ECHA
EUROPEAN CHEMICALS AGENCY

REACH

Factsheet

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Interface between REACH and Cosmetics regulations

In 2013, the European Commission published a Communication on the Cosmetics Regulation. It explained that the testing and marketing bans in the Cosmetics Regulation apply only where animal testing is carried out to meet the requirements of that legislation. This factsheet seeks to clarify the practical meaning and implications of this communication in the context of REACH.

BACKGROUND

The Cosmetics Regulation[1] prohibits the placing on the market of cosmetic products, or products containing ingredients, which have been tested on animals to meet the requirements of that regulation using a method other than a validated alternative method.

The animal testing ban set out in the regulation consists of four separate prohibitions:

- a ban on the performance of animal testing for cosmetic products that came into force on 11 September 2004 (the testing ban);
- a ban on the performance of animal testing for ingredients which came into force on 11 March 2009 (the testing ban); and
- the bans on placing such cosmetic products or cosmetic products containing ingredients on the market in the European Economic Area. These came into force on 11 March 2009 and 11 March 2013 for tests concerning repeated dose toxicity, reproductive toxicity and toxicokinetics.

In short, the marketing bans complementing the animal testing bans of the Cosmetics Regulation came fully into force in March 2013.

1 Regulation (EC) No 1223/2009.

REACH REQUIREMENTS FOR REGISTRANTS THAT MANUFACTURE/IMPORT A SUBSTANCE USED IN COSMETIC PRODUCTS

Following the Commission communication, the relationship of the testing ban enshrined in the Cosmetics Regulation and the REACH information requirements can be described as follows:

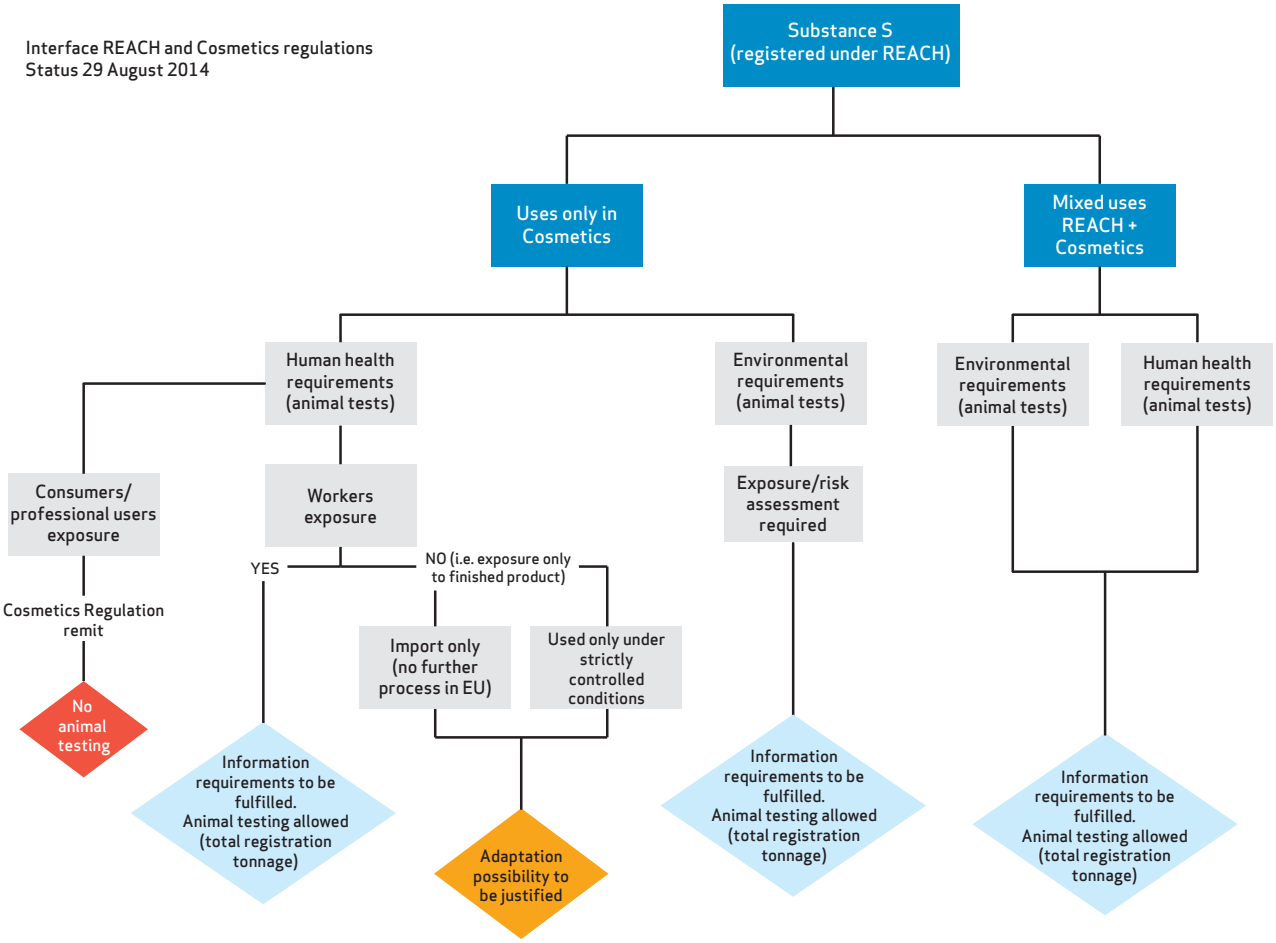
1. Registrants of substances that are exclusively used in cosmetics may not perform animal testing to meet the information requirements of the REACH human health endpoints. The exception is any testing required to assess the risks from exposure to workers[2];
2. Registrants of substances that use the substance also for non-cosmetic uses (i.e. mixed-use substances) are permitted to perform animal testing, as a last resort, for all human health endpoints;
3. All registrants (whether or not they only use the substance for cosmetic purposes) are permitted to perform animal testing, as a last resort, for all environmental endpoints.

