

L 11, 20-22 68161 Mannheim Telefon 0621/30980860 Telefax 0621/ 1229172 bdih@bdih.de www.bdih.de

Statement by BDIH

concerning the relevance of the draft of the ISO "Guidelines on technical definitions and criteria for natural and organic cosmetic ingredients and products" - ISO 16128

BDIH points out that, contrary to several statements, the current drafts of the Guideline ISO 16128 are not an initiative of the EU. ISO 16128 will, in case of its adoption by ISO, have no effects on the legal situation in the EU or the criteria of the standards for natural cosmetics of BDIH and COSMOS-standard AISBL. ISO 16128 is no basis for a "certification" or "notification" of cosmetic products and their ingredients. Advertising statements referring to the Guideline can in individual cases be judged as consumer deception.

The Occasion

After publication of the draft of ISO 16128 – Part 1, several announcements represented the content and the importance of the draft guidelines in an incorrect or unclear manner, and thus lead to irritations in the industry and the interested public. Aside from an incorrect allocation of the activities to the legislative bodies of the EU, especially a direct impact on the legal position concerning advertising using the terms "nature" and "organic" for cosmetic products and ingredients was assumed, or the significance of the certification of natural and organic cosmetics according to known standards for natural cosmetics was questioned. BDIH wants to counteract further misinterpretations with the following explanation.

The facts concerning ISO 16128

ISO 16128 is a project which is currently being processed by ISO (International Organization for Standardization), with the objective, described in the introduction of the drafts, to promote a greater choice of natural and organic components for the production of a wide range of cosmetic products.

It is thus not an initiative of the EU and its institutions, nor are they involved in the consultations. The drafts are discussed worldwide exclusively by the members of the ISO with voting rights, which are the national standardization institutions (in Germany: DIN). However, the content of the drafts can be commented by interested parties with guest status without the right to vote.

In the case of their adoption, the guidelines do have neither legal force nor another binding effect for national or supranational legislation or jurisdiction. Also, the guidelines are not a "harmonized standard" that, when followed implicates the compliance with European law, as this is only the case

for European Standards (EN) that were adopted by the Commission as result of a standardization mandate issued by the latter. These conditions are not met.

On the one hand, the draft guidelines ISO 16128 include definitions of the terms "natural ingredients", "derived natural ingredients ", "derived mineral ingredients " and "non-natural ingredients", as well as "organic ingredients" and "derived organic ingredients ", combined with a purely informative and also non-exhaustive list of chemical and biological processes in connection with these categories (ISO 16128-1). On the other hand, ISO 16128-2 contains rules for the calculation of the natural and organic content in ingredients and products.

However, the draft guidelines do not include criteria concerning the conditions under which cosmetic products or their components can be offered as "natural cosmetics" or "organic cosmetics". There are also no restrictions that exclude certain substances and processes for the use in natural and organic cosmetics. Furthermore, there are especially no provisions on which percentage of "natural" or "organic" is needed in the product for a corresponding labelling to be acceptable. The drafts rather clarify explicitly that they refer neither to advertising statements and labelling nor to the consumer or environment safety, nor to socio-economic aspects, and that the product packaging is not covered by the guidelines as well.

The conclusions for advertising and certification

The totality of all conditions related to the terms "natural cosmetics" and "organic cosmetics" (which also includes the establishment of definitions and rules regarding permitted substances and production processes) is based on the prohibition of consumer deception by advertising law. In the EU, this prohibition regarding cosmetic products is codified in art. 20 of Regulation (EC) N° 1223/2009. This provision especially prohibits such labelling and advertising claims for cosmetic products that imply that these products have characteristics which they do not have. These characteristics also include "naturalness" and ecological ("organic") quality.

In the meantime, a more detailed description of this principle was introduced by the Regulation (EU) 655/2013 laying down common criteria for the justification of claims used in relation to cosmetic products, as well as by the Commission's Guidelines to this regulation. However, specific criteria for the use of the terms "natural cosmetics" and "organic cosmetics" are not included.

For the assessment of the admissibility of respective advertising claims, the public perception is decisive, which takes into account the understanding of the market and the manufacturers, but especially the consumers' perception. The assessment of this public perception in the event of a dispute is ultimately the responsibility of the courts, and on this basis, it must be taken into consideration that even in the EU Member States there are also differences between the public perceptions possible due to differing opinions in the context of the development of a "tradition" of natural and organic cosmetics.

