



The new regulations put under the microscope

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The new EU Cosmetics Regulation

What is really changing?

Dr. Gerd Mildau of the CVUA and Birgit Huber of the IKW explain, in an interview with COSSMA editor Angelika Meiss, what is really new in the Cosmetics Directive, which are the biggest challenges for the manufacturer, and what can be expected with the updating of the substance list and the definition of nanomaterials.

What are the most significant changes in the new EU Cosmetics Directive 1223/2009?



Dr. Gerd Mildau, responsible for cosmetics within the chemical and veterinary investigation office (CVUA) in Karlsruhe,

Germany: Firstly not everything in the EU Cosmetics Regulation has changed. For instance the definition of cosmetics, the intended use and the reasonably foreseeable use of the product, and the requirement for the product to be safe, remain unchanged. An important point, however, is that the safety assessment requirements have been specified.

Really new is an EU-wide product related registration procedure, the so-called **Notification**, plus a **regulation on common criteria for claims**, and a **traceability procedure for products** on the market.



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

Germany: In addition there is an introduction of a **notification on undesirable effects** in cosmetics. Serious undesirable effects must in future be notified to the competent authorities. This refers to such cases which after intended and reasonably foreseeable use a consumer needs, for example, to spend some time in hospital. Such cases are of course extremely rare.

The Cosmetics Regulation also lays down **regulations for nanomaterials**. This makes cosmetics the first consumer products for which this category of ingredients is explicitly regulated.



Oxidative eyelash colorants can continue to be used by referring to the forthcoming new regulations

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What new points will the manufacturer of cosmetics have to note when adopting the major requirements?

Huber: There are already a number of different requirements which occupy the manufacturers at the same time. Firstly the safety assessments have to be adopted progressively, but also the products have to be declared to the **CPNP Notification Database** at the European Commission, which is complex.

Mildau: And with regard to the reporting obligation of undesirable effects: as far as I know German manufacturers have already taken this problem on board in their own organisations to comply with their due diligence. In addition to this, however, there is a new requirement for serious cases. Here the European legislators are attempting to create a cosmetovigilance system. With such a system it should be recognised at an early stage which substances may have a potentially negative effect on human health.

However, such a system can only work if in serious cases it is clearly identified that a cosmetic product was really the trigger to the problem.

Huber: To know all of the relevant facts can be very time-consuming. And if there is no clear result it must not be declared in order to avoid a data cemetery.

The substance lists in the annexes have not yet been revised. Is there a concrete plan set up to do this?

Mildau: Unfortunately the first draft 1223/09 issued in January 2010 contained a few mistakes in the substance related annexes, in particular in some language versions. At the time it was not, however, planned by the European legislators to issue debugged annexes. The first step was to issue the legal text. These annexes represent the status at the end of 2007, the time when the text was put forward to the European Parliament.

Part of the substance lists has since then been updated or an amending regulation should be published quite soon. All of the amendments to the Cosmetics Regulation after 2009 are included. However the errors in the appendices before 2009 must be corrected.

The working group, consisting of experts from member states, from the European cosmetics industry and the Commission, does not have much time left. On July 11th 2013 the full EU Cosmetics Regulation comes into force, including the annexes. Thus by this date everything should be corrected. Until that date the current EU Cosmetics Directive remains in force, with its annexes. However this Regulation must be referred to from July 11th

should the outstanding corrections not be published in time.


Huber: Substance related deviations are sometimes related to changes in the definitions. For this purpose a preamble to annexes II to VI has been created. With regard to hair care products it is, for example, that eyelashes, as per the new definition, do not fall within the scope of hair care.

Because hydrogen peroxide is, however, not specifically approved for use in eyelash products, as from July 11th 2013 the whole oxidative eyelash colorants product group would no longer be permitted.

Based on the collaboration of various interested parties the SCCS has relatively short term issued a positive evaluation of the main ingredients used in eyelash colorant products. The Commission has even presented a leg-

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islative amendment. Even if this text has not been published by July 11th 2013 producers will have the possibility to continue their sales by pointing to the forthcoming regulation.

Which substances are subject to new restrictions?

Huber: In the legislation it is planned that the Annex IV which refers currently to colorants (for the skin or for products themselves) will also be expanded to hair colorants. For this purpose the precursors of oxidative hair colorants are defined in the new legislation as hair colorants. Firstly the extensive risk assessment for hair colorant substances must be completed, and for which there is an ambitious programme from the EU Commission and the industry. The industry has committed itself to submit the data confirming the safety of the hair colorants used to the EU's Commission scientific committee.

Meanwhile the SCCS has already evaluated the majority of the hair colorants used. As soon as all of the substances have been evaluated the positive list will be expanded and then only the substances appearing on the list will be permitted for use in hair colorants products.

Mildau: The regulations covering nanomaterials are also new, as the implementation provisions of CMR substances. A "CMR substance" is classified in the regulations on hazardous materials as carcinogenic, mutagenic or toxic for reproduction. According to the Regulation even substances classified as CMR 1A or 1B may be used in cosmetics preparations in exceptional cases, i.e. strict requirements are to be met.

There should be in general according to the interpretation of the EU Commission a dynamic reference to the chemicals legislation of forbidden CMR substances. In Annexes III to VI of the Cosmetics Regulation only substances with a known CMR history will be included. These will be only substances evaluated by the SCCS and approved via the comitology procedure (this is the Standing Committee procedure in line with article 32) with restrictions such as percentage limits, or warnings, and with a requirement for a regular evaluation.

CMR substances not approved by the SCCS will no longer appear in the negative list of Annex II. Thus companies, and in particular the safety assessors, must have the chemicals legislation permanently in mind.

What new requirements are there in relation to nanomaterials?

Huber: Although a definition of nanomaterials is included in the cosmetics legislation this definition does leave a few unanswered questions. There is also a horizontal definition from the Commission relating to all products concerned. Because there are so far no official explanations with regard to horizontal recommendations the European cosmetics industry has created its own guidelines for interpretation.



Finally all substances classified as nanomaterials must be notified separately since January 11th 2013 unless they are in the annexes of the regulation subject to authorisation or they will have been specifically authorized.

Such authorisations do not yet exist but for the most commonly-used substances, such as titanium dioxide and zinc oxide, approval is expected by July 11th 2013.

Until an official definition is published we recommend companies to use the guidelines of the European cosmetics industry as a guide. Within the notification full toxicological data on the nanomaterial must be submitted in order to confirm the safety of the substance. There is a special procedure for this within the CPNP process.

Mildau: Another new point is the marking of nanomaterials from July 11th, 2013, within INCI. Here the name of the affected substance will be expanded with the suffix "nano" in parentheses. Within the product information file a manufacturer must document which nanoparticles are used. Analysis of nanoparticles in the final product is another big challenge. Whether it can be achieved will be known when nanomaterials are precisely and officially defined.

gerd.mildau@cvuaka.bwl.de, www.cvuaka.bwl.de
 bhuber@ikw.org, www.ikw.org

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