



DRAFT

**Understanding REACH Regulations
and Their Impact On
The Herbal Products Industry[®]**

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While IASC believes that all of the information contained here is accurate, any company who chooses to use this information is advised to discuss all aspects related to REACH compliance with a qualified attorney or consultant.

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What is REACH?

REACH is the acronym for the European Union (EU) regulation **Registration, Evaluation, Authorization and Restriction of Chemicals**. The law took effect on June 1, 2007 and will be phased in over an 11 year period. It was developed and implemented to replace about 40 other legislative controls in an effort to streamline and improve the former legislative framework on chemicals marketed in the EU. REACH places greater responsibility on industry to manage the risks that chemicals may pose to consumer health and the environment.

How does REACH impact herbal products such as dietary supplements and foods?

Manufacturers of the following will have NO REQUIREMENT to register under REACH:

- Products manufactured and marketed as dietary supplements¹, or;
- Products manufactured and marketed as a food or feedingstuffs², or;
- Products manufactured and marketed as a medical device³

These products are regulated by other, pre-existing regulations and are not subject to REACH⁴.

How does REACH impact herbal products such as cosmetics?

Ingredients in cosmetics and personal care items are subject to almost all provisions of REACH (Title IV does not apply to cosmetics). Cosmetics and toiletries are considered as preparations under REACH.

From the ECHA [REACH Guidance on Registration](#):

***Preparation** means a mixture or solution composed of two or more substances (Article 3(2)). Typical examples of preparations include paints, varnishes, [and] inks. Preparations can contain several substances. ...REACH obligations apply individually to each of those substances depending on whether the individual substances are within the scope of REACH.*

¹ Regulated by Directive 2001/83/EC, relating to medicinal products for human use.

² Regulated by the Food Safety Regulation 178/2002/EC

³ Regulated by either 726/2004/EC or 2001/82/EC

⁴ See Article 2, Sec. 6 for a complete list

Therefore, there may be a requirement for some manufacturers to register a cosmetic preparation containing depending on the ingredient and chemical(s) used in the manufacturing process.

How does REACH apply to Raw Materials/Ingredients?

Raw materials/ingredients, particularly those with substances defined as naturally occurring, may not need to be registered under the regulations. The following information will help suppliers of raw materials/ingredients and manufacturers further understand their requirements.

According to Article 2, Section 7 of the regulations:

7. The following shall be exempted from Titles II, V and VI:
 - (b) substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation;

Annex V lists the following information (please note #8, in bold):

ANNEX V

EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)

1. Substances which result from a chemical reaction that occurs incidental to exposure of another substance or article to environmental factors such as air, moisture, microbial organisms or sunlight.
2. Substances which result from a chemical reaction that occurs incidental to storage of another substance, preparation or article.
3. Substances which result from a chemical reaction occurring upon end use of other substances, preparations or articles and which are not themselves manufactured, imported or placed on the market.
4. Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:
 - (a) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticiser, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculant, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or
 - (b) a substance solely intended to provide a specific physicochemical characteristic functions as intended.
5. By-products, unless they are imported or placed on the market themselves.

6. Hydrates of a substance or hydrated ions, formed by association of a substance with water, provided that the substance has been registered by the manufacturer or importer using this exemption.
7. The following substances which occur in nature, if they are not chemically modified: minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components thereof, crude oil, coal, coke.
8. **Substances occurring in nature other than those listed under paragraph 7, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC.**
9. Basic elemental substances for which hazards and risks are already well known:

The following information is taken from Section 3/39, definitions – Substances which occur in nature:

39. Substances which occur in nature: means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;

Therefore, a raw materials supplier providing ingredients that are processed in accordance with the above definition, or are not processed in any way that chemically modifies the raw material/ingredient, the material is exempt from registration.

For companies who manufacture or market products other than Herbal Products or those items mentioned above

Manufacturers and/or marketers of products other than those listed above should consult with an expert on REACH regulations to determine any requirements under the law.

All manufacturers and importers of chemicals must identify and manage risks linked to the substances they manufacture and market. For substances produced or imported in quantities of 1 metric ton or greater per year per company, manufacturers and importers need to demonstrate that they have appropriately done so by means of a registration dossier, which shall be submitted to the European Chemicals Agency (ECHA), the organization that was created to manage the registration, evaluation, authorization and restriction processes for chemical substances.