Since national standardisation institutes of all continents are involved in the development of ISO 16128, whereby no unanimity is required, but decisions are made by majorities, the definitions and criteria therein cannot be equated to the relevant public perception in individual countries.

For example, the approach described in ISO 16128-1, according to which an ingredient is only assumed "non-natural "if its fossil fuel origin is greater than or equal to 50 % by molecular weight, is not compatible with the public perception in Germany.

This essentially also applies to the category "ingredients of natural origin" defined in ISO 16128-1, which applies in the case of a molecular weight greater than 50 % of substances of natural origin and as for the rest allows petrochemical components. It is against the German public perception to declare an ingredient that may consist of petrochemical moieties of nearly 50 % to be an ingredient "derived from nature". This also applies to Austria where the public perception concerning natural cosmetics is described in the chapter B 33 of the Austrian food codex.

Thus, in BDIH's view, the risk of deception is given if the definitions of the ISO Guideline 16128 would be used in the advertising of cosmetic products without further clarification. It presumably would also be misleading to refer to "natural cosmetics according to ISO 16128", because the Guideline ISO 16128 does not contain provisions specifying under which conditions a product is natural or organic cosmetics, as explained above.

From this, it also results that ISO 16128 cannot be a basis for a "certification" or "notification".

BDIH thus considers the standard for natural cosmetics it has developed in cooperation with leading manufacturers of natural cosmetics as well as the harmonized COSMOS-standard developed in cooperation with other European organizations to be further essential in order to provide the consumer with a reliable distinctive mark for natural and organic cosmetics. With these standards, important criteria according to the public perception are specified that are explicitly not addressed by ISO 16128. For example, in the Guideline ISO 16128 there is no equivalent for the public perception according to which no ingredients of dead vertebrates are to be used in natural cosmetics. ISO 16128 equally does not take into account further important aspects of animal welfare (housing conditions during the production of animal products, like milk and eggs, prohibition of animal tests regardless of place and purpose).

The standards for natural cosmetics supported by BDIH furthermore include, taking into account the public perception, prohibitions of substances which contain genetically modified organisms, of irradiation, of nanomaterials, as well as regulations on environmentally friendly packaging. With this, the significance of these standards is not affected, even in the event of final adoption of the Guideline 16128 by the ISO, and there is also no reason to reduce the existing high requirements of these standards with a view to ISO 16128.

BDIH

BDIH, the Federation of Manufacturers and Distributors for pharmaceuticals, health products, food supplements and cosmetic products represents as a non-profit organization the interests of enterprises in the area of health relevant products since 1951. With its standard for certified natural cosmetics, it introduced in 2000 the first control system which is independent of companies and a control mark, which is meanwhile recognized as a reliable distinctive mark for genuine natural and organic cosmetics by consumers and consumer organizations, as well as manufacturers and authorities. Meanwhile, more than 8.000 products were awarded with the control label. Because of the international interest, the label is now also awarded worldwide to companies in over 20 countries. This is true for a large part of the >300 brands with certified products.

BDIH is founding member and represented in the board of the COSMOS-standard AISBL that created the harmonized international standard for natural and organic cosmetics and in which, aside from BDIH, all the main organizations for the certification of natural and organic cosmetics from France, Italy and Great Britain are involved.

BDIH is furthermore member of the umbrella association of the German food industry (BLL) as well as the European umbrella organization for Health Product Manufacturers (EHPM) and is also represented on its board of directors.

As to the work of ISO on the Guideline ISO 16128, BDIH has been involved since the beginning, and on its behalf, Dr. Roland Grandel is member and current chairman of the relevant working group of DIN, which is the German ISO member. DIN has not agreed to the drafts of the Guideline up to now and has critically and continually commented its contents in light of the public perception evolved especially in Germany.

Furthermore, BDIH provides input for the commenting of the ISO Guideline 16128 by COSMOS-standard AISBL, which participates in the meetings of the ISO with liaison status and in addition, coordinates with other international and national representatives.

BDIH will continue to critically attend the discussions at ISO-level and will, by itself and also via its memberships in umbrella associations, influence future EU initiatives for specific requirements on the advertising of natural and organic cosmetics.

In the framework of the forthcoming BDIH cosmetics conference on 4th December 2014 in Mannheim, Dr. Grandel will present the ISO Guideline 16128 and comment it from the perspective of a directly involved expert. The event is open to the public. Further details regarding the agenda as well as the registration are available at www.bdih.de.

Mannheim, 12.11.2014

Harald Dittmar Rechtsanwalt Managing Director, BDIH