REACH: impact on the US cosmetics industry?

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Summary

The Registration, Evaluation, Authorization and restriction of Chemicals (REACH) is a recent European regulation on chemical substances meant to protect human health and the environment. REACH imposes the "precautionary principle" where additional data and definitive action are required when uncertainty is identified. The cosmetics industry is only partially concerned by REACH: while the stages of registration and evaluation apply to cosmetics, those of authorization and restriction most likely will not, as cosmetic ingredients are already subject to regulation by various agencies and directives. REACH has potential benefits to the industry including the possibility of reassuring consumers and improving their image of chemicals and cosmetics. However, REACH also has potential disadvantages, mainly with regard to impeding innovation. The American cosmetics industry will be affected by REACH, because all US manufacturers who export substances to Europe will have to fully comply with REACH.

Keywords: cosmetic, cosmetic legislations, safety

Introduction

On June 1, 2007, a new European regulation on chemical substances, Registration, Evaluation, Authorization and restriction of Chemicals (REACH), came into force. REACH, based on the precautionary principle,* is on everyone's lips not only in Europe but also in the United States: industry professionals, consumers, members of environmental organizations, and even cosmetologists are talking about it and wondering what it really means.

Broadly speaking, REACH will impact those in the US cosmetics industry who export to the European Union. More specifically, however, what is REACH? What effects will it have on the US cosmetics industry? What are the advantages and disadvantages of this new regulation for the US cosmetics industry?

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*The precautionary principle advocates preventative action to prevent possible threats even before their likelihood, possible extent or cause and effect relationships have been scientifically established.[1]

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REACH: definition and historical background

Definition

REACH[2] is a European regulation meant to protect human health, the environment, and the free movement of chemical substances within the European Union (EU). Ultimately, REACH requires manufacturers, importers, and downstream users to ensure that the chemical substances they are using are inherently safe.

REACH admonishes the "no data, no market" rule and imposes the "precautionary principle", where additional data and definitive action are required when uncertainty is identified.

Historical background

In a meeting of the Environmental Council in April 1998, a number of European countries drew attention to the

lack of regulation and control of chemicals and to the need for complete reform. The Council of Ministers had previously assessed the legal instruments that monitor chemicals in the EU and published a White Paper in February 2001: "Strategy for a future chemicals policy".[3] One of the conclusions of this White Paper is that legislation alone is unable to provide the desired level of protection from nefarious chemicals. The European Commission thus decided to act on this White Paper and establish a new regulation based on the precautionary principle; REACH was born, adopted by the Parliament and the European Council on December 18, 2006, and finally entered into force on June 1, 2007.

REACH and the cosmetics industry

The major challenge posed by REACH to the cosmetics industry is to ensure the absolute safety of ingredients by assessing detailed data dossiers that need to be prepared and submitted by suppliers. In Europe, REACH supplements the cosmetics directive 76/768/EEC,[4] which already covers the safety of ingredients in cosmetics. In the United States, REACH complements the rules of the Food and Drug Administration (FDA) that regulate the cosmetics industry.

Cosmetics are defined by REACH as preparations of several substances in a container (the packaging). REACH requires that manufacturers and importers of chemical substances register them with the European CHemicals Agency (ECHA)[5] located in Helsinki, Norway. REACH is composed of four stages: registration, evaluation, authorization, and restriction of chemicals.

Registration

Any substance, alone or in preparations or formulations, must be registered. The manufacturer or importer of chemicals must apply to REACH for registration and pay a fee. This application cannot be filed by the downstream user of the substance (i.e., manufacturers or distributors). The registration requirement applies to both existing substances on the European INventory of Existing Commercial chemical Substances (EINECS) list marketed prior to September 1981, as well as to new substances that are already covered by a notification requirement under the directive 67/548/EEC.[6] These new substances are part of European LIst of Notified Chemical Substances (ELINCS) since September 1981. They will be registered in stages based on the thresholds of tonnage and their presumed toxicity, with all substances being registered within 11 years of the implementation of REACH (Fig. 1).

