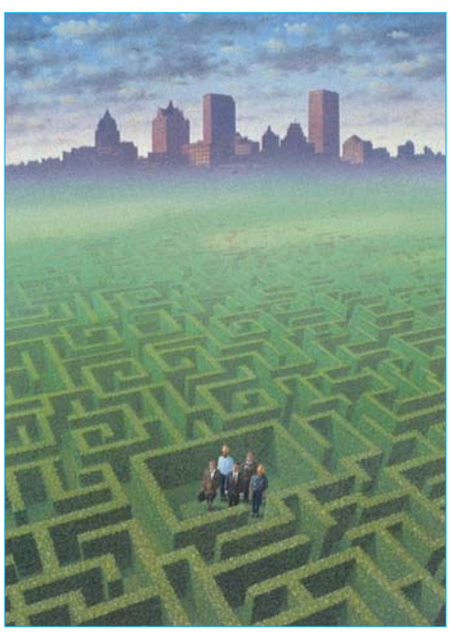
SWISS SCC Conference

"Directions in the Jungle of the Current Cosmetics Relevant Legislation"

Olten, Switzerland, 11th November 2008



The subject matter of the SWISS SCC conference at the end of 2008 was "directions in the jungle of the current cosmetics relevant legislation" and has revealed relevant paths out of this labyrinth. This topic was of high interest for members of the SWISS SCC (Swiss Society of the Cosmetic Chemists) and the SKW (The Swiss Cosmetics and Detergent Association) as more then 80 members of both associations participated. In the future the SWISS SCC and the SKW will increase their ref. cooperation.
The legislation and regulations to assure safety of man and the environment are becoming more complex and manifold. This is not only but particularly valid for cosmetics.

Cinzia Vela, Impag AG, Zürich, Switzerland concentrated in her speech on the "REACh implementation in Switzerland". Switzerland, being located in the middle of Europe has high trade relationships with many European countries purchasing, selling and producing products and raw materials. Impressively *Cinzia Vela* highlighted various scenarios of decisions including the risks or advantages, as i.e. the shifting of REACh into a daughter company or the question of allocation an exclusive agent.
The company Impag AG, Zürich, Switzerland, offers consulting in any kind of cosmetics legislations and regulations, especially also in the sector of REACh (www.impag.ch)

Birgit Huber, IKW, Frankfurt, Germany, highlighted the "Revision of the EU – cosmetics guideline". Till now the targeted simplification has not really been visible. Publication of the cosmetic decree (KVO) is planed in the first quarter of 2009. New is an extensive list of "definitions". Safety aspects have been tightened. The safety assessor becomes even more important, the IKW (Industrial Body Care and Detergent Association, Germany) offers special courses and an Internet-homepage forum for safety assessors. The trade/distributors have to take more responsibility ref. documentation and conformity. cGMP/DIN EN ISO Norm 22716 is the base for production. The new KVO will be implemented 36 months after publication. The use of nano-particles is still under discussion.

Andrea Weber, Dr. Babor GmbH & Co KG, Aachen, Germany, showed the "Core elements of a safety assessment". Based on paragraph 5b of the KVO, a proposal of safety assessment has already been published by the DGK (German Society of Cosmetic Chemists) in the *SÖFW-Journal*, **131**, 8 (2005). The 3 core elements mentioned therein, i.e. the product characteristics, the safety assessment and the documentation respectively the explicit validity are accepted by the Authority in Germany: The authority examiner must be enabled to trace the safety assessment. If "higher" numbers of adverse reactions occur in the market, the safety assessment has to be renewed/reworked. A safety assessment nevertheless is not based on a rigid "check list". Each product has to be individually considered and assessed separately.

The speech of *Dr.-Ing. Hartmut Schiemann*, Procter & Gamble Service GmbH, Darmstadt, Germany, concentrated on "GMP experiences" in the past, present and future. From a historical point of view GMP derives from the pharmaceutical sector, but already plays a role in cosmetics starting mid of the 90's, when the IKW published a manual and the Colipa the ref. Guidelines. Since the beginning of 2008 the statutes of the norm DIN EN ISO 227156 have been binding for cGMP. GMP is an instrument to assure the quality and the reproducibility, all production steps

Picture: *Participants in the auditorium.*

Picture: *Speakers Andrea Weber and Dr.-Ing. Hartmut Schiemann.*

Picture: *Auditorium*

incl. process control and retraceability. The norm however is not tailor-made. It offers the producer in cosmetics some free scope. According to the norm DIN EN ISO 227156 the major elements of cGMP are in the sector of organisation, staff, education, training, facility, equipment, material flow, production, quality assurance, dealing with complaints and internal or external controls and audits. The norm / cGMP has to be adapted to the company specific requirements, always also considering common sense and self responsibility.

Dr. Brigitte Zimmerli-Matter, PCR Pharmaceutical Consultancy in Registration GmbH, Solothurn, Switzerland, shared her knowledge of "cosmetics in the regulatory gray zone" with the participants. Even if cosmetics, pharmaceuticals, medical devices and food theoretically seem to be clearly regulated, there are gray zones in practice. Cut offs in some cases are very difficult. Therefore each product has to be individually judged based on clear criteria ref. formula composition, pharmacology, intended use, product presentation and user risks. Depending on the different interpretation it could be possible that one product is categorized differently and legal proceedings have to come in to clarify it. Gray zones are i.e. in itching, impure skin, "cosmeceuticals", skin bleaching, brittle hair or split nails, especially the territory where "beauty from within" is touched.

Dr. Andreas Weber, Federal Office for environment, Bern, Switzerland, introduced the topic of "Requirements of the chemical law to the environmental compatibility of cosmetics". The legally necessary safety assessment of cosmetics (KVO) only refers to human safety. With regard to the environment, the environment protection law is binding (USG SR 814.01) and on decree level the chemical decree (ChemV, SR 813.11). Ref. REACh the environmental compatibility of materials has to be assessed additionally. The principle of self control plays a major role in Switzerland in contradiction to the EU. The manufacturer is primarily responsible. His duties are to fulfil basic requirements of data collection and of data assessment ref. environmental hazard and risk. The assessment of perfumery components i.e. is based on the official assessment according annex 1 of the guideline 67/548/EG, of the EFFA code of practice, the US-EPA calculation program and/or the REACh decree, the PBT candidate list.

To summarize : The jungle of the cosmetic legislation has been somewhat cleared at the end of this conference day – even if an open plain still seems to be far away on the horizon. However the "creativity of the jungle" also offers valid leeway in cosmetics. Each person working in cosmetics can fill this space in a positive way and on their own responsibility, obeying principle rules and legislation. The safety of man and the environment should be at first place to assure a future worth living for us and for further generations.

Picture: *Catherine Schneider, Vice President of the SWISS SCC.*

Activities of the SWISS SCC in 2009/2010

Usual conference language is German.

- 16.-17.01.2009: Annual meeting/general assembly, Pfäffikon, Switzerland "True Lies – Wahre Lügen"
- 31.01.-07.02.2009: SWISS SCC Winterseminar, Champfèr, Switzerland "Kosmetik im Dienste von Schönheit und Gesundheit"
- 10.11.2009: SWISS SCC Advanced Training, Olten, Switzerland – topic will be announced in spring 2009
- 05.-07.05.2010: Forum Cosmeticum in Interlaken, Switzerland

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