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BACKGROUND

Claims: True or false? September's Karlsruher Kosmetiktag

Interview with Dr. Gerd Mildau, Head of Cosmetics Central Laboratory, Chemical and Veterinary Investigation Office (CVUA) Karlsruhe, Germany
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Cosmetic claims: What claims are legal and when do they go too far? 140 experts (industry stakeholders and experts from official investigation laboratories and competent authorities) from Germany, Austria and Switzerland discussed this topic at the Cosmetic Days* in Karlsruhe.

*September's Karlsruher Kosmetiktag 2016, organised by the Cosmetics Central laboratory Chemical and Veterinary Investigation Office (CVUA) Karlsruhe, focussed on the topic "Claims and Truth"

What were the main insights provided by Dr Annemarie Burkhard from the Landesuntersuchungsamt of Rhineland-Palatinate in her update on cosmetic claims?
Dr Gerd Mildau (GM): Being a member of the European claims working group, she provided an update on the latest results of the unpublished guidance draft. If anti-ageing claims clearly indicate a younger-looking appearance after the use of the product, this claim has to be substantiated. An in-use test on humans is required only with this concrete type of claim. It is evident that unfair claims are illegal. This also applies when approved ingredients are denigrated, e.g. certain types of parabens in the claim "without harmful parabens". Claims that are somewhat more general such as "without parabens" or "without triclosan", however, create a legal grey zone. It is true that in the new version of the guideline they are considered to be unfair, but one potential interpretation of this claim is that certain consumers require this type of information to be in line with their chosen personal lifestyle.
It is illegal to claim that a product has "no preservatives" when the product contains multifunctional ingredients with a preserving action.

Dr Andreas Reinhart from Reinhart Rechtsanwälte gave an overview of the latest judicial decisions on cosmetic claims. What was the take-home message?
GM: Dr Reinhart emphasised that neither guidelines nor judicial decisions can be equated with the current European legislation. They only serve as a useful reference point for interpretation. Only judicial decisions issued by the European Court of Justice are as binding as current legislation. Using the example of two rulings issued by the German Federal Court of Justice, he showed that single scientific studies can be sufficient for evidential support. He showed a piece of deceptive packaging to explain that courts have recently considered the consumer as fleeting: eye-catching claims draw their attention, whether they're substantiated or not. When it comes to expensive technical products, consumers tend to be well-informed. He stressed that guidelines are characterised by the fact that there are no transitional periods, in contrast to changes in regulations. After all, guidelines are only recommendations issued by the commission. In his eyes, no judge would accept number games as an argument when it comes to the question whether a claim of "zero percent aluminium" is misleading, in the light of analysed traces of aluminium by an official laboratory. The only thing that counts here is whether the aluminium is an active part of a raw material at the time of production.

Dr Wilfried Petersen from Dr. Straetmans drew up a scenario of the free-from preservatives in view of the guidelines on cosmetic claims which are currently being amended. What were the implications he outlined?
GM: Ingredients that are not listed in Annex V cannot primarily be used for preservation, but they can still have a microbial effect. When such multifunctional ingredients also have a preserving secondary

effect, this complies with Article 2 of the 1223/09 Cosmetics Regulation. The claim "free from preservatives", however, is misleading once a microbiological challenge test has been performed. There are a few products that do not require a microbiological challenge testing, e.g. water-free massage oils. But even in this case, the claim "no preservatives" would be misleading as this is implicit advertising. It would be okay to claim "free from synthetic preservatives" using essential oils but would this be patently honest? It is always a matter of discretion, if the information required for consumers is considered justified.

In what ways have cosmetic claims changed in the past few decades and what should a producer of active ingredients do to claim the efficacy of new active ingredients, according to Angela Kleiner from Croda?

GM: Customisation is the future. A good example is **Shampyou**, a shampoo that consumers can mix themselves with the help of certain ingredients. Consumers expect more and more that products meet their personal needs. This is why consumers seek innovations in terms of efficacy. However, this always involves matching efficacy with skin tolerance and safety. The wish list of consumers also features active ingredients for scars, for hair growth, permanent hair colours without oxidation process, long-lasting antiperspirants and ingredients for improving facial contours. For these claims there are effective state-of-the-art in vivo and in vitro tests that can substantiate marketing claims sufficiently.

