Nanomaterials, notification requirements and more

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Cosmetics industry as a pioneer in consumer information about the use of nanotechnology

An update on the EC Cosmetics Regulation

What do the provisions of the new EC Cosmetics Regulation mean in practise? Birgit Huber of IKW and Dr. Gerd Mildau of CVUA Karlsruhe comment on the current status concerning nanomaterials, the notification requirements and the Transatlantic Trade and Investment Partnership, TTIP.

What aspects of the new EC Cosmetics Regulation have turned out to be a challenge for the cosmetics manufacturers in practice and what problem-solving approaches are available?

Birgit Huber, Deputy Director General – The German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW), Frankfurt: Already the previous Cosmetics Directive had placed high demands on the manufacturers of cosmetic products for many years. In particular in terms of safety, the requirements had already increased considerably before the entry into force of the EC Cosmetics Regulation. Information events and continuing education programmes* have, however, provided the essential information at an early stage and in a profound manner – in particular also for medium-sized companies. Nonetheless the EC Cosmetics Regulation includes several new provisions which involve an additional bureaucratic effort for manufacturers, such as the product notification to the CPNP database.

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Notification requirement for manufacturing site continues to apply

What challenges result from the current status in respect of nanomaterials for the cosmetics industry and how do the surveillance authorities check compliance with the provisions?

Birgit Huber: On the one hand, the Cosmetics Regulation requires since July 11th 2013 that all ingredients which are included as nanomaterials are labelled. Cosmetic products hence play a pioneering role by proactively informing consumers on the product packaging about the use of this technology. Apart from labelling, there are other requirements to be met by cosmetic products containing nanomaterials.

Dr. Gerd Mildau, Head of the Central Laboratory for Cosmetic Products at the Chemical and Veterinary Investigation Office (CVUA): Cosmetics with nanomaterials, which are not expressly permitted under the Regulation, must be notified to the European Commission no later than six months before they are placed on the market. In this way the Commission gains a European overview of the nanomaterials used. In January 2014 a catalogue of notified nanomaterials to be continuously updated was supposed to be published. However, this catalogue was not published because the Commission is currently clarifying with various manufacturers whether the nanomaterials notified by them are actually such materials within the meaning of the definition. However, a publication is to be expected soon. The official surveillance body currently checks compliance with the provisions merely by having a look at the product information file.

Based on the specifications of the different raw materials it can be checked whether nanomaterials within the meaning of the definition of the EU Cosmetics Regulation are used. Analysing official samples in the investigation offices is, however, not expedient. Whether nanomaterials of a certain substance are contained in cosmetic products (which would then have to be notified and declared) can only be determined by combining various analytical methods, such as the outer appearance by scanning electron microscopy or Raman spectroscopy, the aggregation behaviour via dynamic light scattering and the particle size frequency distribution by ultracentrifu-

gation, field flow fractionation, single particle ICP-MS or static laser light scattering. All this information is necessary in order to be able to assess analytical results in a reliable manner. Partial results may merely provide useful information to inspect product documents on-site.

According to the supplementary German Cosmetics Ordinance of July16th 2014 the notification of the manufacturing site continues to be required. What exactly has to be done under this provision?

Dr. Gerd Mildau: Yes, that's correct. Based on recital 56 of the EC Cosmetics Regulation, Germany continues to apply the already nationally regulated duty of notification of the manufacturing site. This is not regulated by the EU Cosmetics Regulation. According to this provision, the place of manufacturing and/or first import into the EU must be notified informally (prior to the first import). The notification has to be made vis a vis the respectively competent authorities at the production site and/or at the site of the first import. A list of these public authorities is published on the website www.bvl.bund.de under the keyword "Article 34".

"Whoever manufactures cosmetic products in Germany" is obliged to make a notification in accordance with § 3 of the new German Cosmetics Ordinance. This hence covers all companies which operate their own production site for the manufacturing of cosmetic products in Germany.

Birgit Huber: Since this is a continuation of the existing duty of notification, no new notification is necessary if a company has already made such a notification based on the previous Ordinance (§ 5d of the previous German Cosmetics Ordinance) to the competent authority. The letter with which the notification was made at that time should, however, still be available internally. Under certain circumstances it is recommended to verify whether the public authority to which the notification was made is still included in the above-mentioned list. In cases of doubt, it might be advisable to make a new notification.

Since the German Regulator does not refer in this case to the terms of "manufacturer" or "responsible person" defined in the EC Cosmetics Regulation, this means that companies which do not operate their own production sites in Germany do not have to make any such notification according to the new provisions, even if they act as responsible persons for cosmetic products. As in the past, the notification may also be made through an agent.

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Impact of TTIP on cosmetics

What impact does the international Transatlantic Trade and Investment Partnership (TTIP) have on the cosmetics industry?

Birgit Huber: TTIP is important for the cosmetics industry for many different reasons. At the end of the day, the aim is to counter through a joint approach a fragmentation of worldwide and frequently competing standards. The objective is not to leave the conditions for global competition and hence for our competitiveness and our jobs to third parties. In this connection the recognised high western standards play a particularly important role.

However, it is necessary to still make some adjustments in the meantime. Above all in the field of legislation, a lot remains to be done, since cosmetics legislation in the EU and in the USA are quite different. In the EU there is a proven comprehensive definition for cosmetics products, whereas in the USA there are different definitions, and the definition for cosmetic products is much narrower. An example: many products which are considered as cosmetic products here in Europe are so-called OTCs (over-the-counter drugs) in the USA. These include for instance sunscreen agents and toothpastes. Moreover there are differences in the labelling of products. Here a harmonisation would be desirable in order to avoid a permanent need to adjust product packages. Of course it must be ensured in this connection that consumers continue to be provided with the necessary information. A very important point, which in our view needs to be clarified, concerns the currently different standards regarding safety requirements to be met by cosmetic products. The safety standard for cosmetics is very high in the EU; it is even considered to be one of the highest. I would, therefore, like to stress that we have no interest in this standard being lowered in future.

Dr. Gerd Mildau: I assume that the EU Cosmetics Regulation will not be affected by it. Article 1 stresses after all expressly that for cosmetics products on the European market a high level of protection of human health must be ensured. ■

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*Continuing education events on legal issues can, for instance, be found on https://extranet.ikw.org/ikw-mitgliederbereich.php

Further information can be found on the Internet – see Internet panel

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Birgit Huber of the IKW and Dr. Gerd Mildau of the CVUA give an update on the new EC Cosmetics Regulation in practice

Focus: Cosmeceuticals

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