environmental affairs
Department:
Environmental Affairs
REPUBLIC OF SOUTH AFRICA

THE ABS CAPACITY DEVELOPMENT INITIATIVE
L'INITIATIVE DE RENFORCEMENT DES CAPACITES POUR L'APA

Schweizerische Eidgenossenschaft
Confédération suisse
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Swiss Confederation

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

EU regulatory requirements

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A. Introduction

Why should I comply with REACH, CLP and the EU Cosmetic regulations?

- A compliant and professional market approach will ensure the growth of the Biotrade industry in Southern Africa;
- Compliance would mean ease of access to large markets with huge buying power, sophisticated and highly regulated markets i.e. EU, US;
- Compliance would achieve the sustainable goals and aim of the ABS programme by:
    - *Creating Jobs;*
    - *Creating sustainable value chains;*
    - *Creating high value sustainable markets through confidence and reliability of the products;*
    - *Productive and sustainable use of Southern African biodiversity.*

B. Definitions & Regulatory Background

B.1. REACH

1.1. What is a vegetable oil?

Vegetable fats and oils are substances that are generally obtained from the seeds of oil seed plants (rape, flax, sunflower etc), although some other parts of the plants may also yield oils. Vegetable oils and fats are mainly composed of triglycerides, which contain a range of fatty acids of different chain lengths; for example they can be rich in palmitic, oleic or linoleic acid (source: European Chemicals Agency, http://echa.europa.eu/).

1.2. What is an essential oil?

An essential oil is defined as a volatile part of a natural product, which can be obtained by distillation, steam distillation or expression in the case of citrus fruits. It contains mostly volatile hydrocarbons. Essential oils are derived from various sections of plants. The oil is "essential" in the sense that it carries a distinctive scent, or essence of the plant (source: European Chemicals Agency, http://echa.europa.eu/).

Did you know?

The European Federation of Essential Oils (EFEO) and the International Fragrance Association (IFRA) have published guidance for characterising essential oils. Follow this guidance when you are identifying essential oils for REACH and CLP purposes.

1.3. What does REACH mean?

REACH (EC 1907/2006)

- *Stands for: Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Adopted 1 June 2007;*
- *Protection of human health;*
- *Protection Environment ;*
- *Reduce the number of tests conducted on animals ;*
- *Enhancing the competitiveness of the EU Chemical industry.*

1.4. Where is REACH implemented

- *REACH applies to the European economic area (EEA), that is, all EU member states, including Iceland, Liechtenstein and Norway;*
- *REACH is a Regulation, not a Directive (applies directly in the EEA).*

B. Definitions & Regulatory Background

B.1. REACH

1. 5. Applicability

REACH applies to substances:

- *It applies to all individual chemical substances on their own, in mixtures or in articles;*
- *Each substance needs its own registration.*

Botanical name: *Helichrysum odaritissimum essential oil.*

REACH: *substance (pure oil to be registered as a substance).*

If I am exempt from REACH registration do I still have any obligations under REACH?

- *YES! Manufacturers/formulators of vegetable oils must still keep a dossier proving exemption from REACH registration.*

Exemption from REACH registration ≠ Exemption from REACH regulation

Did you know?

- *Both existing and new chemicals could be treated in exactly the same way;*
- *The onus for assessing the impact of substances on human health and the environment is placed on the manufacturers and importers of substances ("NO DATA, NO MARKET");*
- *Information from registrations is used by authorities and published by ECHA on its website;*
- *Registration of chemicals already occurred in the European market in a stepwise manner: in 2010, 2013 and 2018;*
- *Post these dates an Inquiry must be made to ECHA.*

B. Definitions & Regulatory Background

B.1. REACH

1.6. EC 1223/2009

- Article 2 1(a): means any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly for
    - *cleaning them;*
    - *perfuming them;*
    - *changing their appearance;*
    - *protecting them;*
    - *keeping them in good condition correcting body odours.*

Note

- *A substance or mixture intended to be ingested, inhaled, injected or implanted into the human body shall not be considered to be a cosmetic product;*
- *Nutro cosmetics are NOT cosmetics - the primary function of the cosmetic must be as per the allowable definition for cosmetics.*

B. Definitions & Regulatory Background

B.2. CLP

2.1. What is CLP?

- Classification, Labelling and Packaging of substances and mixtures (EC 1272/2008)
- Based on the United Nations' Globally Harmonised System (GHS). Its purpose is to ensure:
  - *a high level of protection of human health;*
  - *protection of the environment;*
  - *free movement of substances, mixtures and articles;*

- CLP is legally binding across the Member States and directly applicable to all industrial sectors
- It requires manufacturers, importers or downstream users of substances or mixtures to classify, label and package their hazardous chemical products appropriately before placing them on the market.