How does Dr. Hauschka prove the efficacy of its products, according to Hans-Jörg Rösch?

GM: Dr. Hauschka differentiates between claims that can be objectively supported by sources such as renowned literature databases (e.g. about plant extracts), instrumental studies or clinical tests, and subjective findings obtained by in-use tests or panellists evaluating products. The company uses a modular weight of evidence claim concept. In practise, a combination of instrumental and panellist tests has proved useful. In in-use tests, the rate of approval amounts to between 80 and 90 percent. This acceptance is as important as classical instrumental studies such as Corneometre or Cutometre measurements or the determination of the skin barrier with the help of a Tewameter.

What, according to Bernd Söllner from Emil Kiessling, are the main challenges involved in claim support from a contract manufacturer's point of view?

GM: When using hard claims, it is important to know how reliable data are. The design of a study has to correspond to the actual meaning of a claim. In claims, grammatical nuances have to be taken into account rather often. It is a lot harder to prove the claim "panthenol increases the moisture content of the skin", for example, rather than the claim "the formulation with panthenol increases the moisture content of the skin".

There is nothing wrong with using test results of different studies when formulations are comparable. With claims referring to ingredients, the concentration of an ingredient in a product has to be chosen in accordance with the bio-availability at the site of action. Manufacturers of private label products have to communicate well with the brand owner, who does not necessarily have all of the product information at hand.

What were the main new aspects in the field of prohibited misleading descriptions and consumer expectations, according to Matthias Ibel from IKW?

GM: The interpretation of the claim "without perfume" issued by a German judicial decision has shaped the new version of the claims guidelines so that the claim also refers to essential oils. When talking about preservatives, it is of course important to differentiate between the denigrating "without harmful parabens" and the claim "without parabens". Using this type of claim in the field of preservatives does not do the industry any favours, but it is questionable if it is really misleading for the purposes of article 20 of the cosmetics regulation 1223/09. The consumer could also interpret this claim like this: "The product does not contain parabens and that is something out of the ordinary." The claim "without parabens" can easily be substituted by other substances. This means that there is no legal certainty. Also questionable is the interpretation that the claim "free from animal-derived ingredients" could denigrate certain ingredients; after all, it is a personal choice to lead a vegan lifestyle, and information should be provided for those who do.

In what way could ISO 16128 constitute the risk to be misleading, according to Dr Roland Grandel from BDIH?

GM: When it comes to claims such as "natural" or "organic", the general prohibition of misleading claims in article 20 1223/09 applies as well, even though these claims are not protected by law. However, ISO 16128 only provides technical definitions and criteria for natural and organic ingredients and products. It

defines groups of components as well as production processes. However, the norm does not mention explicitly what natural content makes a natural cosmetics product and what organic percentage makes an organic cosmetic product. ISO 16128 does not tackle either potential claims in terms of natural cosmetics or organic cosmetics or socio-economic criteria such as fair trade. Genetic modification is not banned in general. In addition, there is no limitation for the use of raw materials from dead animals. Due to these inadequacies, Germany is the only ISO member who voted against the draft. The claim "natural cosmetics in accordance with ISO 16128" would be misleading as the norm does not define any shares. Claims about "natural derived ingredients" are a problem, too.

What were the major learnings from Dr Frank Pflüger's (Baker & McKenzie) presentation on the latest court cases concerning the regulation of claims?

GM: Formerly, the German courts often took judicial decisions from medicinal products into consideration for cosmetics, although the intentions of use and the requirements to claims are different. The regulation of medicines stipulates that prescription products shall not be claimed basically (exemption: OTC medicines). Today, however, judging cosmetic claims has become somewhat more specific. In specific cases, claims such as "medicinal cosmetics" or "dermo-cosmetic care of wounds" have been accepted by a German court (Frankfurt 2014, 2-03 O 402/13). Apart from this, the Higher Regional Court of Hamm came to the conclusion that ISO norms or private labels do not define any regulations. Eye-catching "free from…" claims are still criticised as they tend to influence consumers considerably. Therefore he recommends for cosmetics the "pull-approach" coming from medicines. The judicial decision issued by the European Court of Justice concerning the "pull-approach" has caught the attention in the field of medicinal products. In 2011, the EuGH decided that the consumer is quite capable of obtaining promotional information for prescription medicines from the Internet, whereas the "push-approach", which means that the industry actively provides the consumer with promotional information, has been deemed illegal. We have to wait and see in the future how courts will judge pushed claims such as "free from parabens/triclosan" in the light of the new guideline, where they are discouraged.