For each registration, a file detailing the physical, chemical, toxicological, and ecotoxicological properties of a substance, along with an evaluation of its health and environmental risks, must be submitted to ECHA within the deadlines set out in Fig. 1. Prior to the registration,

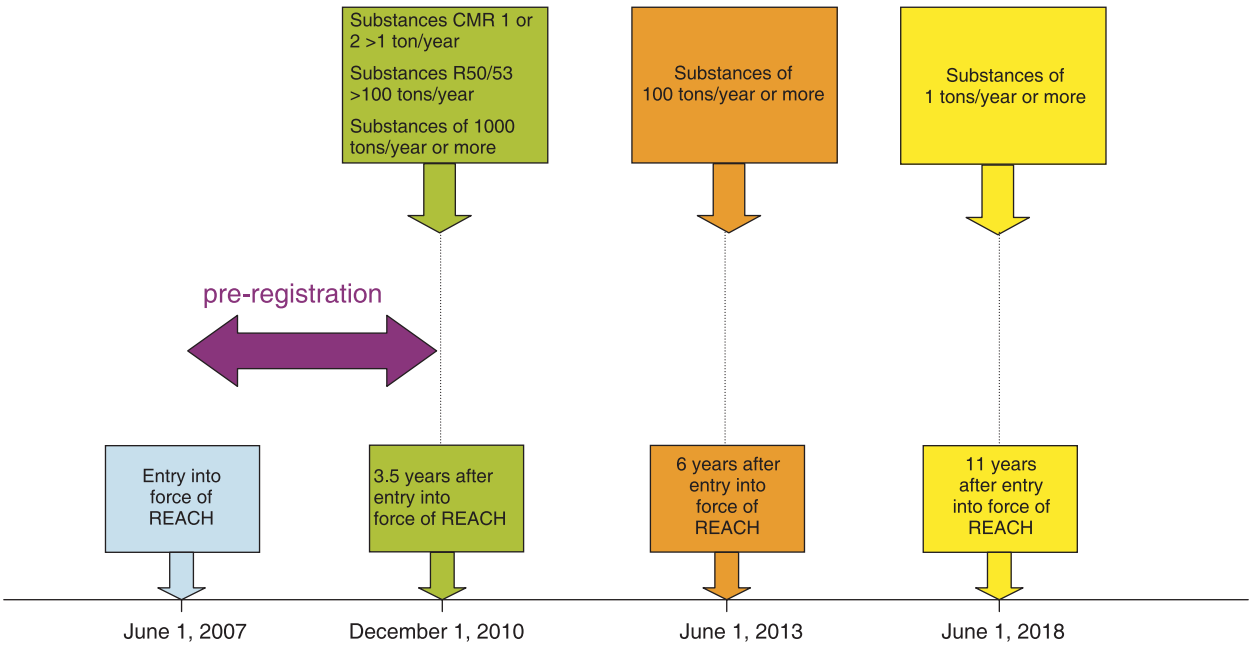

Figure 1 Stages of registration.
Substances CMR 1 or 2 recognized strongly or probably Carcinogenic, Mutagenic or Reprotoxic; Substances R50/53 known to be highly toxic to aquatic organisms and may cause long- term adverse effetcs on the aquatic environment.

manufacturers and importers must pre-register their substances, entering them in a transitional period and enabling them to pursue commercial activities.[2] The pre-registration is free and requires minimal information: name of the substance, EINECS number, contact information, and expected registration date. Pre-registration began on June 1, 2008 and ended on December 1, 2008. Pre-registrations were submitted electronically via REACH-IT on the ECHA website.[5]

Evaluation

Two types of evaluation are planned: review of files and assessment of substances.

The review of files is an optional step carried out entirely by ECHA to verify the conformity of the application and the complete nature of the file, especially in regard to the intrinsic properties of the substances in question. Given the number of files registered at ECHA, this review process covers only 5% of applications per slice of tonnage; however, this review is mandatory for all applications involving animal testing.

