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REACH and the Regulations for Cosmetics

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Abstract

To completely implement REACH, work is still in progress. Starting in 2006, where large units were considered and over the years smaller units and niches were included. The European Cosmetic Regulation replaced national regulations in 2013 after a three-year transition period. This paper presents the main points of the REACH regulation and the Cosmetics Regulation. The differences and similarities are crystallized. These are further clarified using the example of salicylic acid.

Including the EU Cosmetics Regulation in REACH would result in major consequences: the number of animal experiments will increase; costs for the production of cosmetics would be increased by additional fees for authorisation and safety data sheets, which, at the end would encourage companies to find alternatives for substances of concern.

For a selected instance, Salicylic acid is not included among the substances subject to authorization, which is why no authorization fees are payable in this case either. Cosmetic products are generally excluded from authorization.

Guidelines on Registration, Authorization and Restriction have been prepared for companies to facilitate their first steps.

Content

List of Abbreviations

REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
ECHA	European Chemical Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
SVHC	Substances of very high concern
CLP	Classification, Labelling, Packaging
PBT	persistent, bioaccumulative, toxic
vPvT	very persistent or very toxic
CMR	carcinogenic, mutagenic, toxic to reproduction
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
SCCS	Scientific Committee for Consumer Safety
CPNP	Cosmetic Products Notification Portal
CAS numbers	Chemical Abstracts Service numbers
EC numbers	Enzyme Commission numbers
SIEF	Substance Information Exchange Forum

1. Problematics

Both, REACH and the EU Cosmetics Regulation cover the management of chemical compounds in EU member states. This paper analyses whether this is a double regulation or covers different aspects. Furthermore, the consequences of a substitution of the EU Cosmetics Regulation by REACH will be identified by working on following topics.

- Coverage and Legal Status of REACH
- Coverage and Legal Status of European Cosmetics Regulation
- Matches and Mismatches of REACH and European Cosmetics Regulation
- Suggestion for Application Guidelines

It starts by looking through the legal texts, then visiting various sources, such as the ECHA homepage and the REACH helpdesk, to get even more information. With the help of an example, the differences between the two regulations will be illustrated and costs will be discussed in more detail. A guide for companies will be compiled to facilitate the introduction of the subject matter.

2. Management of chemical compounds in industrial processing

There are various regulations governing the handling of substances. Depending on the field of application, a specific one is used. For food additives, for example, there is the Food Supplements Regulation, for medicinal products there is the Pharmaceutical Regulation, etc. This paper deals mainly with those regulations that relate precisely to this topic: The REACH Regulation and the Cosmetics Regulation.

2.1. Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)

2.1.1 General

REACH stands for Regulation, Evaluation, Authorization and Restriction of Chemicals. This regulation has been enacted to protect human and environmental health. It also aims to facilitate trade of substances as preparations or products within the EU.[1] In addition, attempts are being made to reduce animal testing by promoting alternative methods for the identification of adverse effects in substances. In general, the precautionary principle applies: all actors along the supply chain must ensure that the substances they either produce, sell or use do not have a negative impact on human health or the environment.[2] REACH also applies to substances that are not immediately thought of as chemicals. Paints, varnishes, detergents and many other substances used in everyday life are covered by the regulation. REACH came into force on 1 June 2007. Under this Regulation, companies will be given an essential role: they will be responsible for safe use of substances they produce or import into the EU, and possible risks must be identified. All information concerning the substance must be communicated to users. If the risks are too high or cannot be controlled, ECHA (European Chemicals Agency) can restrict the use of this substance. The aim is to replace hazardous substances with less hazardous ones. There are three main groups of actors relevant to REACH: The manufacturer, the importer and the downstream user. The manufacturer bears a great responsibility in so far as he produces chemicals for his own use, for sale or export. The importer must act in accordance with the REACH regulation if he imports substances from non-EU countries. If the downstream user uses chemicals or other relevant substances, he also has an essential role in REACH. The more detailed obligations are discussed below.[3]

[1] Article 1, paragraph 1, REACH Regulation
[2] Article 1, paragraph 3, REACH Regulation
[3] European Chemicals Agency

2.1.2 Definitions

The REACH Regulation uses terms that need to be defined to avoid misunderstandings. The explanations can be found under Article 3 of the Regulation and important ones are summarised briefly. A substance is a chemical element or its compounds. It is produced in its natural form or in such a way that only contaminants caused by the manufacturing process or additives for stability are present. In contrast, a mixture consists of two or more substances. A product is defined by its function and not by its chemical composition. A phase-in substance is a substance, which is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS).[4]

2.1.4 Exceptions

There are several substances that are excluded from REACH. These are radioactive substances, bonded substances, non-isolated intermediates, dangerous substances transported by road, rail, air or sea[5], and waste.[6] Excluded from registration, downstream user, evaluation and authorization are medicinal products for human and veterinary use, food and feed (including food additives, flavourings, additives in animal nutrition and animal nutrition).[7] Human and veterinary medicinal products, cosmetic products, medical devices, food and feed are not affected by the communication of information along the supply chain. [8]Additionally, excluded from registration, downstream user and evaluation, but not from authorization are substances that are proven not to be dangerous.[9] These include sugars such as galactose, sucrose and lactose. Ascorbic acid, water, noble gases, starch and cellulose are also included.[10] Another exception are substances for which registration was not considered necessary, as the exclusion does not harm the aims of the REACH regulation.[11] Selected examples are: when a chemical reaction occurs during the storage of substances, which in turn results in the formation of substances; natural substances such as ores, minerals or natural gas, which are not chemically modified; hydrogen and oxygen.[12] A substance recovered in the same supply chain and is identical to the source substance and a substance recovered from a registered substance but not necessarily within the same supply chain are also excluded from registration, downstream users and evaluation.[13]

