## Initiating a Dialogue about Safety of Cosmetic Products

With this lecture I can only give a few glimpses on a study that I performed on behalf of the Austrian Ministry of Social Security and Generations in 2001/02. It was one ambition of this study to analyse interfaces between cosmetic and chemical regulation by means of literature screening and case studies. The study also wanted to challenge how cosmetic regulation should react to new criteria in substance policy and risk analysis as there are: Precautionary principle, substitution principle and integrated risk assessment. This seems justifiable since serious reforms in the European chemicals as well as food policy are under way. These reforms are outlined in white papers (e.g. Chemicals White Paper).

The term „cosmetics" is associated with make up and face masks, but also shower gels, hair dyes, soaps and sunbathing products are covered by the corresponding legislation.

Since these products are applied to the skin and the mucous membranes, there is a certain perception of them by consumers. Cosmetic products are associated with wellness, health and youth and it assumed that they generate no adverse effects to health.

Since cosmetic products are so special, a separate legislation has been developed within the EU. Core element of this legislation is Directive 76/768/EEC including several Annexes. This Directive lays down definitions what a cosmetic product is allowed and intended to do (...applied on different parts of human body to clean, perfume or keep a good condition...). Further basic criteria for product safety (data provisions) are given together with lists restricting, limiting or banning cosmetic ingredients.

**What is the target of legislation?** The target is laid down in article 2: "...a cosmetic product must not cause damage to human health...". Since cosmetic products are often complex mixtures of ingredients, this means:

- There has to be "sufficient toxicological" knowledge about the applied ingredients and possible reaction products.
- The "toxicological" knowledge has to be sufficient to make a scientific sound risk assessment to guarantee the legislative "target".

To give an impression about dimensions: There are more than 6000 substances included in the *Inventory of Cosmetic Ingredients* (i.e. list of substances declared by the industry to form part of cosmetic products and published and updated by the EU Commisssion). Yet the need for assessments is yet reduced by structure/activity considerations (this means, that certain chemical structures correspond with high/low toxicological risk). On the other side this is complicated by the fact that some types of ingredients are complex mixtures (perfumes may comprise of several hundred different chemicals), or contain impurities (plant as well as synthetic products).

Now I want to digress a little bit and loose some words about the use of the terms "safety" and "risk" within cosmetic regulation, since it is a good example how terminology can

influence anticipations and perceptions: Cosmetic regulation (e.g. legislation, documentation) prefers to use the term "safety". Alternatively the term "risk" can be used, but this term is associated with "danger" or "hazard". Keeping in mind the application context of cosmetic products (very "near" to the body, nearly daily application) the term "risk" is not as attractive as "safety". Basically "risk" and "safety" are complementary (safety exists if there is no or negligible risk), but it was a result of my evaluations that there are good reasons to switch over to the term "risk":

- Theory of risk analysis is theoretically describing risks. Risk analysis consists of three subsequent steps and according measures, the whole process is iterative (always starting again with new assumptions). The three main steps in risk analysis are risk assessment (evaluations and conclusions) followed by risk management (decisions and measures). Since the process is iterative new questions are formulated basing on monitoring and surveillance of products and ingredients. The whole process is essentially supplemented by risk communication.
- Applying this theory can lead to a better understanding what cosmetic legislation is doing. Therefore cosmetic legislation can be perceived as a risk management measure and is therefore not fundamentally different from other risk management measures such as chemical legislation. Existing differences are not essentially natural but have to be justified.
- The risk assessment of cosmetics is not fundamentally different from that of chemicals and if it there are differences, they have to be justified too. This is not a theoretical problem alone but of great relevance (e.g. different assessment of CMR properties in chemical and cosmetic legislation).
- The risk analysis uses a rather harmonised set of terms, enabling, as far as possible, a comparison of risks.
- Since risk communication forms an essential part of theory, it is easier to debate how important stakeholders deal with this task.

As mentioned before there has to be sufficient toxicological knowledge about cosmetic ingredients. **How is this guaranteed and who is providing this knowledge?**

Two stakeholders play a core part in this issue:

- The Scientific Committee on Cosmetic Products and Non-food Products intended for Consumers (SCCNFP): It acts as an advisory body for the Commission mainly on request. Risk assessment of "critical ingredients" is done by this Committee and may lead restrictions and use limitations, but also to a certification of their safety. For instance only preservatives or UV filters assessed by the SCCNFP are allowed in cosmetic products and therefore listed in the Annexes of the Cosmetic Directive 76/768. The risk assessment results are presently published in the Internet.

- Cosmetic Products have to be assessed by the manufacturer himself (normally he delegates this task to a specialist) basing on a toxicological assessment of their ingredients. There is no public access to these dossiers.

**How is it assumed that the toxicological knowledge is sufficient to make a safety statement?**

Therefore a basic toxicological principle exists: The dose of the substance applied by (exposure) is compared with the dose creating adverse effects in animal trials. This works well as long as threshold values can be defined. To under-run threshold values by a certain extend (safety factors are added) means creating sufficient "safety".

Not specific threshold values can be given if there are certain mutagenic (carcinogenic) or allergic effects. The problem is also complicated if such effects are proven by epidemiological studies. For example a study found out, that hair dyes represent a slightly elevated risk to get bladder cancer for professionals. Is there immediate call for action? There is no answer to this question written down in legislation or the according guidance documents. A discussion about the application of the precautionary principle should be initiated to create a framework for its application.

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