2.2. What are your obligations under the CLP Regulation as a non-EU manufacturer?

- The obligation to ensure that a product is classified, labelled and packaged in accordance with the CLP Regulation lies with the EU-importer;
- However, the non-EU manufacturer of a substance or a mixture should cooperate with their importer to check the relevant requirements regarding the packaging and labelling of their product;
- The non-EU manufacturer should also cooperate to ensure proper hazard classification of the product;
- One of the main aims of CLP is to determine whether a substance or mixture displays properties that lead to a hazardous classification.

2.3. What are hazard classes or categories?

- When a substance/chemical classifies as hazardous under CLP, the hazards are identified by assigning a hazard class or category;
- The hazard classes in CLP cover:


Physical


Health


Environmental

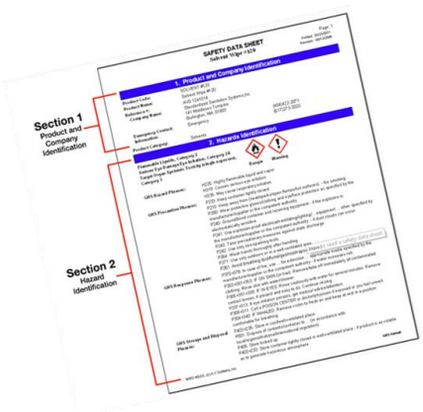

& Additional Hazards

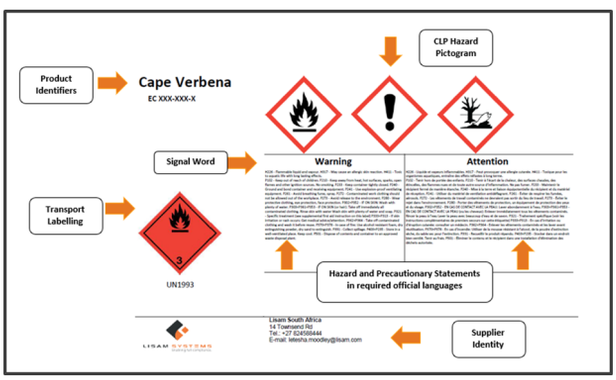
B. Definitions & Regulatory Background

B.2. CLP

2.4 Why do we need harmonised classification and labelling?

- Once a substance or mixture is classified, the identified hazards must be communicated to other actors in the supply chain, including consumers;
- Hazard labelling allows the hazard classification, with labels and safety data sheets, to be communicated to the user of a substance or mixture, to alert them about the presence of a hazard and the need to manage the associated risks.

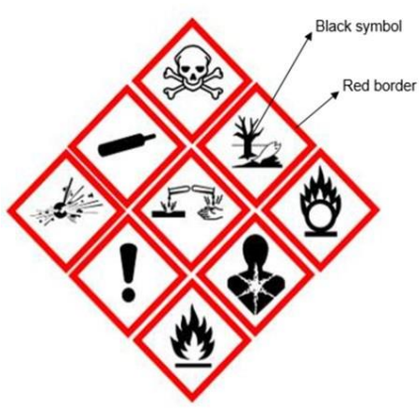




2.5 Why do we need harmonised classification and labelling?

- CLP sets detailed criteria for the labelling elements: pictograms, signal words and standard statements for hazard, prevention, response, storage and disposal, for every hazard class and category;
- It also sets general packaging standards to ensure the safe supply of hazardous substances and mixtures;
- The classification and labelling of certain hazardous chemicals is harmonised to ensure adequate risk management throughout the EU.