[4] Article 3, paragraph 1, 2, 3, 20 (a), REACH Regulation
[5] Article 2, paragraph 1, a, b, c, d, REACH Regulation
[6] Article 2, paragraph 2, REACH Regulation
[7] Article 2, paragraph5, a, b, REACH Regulation
[8] Article 2, paragraph 6, a, b, c, d, REACH Regulation
[9] Article 2, paragraph 7, a, REACH Regulation
[10] Annex IV, REACH Regulation
[11] Article 2, paragraph 7, b, REACH Regulation
[12] Annex V, REACH Regulation
[13] Article 2, paragraph 7 (c, d), REACH Regulation

2.1.3 Duties under REACH

There are obligations that companies must fulfil regarding REACH. They are more or less extensive, depending on what part this company takes. The special feature of REACH is that the information transfer runs in both directions: This means that not only the manufacturer has to pass on information to the downstream user, but also vice versa. If the substances are hazardous chemicals, the manufacturer must provide a safety data sheet. There are also obligations for substances that are present in the candidate list. This list contains chemicals that are declared as substances of very high concern (SVHC).[14]

The safety data sheet must be made available to the consumer by the supplier if the substance or mixture is considered as dangerous according to CLP (Classification, Labelling, Packaging) (EG) Nr. 1272/2008, or if the substance is considered to be PBT (persistent, bioaccumulative, toxic or vPvB (very persistent or very bioaccumulative). The consumer may also request the safety data sheet from the supplier if the mixture is not classified as dangerous but contains at least one substance hazardous to health or the environment with a concentration greater than 1 % by weight (non-gaseous) or greater than 0.2 % by volume (gaseous).[15]

Even if a safety data sheet (according to the paragraph above) does not have to be available, there is still information that is passed on along the supply chain:[16] This includes the registration dossier and registration number, the registration date, the result of the completeness check and any further information.[17] In addition, any authorization requirement, restrictions and necessary information on the substance to identify and apply appropriate risk management measures shall be submitted.[18]

A safety data sheet should always include the following points:[19]

1. Identification of the substance/mixture and of the company/undertaking
2. Hazards identification
3. Composition/information on ingredients
4. First-aid measures
5. Fire-fighting measures
6. Accidental release measures
7. Handling and storage
8. Exposure controls/personal protection
9. Physical and chemical properties

[14] REACH Helpdesk
[15] Article 31, paragraph 1, REACH Regulation
[16] Article 32, paragraph 1a, REACH Regulation
[17] Article 20, paragraph 4. REACH Regulation
[18] Article 32, paragraph 1b, c, d, REACH Regulation
[19] Annex II. REACH Regulation

10. Stability and reactivity
11. Toxicological information
12. Ecological information
13. Disposal considerations
14. Transport information
15. Regulatory information
16. Other information

2.1.5 Registration

The principle of REACH is no data no market. This means that only registered substances, mixtures or products may be placed on the market. If the substance (mixture or product) is not one of the exceptions mentioned in 2.1.4, it must be registered if more than one tonne is produced or imported. It is worth noting, that monomers used as on-site isolated or transported isolated intermediates are not exempted from registration as well. Polymers have a certain exception, as they are defined by the monomer of which they consist at least two per cent by mass and the total amount of monomer is one tonne. Therefore, for polymers, only the monomers need to be registered.[20] A substance in products is subject to registration if it is present in a quantity of more than one tonne and is released during normal handling.[21] Substances that require authorization (explained below) in products must be notified to ECHA if they are present in quantities of more than one tonne and the concentration is more than 0,1 percent by mass and exposure to humans and the environment cannot be excluded under normal handling.[22][23] Substances that have already been registered for a specific use do not need to be re-registered.[24]

2.1.6 Evaluation

ECHA is responsible for the evaluation of the registration dossiers. For testing proposals, priority shall be given to registrations possessing PBT-, vPvB-, CMR- (carcinogenic, mutagenic, toxic to reproduction) properties or manufactured or imported in quantities of more than one tonne. If the exposure is not controlled and the substances are listed in Annex I of the CLP Regulation ((EC) No. 1272/2008), the corresponding registrations will also be given priority.[25] Selected hazard classes are now explained in more detail. Physical hazards such as explosives; flammable gases, liquids and solids; oxidizing gases, liquids and solids; gases

[20] Article 6, paragraph 1, 2, 3 (a, b), REACH Regulation
[21] Article 7, paragraph 1 (a, b), REACH Regulation
[22] Article 7, paragraph 2 (a, b), 3, REACH Regulation
[23] Annex XIV
[24] Article 7, paragraph 6, REACH Regulation
[25] Article 40, paragraph 1, REACH Regulation

under pressure; health hazards such as acute toxicity, corrosivity and respiratory sensitization; environmental hazards such as water contamination.[26]

ECHA also checks the registration dossiers to ensure that the information provided, the chemical safety reports and the chemical safety assessments fulfil the requirements.[27]

2.1.7 Technical dossier and CSA/CRA

Technical dossier

Each registration of a substance must consist of a technical dossier containing the following items:[28]

1. Identity of the manufacturer or importer
2. Identity of the substance
3. Information on the manufacture and use of the substance
4. Classification and labelling of the substance
5. Guidelines for safe use
6. Study summaries of information on intrinsic properties
7. If necessary: qualified study summaries of information on intrinsic properties
8. Information whether points 3, 4, 6, 7 (and possibly also the CSR) have been verified by an expert
9. Further testing proposals, if necessary
10. Information on exposure of the substances (with a quantity of 1-10 tons)
11. A request for confidential treatment of the information, where relevant

The chemical safety assessment (CSA) and the chemical safety report (CSR) serve as documentation to assess risks that manufacturers and also downstream users have the necessary knowledge to deal with these risks.