A complete copy of the legislation can be found here:

<http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2007:136:SOM:EN:HTML>

What needs to be registered?

It is only the SPECIFIC CHEMICAL SUBSTANCES in an ingredient, product, preparation or “articles” that are required to be registered by the regulations, and not necessarily an entire product. For example, a company’s product or “article” that contains or has added glycerine will be required to register that chemical. The terms “chemicals” and “substances” are used interchangeably in the regulations.

A “substance”, as defined in the REACH regulations under Article 3, Sec. 1, is 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.

An article is defined as an object composed of one or more substances which during production is given a specific shape, surface or design which determines its function to a greater degree than does its chemical composition (EX: a computer. See sec. 3.3 of the Guidance for Articles for further details).

http://reach.jrc.it/docs/guidance_document/articles_en.pdf

There are certain chemicals that are exempt from registration (see section below – What Chemicals Are EXEMPT From Registration). Chemical substances that require registration must also be imported in amounts greater than 1 metric ton in weight – and that measurement is not calculated by the total weight of the entire product, but by the total weight of the actual chemical substance being imported. It is recommended that a chemist or other appropriate individual with equivalent knowledge assist with these processes.

Who needs to register?

As shown above, manufacturers or marketer of dietary supplements, food substances, or medical devices have no obligations under REACH. Marketers or producers of cosmetic or personal care products **may** need to register.

The regulations and guidance use the term “actors” to define who needs to register and is involved in the registration processes. There are three main types of actors involved in the REACH processes: **Industry**, **Authorities** and **Third Parties**.

Industry

The role of companies under REACH is determined by the activity they carry out with a substance. The following types of industry actors are:

- **Manufacturers of substances:** means any natural or legal person established within the EU who manufactures a substance in one or more Member States. Manufacturing means production or extraction of substances in their natural state.
- **Producers of articles:** means any natural or legal person established within the EU who makes or assembles an article in one or more Member States.
- **Importers (of substances and articles):** means any natural or legal person established within the Community who is responsible for import. Importing means the physical introduction into the customs territory of the European Union.
- **Downstream Users** may be any industrial user of chemicals, whether formulators of preparations (e.g. paint producers) or users of chemicals such as oils or lubricants in other industrial processes or producers of manufactured articles such as electronic components.
- **Distributors**

Companies dealing with chemicals may have more than one role under REACH, even for a single given substance.

Example : a company may use a substance which they buy from 2 different suppliers, one being inside the EU, and the other one outside the EU. This company is then a downstream user for the part of the substance sourced inside the EU and an importer under REACH for the imported part of substance.

When cosmetics and personal care products are manufactured outside of the EU and imported into the EU markets, in some cases registration may have been completed by an upstream manufacturer; e.g., the ingredients are imported from Europe, and are re-exported as a part of the consumer product. If the ingredients are not registered, and exceed the threshold quantity, the importer of the consumer products into the EU is responsible for the registration.

All manufacturers of substances or preparations, including cosmetics and personal care, which are located outside the EU and export into the EU can nominate an “only” representative located within the EU to fulfill all registration requirements. This only representative will have to comply with all obligations of importers under the registration title of REACH. In the above example, the importer would be considered a downstream user.

In certain circumstances, companies may also appoint representatives under REACH to carry out certain obligations:

- **Third Party Representatives:** any manufacturer, importer, or where relevant, downstream user, may appoint a third party representative for certain tasks relating to data and cost sharing. The company nominating a representative retains

full responsibility for complying with their obligations under REACH. The identity of a manufacturer or importer or downstream user who has appointed a representative will not normally be disclosed by the ECHA to other manufacturers, importers, or, where relevant, downstream users.

Companies attempting to sell or market products in the EU directly, and do not have an EU corporate or licensed subsidiary, may need to register certain substances using an “only representative”.

- **Only Representatives** can be appointed by non-EU manufacturers/producers of substances, preparations or articles whose products are imported into the EU. They carry out the obligations of importers of substances from those non-EU manufacturers. Importers in the same supply chain are in this case considered to be downstream users. The only representative must have a sufficient background in the practical handling of the non-EU supplier’s substances and the information related to them. He must keep available up-to-date information on quantities

imported and customers sold to as well as information on the supply of the latest update of the Safety Data Sheet.

Authorities

The authorities having obligations and rights in the REACH processes are the Agency (ECHA - specifically set up for REACH <http://echa.europa.eu/> - site is translated in a multitude of languages), the Member States Competent Authorities and the European Commission.