Hazard statement(s)	
H301 + H311 + H331	Toxic if swallowed, in contact with skin or if inhaled
H317	May cause an allergic skin reaction.
H351	Suspected of causing cancer.
H372	Causes damage to organs (Liver, Kidney) through prolonged or repeated exposure if inhaled.



B. Definitions & Regulatory Background

B.3. Cosmetic EU Legislation

3.1. What do you require to sell a COSMETIC PRODUCT in the EU?

- Product Information File;
- Cosmetic Product Safety Report;
- Signed Safety Assessment;
- Responsible Person in the EU;
- Registration on the CPNP: https://ec.europa.eu/growth/sectors/cosmetics/cpnp_en
    - *a. The CPNP is accessible to:*
        - *I. Poison Centres*
        - *II. Competent Authorities*
        - *III. Responsible Person*
        - *IV. Distributors (where legal RP)*

3.2. What is an RP?

- Legal appointment of a Responsible Person (RP)
    - *a. RP is LEGALLY responsible for the SAFETY and COMPLIANCE of the cosmetic product*
    - *b. Default RP:*
        - *I. EU Manufacturer*
        - *II. EU Importer*
        - *III. Distributor if product is changed in any way*
    - *c. RP Legally appointed*

B. Definitions & Regulatory Background

B.3. Cosmetic EU Legislation

3.3. What is required - PIF detail

Product Information File

- Description
- Data on Animal Testing
- Description and method of Manufacture - GMP Statement
- Claims and Effect

Cosmetic Product Safety Report

PART A
Cosmetic Product Safety Information

- Composition of Cosmetic Product at substance level and function of each component in formulation;
- Physical and chemical characteristics of cosmetic product and components;
- Stability;
- Microbiological quality – product and raw materials (including Challenge test);
- Impurities;
- Clinical and Market trials;
- Packaging material information;
- Foreseeable use, storage conditions and misuse;
- Market surveillance;
- Exposure to the Cosmetic Product -Margin of Safety (MoS) calculated for each component including contaminants based on the human toxicological profile of each component;
- Undesirable effects;
- Additional Information;

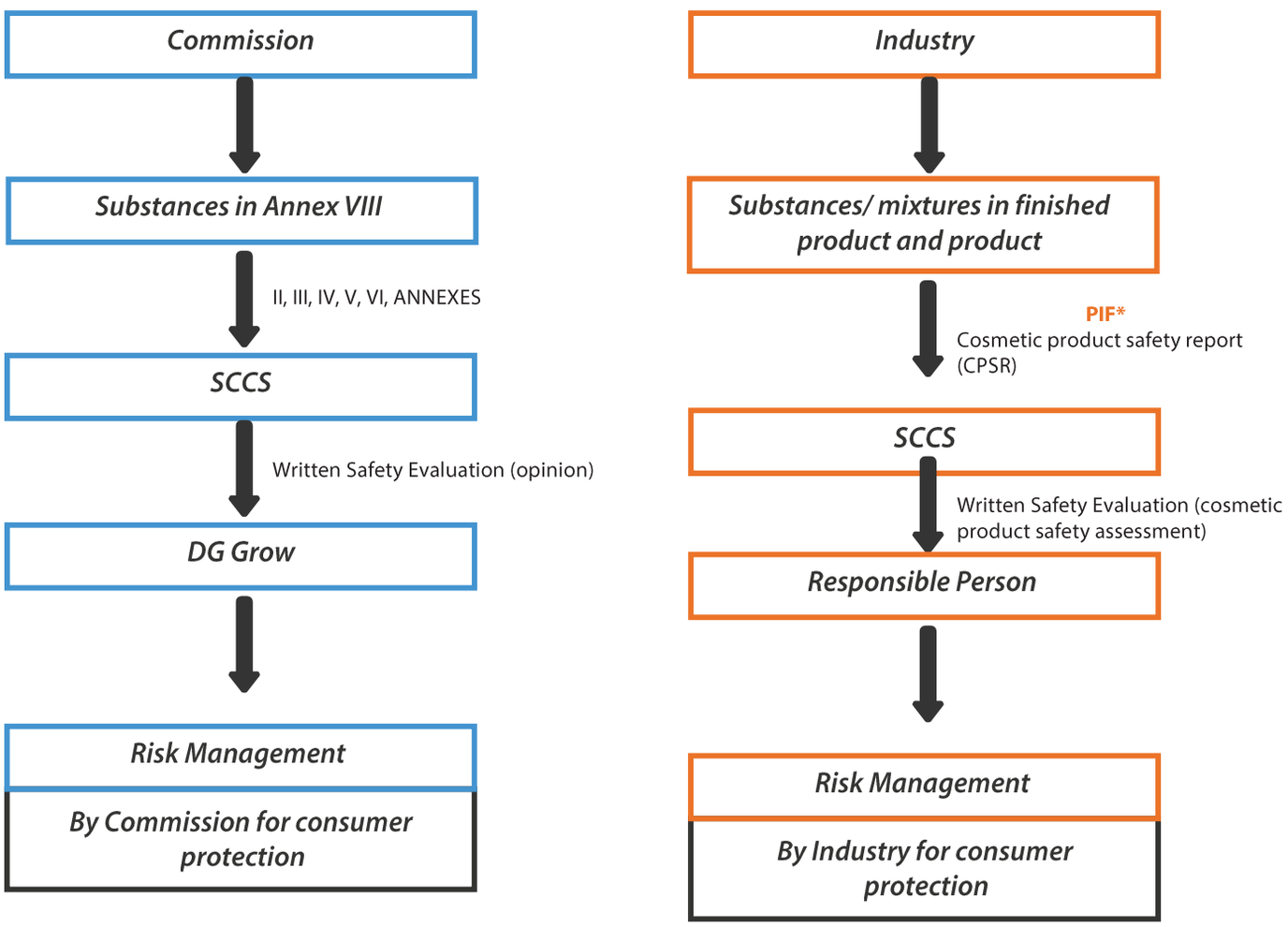
PART B
Cosmetic Product Safety Assessment