CSA

A chemical safety assessment may only be carried out by persons who also have specialist knowledge in this subject and attend prescribed courses (including refresher courses). In the chemical safety assessment, the producer must describe the production and use of the substance, while the importer only has to provide information on the use. It is important to note

[26] Annex V, CLP-Regulation
[27] Article 41, paragraph 1 (a, c), REACH Regulation
[28] Article 10, REACH Regulation

that the entire life cycle of the substance should be considered. For substances that are structurally similar to other substances, they can be combined into substance categories and thus the same CSA can be used. For the CSA, enough information on the substance must be found. This includes, among other things, the hazard of the substance, the use, safety measures within the company and risk management measures. If more information is needed for the assessment of substances imported or produced in the EU in quantities of more than 10 tonnes, the producer or importer can carry out tests.[29]

Proceedings of the CSA[30]

1. Identification of adverse effects on human health
2. Identification of adverse effects on human health due to physico-chemical properties
3. Identification of adverse effects on the environment
4. Determination of PBT and vPvB properties
5. Exposure assessment
6. Risk assessment

Steps 5 and 6 have to be carried out if the CLP Regulation classifies it as a hazardous substance[31] or if the substance has PBT/vPvB properties.

CSR

The chemical safety report, which is divided into two parts, now summarises all the results of the chemical safety assessment and lists the main points of the assessment.

Part A

1. Summary of risk management measures
2. Declaration that risk management measures are implemented
3. Declaration that risk management measures are communicated

Part B

1. Identity of the substance and physical and chemical properties
2. Manufacture and uses
3. Classification and labelling
4. Environmental fate properties
5. Human health hazard assessment
6. Human health hazard assessment of physico-chemical properties

[29] Annex I, Introduction, REACH Regulation
[30] Article 14, paragraph 3, REACH Regulation
[31] Annex I, CLP-Regulation

7. Environmental hazard assessment
8. PBT and vPvB assessment
9. Exposure assessment
10. Risk characterisation[32]

2.1.8 Authorization

The authorization includes several aspects. On the one hand, the aim is for the internal market to function well, and on the other, to gradually replace substances of very high concern with alternatives and to control the risks they pose. The actors along the supply chain are responsible for the search of technically possible and economically viable substances.[33]

Annex XIV of the REACH Regulation lists those substances that may not be used. These include PBT, vPvB, carcinogens, substances toxic to reproduction and mutagens. [34] However, there are exceptions that allow the use of the above substances: substances used in scientific research and development,[35] Pesticides, biocidal products, motor fuels, petroleum products as fuel,[36] cosmetic and food products.[37]

2.1.9: Restriction

If a substance is restricted, it may be used for research and development purposes. It is also worth noting that cosmetic products are completely excluded, as the Cosmetics Regulation already refers to human health, but not to the risk to the environment.[38]

[32] Annex I, paragraph 7, REACH Regulation
[33] Article 55, REACH Regulation
[34] Annex XIV, REACH Regulation
[35] Article 56, paragraph 3, REACH Regulation
[36] Article 56, paragraph 4 (a, b, c, d), REACH Regulation
[37] Article 56, paragraph 5 (a, b), REACH Regulation
[38] Article 67, paragraph 1, 2, REACH Regulation

2.2. Regulations for Cosmetics

2.2.1 General

On 11 July 2013, after a three-year transition period, the EU Cosmetics Regulation replaced national regulations. [39]The Cosmetics Regulation aims to protect human health. According to the Cosmetics Regulation, substances that pose a risk to the environment should be regulated by the REACH Regulation, as the latter carries out cross-sector assessments. The Cosmetics Regulation only regulates cosmetic products, pharmaceuticals are treated separately. This becomes more visible with the definitions under 2.2.2. Furthermore, a cosmetic product should be safe under normal and reasonable handling and its packaging should be easily distinguishable from foodstuffs.[40] To ensure safety, cosmetic products must be labelled and instructions for use and disposal must be provided.[41]

2.2.2 Definitions

A cosmetic product is a substance or mixture that comes into contact with the human body, such as skin, hair, nails or oral mucosa. A cosmetic product is used to clean, care for, protect and influence the body odour of applied body parts. Conservatives are those substances intended to prevent the spread of microorganisms, while dyes are used to colour desired parts of the body by reflection and absorption of visible light. [42]

2.2.3 Duties

Persons with responsibility have obligations as manufacturers and distributors. They must ensure that the cosmetic product is safe and intervene in the event of product faults.[43] Retailers are responsible for verifying that labelling information and language requirements comply with the law and that the best-before date is still valid before placing them on the market. If they identify an error, it must be corrected, or the product removed from the market. If the cosmetic product poses a major risk, the retailer must inform the responsible person immediately.[44] Before cosmetics can be placed on the market, a safety report must be prepared. This includes:[45]

1. Quantitative and qualitative composition of the cosmetic product
2. Physical/chemical characteristics and stability of the cosmetic product
3. Microbiological quality
4. Impurities, traces, information about the packaging material

[39] Article 39, 40, EU Cosmetics Regulation
[40] Reason for consideration, paragraph 3, 5, 6, 9, 10, Cosmetics Regulation
[41] Article 3, Cosmetics Regulation
[42] Article 2, paragraph 1 (a, l, m), Cosmetics Regulation
[43] Article 4, Cosmetics Regulation
[44] Article 6, paragraph 2, 3, Cosmetics Regulation
[45] Article 10, paragraph 1, Cosmetics Regulation

5. Normal and reasonably foreseeable use
6. Exposure to the cosmetic product
7. Exposure to the substances
8. Toxicological profile of the substances
9. Undesirable effects and serious undesirable effects
10. Information on the cosmetic product[46]