What, according to Dr Reinhold A. Brunke, are the most important findings from the EU working groups on claims?

GM: His initial statement was that there is no need for "free from" claims. In his view, marketing should emphasise the numerous advantages of a product instead of stressing "empty" cosmetics. He also considers the debate about multifunctionals as pointless. Even if substances have a preserving action as a secondary function, he thinks that it is not justified to claim "no preservatives". The same applies for menthol and benzyl alcohol and the claim "without perfume". "Free from" claims should be only used when a benefit for consumers has been documented in the absence of a substance. Dr Brunke also explained that organisations and the press often unjustifiably defame substances such as parabens, UV filters, palm oil, talcum, vitamin A, silicon oils, fluorides, nanomaterials and aluminium salts.

How did the product-testing organisation Stiftung Warentest come to the conclusion that anti-wrinkle claims don't work, and what was the reaction to this?

GM: In its testing report from January 2016, the product-testing organisation considered modern instrumental testing procedures as inadequate for proving the claim "visible effect within four weeks". The advisory committee preferred a randomised half-head test with 30 women and blinded test samples against a standard moisturising cream for 4 weeks and an application twice daily as a suitable testing design. The documentation was done with the help of high resolution photos with standardised shooting conditions (before and after comparison).

The result of the randomised evaluation by three experts: none of the products showed a visible effect. There were no visible changes in the depth of lines and wrinkles after four weeks of having used the product and the standard cream. This is why all nine creams were rated "poor". The experts from testing institutes and from the industry claimed that the result was not surprising at all, as the chosen testing strategy was not suitable. The real anti-ageing effect can only be shown with the help of instrumental methods. The discussion showed that in this case the marketing department has to be criticised, as claims such as "visible effects" cannot be proven in short periods of time. The example clearly showed how important it is for cosmetic experts and those in charge of marketing to agree on a common testing strategy and interpretation of the results.

In what way did the ecological product testing magazine Ökotest analyse the anti-ageing claims of natural cosmetics products, and why were the products not classified as inadequate?

GM: Ökotest pursues a different strategy from the product testing organisation Stiftung Warentest.

They do not test the anti-ageing efficacy, as they are convinced that there is no way of preventing the natural process of skin ageing. Even if there were products preventing skin-ageing, this influence on the dermis would not be in line with the definition of a cosmetic effect. Ökotest instead concentrates on analyzing whether ingredients comply with the cosmetics regulations or if they are capable of producing undesirable effects. Allergy triggers, such as fragrance allergens, formaldehyde, Isothiazolinones, parabens (some parabens can act as endocrine disruptors) and products with mineral oils are increasingly banned. In addition, Ökotest looks at the claims and asks the producers to send information to prove the claims. Most producers only supply in vitro studies. The discussion after the presentation showed that due to data privacy protection, the producers only present information to the competent authorities, so the fact that this information is not sent to the magazine does not mean that claims cannot be substantiated.

What, according to Dr Ulrike Heinrich from DermaTronnier, are the major methods used to measure the cosmetic effects?

GM: First of all, she stressed that a high quality anti-ageing product should take all factors that lead to skin ageing into consideration. After all, an increased inflammation process of the somatic cells (also skin cells) increasingly damages the cells and finally leads to cellular death. Anti-ageing products should have a skin-firming, wrinkle-reducing, moisturising, anti-irritant, and whitening effect. Some day care products should also protect from UV light. This means that a number of different active ingredients have to act within a suitable galenic formulation. When testing the quality of such a product, all those aimed improvements should be tested instrumentally as well as by the subjective opinion of the user. Modern testing methods include SELS (Surface Evaluation of Living Skin), moisture measurement with the help of a Corneometre, measurement of the transepidermal water loss (TEWL) to test the barrier performance of the skin, and photos to test the attractivity as well as measurements of reddened skin or pigmentation with Chromametres.

The CVUA Karlsruhe examined the safety of caffeine-containing slimming products. What was the assumption and what was the result according to Evamaria Kratz?