- Assessment conclusion and reasoning;
- Labelled warnings and instructions of use;
- Assessor's credentials
- Assessor's approval (signing) of part B.

B.3. Cosmetic EU Legislation

3.4. What is the safety assessment process? - Understanding the roles and responsibilities of the safety assessment process

Two channels (regulatory and industry) are required in the Safety Assessment Process



PIF*: *Product Information File*

Figure1: Human health safety evaluation of cosmetic ingredients in the EU

Reference: SCCS NoG rev 10 2018

B.3. Cosmetic EU Legislation

3.5. What Guidelines must I adhere to?

1. Independent non-food scientific Committees:
    a. *Scientific Committee on Consumer Safety (SCCS)*
    b. *Scientific Committee on Health, Environmental and Emerging Risks (SCHEER)*
2. SCCS Notes of Guidance (NoG – latest: Rev 10)
3. SCCS opinions
4. Proven Scientific approaches
5. The European Food Safety Authority (EFSA)
6. The European Medicine Agency (EMA)
7. The European Centre for disease Prevention and Control (ECDC)
8. The European Chemical Agency (ECHA)
9. General principles of Toxicology

Section 9 of the regulation states:

- "Cosmetic products should be safe under normal or reasonably foreseeable conditions of use. In particular, a risk-benefit reasoning should not justify a risk to human health." The safety risk is assessed by looking at the:

Hazard **Exposure** **Risk**

B. Definitions & Regulatory Background

B.3. Cosmetic EU Legislation

3.6. Why the requirement for Cosmetic Regulations in the EU

- EEC – 28 Nations;
- 512 Million Citizens;
- 22% of the global GDP;
- Ensure free movement of goods;
- Provide for a self-regulated system;
- Accessibility of product Information (PIF);
- Market surveillance and reporting (RP and Authorities);
- Protecting Human Health at a high level by:
    - *assessment of exposure risk based;*
    - *applying current scientific principles and knowledge;*
    - *applying the most relevant toxicological principles.*

Summary

What is the difference between an Only representative and a Responsible person?

Only representative (OR)	*Responsible Person (RP)*
The Only Representative (OR), is a natural or legal person that would fulfil the obligations of companies importing a substance on its own, in mixtures or in articles under REACH which stands for Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and does not apply to cosmetics.	The Responsible person (RP) is legally responsible for the safety and compliance of cosmetic products under the EU cosmetic Regulation.