2.2.4 Substance Regulations

There are various instructions governing the use of hazardous substances. Substances listed in Annex II of the Regulation may not be ingredients of cosmetic products. Annex III of the Regulation contains substances that may be used in a restricted manner. However, the restrictions must be apparent to the end consumer by means of additional information. In addition, it is also specified which dyes and conservatives as well as UV filters may be used. Permitted substances can be found in Annex IV, Annex V and Annex VI of the Cosmetics Regulation.[47] Substances classified as CMR in the CLP Regulation may not be used in general, but there are exceptions. Substances of category 2, i.e. substances suspected of having a carcinogenic effect on humans[48], may be exempted from the restriction if the SCCS (Scientific Committee for Consumer Safety[49]) has concluded that they are safe.[50] Similarly, substances of category 1a (carcinogenic in humans by detection in humans) and 1b (probably carcinogenic in humans by detection in animals)[51] are generally prohibited. Such substances may nevertheless be used in exceptional cases, i.e. if food safety is ensured, if no other alternatives are available, or if the exposure for a particular use of the product category is known.[52] Nanomaterials are also covered by this Regulation. It must be ensured that the nanomaterials used do not pose a health risk. They are subject to certain rules that have to be respected for their use in cosmetic products.

1. Identification of the nanomaterial and its chemical name
2. Size of the particle and physical and chemical properties
3. An estimate of the quantity per year
4. Toxicological profile
5. Safety data of the nanomaterial

[46] Annex I, Cosmetics Regulation
[47] Article 14, paragraph 1, Cosmetics Regulation
[48] Table 3.6.1, CLP Regulation
[49] Reason for consideration, paragraph 28, Cosmetics Regulation
[50] Article 15, paragraph 1, Cosmetics Regulation
[51] Table 3.6.1, CLP Regulation
[52] Article 14, paragraph 2, Cosmetics Regulation

6. Reasonable, foreseeable exposition conditions[53]

2.2.5 Registration

There is also a portal for cosmetics (CPNP: Cosmetic Products Notification Portal) on which cosmetics must be registered throughout the EU. The following points are essential.

1. Name and address of the person responsible
2. Name and category of the cosmetic product for categorisation
3. Country of origin in the case of imports
4. Member states where the cosmetic product is placed on the market
5. Person to contact
6. Information on composition
7. Information on nanomaterials
8. CAS or EC number of CMR substances[54]

2.3. CLP-Regulation

The CLP Regulation entered into force on 20 January 2009. This is a Regulation on Classification, Labelling and Packaging of Substances or Mixtures.

This regulation deals with the classification of substances and mixtures as well as the rules for the labelling and packaging of dangerous substances and mixtures. The aim is to achieve uniform labelling.[55] Such markings are made by means of hazard pictograms. Each pictogram is responsible for a specific hazard posed by a substance.[56] So far there are nine different pictograms:[57][58]

Table 1: Pictograms and meanings

Pictogram	Meaning
Physical hazards	
	For explosive substances/mixtures and products containing explosive substances

[53] Article 16, paragraph 1, 3, Cosmetics Regulation
[54] WKO-Leitfaden zur EU-Kosmetikverordnung, p.9
[55] Article 1, paragraph 1, CLP-Regulation
[56] Article 19, paragraph 1, CLP Regulation
[57] http://www.unece.org/trans/danger/publi/ghs/pictograms.html
[58] Umweltbundesamt-Pictograms

	For flammable gases, aerosols, liquids or solids
	For flammable (oxidizing) gases, liquids or solids
	For gases under pressure
Physical and Health hazards	
	For substances and mixtures which are corrosive to metals, corrosive to skin and/or severely damaging to eyes
Health hazards	
	For acutely toxic substances and mixtures
	For substances and mixtures which irritate the skin, eyes or respiratory tract
	For carcinogens or substances and mixtures which are respiratory sensitisers
Environmental hazards	
	For substances and mixtures which pose an acute or chronic risk to water

3. Selected REACH exceptions

3.1. Cosmetic products

Substances in cosmetic products must be registered in accordance with REACH. However, there is no obligation to pass on information along the supply chain. This also means that no safety data sheets have to be written, information does not have to be passed on to the downstream user, and information on substances in products is therefore not mandatory. Information from bottom to top (to the upstream actor in the supply chain) is also not mandatory for cosmetic products. Furthermore, the chemical safety report only has to include the risks to the environment, but not those to human health. For substances listed in Annex XIV of the REACH Regulation (see 2.1.7) no authorization application is required. However, these substances must be used in accordance with the Cosmetics Regulation (see 6.1.3).[59]

Since 11 September 2004, there has been a ban on animal testing for cosmetic substances, and since 11 March 2009 the ban on animal testing has also applied to ingredients in cosmetic products. [60] If a company registers a substance that is used exclusively for cosmetic products, animal testing is not permitted unless it poses a risk to the employee. Companies that do not use a substance exclusively in cosmetic products may carry out animal testing as a last resort for all human health endpoints. However, all companies are allowed to perform animal testing as a last resort to determine environmental endpoints.[61]

3.2 Pharmaceuticals

As in 2.1.4, certain exceptions also apply to pharmaceuticals. Pharmaceuticals are generally excluded from registration, downstream users, evaluation and authorization. Furthermore, no information has to be passed on along the supply chain if the finished product is intended for the end user. It is important to note that starting materials used for synthesis are subject to all the requirements of the REACH Regulation. Isolated precursors and intermediates resulting from production must also fulfil all requirements of the REACH regulation.

