COMPLIANCE

Complying with REACH

Registration, Evaluation, Authorisation and Restriction of Chemicals

ABioSA GUIDE

AUGUST 2021

This ABioSA guide focuses on regulatory requirements for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Registrations.

It aims to help small biotrade businesses to understand the basic concepts of REACH, what it means to be REACH exempt and the general requirements of a REACH Registration.

forestry, fisheries & the environment
Department:
Forestry, Fisheries and the Environment
REPUBLIC OF SOUTH AFRICA

THE ABS CAPACITY DEVELOPMENT INITIATIVE

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Economic Affairs SECO

Contents

Acknowledgements

This guide is part of a series of knowledge products produced by ABioSA. These knowledge products and other biotrade resources can be found at www.abs-biotrade.info/projects/abiosa/resources

A glossary of biotrade terms can be found at www.abs-biotrade.info/resources

Lisam was commissioned by the project ABioSA to develop and publish this guide. ABioSA is funded by the Swiss State Secretariat for Economic Affairs (SECO), integrated in the governance structure of the ABS Initiative, and implemented by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH. Although every effort has been made to provide complete and accurate information, GIZ, SECO and Lisam make no representations or warranties, express or implied, as to its accuracy at the time of use.

Adrie El Mohamadi
Component Manager
The ABS Capacity Development Initiative
(ABS Compliant Biotrade in Southern Africa)
Center for Cooperation with the Private Sector (CCPS)

Deutsche Gesellschaft für
Internationale Zusammenarbeit (GIZ) GmbH
+27 12 423 7955 | +27 82 902 4083
adrie.elmohamadi@giz.de
www.giz.de & www.abs-biotrade.info

The ABS Initiative is funded by

Federal Ministry for Economic Cooperation and Development

NORWEGIAN MINISTRY OF FOREIGN AFFAIRS

Schweizerische Eidgenossenschaft
Confédération suisse
Confederazione Svizzera
Confederaziun svizra

Swiss Confederation

Federal Department of Economic Affairs, Education and Research EAER
State Secretariat for Economic Affairs SECO

and implemented by

giz Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

Glossary

- **CSR** - Chemical Safety Report
- **EC number** - The European Community number is a unique seven-digit identifier that was assigned to substances for regulatory purposes within the European Union by the European Commission. The EC Inventory comprises three individual inventories, EINECS, ELINCS and the NLP list.
- **ECHA** - The European Chemicals Agency is an agency of the European Union which manages the technical and administrative aspects of the implementation of EU Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- **EEA** - European Economic Area
- **EU** - European Union
- **IUCLID** - International Uniform Chemical Information Database
- **REACH** - Registration, Evaluation, Authorisation and Restriction of Chemicals
- **SIP** - Substance Identification Profile

What is REACH?

REACH is a regulation adopted by the European Union (EU) to improve the protection of human health and the environment from the potential risks of chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances to reduce tests on animals.

REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1 June 2007. The primary aims of REACH are to ensure the protection of human health and the environment, encourage the free circulation of substances and enhance competitiveness and innovation.

REACH places the burden of proof of compliance on companies. To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU. They have to demonstrate to the European Chemicals Agency (ECHA) how the substance/s can be safely used, and they must communicate the risk management measures to the users.

If the risks cannot be managed, authorities can restrict the use of substances in different ways. In the long run, the most hazardous substances should be substituted with less dangerous ones.

How does REACH work?
REACH establishes procedures for collecting and assessing information on the properties and hazards of substances.

Companies need to register their substance, and to do this they need to work together with other companies who are registering the same substance.

ECHA receives and evaluates individual registrations for their compliance, and the EU Member States evaluate selected substances to clarify initial concerns for human health or for the environment. Authorities and ECHA's scientific committees assess whether the risks of substances can be managed.

Authorities can ban hazardous substances if their risks are unmanageable. They can also decide to restrict use or make the substance subject to prior authorisation.

REACH's effect on companies
REACH impacts on a wide range of companies across many sectors, even those who may not think of themselves as being involved with chemicals.