GM: The cosmetics regulation does not limit the use of caffeine in cosmetics as long as the product is safe. The efficacy studies by various producers showed a differing content of percutaneous resorption (between 4 and 70%). The NOAEL (No Observed Adverse Effect Level) (rat, 150 mg/kg bw/d) and the different assumptions on exposure led to a margin of safety (MoS) of between 12 and 1510 at a content of 5% caffeine. The study design concerning the improvement of cellulitis leads to a lot of questions which in many cases could not be answered by the producers. This led to the conclusion that in many cases caffeine-containing anti-cellulitis creams either have an inadequate safety assessment or the studies have proven that their effects are often scientifically not sound.

What, according to Panagiotis Steli-opoulos (CVUA), means scientifically proven? What role do scientific studies play and what is the role of statistic evaluations? And how high is the risk of misinterpretation?

GM: Before performing a scientific study, it is relevant to define the scientific problem very precisely in order to eliminate factors that might falsify the results. Aspects to take into consideration are: an open study, a simple or a double-blinded study, number of panellists, key assumption about the distribution of data (e.g. Gaussian normal distribution). The interpretation of the results can either confirm the hypothesis or not. Statistics serve to maintain the degree of confidence in the results. The constructed example of a statistically-proven significant reduction of wrinkles showed clearly that there can be a spurious correlation. This shows that a statistical analysis alone does not prove anything. It merely indicates that there is a potential correlation. Without a logical and consistent theory which explains the causal relation between cause and effect, without a mechanism of action which proves the observed effects, there is no convincing scientific proof.

Could you please summarise what is different about the brand Bilou as presented by Mareike Matz from Philosophy Brands? What is different about a brand based on a YouTube celebrity? In what way are the brand's products different from other products (foam, fragrances)?

GM: She presented a concept in which a social media artist managed to establish a successful brand for a young target audience. This is why nine million people were reached at the launch of the brand. In a highly competitive market – 700 new products were launched in Germany in 2015 – this created a definite competitive advantage. The young target audience was addressed with consumer-relevant claims such as "cruelty-free and vegan" and a drawing of a rabbit. The problem of implicit advertising is worked around with the commentary "animal testing is fortunately banned according to article 18 of the EU cos-

metics regulation". The ingredients are "evaluated" by a so-called INCI evaluation app. The product text stresses "Made in Germany" as well as "sustainability and responsibility".

How does a consumer advice agency work, according to Sabine Holzäpfel from Verbraucherzentrale Baden-Württemberg ?

GM: She explained how a consumer advice centre works: market monitoring, consumer research, consumer advice, opinions on legal projects, public relations and class action in the case of unfair competition. It includes analysing undesirable cosmetic claims as well as deceptive packaging. The consumer advice centre uses warning letters for law enforcement. If a company does not issue a declaration of omission they are taken to court.

What will be the main challenges for surveillance authorities in implementing the amended guidelines on cosmetic claims?

GM: Implicit advertising such as "not tested on animals" on the front of the products or being illustrated with appealing photos should be omitted even when there is an explanatory comment in the footnote. The court's ruling on cosmetic claims considers the consumer to be fleeting. This refers to eye-catching advertising, which promises concrete advantages, but ends up being misleading without the small print. The mushrooming "free from" claim must also be critically assessed. There is no doubt that unfair claims such as "without harmful parabens" are illegal. Claims that are more general constitute a legal grey zone. Here only judicial decisions, e.g. by the European Court of Justice, can provide more clarity. In terms of efficacy tests, it would be an advantage to develop standardised objective evaluation methods in order to be able to assess the most important factors in a reproducible and reliable manner. In the field of statistical data, the surveillance authority will have to bear in mind that causal relations between cause and effect are evident.

It will also be relevant to set priorities in order to attach more relevance to the claims with health implications or a risk for consumers.

What will be the main challenges of the cosmetic industry caused by the amended guidelines?

GM: The cosmetics industry should have access to the ingredients suppliers' study results, especially in the field of active ingredients. They should also have a contact here to tackle all questions involved with the effect of an ingredient. The scientific requirements concerning the substantiation of claims has become more concrete with the guidelines. Answers in terms of the transferability of study designs to the concrete product have to be available. The example of the anti-ageing test showed that the agreement between testing and claiming strategy was inadequate. The marketing department has to cooperate more closely with product development and safety assessment (as demonstrated in the case of caffeine). The case of "free from" claims shows clearly that markets can be created artificially thus hampering a target audience for high quality and safe products.