[59] Kosmetika unter REACH-Umweltbundesamt
[60] Interface between REACH and Cosmetics Regulations, p.1
[61] Interface between REACH and Cosmetics Regulations, p.2

4. Scaling

4.1 REACH Implementation and Development

4.1.1: Early days

The European Commission wanted to achieve a Community policy on chemicals and first mentioned this purpose on 13 February 2001, after which the Commission brought the legislative proposal to REACH and presented it to the European Parliament and the Council in November 2003. The Committee on the Environment, Public Health and Food Safety was responsible for the governance of the European Parliament, the first reading opinion was submitted on 17 November 2005. On 13 December 2005, a Political Agreement for a Common Position was reached by the Council, where a proposal for the REACH-Regulation was made. The second reading began in September 2006 and was based on the formal adoption of the Common Position by the Environment Council in June 2006. The final version of the REACH Regulation was achieved in early December with the agreement of the representatives of the European Parliament and the Council. It was finally adopted at the Environment Council on 18 December 2006.[62]

4.1.2: Impact Assessments

In order to be able to assess the effects of the REACH Regulation, several studies were carried out by the European Commission.

The benefits of the REACH Regulation were discussed, which are briefly summarised below:

This study deals with the environmental, human health and economic benefits, whereby the last one does not get such a big place in the study. Above all, it is assumed that REACH would save costs in the long term in regard to people and the environment, as this regulation is intended to prevent damage. Competitiveness is mentioned as an advantage for the economy.[63]

The Announcement Effect that arises in the market in relation to the candidate list. This means that substances that are on the candidate list (SVHCs) are immediately visible to all producers and importers, which increases the incentive to search for substances of non-concern.[64] However, these substitutions take place more or less quickly. The following reasons are given in this study. Downstream users play an essential role: On the one hand, they can insist on avoiding hazardous substances from the products they purchase, and on the other hand, they often do not even know about the danger of some substances in the products. Various campaigns by NGOs can raise awareness among consumers, who in turn demand products

[62] European Commission-Environment
[63] Analysis of Studies Discussing Benefits of Reach
[64] European Commission- Environment

without SVHCs from companies. This leads to the fact that companies do not want to lose their good reputation and thus guarantee the safety of the products. Another point to replace SVHCs immediately is that alternatives are already available which are also economically viable, easy to handle and easily available. It is also important to mention that companies must recognise and accept the hazards posed by substances or articles produced. Rapid substitution can also be found in those companies where good risk management is well established. Ultimately, it is legal pressure that is decisive for substitution. If companies were not willing to voluntarily replace SVHCs before, after a certain time there will be no authorization for such substances.[65]

4.1.3: Enforcement

The enforcement of the REACH regulation is the responsibility of the member states, whereby each member state must find the necessary enforcement measures (e.g. sanctions) for itself and make them available to the European Commission.[66]

4.1.4: Report of Austria

Report of 2010 compared to 2010

Table 2: Comparison regarding then helpdesk between Report of 2010 and 2015[67]

Helpdesk	Report 2010	Report 2015
Pre-registration (%)	8	0
Registration (%)	18	14
Evaluation (%)	no information	0
Authorization (%)	1	2
Restriction (%)	4	3
Testing (%)	1	1
Data sharing (%)	no information	1
Enforcement (%)	3	1
CSR preparation (%)	no information	0
CLP (%)	3	Classification: 8 Labelling: 7 Packaging: 1 Classification and labelling inventory: 3
SIEFs (%)	2	2
REACH-IT (%)	5	2

[65] Case study on “Announcement effect” in the market related to the candidate list of substances subject to authorisation
[66] European Commission-Environment
[67] European Commission-Environment, Member States Reports on the operation of REACH (Art.117)

IUCLID5 (%)	4	1
Downstream user obligations (%)	13	14
Obligations regarding articles (%)	15	8
Safety Data Sheets (%)	16	22
SVHCs	no information	8
Other (%)	6	0

Table 1 shows the percentage of requests in 2010 and 2015, and the number of requests for registration and pre-registration has decreased, suggesting that manufacturers and importers have already got used to the regulation. Requests for CLP, the Safety Data Sheet and SVHCs have increased. This is also due to the fact that there is a greater focus on registration in the early stages and implementation will only become relevant later.

4.1.5: Registration Deadlines

The law has been in force since 1 June 2007, with some transitional periods. The first registration period expired on 30 November 2010. During these 3.5 years, all substances imported or produced into the EU in quantities exceeding 1000 tonnes per year had to be registered. Substances which are very toxic to aquatic organisms and which have long-term harmful effects in the aquatic environment had to be registered for quantities above 100 tonnes per year up to this point, CMR substances for quantities above one tonne per year. The second deadline was 31.03.2013, by which time all substances with a quantity of 100-1000 tonnes per year had to be registered. Substances with a quantity between 1-100 tons per year fall into the last registration period, which ended on 31.05.2018.

4.2 EU Cosmetics Regulation

4.2.1: Early days

The EU Cosmetics Regulation has been in force since 11 July 2013, although there was previously a transitional period of three years. This regulation replaces all previous regulations of the individual member states.[68]

4.2.2: Market

There is no authorization requirement for cosmetic products, which means that they are not checked before they are placed on the market. However, they must meet all the requirements

[68] AGES- Kosmetikrecht

of the Cosmetics Regulation. A safety assessment must also be carried out at least before they are placed on the market. If a cosmetic product is ready to be placed on the market, there will still be ongoing checks and assessments.[69]

4.2.3: Producers and Distributors

Manufacturers and distributors have a great responsibility in the production of and trade in cosmetic products. These are already summarised under 2.2.3. In addition, cosmetic products must be notified before being placed on the market by electronic notification. The Cosmetic Products Notification Portal (CPNP) exists for this purpose.[70]

[69] AGES-Service Kosmetik
[70] AGES-Die verantwortliche Person und ihre Aufgaben

5 Example: Salicylic acid (Benzoic acid)

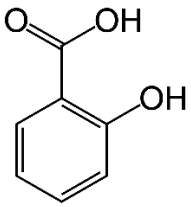
To give an insight into the reason for this work, the differences between the two regulations are explained using salicylic acid as an example.