If you make chemicals, either to use yourself or to supply to other people (even for export), then you will probably have some important responsibilities under REACH.

If you buy anything from outside the EU/EEA, you are likely to have some responsibilities under REACH. It may be individual chemicals, mixtures for onward sale or finished products.

If you are a company established outside the EU, you are not bound by the obligations of REACH, even if you export products into the customs territory of the EU. The responsibility for fulfilling the requirements of REACH - such as registration - lies with the importers established in the EU, or with the 'only representative' of a non-EU manufacturer established in the EU.

When is REACH Registration required?

What does it mean to be REACH exempt?
To be exempt from REACH a substance must comply with the provisions of Article 2(7)(a)/(b) of European Commission (EC) Regulation **No 1907/2006**.

Article 2(7)(a) covers substances included in Annex IV, where sufficient information is known for them to be considered to cause minimum risk because of their intrinsic properties. Article 2(7)(b) covers substances included in Annex V, where registration is deemed inappropriate or unnecessary, but where REACH will still apply.

According to Article 2(7)(a)/(b) of EC Regulation 1907/2006, some substances are completely exempt, while some substances are exempt based on their use, and others on the history/origin.

A substance that meets the conditions of Article 2(7)(a)/(b) of EC Regulation 1907/2006 can be placed on the market without a REACH Registration Number (ECHA, 2012). The flow diagram below indicates the steps required to determine if the substance is exempted from REACH.

Is my substance exempted from REACH Registration?

Step 1: Check if your substance is exempt from registration	**Step 2:** Check if the use of your substance is exempt from registration	**Step 3:** Check if your substance is exempt from registration due to its origin or history
The following substances do not need to be registered, irrespective of their use: • Polymers • Substances included in Annex V to REACH • Substances included in Annex IV to REACH • Radioactive substances giving off such radiation that humans and the environment need to be protected • Substances covered by the national exemption	**The following substances do not need to be registered when only used:** • As non-isolated intermediates • For research and development (5-year exemption, extension is possible) • In food or feeding stuffs (including use as additives or flavorings) • In medicinal products for human or veterinary use • In biocidal products or plant protection products as active substances	**The following substances do not need to be registered:** • Substances already registered, exported and re-imported to the EEA • Substances under customs supervision, with a view to re-exportation • Waste • Substances produced from the recovery of waste generally need to be registered, excepting recovered substances already registered

Figure 1: *Overview of substances exempted from REACH – adapted from ECHA (ECHA, n.d.)*

Companies that wish to benefit from the exemption must first assess whether the substance qualifies for it. Upon request from the authorities, the company must provide appropriate supporting information to prove that the substance complies with the exemption conditions (ECHA, 2012). For further information on the minimum analyses needed to prove exemption, refer to the **ABioSA guide** 'Tests for EU compliance - Minimum analysis required for oils and cosmetic products', and 'Product Information File - Regulatory documents and information needed to create a PIF'.

REACH requirements for vegetable/seed and essential oils

Legislative requirements
According to Article 10 (information to be submitted for a general registration process) of EC Regulation 1907/2006, a technical dossier including the information mentioned in Annex VI of EC Regulation 1907/2006 must be submitted. (Refer to **Figure 2** below).

For substances manufactured/imported in quantities over 10 tonnes, a Chemical Safety Report (CSR), should also be provided (EC, 2006). The information requirements for a REACH Registration are dependent on the tonnage of the substance being manufactured or imported. For the lowest tonnage band (1-10 tonnes) the requirements of Annex VII will apply; each time a higher tonnage band is reached, additional requirements are needed (EC, 2006). See section on Tonnage (page 13) for additional information on the tonnage requirements.

Manufacturers/importers of vegetable/seed oils that comply with Annex V of EC Regulation 1907/2006, and thus exempt from registration, should gather existing information or generate new data (by suitable testing) to prove exemption. Essential oils that do not meet the conditions for exemption must comply with Annex VI of EC Regulation 1907/2006. The flow diagram below depicts the steps listed in Annex VI of EC Regulation 1907/2006.

