Incentives for a Dialogue on the Safety of Cosmetic Products

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Abstract

A considerable amount of cosmetic ingredients are industrially manufactured chemicals that also find application in washing and cleaning agents, pharmaceutical and other goods and are thus also affected by a comprehensive European substance policy. There is a considerable lack of knowledge about the properties and risks of chemicals, which has prompted the European Commission to initiate a process to reform European chemical legislation, which resulted in a proposal for a new approach in perceiving and dealing with these risks. A study was carried out by the IFZ on behalf of the Austrian Ministry of Social Security and Generations in order to analyse critical interfaces and discrepancies between cosmetic legislation and present and future chemical policy and to start a discussion about this topic. The study started with a series of interviews with cosmetic experts from authorities, the cosmetic industry, health care and consumer protection institutions. These interviews were analysed in a report together with literature screenings and case studies. It was the intention to pool and present appropriate 'questions' and give incentives for a further discussion process. A subsequent step was to host a workshop bringing together stakeholders at a European level to discuss some of the issues revealed.

A separate legislation for cosmetic products

Cosmetics are applied to the skin and mucous membranes. As they are associated with wellness, health and youth there is a specific perception of them by the consumers. They are generally assumed to have no adverse effects on human health. Since there is a *very near to the body* context of use and a specific perception of their functionality a separate (*sectoral*) legislation was developed within the European Union laying down a framework of definitions and rules about cosmetic products and their ingredients. The legislation provides basic criteria for product safety and data provisions and includes lists of substances which are subject to

restrictions, bans or specified applications. According to the core element of this legislation, Directive 76/768/EEC (Cosmetic Directive), *a cosmetic product must not cause damage to human health*. This implies that there must be sufficient toxicological knowledge about cosmetic ingredients and their possible reaction products to exclude negative impacts on human health. The responsibility to comply with this requirement is mainly assigned to the manufacturer of the product, who must assess safe product use and guarantee that his product complies with the criteria laid down in the Cosmetic Directive.

Cosmetic products may be well defined and discerned from other consumer goods, but this is not the case for the cosmetic ingredients. To give an impression of the dimensions of this issue: about 37% of more than 6000 substances included in the *Inventory of Cosmetic Ingredients* (SCCNFP 2000) are also listed in the EINECS (*European Inventory of Existing Chemicals*) and therefore covered by the provisions of Directive 67/548/EEC and Directive 76/769/EEC. If such substances are applied in products they must be labelled according to their hazards, they may even be restricted or banned. If applied in cosmetics, however, they are exempt from these measures. Instead, they are regarded as cosmetic ingredients and consequently subject to a separate risk assessment considering specified human health effects and defined exposure situations (SCCNFP October 2000).

Do different legislative approaches ensure the same protection level?

The term *risk* is predominantly applied to the controlling, description and handling of the hazardous impact of substances and products and forms the basis of the *risk analysis* concept. The impact of this concept on the regulatory practice is presented and discussed in a report of the Scientific Steering Committee (European Commission 2000). Risk analysis is thought to be an iterative process starting with questions and observations arising from monitoring and surveillance. For instance, a monitoring result may be the fact that a substance causes a significant

amount of allergic reactions and therefore constitutes a call for action. Such findings flow into a risk assessment procedure including evaluations and conclusions followed by risk management measures. Risk assessments at a European level are commonly performed by advisory institutions (i.e. Scientific Committees), their results being considered as recommendations for the legislator. The management of risks as a legislative process is initiated by the European Commission; other decision makers participate in this process depending on the impact of the measure (national authorities, European Parliament and the Council). According to this, cosmetic legislation may be perceived as a sort of risk management. From this point of view there is no fundamental difference to chemical legislation and risk assessments of cosmetic ingredients should not lead to results different from those obtained by chemical regulations.

The study (Klade 2000) and the workshop tried to reveal whether separate risk management approaches (i.e. marked off legislations) shift the *toxicological* perception of the same substance and lead to different conclusions in the risk management. During the course of the enquiries it became obvious that some of the discrepancies between cosmetic and chemical regulations correspond with a slightly different use of terms. In principle the terms *risk* and *safety* may be used in a complementary way (i.e. absence of risk means presence of safety), but cosmetic legislation as well as the corresponding assessment reports predominantly prefer the term *safety* or *safe use*. These terms obviously generate different pictures and connotations. Keeping in mind the application context (on the body, nearly every day application) the term *risk* may not be attractive for products such as cosmetics, since they may be associated with *danger* and *hazard*. On the other hand, the term *safety* is not associated with *little risk* or *controlled risk* but with *no risk*.