5.1 Datasheet

5.1.1: Salicylic acid

$C_7H_6O_3$

CAS no: 69-72-7



Salicylic acid consists of a benzene ring and is therefore counted among the aromatic compounds. It also contains carboxy groups and hydroxy groups, which is why it belongs to the hydroxycarboxylic acids. Salicylic acid is known for the production of aspirin (acetylsalicylic acid) but it is also used in cosmetics.

5.1.2: Salicylic acid in the REACH Regulation

Salicylic acid is registered on the ECHA homepage. Thus, some evaluations and findings are available, which will now be explained:

There are two different types of registration: Full registration for 1000-10000 tonnes per year and registration as an intermediate.

General Information

Salicylic acid is known to be harmful if swallowed, causes serious eye damages and is suspected of damaging the unborn child. In addition, salicylic acid is suspected to have a reproductive toxic effect.

There is a pre-registration and registration of this substance. It may only be used by those companies that have a valid registration (22 active registrations are submitted).

Salicylic acid is not considered to be PBT or vPvB. It is used in a variety of applications, including pharmaceuticals, polymers, fragrances and perfumes, and cosmetics. A CSA has been made for this substance and no authorization is needed.

5.1.3: Salicylic acid in the Cosmetics Regulation

Salicylic acid can be found in Annex V of the Cosmetics Regulation under "List of preservatives allowed in cosmetic products". As a preservative, the concentration of the acid must not exceed 0.5% and products containing salicylic acid as a preservative must not be used for children under 3 years of age.[71] Furthermore, there is an exception in Annex III of the Cosmetics Regulation (list of substances which cosmetic products must not contain except subject to the restrictions laid down below). Here, 3.0% of the salicylic acid may be present in hair products that are rinsed out or 2.0% of the acid in other products, whereby it must be made clear that the salicylic acid does not appear as a preservative. These products are also not suitable for children under 3 years of age.[72]

Salicylic acid is classified as a CMR substance in category 2. In order to still be allowed to use it in cosmetic products, an opinion of the SCCS was issued on 21 December 2018. The SCCS concludes that cosmetic products containing salicylic acid are safe according to the above restrictions, provided that they do not involve inhalation or eye contact.[73]

5.2 Investments for Salicylic acid

5.2.1: Investments with respect to REACH

Registration

The fees for companies can be found on the ECHA homepage. These are broken down separately for large, medium and small enterprises. On the ECHA homepage there is also a link to find out whether an enterprise is a small or medium-sized enterprise. [74] For the fees there is a special fee regulation (EC) No 340/2008, whose important points are being worked out.

The fees are divided into standard fees and reduced fees. The latter concerns small and medium-sized enterprises. Thus, first of all the size of the enterprise is of great importance. This is determined as follows.

[71] Annex V, Cosmetics Regulation
[72] Annex III, Cosmetics Regulation
[73] Scientific Committee on Consumer Safety SCCS, p. 3
[74] https://ec.europa.eu/growth/tools-databases/SME-Wizard/smeq.do;SME_SESSION_ID=-saXfwNi_5c8APtRL_fp5rgAl3FsiCQZVPPERB6sgjgob8iYFPCZ!1862496024?execution=e1s1

Table 3: Size of enterprise[75]

Company	Number of employees	Highest annual turnover [Million €]	Highest annual record [Million €]
Medium	<250	50	43
Small	<50	10	10
Micro	<10	2	2

For substances or mixtures subject to the general obligation to register[76], or to register substances in products[77], or registrations that are submitted jointly[78], the following fees are payable:

Table 4: Standard fees: normal registrations[79]

Amount [t]	Fee [€] single/joint submission
1-10	1600/1200
10-100	4300/3225
100-1000	11500/8625
>1000	31000/23250

Table 5: Reduced fees: normal registrations[80]

Amount [t]	Fee [€] medium enterprise, single/joint submission	Fee [€] small enterprise, single/joint submission	Fee [€] micro-enterprises, single/joint submission
1-10	1120/840	640/480	160/120
10-100	3010/2258	1720/1290	430/323
100-1000	8050/6038	4600/3450	1150/863
>1000	21700/16275	12400/9300	3100/2325

[76] Article 6, REACH Regulation
[77] Article 7, REACH Regulation
[78] Article 11, REACH Regulation
[79] Annex I, Fee Regulation
[80] Annex II, Fee Regulation

In turn, there are separate fees for on-site isolated intermediates[81], transported isolated intermediates[82] and their joint submission[83].

Table 6: Standard fees: registrations concerning intermediates[84]

Fee [€] single/joint submission
1600/1200

Table 7: Reduced fees: registrations concerning intermediates[85]

Fee [€] medium enterprise, single/joint submission	Fee [€] small enterprise, single/joint submission	Fee [€] micro-enterprises, single/joint submission
1120/840	640/480	160/120

There are also costs for updating the quantities produced or imported.

