



Legal Implications of the European Commission's Proposal for a Revised Chemicals Regulation ("REACH")

Towards a new EU Chemicals Policy
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Principle

- **All manufacturing and import of cosmetic ingredients¹ is subject to registration.**

Exemptions (among others)

- **Non-isolated intermediates (out of scope)**
- **Substances in Annex II (e.g. H₂O, castor oil, lecithin)**
- **Substances in Annex III (e.g. substances occurring in nature unless chemically modified during manufacturing or dangerous² (Dir. 67/548))**
- **Below 1 ton per year**
- **Polymers**

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1. Whether as such or as part of a cosmetic product. For “articles” only if intended to release substances, e.g. a soap.
 2. E.g. Irritant, sensitizing, flammable. Includes those that are “self-classified” as dangerous, not only those with a harmonized Annex I classification.



Principle

- **In those cases in which the cosmetics industry uses /places on the market ingredients that are subject to authorization (listed in Annex XIII), substances that are CMRs¹ cannot be authorized for uses in cosmetics products². However, authorization needed if substances are PBT, vPvB or of equivalent environmental concern unless they are identified in those categories just for their human health impact³.**

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1. Carcinogenic, mutagenic, toxic for reproduction – includes self-classified substances.
 2. Why not also “as”?
 3. Reasoning: Cosmetics legislation does not address environmental risks. PBT = persistent bio-accumulative and toxic; vPvB = very persistent and very bio-accumulative; of equivalent concern: case by case e.g. endocrine disruptors.



Principle

- **(Article 65 (4)) Any human health risks relating to use of a chemical substance in cosmetics will not be included in Annexes XVI or XVII. In other words, substances used in cosmetics will be subject to Annexes XVI, XVII restrictions in principle, except for cosmetic human health risks (inclusion of environmental risks is possible).**



Legal Obligations for Cosmetics Manufacturers under REACH

- **Registration of substances manufactured or imported. Includes preparation of Chemical Safety Assessment and Chemical Safety Report ('CSR')¹ for substances above 10 tons (per manufacturer/importer)**
- **Provision of safety data sheet ('SDS') (both substances and preparations) if substance/preparation is dangerous – except for consumers. To be updated.**
- **If substance/preparation is not dangerous, all actors in supply chain have nevertheless to inform immediate downstream user/distributor about:**
 - Registration number
 - Authorization (requirement)
 - Details of restrictions
 - Other available and relevant information,**To be updated.**

1. But Article 13 (5): CSR need not include consideration of human health risks from use in cosmetic products.

Legal Obligations for Cosmetics Manufacturers under REACH (Cont.)

- **Provision of information up the supply chain (to next actor, distributor) – new information on hazardous properties; any other information that might call into question the appropriateness of the risk management measures identified in SDS**
- **Record keeping for a minimum of 10 years (after last supply/manufacturing/import/use)**
- **Make information available on request to competent authority**
- **Downstream user to prepare CSR for any uses outside¹ the conditions described in the exposure scenario communicated in the supplier SDS (not if no SDS or no CSR required (below 10 tons)). Keep CSR available and up-to-date**

1. Downstream user may inform supplier of his uses in order to enable manufacturer/importer to make this an identified use. “Sufficient information” to be provided – but Art. 13 (5).

Legal Obligations for Cosmetics Manufacturers under REACH (Cont.)

- **Article 35:** as downstream user, report to Agency certain information if use outside exposure scenario communicated by supplier (likely, because of Art. 13 (5)).
- **Article 34 (5):** downstream users to identify, apply, recommend measures to control risks identified in SDS or their own chemical safety assessments
- **Downstream users to inform Agency of use of substances subject to authorization (Art. 63)**
- **Notify (and update) Agency of marketing of substances subject to registration or dangerous (Art. 109 and 110) for inventory**
 - Identity of manufacturer/importer
 - Identity of the the substance
 - Hazard classification
 - Hazard label
 - Concentration limits.



