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COSMOS Position on Mineral UV-Filters in Organic and Natural Cosmetics

The precautionary principle and nanotechnology

The precautionary principle is one of the general principles of the COSMOS-standard (the standard). 5.1 of the standard prohibits the use of an ingredient, a technology or a process when there is scientific evidence concerning a health or environmental risk.

According to the precautionary principle, 5.1.1 of the standard does not allow nanomaterials. However, the standard recognizes that there may need to be exceptions, for which applications supported by technical dossiers will be considered.

Nanomaterial is defined in chapter 4 of the standard as "(taken from Regulation (EC) No. 1223/2009) - an insoluble or biopersistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm". However, it has since emerged that this EU definition is unclear and discussion about necessary amendments of the nano-material-definition is going on.

By application of the precautionary principle, the COSMOS Board took the decision three years ago to ban TiO₂ and ZnO as UV filter due to the potential content of nano-material, in anticipation of the EU clarifying their definition within two years. As there is no sign of this happening at short notice, and taking into consideration the main conclusion of SCCS about the safety of TiO₂ and ZnO in their nano form as UV filter filter (which have recently been incorporated into the EU Cosmetics Regulation – see below) we now feel obliged to reconsider our current position.

UV filters

TiO₂ and ZnO are globally used as UV-Filters in sunscreens and other cosmetic products and are effective alternatives for other UV filters of petrochemical origin.

The COSMOS Board considers, on the one hand that these UV filters fulfil the requirements for natural ingredients according to the provisions of the standard and contribute significantly to the safety of consumers, but on the other hand that specific requirements have to be introduced in order to implement the precautionary principle and to minimise potential risks.

Therefore, the COSMOS Board will recognize these UV filters as acceptable under the standard if the following conditions are met:

- As per chapter 2 of the standard, the raw material must fulfil the requirements of the Cosmetic Regulation (EC) 1223/2009 (namely the regulations (EU) 2016/1143¹ and (EU) 2016/621² amending Annex VI of Regulation (EC) 1223/2009 for TiO₂ and ZnO respectively)
- The particle size distribution (number of particles) under 100 nm must be less than 50%
- The mass distribution (weight of particle fraction) under 100 nm must be less than 10%.

COSMOS only sets the requirements for the certification and approval of natural and organic cosmetic products and ingredients according to the COSMOS-standard. The standard therefore does not imply that allowed materials are in compliance with any particular legal requirements that are applicable in different countries, whether for nanoparticles or other specifications or claims. It is the manufacturer's own responsibility to check legal requirements for the use and labelling of ingredients whether they are marketed in the EU or in other regions of the world.

¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R1143>

² <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0621>