ROADMAP: REACH Registration - A Step by Step Approach

C. ROADMAP

STEP 1: Know your portfolio

What kind of products does your company produce for export to the EU? Is it a substance?

Substance

Does my substance need to be registered?

- Check if your substance as such is exempted from registration (e.g. Substances covered by Annex V);
- Check if the use of your substance is exempted from REACH (e.g. Active substances used in biocidal products or plant protection products);
- Check if your substance is exempted from registration because of its origin or history(e.g. Substances under customs supervision, with a view to re-export).

Do I reach the one tonne a year threshold?

NO

The importer does NOT need to register the substance.

YES

What is your tonnage band?

Your volume determines your tonnage band, and your tonnage band determines the amount of your registration fee and which information you will need to provide for your registration.

There are four tonnage bands for standard registrations:

1-10 tonnes a year;
10-100 tonnes a year;
100-1 000 tonnes a year;
and more than 1 000 tonnes a year.

Note:

(If your volume reaches the lower limit of a tonnage band, this will be your tonnage band for registration).

C. ROADMAP

8 *STEP 2: Appoint an only representative (OR)*

As a non-EU manufacturer you should start by appointing an only representative (OR) to fulfil obligations of importers under REACH.

Why?

Requirements for REACH and CLP, such as registration or labelling, lies with the importers established in the European Union, or for REACH obligations, with the only representative of a non-EU manufacturer established in the European Union.

More Importantly

Non-EU manufacturers should opt for an OR as communication of information needed by the importers would require the disclosure of confidential business information.

Responsibility of the Non-EU manufacturer

To send a letter confirming this appointment to their OR who must have it available in case of inspection by the relevant Member State's enforcement authority.

Responsibility of the OR

- To comply with all the obligations of the importers
- To submit an inquiry, followed by a registration dossier for the substance imported into the EU to the European Chemicals Agency (ECHA)
- To keep the information available and updated.

Note:
Only representatives can represent more than one non-EU manufacturer for one or more substances. This can be a more cost-effective option for SME's wanting to do a joint registration.

C. ROADMAP

STEP 3: Find co-registrants

The OR/importer will make an Inquiry with ECHA whether a registration has already been submitted for that substance.

Prepare an electronic inquiry dossier. When preparing the dossier, specific attention should be paid to the substance identity information.

The inquiry dossier will then be used by ECHA to direct inquirers to the relevant Co-Registrants page in REACH-IT where they can find contact details of the Lead registrant, other registrants and potential registrants of the same substance.

For substances where no registrants or potential registrants exist or with ambiguous identifiers, ECHA verifies the substance identity information.

If ECHA is able to conclude on the substance identity of the inquired substance, the Agency directs inquirers to the relevant Co-Registrants page in REACH-IT.

ECHA puts potential registrants and previous registrants in contact with each other to share data and to submit a joint registration.

C. ROADMAP

STEP 4: Share data

Why should I share data?

- *The requirement to share information about the substances manufactured, imported, placed on the market and used in the EU is a fundamental aspect of REACH;*
- *By doing this, registrants of the same substance can reduce registration costs and avoid unnecessary testing, especially on vertebrate animals;*
- *When information is available, studies involving vertebrate animal testing must be shared between registrants to prevent tests being duplicated. New studies on vertebrate animals cannot be repeated;*
- *Studies that don't involve vertebrate animal testing should also be shared to reduce the costs of registration.*

STEP 4: Share data- *Joint submission*

Why should I share data?

- *When a substance is intended to be manufactured in the Community by one or more manufacturers and/or imported by one or more importers, and/or is subject to registration under Article 7, the following shall apply…"*

The Lead registrant will supply the following information with the agreement of the other assenting registrants:

- the classification and labelling of the substance as specified in section 4 of Annex VI
- study summaries of the information derived from the application of Annexes VII to XI;
- robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I;
- proposals for testing where listed in Annexes IX and X;
- an indication as to which of the information submitted under (iii), (iv), (vi), (vii) or subparagraph (b) has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience.