Table 8: Standard fees for updates[86]

Amount [t]	Fee [€] single/joint submission
1-10 to 10-100	2700/2025
1-10 to 100-1000	9900/4725
1-10 to >1000	29400/22050
10-100 to 100-1000	7200/5400
10-100 to > 1000	26700/20025
100-1000 to >1000	19500/14625

[81] Article 17, REACH Regulation
[82] Article 18, REACH Regulation
[83] Article 19, REACH Regulation
[84] Fee Regulation, Annex II
[85] Annex II, Fee Regulation
[86] Annex III, Fee Regulation

Table 9: Reduced fees for updates[87]

Amount [t]	Fee [€] medium enterprise, single/joint submission	Fee [€] small enterprise, single/joint submission	Fee [€] micro-enterprises, single/joint submission
1-10 to 10-100	1890/1418	1080/810	270/203
1-10 to 100-1000	6930/5198	3960/2970	990/743
1-10 to >1000	20580/15435	11760/8820	2940/2205
10-100 to 100-1000	5040/3780	2880/2160	720/540
10-100 to > 1000	18690/14018	10680/8010	2670/2003
100-1000 to >1000	13650/10238	7800/5850	1950/1463

Finally, there are fees for other updates, which are summarized below.

Table 10: Standard fees: other updates[88]

Update	Fee [€]
Change of legal personality	1500
	single/joint submission
changes to the information contained in the application	1500/1125

Table 11: Reduced fees: other updates[89]

Update	Fee [€] medium enterprise,	Fee [€] small enterprise,	Fee [€] micro-enterprises,
Change of legal personality	1050	600	150
	single/joint submission	**single/joint submission**	**single/joint submission**
changes to the information contained in the application	1050/788	600/450	150/113

[87] Annex III, Fee Regulation
[88] Annex III, Fee Regulation
[89] Annex III, Fee Regulation

Authorization

Table 12: Standard fees for Authorization[90]

	Fee [€]
Basic fee	50000
Additional fee per substance	10000
Additional fee per use	10000
Additional fee per applicant	
Standard	37500
Medium enterprise	30000
Small enterprise	18750
Micro-enterprise	5625

Table 12: Reduced fees for Authorization[91]

	Fee [€] medium enterprise	**Fee [€] small enterprise**	**Fee [€] micro-enterprises**
Basic fee	40000	25000	7500
Additional fee per substance	8000	5000	1500
Additional fee per use	8000	5000	1500
Additional fee per applicant			
Medium enterprise	30000		
Small enterprise	18750	18750	
Micro-enterprise	5625	5625	5625

5.1.5: Investments with respect to EU Cosmetics Regulation

Cosmetic products must be registered under REACH, which is why the fees in Tables 3 to 10 above also apply to them. However, the costs for safety data sheets and for the more detailed chemical safety report will not apply.

In addition, cosmetic products are exempt from authorization and therefore from the fees in Tables 11 and 12.

[90] Annex VI, Fee Regulation
[91] Annex VI, Fee Regulation

6 REACH and the EU Cosmetics Regulation

6.1 Concept

First, the topic had to be narrowed down, as there are many aspects of the REACH regulation that can be examined more closely. It was therefore decided to compare the REACH regulation with the cosmetics regulation and to work out similarities and differences. A further point is to involve companies as well. It was tried to describe the most important points of the REACH regulation and the cosmetics regulation in a way that is understandable for everyone. Also, a short guideline should help companies to get a better start on the subject.

Basically, both chemical and legal knowledge is required for this matter. This combination is rather unusual, which is why REACH may still cause irritation 14 years after its entry into force.

The first contact point for everything concerning REACH is the ECHA homepage. However, it is very confusingly structured, so that it takes some patience to find the necessary information. At first the REACH regulation seems strange to non-lawyers, but after some time of working on it, it is possible to understand it correctly. The REACH-Helpdesk Austria is also a great help in this respect, where a lot of relevant information can be found quickly and clearly and can thus be used in addition to the regulation. The Environment Agency Austria also provides information on this topic and can thus provide support in case of questions.

There is so much information on this topic that it is easy to lose the overview, which is why it is important to think in advance about what really needs to be treated and what can rather be put aside in this case. Here a clear structure of the thesis was essential, so that one does not get lost in anything.

In contrast, there are not so many different sources of information on cosmetics, so the work was mainly done with the corresponding legal text.

6.2 Guidelines for industrial application

6.2.1: Application of REACH to Cosmetics

As there are already some regulations for cosmetic products in the REACH regulation, the question arises how useful a complete extension of the cosmetics regulation can be. The biggest difference between the two regulations is visible in the handling of animal testing.

As mentioned in 3.1.1, animal testing for cosmetics is generally prohibited, with exceptions. The REACH Regulation aims to avoid unnecessary animal testing and tests on vertebrate animals will only be carried out if absolutely necessary.

It is now a matter of answering the question mentioned in the introduction: "Does it make sense to apply REACH to cosmetics?

But this cannot be answered simply with yes or no. After a long time of research and discussion on this topic with the available information, it would theoretically make sense to establish the same rules for cosmetics as for those substances that have so far been covered by REACH. For example, there would be no need to pass on information along the supply chain and thus no need for safety data sheets. The chemical safety report is also only relevant for risks to the environment, but not for those to human health. This reduces the costs. Substances listed in Annex XIV of the REACH Regulation, i.e. those that require authorization under REACH, are also not subject to authorization in cosmetics, provided that they comply with the specifications of the Cosmetics Regulation. However, if such substances were covered by REACH, more companies would certainly be willing to find substitutes and stop using them (even though very low concentrations may be safe). Using salicylic acid, an attempt was made to identify the major differences between the two regulations. According to ECHA, salicylic acid is suspected to be toxic for reproduction, but a certain percentage is allowed in cosmetics. Companies that do not use salicylic acid for cosmetic products must prepare safety data sheets and the CSR including human health and environmental risks. It can therefore be assumed that the financial outlay involved in placing substances on the market that are not cosmetics is much higher.

On the other hand, an extension, which above all would involve a great deal of bureaucracy, will not be feasible from a practical point of view, as there are major differences even on the issue of animal experiments. Nor is it easy to implement the regulation concerning information along the supply chain. Exceptions for the end user would again be needed.