The assessment of substances is meant to contradict or confirm a suspicion of toxicity. It will, where appropriate, require the applicant to conduct additional testing or lead to proposals for risk management. This assessment applies only to substances produced in quantities greater than 100 tons per year and those for which tests on vertebrate organisms are proposed. Regarding cosmetics, chemical risks are already covered by Directive 76/768/EEC and therefore no additional report on chemical safety of cosmetic ingredients is required.

Authorization

Some substances will require an authorization that will be issued only if there is no alternative, if the socio-economic benefits outweigh the risks, or if the health or environmental risks are controlled. All authorization requests must include an analysis of alternatives and a substitution plan. The goal is to encourage the adoption of substitutes whenever possible.

The authorization process consists of two steps:

- The insertion of substances eligible for authorization in the annex XIV of the regulation; once a substance is found in this annex any use must be authorized;
- The granting of authorization, for some users, on a case-by-case basis and upon specific requests by manufacturers or importers.

No authorization is scheduled for ingredients used in cosmetic products that are governed by Directive 76/768/EEC.

Restriction

The restriction process is REACH's "safety net". It allows national authorities to provide risk management measures for any substance. Once a substance is deemed to generate risks that are not adequately controlled and warrants action at the Community level, an application must be filed to include it in Annex XVII. This application specifies restrictions on the substance. REACH distinguishes several categories of highly toxic substances: Carcinogenic, Mutagenic, Reprotoxic (CMR) substances and substances dangerous to the environment. Seeing that CMR substances are already banned in cosmetic products, cosmetic ingredients are therefore not directly affected by these restrictions.

In terms of packaging, REACH applies only to substances considered "extremely worrying": Persistent, Bioaccumulative, Toxic substances (PBT), very Persistent, very Bioaccumulative substances (vPvB), CMR 1 & 2 beyond certain thresholds (0.1% in relation mass by mass of article), and those substances present in quantities exceeding a total of 1 ton per year per manufacturer or importer.

Advantages and disadvantages of REACH for the cosmetics industry

Expected advantages

REACH does have a number of possible benefits.

1 REACH helps to centralize and harmonize rules in a single document that all EU countries must abide by.

2 In the context of the growing controversy on ingredients contained in cosmetics (allergies, cancer, reproductive problems), REACH should help to reassure consumers.

3 REACH also raises a new standard regarding animal testing. REACH explicitly states that animal testing should be kept at a minimum and that alternative testing methods should be used whenever possible.

4 REACH may lead to an increased exchange of information between industry professionals. Indeed, in order to foster exchanges of technical data, discussion forums will be established starting January 2009. These forums are mandatory for all manufacturers and importers affected by the same substance but optional for downstream users.

Potential disadvantages

While REACH does have potential benefits, this new regulation is also expected to have some negative consequences for the industry.