Annex VI – Information requirements referred to in Article 10 on fulfilling the requirements of Annexes VI to XI

Step one: Gather and share existing information
The registrant should gather all existing information on the substance; this can include data obtained from literature. Whenever praticable, substances should be submitted as Joint Registrations so that data can be shared, thus minimising testing and reducing costs. The registrant should collect all available and relevant information for all endpoints regardless of whether or not it is relevant to that specific tonnage band. Alternate sources can be used to locate this information (e.g. QSAR, read-across, in-vivo and in-vitro testing), as this may aid in the identification of hazardous properties that can (in certain cases) replace the need for animal testing. Further information on exposure, use and risk management measures should also be collected. By assessing all the information gathered, the registrant can determine the need to generate further information.

↓

Step 2: Consider information needs
The registrant should determine, according to the tonnage band, the information needed according to the respective Annex. This information should be considered in connection with Annex XI, which allows for variation from the standard approach. In order to determine the information needed, the exposure, use and risk management should be considered.

↓

Step 3: Identify information gaps
To assess the information gaps, the information needs should be compared to the information available. The registrant should ensure that the available data is relevant and is of sufficient quality to fulfil the registration requirements.

↓

Step 4: Generate new data/propose testing strategy
For information gaps that need to be filled, new data should be generated, or a testing strategy proposed. As a last resort, when all data sources have been exhausted, new tests on vertebrates can be conducted.

Figure 2: *Steps for fulfilling the information requirements listed in Annex VI of EC Regulation 1907/2006*

Additional information

1. General registration information

1.1. Registrant:

1.1.1. Name, address, telephone number, fax number and email address.
1.1.2. Contact person.
1.1.3. Location of the registrant's production and own use site/s, as appropriate.

1.2. Joint submission of data: *Article 11 (Joint submission of data by multiple registrants) or Annex 19 (Joint submission of data on isolated intermediates by multiple registrants allows) foresee that parts of the registration may be submitted by a Lead Registrant on behalf of other registrants. In this case, the Lead Registrant shall identify the other registrants specifying:*

1.2.1. Their name, address, telephone number, fax number and email address.
1.2.2. Parts of the present registration which apply to other registrants.
Mention the number/s given in this Annex or Annexes VII to X, as appropriate.
Any other registrant shall identify the Lead Registrant submitting on his behalf specifying:
1.2.3. Their name, address, telephone number, fax number and email address.
1.2.4. Parts of the registration which are submitted by the Lead Registrant.

1.3. Third party appointed under Article 4 (general provisions):

1.3.1. Name, address, telephone number, fax number and email address.
1.3.2. Contact person.

2. Identification of the substance/s

The information given in this section should be sufficient to allow each substance to be identified. If it is not technically possible or not scientifically necessary to give information on one or more of the items below, then the reason should be clearly stated:

2.1. Name or other identifier of each substance:

2.1.1. Name/s in the IUPAC nomenclature or other international chemical name/s.
2.1.2. Other names (usual name, trade name, abbreviation).
2.1.3. EINECS or ELINCs number (if available and appropriate).
2.1.4. CAS name and CAS number (if available).
2.1.5. Other identity code (if available).

2.2. Information related to molecular and structural formula of each substance:

2.2.1. Molecular and structural formula (including Smiles notation, if available).
2.2.2. Information on optical activity and typical ratio of (stereo) isomers (if applicable and appropriate).
2.2.3. Molecular weight or molecular weight range.

2.3. Composition of each substance

2.3.1 Degree of purity (%).
2.3.2. Nature of impurities, including isomers and by-products.
2.3.3. Percentage of (significant) main impurities.
2.3.4. Nature and order of magnitude (ppm, %) of any additives (e.g., stabilising agents or inhibitors).
2.3.5. Spectral data (ultra-violet, infra-red, nuclear magnetic resonance or mass spectrum).
2.3.6. High-pressure liquid chromatogram, gas chromatogram.
2.3.7. Description of the analytical methods or the appropriate bibliographical references for the identification of the substance and, where appropriate, for the identification of impurities and additives. This information shall be sufficient to allow the methods to be reproduced.