This means that the Cosmetics Regulation does not restrict testing under REACH, if:

- this testing is required for environmental endpoints; or
- the substance is also registered for non-cosmetic uses.

Even if a substance is registered exclusively for cosmetic use, the animal testing requirements continue to apply to tests needed to assess the risks from exposure to workers in the Chemical Safety Assessment.

Registrants may determine the requirements that apply to their specific situation in accordance with the following graph:



2 "Workers" in this context are to be understood as persons who are actively involved in a particular activity of a production or manufacturing site, where they may be exposed directly or indirectly to chemical substances. On the other hand, professional users who use the cosmetic product as part of their professional activity (e.g. hairdressers) and consumers shall not be considered as "workers".

POSSIBILITY TO ADAPT INFORMATION REQUIREMENTS IF THE SUBSTANCE IS ONLY USED IN COSMETICS

In general, testing for human health endpoints can be adapted ('waived'), if:

- the substance is used solely as a cosmetic ingredient; and
- the testing would not be necessary to fulfil the REACH requirements for assessment of worker exposure.

Potential relevant worker exposure to REACH registered substances may occur during the following stages:

- manufacture;
- formulation;
- packaging.

Such adaptation possibility may, for example, arise when:

1) The cosmetic product is imported in its finished state and not further processed within the EEA (i.e. there is no identified human or worker exposure other than to the finished cosmetic product in the EEA); or
2) With the exception of the life-cycle stage, which covers the use as a cosmetic product, the substance is otherwise handled only under strictly controlled conditions and worker exposure can be excluded.

Consequently, registrants that manufacture or import their substance only for cosmetic uses can make use of specific adaptation possibilities for the relevant human health endpoint. These possibilities and further technical details on how to indicate such waivers in the technical registration dossier are described in ECHA's Q&As, available at:

» http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/cosmetics

Important: The option to waive human health endpoints, on the basis of the use of a substance in a cosmetic product is only available for registrants that **register a substance solely for cosmetic uses. It is not available for registrants that register a substance for both cosmetic and non-cosmetic uses**.

INTERMEDIATES AS DEFINED IN REACH ARE NOT AFFECTED BY THE COSMETICS REGULATION

Under the Cosmetics Regulation, "cosmetic product" means any 'substance' or 'mixture' (defined the same way as in REACH) intended to be placed in contact with the external parts of the human body. Thus, substances used to manufacture a cosmetic product but which are not found in the composition of the finished cosmetic product are not cosmetic products and are not affected by the ban on animal testing (referred to in Article 18 of the Cosmetics Regulation). The above-referred waiving possibilities thus do not apply to such substances.

However, where these substances meet the definition of "isolated intermediates" under REACH (see Article 3(15) of the REACH Regulation), subject to fulfilment of the conditions in Articles 17 and 18 of REACH, reduced information requirements apply.

CONCLUSION

There is no general exemption from the information requirements of REACH concerning the registration of substances used as cosmetic ingredients. However, if, in order to fulfil the REACH requirements:

- the registrant does not need to assess the risks arising from exposure to workers; and
- the substance is solely used in cosmetic products,

then, on a case-by-case determination, animal testing shall not be performed.

All registered quantities of the substance may be used and handled by workers during manufacture, formulation and packaging at an industrial scale - regardless of the quantities ending up in the cosmetic product. Therefore, the option to waive human health endpoints on the basis of the end use as a cosmetic product may only be exercised by registrants who **register a substance solely for cosmetic uses. Registrants who register a substance for both cosmetic and non-cosmetic uses may not exercise this waiving option**.

FURTHER INFORMATION

For more information on the interface of REACH and the Cosmetics Regulation, please consult our Q&As available at:

» http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/cosmetics

For more information regarding the Cosmetics Regulation and the requirements therein, please visit the European Commission website:

» http://ec.europa.eu/consumers/consumers_safety/cosmetics/legislation/index_en.htm

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