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REACH AND ITS IMPACT ON COSMETICS

In June 2007, the European Union's Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorization, and Restriction of Chemicals (the "REACH Regulation")¹ entered into force. REACH will impose sweeping new requirements on producers of cosmetic products and will jeopardize the continued viability of many critical substances used in such products.

REACH will require producers of cosmetic products, or their chemical suppliers, to research and disclose the characteristics of the substances they use, permanently defend the continued use of substances that are dangerous to the environment, and in some cases even face an outright ban on them. Over time, cosmetic producers could also face more limited choice as chemical suppliers seek to specialize their portfolios by narrowing the number of substances on offer and thus reducing cost of compliance with REACH.

The Regulation imposes different requirements on products depending on whether they are substances or preparations, or articles. Substances are, in general terms, defined as chemical elements and their compounds in the natural state or obtained by any manufacturing process. Preparations are defined as mixtures or solutions of two or more substances. Examples of preparations include sun creams, toothpastes, and shampoos. Articles, on the other hand, are objects that during production are given a special shape, surface or design that determines their function to a greater degree than does their chemical composition. This memorandum assumes that most cosmetic products are substances or preparations, but some products manufactured by cosmetic producers (e.g., razors with lubrication strip) are likely to be considered as articles, and therefore, will be subject to slightly different requirements.

The Regulation also imposes different requirements depending on whether the materials are manufactured in, or imported into, the EU/EEA.

On this basis, the Regulation is likely to impose, among other burdens, the following requirements on EU/EEA manufacturers and importers of cosmetic products ("cosmetic producers"):

¹ A copy of the Regulation is available at:

(http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_136/l_13620070529en00030280.pdf).

1. Disclosure of Information

- ✓ As of **June 2007**, EU/EEA manufacturers of cosmetic products are required to report to their suppliers any new information they have available on the hazardous properties of the substances they use, and any information affecting the risk management measures indicated in the safety data sheets that suppliers provide to them and that affect identified uses. EU/EEA manufacturers must also supply such information to national authorities or the European Chemicals Agency upon their request.
- ✓ By **January 3, 2011**, importers of substances on their own or contained in cosmetic products in bulk (*i.e.*, not in finished stated intended for the final user) will be required to submit to the European Chemicals Agency a notification on the chemical classification and labeling of their substances if they are: (i) classified as hazardous and they are imported on their own, or as a part of a cosmetic mixture above concentration limits that render the mixture hazardous; or (ii) subject to registration and a registration dossier has not yet been submitted.

2. Registration of Substances

- ✓ REACH requires the registration of substances that are manufactured or imported on their own or in preparations in quantities of one ton or more per chemical manufacturer or importer per year. Both new and old substances, including those that were listed in the EU's EINECS list, will be subject to the registration requirement. Natural substances that are not chemically modified and are not classified as dangerous and other limited number of substances and groups of substances that are listed in Annexes IV and V to the Regulation will be exempted from registration. So-called "phase-in" substances (mostly EINECS listed substances) will benefit from extended phase-in registration deadlines, but only if they are pre-registered by December 1, 2008.

Registration will require submitting (i) a technical dossier with extensive data on the toxic and eco-toxic characteristics of the substance, which will entail substantial testing and data gathering; and (ii) a chemical safety report assessing the hazards, exposure, and risks of use during the entire life cycle for substances manufactured or imported in quantities of 10 tons or more per chemical manufacturer or importer per year. Registration will be substance specific and chemical manufacturer or importer specific: only those chemical manufacturers and importers that have registered within the deadlines will be allowed to market their substances.

EU/EEA importers of cosmetic products, and manufacturers of cosmetic products importing substances or preparations in bulk, are considered as importers of chemicals, and will be liable for pre-registration and registration unless they ensure that their foreign suppliers ensure the REACH compliance of their products and substances by appointing an Only Representative in the EU/EEA.

In contrast, EU/EEA manufacturers of cosmetic products purchasing substances from EU/EEA chemical suppliers are considered “downstream users,” and may rely on their suppliers’ pre-registrations and registrations. It is thus strongly in the interest of EU/EEA manufacturers of cosmetic products to ensure that their EU/EEA chemical suppliers file such pre-registrations and registrations.

- ✓ As of **June 1, 2008**, cosmetic producers must ensure that the “new” substances (mostly non-EINECS listed substances) contained in, or used in the EU/EEA manufacture of, cosmetic products are registered before they are imported into, or supplied in, the EU/EEA.
- ✓ Between **June 1 and December 1, 2008**, cosmetic producers must ensure that all “phase-in” substances contained in, or used in the manufacture of, their cosmetic products are pre-registered. Where the substance is not pre-registered within the deadline, the EU/EEA manufacturers of the substances and the importers of the substances on their own or in cosmetic products will be liable for registration as of June 1, 2008.

The possibility of pre-registration and the benefit of phase-in registration deadlines applies only to so-called phase-in substances, which are mainly EINECS listed substances that were exempted from the notification requirements under the Dangerous Substances Directive. As substances contained in imported cosmetic products were also exempted from the notification requirements of the Dangerous Substances Directive, a number of these non-EINECS substances could now be subject to registration without benefiting from the possibility of pre-registration and phase-in registration deadlines. The current guidance of the European Chemicals Agency is that importers of cosmetic products containing these substances should submit to the Agency an inquiry of whether the particular substance has already been registered and wait to receive an inquiry number before proceeding to registration.