3. Information on manufacture and use/s of the substance/s

3.1. Overall manufacture, quantities used for production of an article that is subject to registration, and/or imports in tonnes per registrant per year, in the calendar year of the registration (estimated quantity).

3.2. In the case of a manufacturer or producer of articles, a brief description of the technological process used in manufacture or production of articles.

3.3. An indication of the tonnage used for his own use/s.

3.4. Form (substance, preparation, or article) and/or physical state under which the substance is made available to downstream users. Included must be the concentration or concentration range of the substance/s in preparations made available to downstream users and quantities of the substance in articles made available to downstream users.

3.5. Brief general description of the identified use/s.

3.6. Information on waste quantities and composition of waste resulting from manufacture of the substance, the use in articles and identified use/s.

3.7. Uses advised against (from SDS), including where applicable, an indication of the uses which the registrant advises against and why (i.e. non-statutory recommendations by supplier). This need not be an exhaustive list.

---

4. Classification and labelling

4.1. The hazard classification of the substance/s- In addition, for each entry, the reasons why no classification is given for an endpoint should be provided (i.e. if data are lacking, inconclusive, or conclusive but not sufficient for classification).

4.2. The resulting hazard label for the substance/s.

4.3. Specific concentration limits.

5. Guidance on safe use: *This information shall be consistent with that in the Safety Data Sheet:*

5.1. First-aid measures (Safety Data Sheet heading 4)

5.2. Fire-fighting measures (Safety Data Sheet heading 5)

5.3. Accidental release measures (Safety Data Sheet heading 6)

5.4. Handling and Storage (Safety Data Sheet heading 7)

5.5. Transport information (Safety Data Sheet heading 14)
Where a Chemical Safety Report is not required, the following additional information is required:

5.6. Exposure controls/Personal protection (Safety Data Sheet heading 8)

5.7. Stability and Reactivity (Safety Data Sheet heading 10)

5.8. Disposal considerations

5.8.1. Disposal considerations (Safety Data Sheet heading 13)
5.8.2. Information on recycling and methods of disposal for industry
5.8.3. Information on recycling and methods of disposal for the public

---

6. Information on exposure for substances registered in quantities between 1 and 10 tonnes per year per manufacturer/importer

6.1. Main use category:

6.1.1. Uses:
a) industrial use and/or
b) professional use and/or
c) consumer use
6.1.2. Specification for industrial and professional use:
a) used in closed system and/or
b) use resulting in inclusion into or onto matrix and/or
c) non-dispersive use and/or
d) dispersive use

6.2. Significant route/s of exposure:

6.2.1. Human exposure:
a) oral and/or
b) dermal and/or
c) inhalatory
6.2.2. Environmental exposure
a) water and/or
b) air and/or
c) solid waste and/or
d) soil

6.3. Pattern of exposure:

a) accidental/infrequent and/or
b) occasional and/or
c) continuous/frequent

ECHA Fees

According to Annex I of the EC Regulation 340/2008, standard fees apply for a substance registered under REACH. Table 1 below shows the standard fees and Table 2 shows the reduced fees for the different sizes of SMEs (EC, 2015).

Table 1: Standard fees		
	Individual submission	Joint submission
Fee for substances in the range of 1 to 10 tonnes	EUR 1,739	EUR 1,304
Fee for substances in the range 10 to 100 tonnes	EUR 4,674	EUR 3,506
Fee for substances in the range 100 to 1,000 tonnes	EUR 12,501	EUR 9,376
Fee for substances above 1,000 tonnes	EUR 33,699	EUR 25,274