Legal Obligations for Cosmetics Distributors under REACH

- **Supply of SDS**
- **Supply of other information up to next actor (new info on hazardous properties; info calling into question risk management procedures identified in SDS) (Art. 31)**



Liabilities for Cosmetics Manufacturers

Sources:

- **GPSD (Directive 2001/95 on general product safety). Must market only “safe products” to consumers. Must monitor safety and recall¹ if necessary. Must notify authorities if recall envisaged. Compliance with specific legislation does not protect from recall. Compliance with REACH does therefore not protect from recall.**

1. Unclear how recall provisions of GPSD relate to Article 126 REACH (safeguard clause) and whether REACH is considered *lex specialis* to GPSD as far as all chemical risks to human health are concerned (likely).



Liabilities for Cosmetics Manufacturers (Cont.)

- **Product Liability Directive (Dir. 85/374)**. Strict civil liability for any defective products (components/raw materials) marketed that cause damage. ‘State-of-the art’ defense may be excluded under national law. Compliance with REACH does therefore not exclude product liability claims.
- **New Environmental Liability Directive**. Strict liability for environmental damage caused by manufacturing/use/storage/processing/filling/release into the environment/on-site transport of dangerous substances and preparations. ‘Permit’ and ‘state-of-the art’ defenses that may be granted under national law may potentially protect REACH compliant manufacturers from liability but only in certain cases – this remains to be seen (interpretation issues).

Liabilities for Cosmetics Manufacturers (Cont.)

- **REACH?** – Article 1 (3): *“This Regulation is based on the principle that it is up to manufacturers, importers and downstream users, to ensure that they manufacture, place on the market, import or use such substances that do not adversely affect human health or the environment ...”* Impact unclear. Probably not independent source of legal liability.
- **Sanctions for Non-Compliance (Art. 123 REACH).**
- **Criminal liability under national law if negligent/intentional non-compliance with REACH causes e.g. death.**

In a Nutshell

- **REACH provides only limited “exemptions” (exemption from restrictions) for substances used in cosmetics, less than for other regulated product categories.**
- **One of the exemptions (Art. 13 (5)) may actually be counterproductive as CSR from supplier is not required to include exposure scenario from use in cosmetics. Under Art. 34 (4), downstream user must complete CSR. Also, downstream user must still identify and apply measures to control risks from SDS, or failing so, his own chemical safety assessment. Therefore high burden on cosmetic manufacturer’s chemical safety assessment – with potentially little input from ingredient supplier.**



CONCLUSION (Cont.)

- **REACH does not protect from (third party) legal liability for products.**
- **Relationships with suppliers and customers as regards provision of information/data are regulated under REACH to a limited extent only. There are no provisions on liability if the information/data provided is not complete or inaccurate. The cosmetics industry would therefore be well advised to provide contractual safeguards for these cases.**



Data Sharing / Data Protection

Data Protection is preclusion of possibility for regulatory authorities to use information submitted by (first) registrant for the benefit of a secondary registrant.

Principles

- **Sharing and joint submission of technical data (in particular intrinsic properties) is encouraged**
- **Data protection, if any, limited to 10 years (Art. 23 (3)) for summaries**
- **No mandatory data sharing for tests not involving vertebrate animals (Art. 23 (4)).**

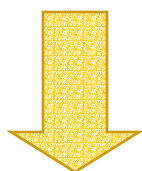
1. Art. 3 (20): Substances currently manufactured/imported and/or marketed (in short).



Data Sharing / Data Protection

Rules on vertebrate animal testing differ

Phase-In'¹ vs. Non-Phase in



SIEF

No forced data sharing between participants - but penalties - and forced sharing for non-participants.



Free access to data if substance registered more than 10 years ago. Mandatory data sharing for substances registered less than 10 years ago.

1. Art. 3 (20): Substances currently manufactured/imported and/or marketed (in short).



- **Article 102: EU institutions**
- **Article 115: Reference to Reg. 1049/2001 (access to documents) plus procedure**
- **Article 116: Types of information not considered confidential**