- ✓ Between **November 30, 2010 and May 30, 2018**, cosmetic producers must ensure that pre-registered “phase-in” substances contained in, or used in the manufacture of, their cosmetic products are registered. The first deadline (*i.e.*, November 30, 2010) applies to Category 1 and 2 CMRs, R50/53 substances (*i.e.* classified as very toxic to aquatic organisms that may cause long term adverse effects in the aquatic environment) if manufactured or imported in quantities of 100 tons or more per manufacturer/importer per year, and other substances manufactured or imported in quantities of 1000 tons or more per manufacturer/importer per year.

3. Downstream User Obligations

- ✓ Where suppliers register their substances, EU/EEA cosmetic manufacturers will be required to check whether their specific use of the substance is covered by their

supplier's chemical safety report as reflected in the safety data sheet provided by their supplier. If their specific use of the substance is not covered, EU/EEA manufacturers of cosmetic products may be required to report to the Agency and prepare a chemical safety report of their particular uses if the substances or the preparations containing them are classified as "dangerous," PBTs, vPvBs or substances raising "an equivalent level of concern;" and they use the substance in quantities of one ton or more per year and in concentrations above specified thresholds.

The chemical safety report must assess the environmental and health risks of use of the substance during the manufacture of the cosmetic product, and the environmental risks resulting from the use of the substance in the cosmetic product.

4. Prior Authorization Requirements

- ✓ EU/EEA manufacturers and importers of cosmetic products may be required to apply for prior authorization of substances of very high concern that they use in the manufacture of, or are contained in, their cosmetic products. Substances of very high concern may include Cat. 1 and 2 CMRs, persistent, bioaccumulative and toxic substances ("PBTs"), very persistent and very bioaccumulative toxic substances ("vPvBs") and other substances giving rise to an equivalent level of concern.
- ✓ By **October 2008**, the European Chemicals Agency is likely to have identified the first list of "substances of very high concern," which may later be subject to the prior authorization requirement. Cosmetic producers using these substances will have to choose between withdrawing from such substances or actively engaging in their regulatory defense. Potential candidates to be listed could include substances that are currently classified as R-50/53 (very toxic to aquatic organisms that may cause long term adverse effects in the aquatic environment). This list will be periodically updated and enlarged by the European Chemicals Agency.
- ✓ By the **end of 2010**, the European Commission could adopt its first list of substances of very high concern subject to authorization. Priority substances to be listed are PBTs, vPvBs and substances with wide or high volume use, such as those used in cosmetic products.

The list will specify the date by which EU/EEA cosmetic manufacturers and importers must ensure that they or their suppliers have applied for an authorization to use the substance in cosmetic products, or in their manufacture, and the date (so-called "sunset date") after which non-authorization applicants or holders must no longer market or use the substance.

EU/EEA cosmetic manufacturers must ensure that they or their suppliers apply for the authorization of the specific use of listed substances that they use in specified

concentrations (e.g., 0.1%) in the manufacture of their cosmetic products. Similarly, EU/EEA cosmetic manufacturers and importers must ensure that they or their suppliers apply for the authorization of the specific use of listed substances in specified concentrations in their final cosmetic products. EU/EEA cosmetic manufacturers and importers will not be allowed to use the listed substances after the sunset date unless they or their suppliers have applied for authorization.

Authorization applicants will be required to show that the risks resulting from the use of their substances are adequately controlled, or that the socio-economic benefits of the use outweigh the risks and there are no suitable alternative technologies. Applicants will also have to search for substitutes and present a substitution plan where substitutes are available.

The REACH Regulation makes clear that the use of Cat. 1 and 2 CMRs in cosmetic products may never be authorized, and that the authorization requirement does not apply to substances used in cosmetic products if such substances are identified as substances raising “an equivalent level of concern” for health reasons.

Applicants who do not obtain an authorization will be banned from using listed substances, unless their supplier or downstream user has obtained such authorization. All cosmetic products marketed in the EU/EEA and containing substances that have been authorized will have to be labeled with the number of the authorization that EU/EEA cosmetic manufacturers or importers, or their suppliers, have obtained.

Where suppliers obtain an authorization covering the use of the cosmetic manufacturer or importer, the latter must notify the Agency of their use of the substance.

5. Restrictions Procedure

- ✓ The REACH Regulation also establishes a fast track procedure through which the Commission may ban the marketing and use of substances that pose an “unacceptable” risk, and envisions the use of this procedure to address the environmental risks from the use of a substance in cosmetic products.
- ✓ From **mid 2009** onwards, the Commission could issue its first bans under REACH of the use of substances in order to address the human health and environmental risks from the use of such substances in the manufacture of cosmetic products in the EU/EEA, and the environmental risks from the use of such substances in cosmetic products.

6. Animal Testing

- ✓ The REACH Regulation confirms that the restrictions of the Cosmetics Directive on testing substances in vertebrate animals continue to apply to substances used in cosmetic products. However, the Regulation could also be interpreted as confirming that

the ban on testing on vertebrate animals of the Cosmetics Directive applies only to the testing that is required to comply with the requirements of the Cosmetics Directive and not to testing on substances mandated by general legislation, such as the REACH Regulation.

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The REACH Regulation is technical in nature and several important provisions are open to different interpretations. It will be important to monitor how the rules are being implemented in more detailed provisions and guidelines.

The information in this memorandum is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

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