Table 1: *Fees for the registration of a substance*

Table 2: Reduced Fees for SMEs						
	Medium enterprise (Individual submission)	Medium enterprise (Joint submission)	Small enterprise (Individual submission)	Small enterprise (Joint submission)	Micro enterprise (Individual submission	Micro enterprise (Joint submission)
Fee for substances in the range of 1 to 10 tonnes	EUR 1,131	EUR 848	EUR 609	EUR 457	EUR 87	EUR 65
Fee for substances in the range 10 to 100 tonnes	EUR 3,038	EUR 2,279	EUR 1,636	EUR 1,227	EUR 234	EUR 175
Fee for substances in the range 100 to 1,000 tonnes	EUR 8,126	EUR 6,094	EUR 4,375	EUR 3,282	EUR 625	EUR 469
Fee for substances above 1,000 tonnes	EUR 21,904	EUR 16,428	EUR 11,795	EUR 8,846	EUR 1,685	EUR 1,264

Table 2: *Reduced fees for SMEs*

To benefit from the reduced SME fees, companies must prove that they fall within the specific company size category. According to Commission Recommendation 2003/361/EC, many factors are considered when determining the company size category. Below is a flow diagram indicating the steps necessary to assess and determine the company size category, as per ECHA (ECHA, n.d.).

How to determine the company size category

Step 1: Assess, at the time of submission, whether the company is:

Autonomous - An enterprise is autonomous if it holds less than 25% (capital or voting rights) in any other company, and if no other company holds more than 25% in the enterprise.

Partner - An enterprise is considered a partner to another enterprise if it holds, either solely or jointly with one or more linked enterprises, at least 25%, but no more than 50%, in another company.

Linked - An enterprise is considered linked to another enterprise if it holds more than 50% of the members' voting rights in another company and/or if an enterprise directly or indirectly controls, or has the capacity to control, the affairs of another company.

Note: *If 25% or more of the capital or voting rights of the enterprise are directly or indirectly controlled, jointly or individually, by one or more public bodies, the enterprise cannot be considered an SME.*

Step 2: Determine the reference year/s for the establishment of financial and headcount data of an enterprise

The starting point is the year of the submission in the REACH-IT system. The data to apply to the headcount of staff and the financial amounts is generally those data points relating to the latest approved accounting period and calculated on an annual basis.

For newly established enterprises whose accounts have not yet been approved, the data to apply is to be derived from a bona fide estimate made in the course of the financial year. If the year end is 31 December 2020, the year of reference will be 31/12/2019 – 31/12/2020.

If the company size changes, the company size category will only need to be amended if this change is maintained for two consecutive years.

Step 3: Determine the headcount, turnover and balance sheet total

Staff headcount: This corresponds to the number of annual work units (AWU). Fulltime employees, owner-managers and partners engaging in a regular activity in the enterprise and benefiting from financial advantages from the enterprise must also be included. Work done by contract/seasonal workers should be included at the appropriate fraction.

Annual turnover: This is determined by calculating the income that your enterprise received during the year in question from its sales and services, after any rebates have been paid out. Turnover should not include value-added tax (VAT) or other indirect taxes.

Annual balance sheet total: This is the value of the company's total assets.

Step 4: Assessment of the company size category by establishing the overall data of the enterprise, including partners and linked enterprises

The relevant data on the partner/linked enterprises should also be added to the information gathered on the headcount, turnover and balance sheet total of the company. This should be done as follows:

- Add the proportional headcount and financial data of the **partner enterprises** as a ratio of the percentage interest in the capital or voting rights (whichever is greater) to the headcount and financial data of your enterprise.
  Note: *If the partner enterprise situated immediately upstream/downstream (directly or indirectly) is linked to another enterprise, 100% of the data of the linked enterprises must be included in the data of the partner enterprise.*
- Add 100% headcount and financial data of the **linked enterprises** to the headcount and financial data of the company in question. If the linked enterprise has any partner enterprises situated immediately upstream/downstream (directly or indirectly) or is also linked in a chain to other enterprises (directly or indirectly), add 100% of the data of all the linked enterprises and the percentage equal to the holding of the partner enterprise/s to the data of the enterprise in question.
- If the company or any of its partners and linked enterprises are drawing up consolidated accounts, the consolidated accounts should be used when establishing the data for the company in question.