6.2.2: Guidelines for industries

Registration:

1.) By 31 May 2018, all transitional periods have expired (see 4.1.5), which means that all chemical substances on the market must be registered.

2.) Substances manufactured or produced in quantities of more than 10 tonnes per year must be subjected to a chemical safety assessment and the results summarised in a chemical safety report. (see 2.1.7)

3.) ECHA carries out a completeness check on registrations received, only then a number is assigned to the registered substance.

4.) To register, the registrant must collect and summarize all available information. In order to avoid animal testing, alternative sources should also be searched for and, if necessary, data from in vivo and in vitro studies should be used.

5.) The next step is to use the data found to determine what the status of the information is and whether further information is required. It is important to know which standard data requirements apply to the substance to be registered and in what quantity it is produced or imported.[92]

   a. substances manufactured or imported in quantities of one tonne or more [93]
   b. substances manufactured or imported in quantities of 10 tonnes or more [94]
   c. substances manufactured or imported in quantities of 100 tonnes or more [95]
   d. substances manufactured or imported in quantities of 1000 tonnes or more [96]

6.) If it is not possible to find all necessary data and information, tests should not be carried out immediately, but test proposals should be submitted. This is also to ensure that registrants of the same substance exchange information and share data.

7.) If a test is unavoidable, tests on vertebrates should not be carried out immediately, but alternative methods should be used.

   a. In-vitro: Test outside a living body (e.g. isolated tissue, cells)
   b. (Q)SAR: models (quantitative) structure-activity relationship (mathematical model)

   Only when the alternatives have been exhausted and are not conclusive tests on vertebrates may be carried out.

8.) REACH provides for data sharing and in addition, registrations can be submitted together. In order to share this data, a request or a pre-registration must be made before registration. Basically, it can be said that phase-in substances are pre-registered

[92] Annex XI, REACH- Regulation
[93] Annex VII, REACH Regulation
[94] Annex VIII, REACH Regulation
[95] Annex IX, REACH Regulation
[96] Annex X, REACH Regulation

and non-phase-in substances and substances that are not pre-registered have to be requested. After the request, ECHA can then identify further registrants of the same substance and establish a contact. All studies that are 12 years or older are provided free of charge, more recent studies are not free of charge and the registrant has to contact the person publishing the information and discuss the further procedure.

9.) For non-phase-in substances, a request should be made before registration. If the substance has already been registered, data can be taken together.

10.) Phase-in substances must be pre-registered to ensure data sharing. All registrants and persons with relevant data belong to the SIEF (Substance Information Exchange Forum). This is also supposed to agree on classification and labelling.

11.) A substance must be registered jointly if it is manufactured or imported by several companies. This obligation applies to phase-in and non-phase-in substances.

a. Always submit together
    1. Information on the inherent properties
    2. Classification and Labelling
b. Voluntarily submitted together
    1. Guidelines for safe use
    2. CSR

12.) Two reports are required for each registration (see 2.1.7)
a. Technical dossier
b. Chemical safety report (more than 10 tonnes per year)

13.) ECHA provides a software for submission. IUCLID and REACH-IT have to be used for this. ICLUID is for compiling the technical dossier while REACH-IT is used to upload the data. An exception is the joint registration of companies: They can directly create the registration dossier in REACH-IT.

<u>Authorization</u>

1.) Only those substances that are listed in Annex XIV of the REACH Regulation require an authorization:

a. CMR substances
b. PBT/vPvB substances

c. Substances with endocrine disrupting properties

2.) For an authorization, an application must always be submitted and it must be evident that the associated risk is controlled and that there is no suitable alternative.

3.) There are several exceptions:

a. Isolated intermediates
b. Scientific research and development
c. Plant protection products, biocidal products, motor fuels
d. Fuels
e. Cosmetic products
f. Materials in contact with food

4.) if at some point the authorization is not available, the substance may no longer be used or manufactured

5.) An authorization always belongs just to the manufacturer or importer; as a distributor, the substance subject to authorization must be obtained from them or a separate application for authorization must be submitted.

Restriction

1.) A restricted substance may only be used under special circumstances. The exceptions are regulated separately for each individual substance/compound and can be found in Annex XVII of REACH.

2.) The restriction does not apply to substances used in scientific research and development.

7 Conclusion and Summary

REACH is a comprehensive regulation that contains many exceptions and is therefore very complex. Not only legal skills are required, but also a scientific background. REACH aims to collect and make available data on chemicals. A lively exchange of data should be supported and alternatives for substances of high concern should be found by means of restrictions, which makes the objectives desirable.

The biggest difference to the Cosmetics Regulation is the different regulations regarding animal testing, which is in principle prohibited for cosmetic products. However, it must also be said that under REACH, too, animal testing should be the last option. The transfer of information along the supply chain is also not required for cosmetic products. In addition, there is no need to apply for authorizations for SVHCs, provided that the specified concentration in such products is not exceeded. In summary, therefore, the two regulations are far apart in terms of costs, as the authorization fees are very high. Costs for safety data sheets and in most cases for animal testing also do not apply to cosmetic products.

However, REACH already interferes with the Cosmetics Regulation to a certain extent. This concerns registration and the chemical safety report for environmental hazards. Animal testing is also prescribed when it comes to the safety of employees in the production of cosmetics. In order to avoid additional animal testing, the general ban in the Cosmetics Regulation makes sense. However, the significantly different costs incurred by substances covered by the two regulations should not be neglected. If an application for authorization for substances of very high concern had to be made for cosmetic products as well, cosmetic manufacturers would also be forced to find alternatives for these substances and people would not constantly come into contact with them, even if the concentrations of such substances mentioned were considered safe.

The guidelines that were made are intended to provide a rough overview of the subject matter and thus serve as a first aid.

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