C. ROADMAP

STEP 4: Share data- *Joint submission*

- *Each registrant shall subsequently submit separately the information specified in Article 10:*

- the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex VI;
- the identity of the substance as specified in section 2 of Annex VI:

- *All companies registering the same substance need to agree on the data for their joint REACH registration. This is a collective responsibility which applies equally to all co-registrant;*
- *Discussions on sharing data must take place before joint registration when a substance is manufactured or imported by more than one company;*
- *Co-registrants must make every effort to make sure that the cost of sharing the information required for joint registration is determined in a fair, transparent and non-discriminatory way;*
- *In practice, companies may agree to submit information jointly with all their co-registrants, or to submit some or all information separately if they do not agree with the information submitted jointly.*

C. ROADMAP

STEP 5: Assess the hazards

Information required depends on tonnage and uses:

- *1-10 tonnes: Possible reduced data requirements for less hazardous substances;*
- *10 tonnes: chemical safety report needed;*
- *Pay attention to data quality: relevance, adequacy and reliability;*
- *Animal testing is the last resort - consider alternatives first;*
- *Some long-term studies require a testing proposal.*

What is a Chemical safety report?

The chemical safety report documents the chemical safety assessment undertaken as part of the REACH registration process and is the key source from which the registrant provides information to all users of chemicals through the exposure scenarios.

What is a chemical safety assessment?

The chemical safety assessment is carried out to demonstrate that the risks from the exposure to a substance, during its manufacture and use, are controlled when specific operational conditions and risk management measures are applied.

If after completing the Chemical safety assessment (CSA) it is found that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

- *(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;*
- *(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;*
- *(c) hazard class 4.1;*
- *(d) hazard class 5.1;*
- *or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:*

The chemical safety assessment shall include the following additional steps:

- *exposure assessment including the generation of exposure scenario(s) (or the identification of relevant use and exposure categories if appropriate) and exposure estimation . . .*

C. ROADMAP

What is an Exposure scenario (ES)?

- *an ES includes the information for a safe use of a chemical (is included in the eSDS);*
- *an ES describes how to use a chemical safely in relation to the USE of the chemical. All human health measures and environmental release are taken into account.*

Am I exempt from submitting a CSR under REACH?

You are exempt if:

- *You use the substance in total quantities below one tonne per year;*
- *You use the substance for Product and Process Orientated Research and Development (PPORD);*
- *The substance is contained in a mixture in a concentration below the concentration limit that needs to be taken into account in classifying the mixture as hazardous (see Article 14(2) of REACH);*
- *The substance is persistent, bioaccumulative and toxic (PBT)/very persistent, very bioaccumulative (vPvB) but is contained in a mixture in a concentration below 0.1% (weight by weight).*

Note

Check whether these exemptions apply before you start preparing a CSR.

C. ROADMAP

STEP 6: Prepare your dossier in IUCLID

After you discuss and exchange data within the SIEF, the lead registrant and each member registrant should have all the relevant information available to create their registration dossiers using the IUCLID format.

To do this you will use the the IUCLID Cloud for SMEs which helps you to avoid any installation and gives you easy access, automated, regular back-ups and updates by ECHA. The cloud version enables the OR to transparently collaborate with all SME clients and to easily and securely share IUCLID information with them.

Check and update the information that is relevant for registration in REACH-IT.

Carefully assess your SME status (Reduced fees may be applicable to smaller SME's).

Set up or join the joint submission in REACH-IT.

Submit your registration dossier: first the lead registrant, then all co-registrants and then follow up on REACH-IT.

The Lead registrant's dossier includes: the information submitted on behalf of all the co-registrants, such as the boundary composition of the substance, classification and labelling of the substance, uses etc. The lead registrant will also add their own company-specific and substance-specific registration information in the same dossier.

The member dossier includes information specific to their company and substance. This covers, for example, information about the identity of their substance (composition, analytical data), the identified uses that are relevant for their company, and the estimated volumes of manufacture or import.

C. ROADMAP

STEP 7: Keep your registration up-to-date

A registration dossier has to reflect the most up-to-date knowledge on how a substance can be used safely.

This is a legal obligation for all registrants, so it is recommended to maintain the co-operation platform with your co-registrants.

The selection for compliance check is either random or concern-based.

The task of the only representative is to keep the information available and updated on the quantities imported, importers covered by the appointment, as well as supply the latest update of the SDS.