Step 5: Determine the size

Once the headcount and financial figures have been established based on Steps 1-4, the size of the company category can be determined. The table below shows the company size category in relation to the headcount and turnover/balance sheet total:

Company size category	Headcount	Turnover total	Balance sheet total
Medium	< 250	≤ EUR 50 million	≤ EUR 43 million
Small	< 50	≤ EUR 10 Million	≤ EUR 10 million
Micro	< 10	≤ EUR 2 million	≤ EUR 2 million

Figure 3: *Steps necessary to assess and determine the company size category as per ECHA*

Tonnage

The tonnage of a manufactured/imported substance affects the cost of the registration fees, as well as the extent of data required to assess the hazards of the substance. The selection of tests required for a REACH registration is dependent on the amount of the substance being manufactured or imported per year in/into the EU market. The table below shows the respective Annex reference per tonnage band. Each Annex in EC Regulation 1907/2006 describes the necessary tests required for the specific tonnage band.

Tonnage per year (manufactured/imported)	Standard information required by REACH
1 to < 10	Annex VII
10 to < 100	Annex VII - VIII
100 to < 1000	Annex VII - IX
1000 or more	Annex VII - X

For more information on the data/tests required per tonnage band, refer to **ABioSA guide** 'Tests for EU compliance - Minimum analysis required for oils and cosmetic products', and 'Cosmetic products in Europe - EU Regulation EC 1223/2009'.

Only Representative (OR) requirements

According to Article 8 of the EC Regulation 1907/2006, in relation to a company outside the EU that manufactures a substance on its own, in a preparation or in articles that are imported, the EU can appoint a person/company within the EU to fulfil the 'only representative' obligations for importers (EC, 2006).

The OR is responsible for compliance with all the applicable obligations under REACH. The OR should have a sufficient background in the handling of the substance and have all substance-specific information available in accordance to Article 36 of the EC Regulation 1907/2006 (EC, 2006).

According to Article 36 of EC Regulation 1907/2006, all information related to the substance must be kept and, upon request, made available without delay to the competent authority. This information must be kept for a period of at least ten years after the last manufacture, import, supply or use of the substance or preparation (EC, 2006).

The OR should keep up-to-date information on the quantities imported and customers. The OR should also keep information on the distribution of the latest updated Safety Data Sheet (SDS) (EC, 2006).

If an OR is legally appointed, the non-EU manufacturer should inform the customers of the appointment; for the purposes of REACH the importers are regarded as downstream users (EC, 2006).

Lead and Joint REACH Registration processes

Lead Registration Process

To engage in communication with ECHA, non-EU members wanting to register a substance under REACH must appoint an OR. The OR will communicate with ECHA on behalf of the non-EU member. Before any testing is done on vertebrate animals, an inquiry dossier should be submitted to ECHA. The inquiry dossier contains information related to the substance identity; this information must clearly describe the manufactured/imported substance (ECHA, n.d.).

Based on the information provided in the inquiry dossier, ECHA will direct the inquirer to other potential registrants or co-registrants. ECHA also provides the inquiring company with a list of study summaries that are available for the substance (ECHA, n.d.).

Next steps include collecting available data, conducting tests as required and creating the registration dossier in the International Uniform Chemical Information Database (IUCLID). IUCLID is a free software platform that records, stores, maintains and exchanges data on the basic and hazardous properties of a substance. All information submitted to ECHA for the purposes of REACH must be done in IUCLID format (ECHA, n.d.). Once the dossier is completed in IUCLID, it is submitted to ECHA and the related fees are paid.

Below is a flow diagram showing the overall process for a Lead Registration:

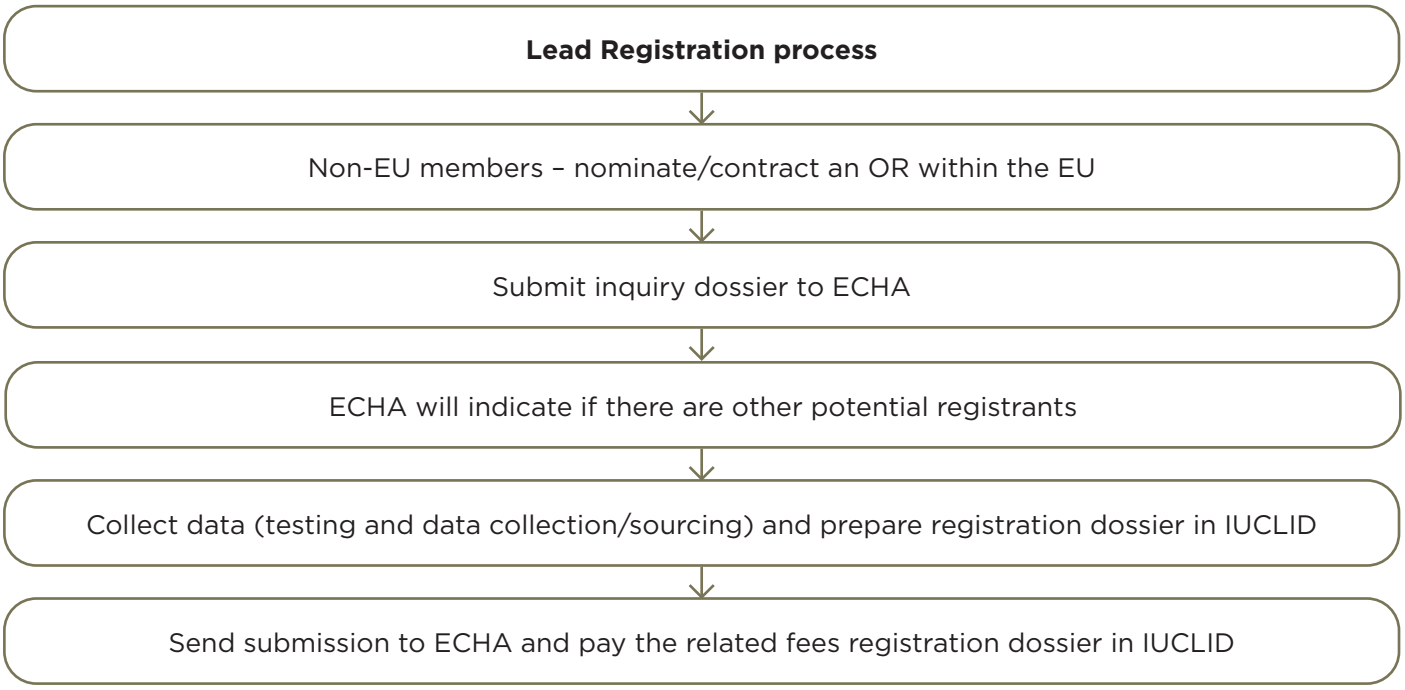

Figure 4: *Summary of Lead Registration process*

Joint Registration process

To engage in communication with ECHA, non-EU members wanting to register a substance under REACH must appoint an OR to communicate with ECHA on behalf of the non-EU member. Before any testing is done on vertebrate animals, an inquiry dossier should be submitted to ECHA. The inquiry dossier contains information related to the substance identity, this information must clearly describe the manufactured/imported substance (ECHA, n.d.).

Based on the information provided in the inquiry dossier, ECHA will direct the inquirer to other potential registrants or co-registrants, ECHA also provides the inquiring company a list of study summaries that are available for the substance (ECHA, n.d.).

Upon receipt of a response from ECHA, the OR can contact the Lead Registrant for access to the Substance Identification Profile (SIP) and possible data sharing. If the substance matches the profile of the registered substance, the Letter of Access (LoA) should be purchased from the Lead Registrant. An LoA is an agreement on the sharing of data and the granting of rights to refer to the data of another Registrant (ECHA, n.d.).

Once the necessary information has been collected and the LoA purchased, the final registration dossier can be completed in IUCLID and submitted to ECHA with payment of the related fees.

Below is a flow diagram showing the overall process for a Joint Registration:

Figure 5: *Summary of Joint Registration process*

Benefits of REACH Registration

The primary aims of REACH are to ensure the protection of human health and the environment, encourage the free circulation of substances and enhance competitiveness and innovation. (EC, n.d.).