One topic of the workshop discussion and also of expert interviews was the relevance of the determination and classification of hazards. For instance, chemical regulations (Directive 76/769/EEC) automatically demand a ban on substances with proven carcinogenic, teratogenic and mutagenic potential (CMR properties) in consumer goods. On the other hand, the same substance applied in cosmetics requires a case-by-case evaluation including exposure considerations—which does not necessarily

lead to a ban. Apart from regulatory measures, this different approach may lead to the impression that cosmetic regulations are less precautionary. In the workshop discussions this position was adopted by stakeholders representing consumer protection issues, while it was the opinion of the industry that *safe use* can also be determined by a safety (risk) assessment including exposure considerations.

The debate on how to deal with CMR properties in substances helps to describe a fundamental problem in chemical policy: How precisely can adverse substance effects be foreseen and what must be done if there is not enough knowledge to make such a forecast? The most commonly applied toxicological principle is to compare the dose (amount) of a substance applied to and reabsorbed by a person with the dose of the same substance creating no long-term adverse effects in animal trials (No Observed Effect Level – NOEL). If the reabsorbed dose is below the NOEL, the substance is considered to be safe for use. This principle also forms the basis of safety/risk assessment in cosmetic regulations and works rather well as long as threshold values can be defined. A risk management may set limits for substance concentrations in products according to the established threshold values. Yet often no specific threshold values can be given for substances with mutagenic or carcinogenic effects. Epidemiological studies reveal that professional hairdressers have an increased risk of contracting bladder cancer when working with hair dyes, though the dyes should have been assessed and found to be safe (Gago-Dominguez et al. 2001). To cope with such findings, a more precautionary approach is proposed by policy-makers and outlined in the Chemical White Paper (European Commission 2001). It is the idea that in case of severe potential effects, e. g. CMR properties or long-term environmental hazards (Richter et al. 2001), the evidence of these properties is sufficient to ban the relevant substance. This must be seen independently from dose exposure calculations as previously outlined, since these considerations are not able to express insufficient scientific knowledge. It has been common practice until now to assume that a substance is safe unless an adverse effect (risk) has been proven. In the view of a future chemical policy this perception must be shifted, so that there is no safety assumed as long as doubts or significant data gaps remain.

The precautionary approach considers a substance to be unsafe as soon as doubts arise due to testing or epidemiological findings or if the existence of data gaps constitute such doubts. This may be sufficient reason to take immediate risk management measures instead of extending assessment procedures.

Considering uncertainties in scientific knowledge benefits sustainable development and is known as the *precautionary principle*. Meanwhile there are strong indications that this principle will be integrated in cosmetic regulations. In 2001 the SCCNFP, the advisory scientific body of the European Commission concerning the assessment of cosmetic ingredients, published an opinion wherein they agreed in principle to adopt the approach taken in the chemical regulations, at least for substances with proven CMR properties (SCCNFP September 2001).

Pros and cons of consumer information about cosmetic products

It is assumed by legislation that the manufacturer must evaluate his cosmetic products and document this in a dossier. Companies must guarantee that their products are safe for use and represent a negligible toxicological risk. As mentioned before this claim is outlined in article 2 of the Cosmetic Directive: *A cosmetic product must not cause damage to human health*. Yet the issue of cosmetic ingredients causing allergic and also other dermatological reactions shows that this claim is hypothetical in daily practice. A considerable number of cosmetic ingredients, such as fragrances and preservatives, cause allergic reactions in consumers. Although the ratio of affected persons to the overall quantity of consumers may be rather low, such adverse effects are severe. Allergies are irreversible and cause cross-reactions. This means that an affected person reacts to the same substance in all types of products. To give consumers the possibility to avoid such substances, it became necessary to provide information about the cosmetic product ingredients. As a risk management measure, a compulsory list of ingredients (with the exception of perfume components) in descending order of their weight must be added

to the product by label, leaflet or card. This obligation is considered to be a great progress in cosmetic legislation and serves as a model for other regulations.

On the other hand, and as mentioned above, there are no product labelling requirements according to Dangerous Substance Directive 67/548/EEC since cosmetics are exempt from this obligation. Consequently no information is provided about the environmental hazards of cosmetics. The study surveyed the environmental properties of some UV filter substances, because they fall under the provisions of the Cosmetic Directive and an immediate entry in the aquatic system can be assumed (Hany & Nagel 1995; Nagtegaal et al. 1997). It was shown that the release from chemical classification and labelling according to determined environmental hazard properties means a loss of product information. This information gap is not compensated by the chemical regulation. Critical ecological properties, such as bio-accumulative potential and insufficient biodegradability remain unconsidered in cosmetic risk assessment. It is proposed that this gap should be closed via an Integrated Risk Assessment screening for any possible adverse effects. A harmonisation and coordination of chemical and cosmetic regulations will be a requisite for this endeavour.

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