory system seeking to control chemicals is facing a major task. Chemicals are everywhere: in human beings, in our surroundings, and in all products we use. One of the key aims of a system to control chemicals is therefore to make as much use of the benefits that chemicals bring to society while managing or eliminating any of their hazardous effects.

Under EU CBRN CoE Project 61, the national legislation of most ASEAN Member States concerning chemicals management has been analysed. In this manual, the focus has been on efforts to control chemicals at the regional level, both in ASEAN and in the EU. Given the deep level of regional integration in the EU, its system for the registration, evaluation, authorisation and restriction of chemicals is of a wide-ranging and detailed nature.

From this analysis, a number of best practices have been identified, namely:

1) The sharing of responsibility at the national level, where greater emphasis is put on companies and individuals to provide information on chemicals;
2) The sharing of tasks at the regional level, where countries do not need to duplicate labour-intensive analyses on chemicals, but can rely on work completed by other countries. This could include setting up a regional structure to accommodate this task-sharing;
3) The use of a global database and format, whereby countries could agree to rely on and maintain only a single database on chemicals and their hazards and use the same format to capture such information;
4) The concept and requirement to authorise use of certain very hazardous chemicals under certain circumstances has proven useful as long as their beneficial use is managed against their risk;
5) The concept and requirement to restrict certain chemicals, which is in place in many countries, has also proven to be successful as the benefits of their restriction outweighs the costs of restricting them; and
6) The encouragement of innovation leads to safer substitute chemicals and alternative testing methods.

These best practices could be considered by states as well as ASEAN and other regional organisations in their development of systems to control chemicals, taking into account regional priorities and needs.