Apart from ensuring protection of human health and the environment, non-EU members/companies can benefit from a REACH Registration in the following ways:

1. In terms of entering the EU market with volumes greater than 1 tonne - The company will not be dependent on the importer's registration to trade within the EU. Having the substance registered to the manufacturer itself allows other importers, who are not REACH registered, to purchase the substance under the registration of the manufacturer.
2. Instilling confidence in the substance - The REACH regulation is internationally known for its aim to protect human health and the environment. In order to be REACH registered the substance must be correctly identified and the hazards assessed, knowing that a substance has gone through this process instills confidence in the quality of the product.
3. Being globally recognised as a REACH registered product.
4. Being compliant - Compliance should be considered an investment and not an expense. To trade successfully in international markets, compliance with this international regulation is key.
5. Trading to bigger markets – Trading is not limited to South Africa; the substance can be sold in the EU, with the importer as the downstream user.

References

EC, 2006. REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). [Online]
Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R1907&from=EN
[Accessed 6 February 2021].

EC, 2015. Official Journal of the European Union, COMMISSION IMPLEMENTING REGULATION (EU) 2015/864 of 4 June 2015 amending Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006. [Online]
Available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R0864&from=EN
[Accessed 6 February 2021].

ECHA, 2012. European Chemicals Agency - REACH Factsheet. [Online]
Available at: https://echa.europa.eu/documents/10162/13655/reach_factsheet_on_communication_obligation_en.pdf
[Accessed 6 February 2021].

ECHA, n.d. ECHA - Does my substance need to be registered?. [Online]
Available at: https://echa.europa.eu/support/registration/your-registration-obligations/does-my-substance-need-to-be-registered
[Accessed 6 February 2021].

ECHA, n.d. ECHA - How to determine the company size category. [Online]
Available at: https://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/how-to-determine-the-company-size-category
[Accessed 6 February 2021].

ECHA, n.d. ECHA - Inquiry. [Online]
Available at: https://echa.europa.eu/regulations/reach/registration/data-sharing/inquiry
[Accessed 8 February 2021].

ECHA, n.d. ECHA - Q&As. [Online]
Available at: https://echa.europa.eu/support/qas-support/browse/-/qa/70Qx/view/scope/REACH/datasharing
[Accessed 9 February 2021].

ECHA, n.d. ECHA - What is IUCLID?. [Online]
Available at: https://echa.europa.eu/support/registration/creating-your-registration-dossier/what-is-iuclid-
[Accessed 9 February 2021].

EC, n.d. Internal Market, Industry, Entrepreneurship and SMEs. [Online]
Available at: https://ec.europa.eu/growth/sectors/chemicals/reach_en
[Accessed 9 February 2021].

Disclaimer:

This report has been compiled specifically for the use of the individual and/or entity to whom it has been addressed. If you are not the individual or entity to whom it has been addressed, you are not entitled to act in accordance with any of the advice and/or views which have been provided herein, without the authorisation of LISAM. Notwithstanding the aforegoing, this report is confidential, and has been compiled based on the facts and circumstances based on information gathered from third parties and provided as a summary to the entity to whom it is addressed, and no third party may make use of any view or advice, as provided herein, without the authorisation of LISAM.

Lisam Systems and Lisam South Africa liability will be limited to the repair of the Report supplied that does not comply in any way. No further damage claims or liability will be recognised. Lisam Systems and Lisam South Africa will not be liable for any direct or indirect damages to the customer or user of the supplied documents. Considering the nature of the services provided, the Lisam Report is subject to a best endeavours' obligation.

The Company undertakes to provide its services in accordance with standard professional practice complying with norms and other established standards, under the terms and conditions of the agreement between the parties, as well as in compliance with the legal and regulatory provisions that apply. Neither the Company, nor any of its directors or employees are liable nor responsible with regard to the services rendered to customers or third-parties, which is based on information supplied by the Customer or individuals that is not clear, is wrong, incomplete, misleading or false. The Company is neither an insurer, nor a guarantor, and declines to accept any liability in this respect. Customers seeking a guarantee against loss and damage must obtain appropriate insurance cover.