The authorities carry out the evaluation, authorization and restriction processes of REACH. In addition, the ECHA and Member States will provide helpdesk assistance. Member States are responsible for enforcement under REACH.

Third Parties

Third parties under REACH include any private and public organization (e.g. private individuals, public authorities, non-governmental organizations, companies providing input on dossiers they are not directly affected by, international organizations and non-EU countries).

Third parties do not have obligations under REACH but they may provide information to the ECHA on substances and be part of a SIEF (Substance Information Exchange Forum).

My company manufactures cosmetics and/or personal care products – do I have to register?

- Producers of cosmetics and personal care products located in the EU are usually downstream users and have no obligations to register ingredients under REACH
- Producers of cosmetics and personal care products located outside the EU have no obligations to register
- It is the importer of the products into the EU who has to register the individual ingredients/substances when present in quantities of 1 metric ton or more per year, and when not yet registered by an upstream manufacturer
- The non-community manufacturer can nominate an “only” representative to fulfill all obligations of an importer under REACH
- In case of the nomination of an “only” representative, the importer is considered a downstream user

What chemicals or substances are EXEMPT from registration?

REACH applies to all substances with a few exemptions: radioactive substances, substances under customs supervision, the transport of substances, and non-isolated intermediates are not covered under REACH. Waste is also specifically exempted.

Polymers are for the time being exempted from registration. Special rules apply for substances used for research and development and for the registration of isolated intermediates.

As mentioned above, there are also lists of exempt substances in the regulations (Annex IV and V in the regulations lists these substances – found starting on p. 94 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:EN:PDF>).

What data am I registering?

REACH requires manufacturers and importers of chemical substances (≥ 1 metric ton/year) to obtain information on the physicochemical, health and environmental properties of their substances and use it to determine how these substances can be used safely. Each manufacturer and importer must submit a registration dossier documenting the data and assessments to the ECHA.

What methods or tools are involved in the process of registration?

The application of the REACH processes requires the use of several tools or methodologies, existing or developed for the purpose of REACH.

A Chemical Safety Assessment has to be performed for all substances manufactured and imported in quantities ≥ 10 metric tons/year to determine and demonstrate the safe use of

a substance. The Chemical Safety Assessment has to be included in the Chemical Safety Report of the registration dossier.

Exposure scenarios are used to assess the exposure to chemicals of humans and the environment and to identify the appropriate risk management measures.

Classification and Labeling of substances involves an evaluation of the hazard of a substance or preparation and a communication of that hazard via a label. If a chemical meets certain criteria for classification, some obligations are triggered, for example a **Safety Data Sheet** should be provided to **downstream users** of the chemical.

Annex XV dossiers are the regulatory instruments for the Authorities (Member States or the ECHA) to propose and justify:

- proposals for a substance to be included on the candidate list for authorization,
- proposals for restrictions, and
- proposals for harmonization of classification and labeling.

To ensure support to all REACH processes, **Information Technology tools** have been developed to store and exchange information and data on chemicals: REACH IT, IUCLID5 and the ECHA website.

Resources

There are guidance documents now available on the ECHA website (http://reach.jrc.it/guidance_en.htm) to assist with registration, pre-registration, data sharing, etc., as well as an online tool called “The Navigator” designed to assist industry in determining its obligations under REACH and find the appropriate guidance on how to fulfill them (http://reach.jrc.it/navigator_en.htm).

ECHA REACH - http://echa.europa.eu/reach_en.asp

ECHA REACH-IT - http://echa.europa.eu/reachit_en.asp - information on how to use the REACH-IT application, including how to submit data to ECHA.

Competent Authorities (CA) and Help Desks:

Each EU member state has to appoint a competent authority or competent authorities with responsibility for performing the tasks under REACH in cooperation with the European Commission and the ECHA. Also, member states have to establish national help desks to provide advice to manufacturers, importers, downstream users, etc:

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Germany: <http://www.reach-info.de/>

UK: <http://www.defra.gov.uk/news/2006/061010b.htm>

Ireland: <http://www.hsa.ie/eng/Sectors/Chemicals/REACH/>

Netherlands: <http://www.vrom.nl/pagina.html?id=22887>

Belgium: https://portal.health.fgov.be/portal/page?_pageid=56,5920388&_dad=portal&_schema=PORTAL