



The new regulations
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microscope

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The new EU Cosmetics Regulation

Safety, responsibility, animal tests, and more



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Will the lack of alternative methods reduce the innovation abilities of the European industry?

What are the new requirements with regard to safety?



Dr. Gerd Mildau, responsible for cosmetics at the German Chemical and Veterinary Investigation Office (CVUA) in Karlsruhe,

Germany: In the new Annex I of the regulation the Commission has clearly structured and defined the contents of the safety assessment for the first time. The safety report will now be obliged to contain the cosmetic product safety information and the related safety assessment will be presented as a logical conclusion to the safety information. To make the content easily understandable the Commission will publish guidelines where all criteria speci-

What changes are expected in the areas of safety, responsibility, animal testing and advertising with the introduction of the new Cosmetics Regulation? Dr. Gerd Mildau of the CVUA and Birgit Huber of the IKW give us some clear answers in an interview with COSSMA editor Angelika Meiss.

fied in Annex I will be explained in more detail.

And what does this mean in concrete terms for the safety assessment?

Mildau: The safety assessment will have, in future, a higher status. The safety assessor must be able to meet certain specific requirements to fulfil this important and scientifically demanding task. He will be required to take responsibility for his legally binding expert opinion that the product is safe. It is of importance to know that nor Annex I neither the relative guidelines, constitute checklists that are followed point by point in this sequence. They serve only as a valuable aid helping the safety assessor in his work. He can also build up the assessment in a different way. The important point is that all of the requirements are met, and when concrete data may be lacking the safety must be ensured and firmly based, e.g. by drawing conclusions by analogy. In Germany this system has been predominantly practised for many years. As a result of there being numerous training courses and discussion for the quality of the safety assessments has improved steadily in recent years. It is therefore not necessary to re-work existing safety assessments if they meet the requirements of Annex I.



Birgit Huber, deputy director of the IKW (German Cosmetic, Toiletry, Perfumery and Detergent Association), Frankfurt,

Germany: In future it will also be made easier to access the product informa-

tion (a new section in the regulation called "Product Information File") for competent authorities: Article 11 (3) of the regulation requires that the information will be easily accessible at the address of the responsible person given on the label. If more than one address is given then the address of the responsible person where the competent authorities can check the necessary data, will be highlighted.

What has changed with regard to product responsibility?

Mildau: In this regulation the responsibility along the supply chain is



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Its increased importance has made the safety assessment a complex and scientifically demanding process

more specifically detailed than in the existing directive. However, in practice, for manufacturers, distributors and importers in terms of the definitions of the regulation there is no real basic change. For example the duty of proof for distributors can be limited only to such labelling deficiencies that can be easily recognised by them. The duty of declaring unsafe products to the authorities, which until now was always included in general product safety law, is now directly included in European cosmetics legislation. A new aspect is that the traceability of cosmetics within the supply chain is specifically regulated.

Huber: If normal delivery documentation is kept for 3 years then this duty is already being fulfilled. To make it more transparent who in the supply chain will be responsible after the introduction of the Cosmetics Regulation a detailed guide is being assembled by the European cosmetics association.

The German version covering cosmetic products is available on the IKW website at http://www.ikw.org/fileadmin/content/downloads/Sch%C3%B6nheitspflege/Leitfaden_Verantwortlichkeiten_02_2013.pdf for download. The English version can be found at <https://www.cosmeticseurope.eu/publications-cosmetics-europe-association/guidelines.html?view=item&id=89>.

How does the new notification procedure work and what are its advantages?

Mildau: By July 11th 2013 all of the products being marketed must be notified via the CPNP data base. This data base fulfils in principle two aspects: On the one hand Europe-wide toxicology centres will have the necessary information required to be able to offer strongly-founded advice about a intoxication, and on the other hand the competent authorities have a broad overview of the products that are on the market.

Huber: Previous experience has shown that there may often be some small difficulties at the first registration, but the system is quickly found to be easy to handle. Meanwhile there is a new electronic interface available which allows data input direct into the CPNP.

What changes are there with respect to animal testing and what will be the consequences for the cosmetics industry worldwide?

Mildau: Since September 2004 animal testing for finished products has been forbidden in the EU; in Germany already since 1998. Furthermore it is also forbidden to market products that have been tested on animals. Animal tests for ingredients of cosmetic products are banned since 2009. It is also forbidden to market cosmetic products if the ingredients have been tested on animals. The only exception until March 11th 2013 was for three safety aspects, namely repeated toxicology, reproductive toxicology, and toxicokinetics. For these three endpoints no alternative methods are available. This approved delay has now expired.

Huber: The German cosmetics industry is one of the most innovative industries. But: it is possible that in the medium to long term the number of innovative cosmetics will reduce and the EU cosmetics industry will find itself less well placed against other markets and suppliers. Because the development of suitable alternative methods calls for further long term research it could mean that new, innovative products can still be sold only outside of the EU. This is how all of those involved see the situation. The alternative methods required could also impact on ingredients currently in use, if, for instance, questions posed by scientists or the authorities on the safety of these ingredients can be answered only by carrying out animal tests.

What is new in the field of advertising?

Mildau: Claims for cosmetics already had to be scientifically supported already and must not mislead consumer.

The EU Cosmetics Regulation now expects to precisely define existing requirements as "general criteria". Here the EU Commission, in cooperation with member states, has prepared a



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Promotional claims must respect the following criteria: truthfulness, evidential support, honesty and fairness

supplementary regulation that should be published before July of this year. Therein it is clearly stated that for claims the following general criteria must be followed: truthfulness, evidential support, honesty and fairness. In this way the consumer should be able to make a clear fundamental decision regarding the purchase of a product.


Huber: This regulation is also planned to be extended by specific guidelines that will, by way of concrete examples, explain the criteria to be applied for cosmetics products. These guidelines should, of course, as far as possible, agree with the already harmonised Europe-wide advertising legislation. In Germany commercial competition law is already very heavily applied by the courts. In this way there is already for competitors and competing associations the possibility to forbid, in very short time, the dissemination of misleading advertising claims. This means, in addition to the possibility of a check by the authorities, additional consumer protection.

Further information and a further interview on the new cosmetics regulation from COSSMA 5/2013, page 24, can be found on the Internet (see Internet panel)
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Downloads

Additional information at
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