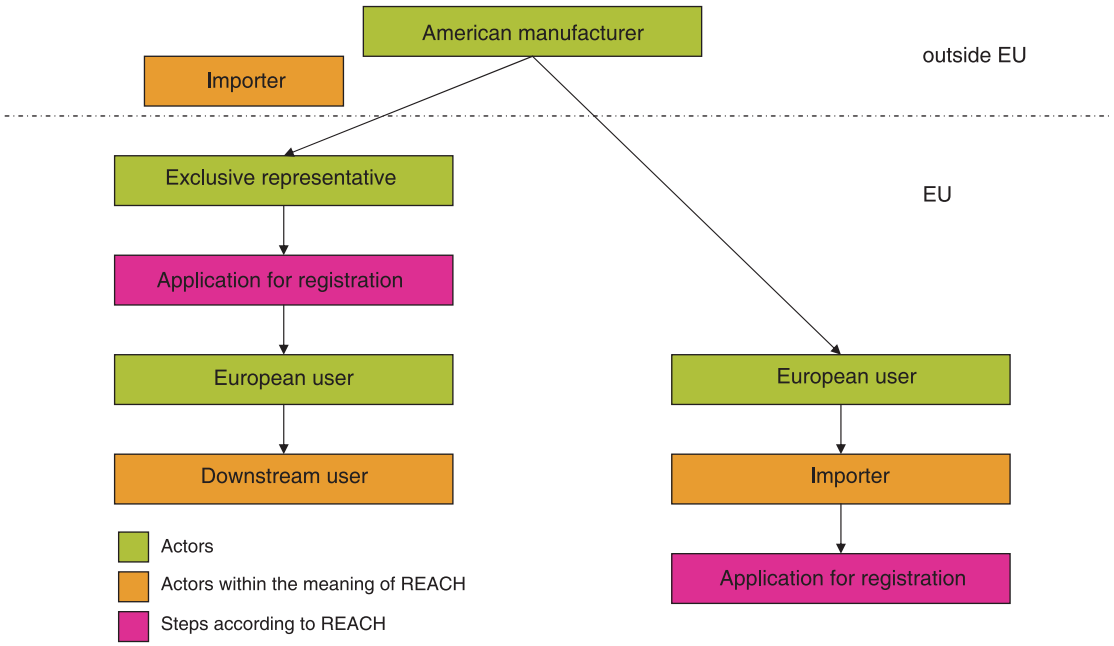

Figure 2 REACH and the United States.

1 REACH poses a significant challenge to manufacturers and importers. Indeed, it has the potential of being very costly (testing) and time consuming (preparation of files and reports), and will impact the supply chain, sales, and procurement.
2 REACH's complexity makes practical application difficult; in particular, the numerous exemptions and restrictions on categories of substances adversely affect implementation.
3 Perhaps the most significant concern is that REACH may impede innovation and the development of new substances due to fears that they would not meet the more stringent European requirements. It is, however, also possible that REACH's mandate to substitute toxic substances with new ones may promote innovation, which would then represent another advantage.

REACH and the United States

Obviously, REACH primarily affects European countries. However, any country that exports chemicals in quantities greater than 1 ton per year to the EU is directly affected by REACH.

Such exporters (including US manufactures) have two options:

The non-EU manufacturer needs an exclusive European representative to import the substances in the EU. This exclusive representative, established in the EU, meets all requirements to import substances from non-European manufacturers, meaning it is the representative's responsibility to submit the files and register the chemical substances. The foreign manufacturer shall inform the European purchaser (who will be considered by REACH as a downstream user) of the presence of the exclusive agent. Thus, the purchaser has no responsibility to register the substances.[7]

Alternately, the non-EU manufacturer sells chemical substances to a European company without prior to registration. The European purchaser then becomes the importer and is thus responsible for registering the chemical substance (Fig. 2).

If a foreign manufacturer is the importer, it can sell its substances but must carry out all the steps of REACH through its exclusive representative. Manufacturers outside the EU, particularly those in the United States, must follow both the regulations of REACH and those of their own regulatory agencies, adding another level of complexity.

For previously registered substances, it is unnecessary for a non-European manufacturer to appoint an exclusive representative.[8]

Conclusion

REACH is a European regulation governing chemical substances that aims to guarantee the highest level of

protection of both human health and the environment. The cosmetics industry is only partially concerned by REACH: indeed, while the stages of registration and evaluation apply to cosmetic ingredients, those of authorization and restriction most likely do not, as cosmetic ingredients are already subject to scrutiny and regulation by the 76/768/EEC directive in Europe and the FDA in the United States.

REACH does offer some potential benefits to the industry, including exchange of information and the possibility of reassuring consumers and improving their image of chemicals and cosmetics. However, REACH also has significant potential disadvantages, mainly with regard to impeding innovation.

The American cosmetics industry will be affected by REACH. US manufacturers who export their substances to Europe will have to comply with REACH and all the procedures of this regulation. This will most likely require additional paperwork and filings in order to comply both with the national FDA regulations and the new REACH requirements regarding exporting to European.

Many questions remain unanswered as to REACH's final impact on the cosmetics industry, in the United States and beyond. It is, however, unlikely that REACH will revolutionize the cosmetics industry, which has already taken the lead in regard to ensuring consumer safety.

Only time will tell how REACH will truly affect the cosmetics industry – positively or negatively.

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