Claims Regulation

What is new?

What changes does the new Claims Regulation entail and what remains unchanged? These questions are clarified by Dr. Gerd Mildau of CVUA Karlsruhe and Birgit Huber of IKW.

If the hair dye contains in the event of a "PPD free" claim PTD despite similar allergenic properties, this is misleading

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What are the essential changes which were published last year in respect of claims?

Dr. Gerd Mildau, Head of the Central Laboratory for Cosmetic Products at the Chemical and Veterinary Investigations Office (CVUA): Claims of cosmetics products had already so far to be supported by verifiable evidence and were of course not supposed to mislead consumers. The EU Cosmetics Regulation provided, however, for a detailed specification of these requirements as "commission criteria". For this purpose the EU Commission has elaborated, after co-ordination with the Member States, a supplementary **Claims Regulation.** This Regulation describes now in more detail that the claims of cosmetic products must always be truthful, supported by verifiable evidence, honest and fair.

This Regulation is supplemented by Guidelines. Based on concrete examples, the criteria defined for claims of cosmetic products are explained in an illustrative and understandable manner. Annex I specifies: Statements on the duration of a cosmetic effect such as "48 hour hydration" are of course only admissible if the set of evidence supports the claimed duration of the effect.

How do claims have to be proven?

Mildau: The evidence to be submitted by the manufacturer in support of a claim depends on how the claim is formulated. If scientific studies are used as evidence in individual cases in order to substantiate an advertising claim, the Guidelines refer to the state of the art practices that have to be taken into account and to the extent to which the applied methodology is valid, reliable and reproducible. Consumer perception tests, which are very popular for advertising in beauty magazines, must correspond in terms of their design and analysis to the principle of statistics. This means that the new Claims Regulation and the Guidelines offer all stakeholders involved a simplification for the concrete implementation. It would, therefore, be useful to supplement the Guidelines in future on an ongoing and practice-oriented basis.

Birgit Huber, Deputy Director General, The German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW), Frankfurt: We believe, however, that the Guidelines have already been over-interpreted in one respect. It was, for instance, stated that results of in vitro tests may only be used to predict effects in vivo if every claim has been confirmed prior to marketing, as a matter of principle, in an additional test with test subjects. We believe that this interpretation goes far beyond the provisions of the Claims Regulation. If in individual cases the impression is given that an in vivo effect is proven, a one-off basic validation of an in vitro method referred to for this purpose must be sufficient. At the end of the day, the concrete claim and the associated expectation of consumers must be tested on the basis of the criteria specified in the Claims Regulation. Overall, it can, however, be confirmed that the new provisions are in conformity with the already existing competition rules of the European Union and confirm at the same time the already existing practice of the public authorities and cosmetics industry.

How are the specifications checked?

Mildau: This is taken care of by the competent authorities which inspect the product documents during plant checks. If certain claims attract the attention at the investigation agencies in risk-oriented sample investigations, the competent authority can verify in a targeted manner the corresponding proof of action in the product information file with the manufacturer. Since this is an on-site inspection, the knowhow of the manufacturer remains protected. There are many different advertising claims of different kinds, so that surveillance has to set priorities. CVUA Karlsruhe checks the claims on effects mainly in accordance with the following criteria: general information which does not have a major influence on purchasing decisions are less important for us, for instance "for velvety soft skin". However, claims which have a considerable influence on the buying decision of consumers are relevant for us, such as e.g. "pigment spots are visibly reduced within three weeks". We attach absolute priority to the verifica-

tion of claims which also relate to consumer health protection such as "concomitant therapy for neurodermatitis".

Huber: In Germany there is already, in addition to these checks by public authorities, an extremely effective system in place to ensure that the rules of competition law are complied with. Competitors and competition protection societies have the possibility to have misleading claims prohibited by courts within very short periods of time. At the end of the day, this is also for the benefit of the consumers.

What changes are the biggest challenges for cosmetics manufacturers and why?

Mildau: As a result of the new Regulation we now have a basis to check the claims used more comprehensively. Since the Commission has to submit a report on the efficiency of the Claims Regulation to the European Parliament by 2016, the Member States will now conduct an increasing number of market surveillance studies in order to gain an overview of the compliance with the ban on misleading claims. However, there will always be marginal areas in which the question of infringement can be discussed.

Huber: As already stated, there are in Germany already two very effective approaches to surveillance in terms of competition and public authorities. That's why I believe that manufacturers in Germany are not up for any major surprises if they have already carefully worked so far. However, there are other countries in which the control system is not yet as comprehensive, and standards will have to be adjusted there.

What is the state of affairs concerning the "free" claims?

Mildau: Originally, the EU Commission and the Member States had the intention to supplement the existing Claims Regulation by a regulation on "free" claims. This was to ensure that such claims are significantly reduced. At present the Commission envisages, however, only to adjust the guidelines to the Regulation. It is difficult to predict at the moment what the final draft will be. However, it is already clearly misleading if in Scandinavia a hair dye claims to be "PPD-free" and the formulation contains PTD. This is an oxidative hair dye which has similar allergenic substances. Such a product would be objected to by us because the misleading actually involves a health risk. There is a misleading effect within the meaning of an unjustified competitive advantage if a product claims to be "preservative-free" but contains substances which have a clear preserving effect. Furthermore, a claim such as "free from damaging butylparaben" is clearly misleading, because butylparaben is authorised and would be negatively highlighted without justification. But also the less eye catching mere advertising of "paraben-free" can give the impression that parabens represent a health risk. **SCCS*** has once more clarified that the authorised parabens are safe. However, for the moment we do not have a basis for any objection for this form of denigration of substances.

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If the claim "hypoallergenic" is explained, it becomes clear that there cannot be a 100% protection from allergies

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Huber: If the Guidelines were tightened this would involve in our view in particular the problem that it would basically become effective without any transitory period. It would then have to be secured that a tightening does not result in a disproportionate destruction of packaging. This would of course have to be tracked very precisely. In Germany we have already initiated many activities for consumer education concerning the need of preservation. There are two explanatory documents of the GDCh Working Group "Cosmetic Products" which are available on www.haut.de** for consumers.

What is the state of affairs concerning the claim "hypoallergenic"?

Mildau: There was a very clear statement by the SCC of 1998 that a global claim of "hypoallergenic" for cosmetic products leads to belief in a wrong safety and that the use of this claim should, therefore, be discouraged. This position paper, which is unfortunately not published on the website of the SCCS, continues to apply in our view. The Claims Working Group is currently dealing with this issue.

Huber: IKW recommended to its members already earlier to use this claim only if the term is explained in more detail. This interpretation by the IKW was unfortunately not even considered by the SCCS at that time, although such an explanation could clarify that there can of course never be any 100% protection from allergies.

Mildau: A uniform set of rules within the EU would be absolutely welcome. The claim is used differently from country to country. Moreover, manufacturers use the repetitive patch test in order to justify the "hypoallergenic" claim. This test can, however, induce also allergies in the test subjects and is therefore largely rejected in Germany on ethical grounds. ■

*SCCS: Scientific Committee on Consumer Safety
**The mentioned documents as well as further information can be found on the internet, cf. Internet panel

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