Nanomaterials and regulation of cosmetics

To the Editor — In November 2009 the member states of the European Union (EU) agreed to recast some 55 directives relating to cosmetics into a single regulation on cosmetic products[1] that is intended, among other things, to streamline human safety requirements and increase transparency. The adoption of this regulation is significant, not least because it is the first piece of national or supranational legislation to incorporate rules relating specifically to the use of nanomaterials in any products. Nanomaterials have been widely adopted by the cosmetics industry[2,3] as a way of adding value to existing products and new products[4]. As such, the inclusion of the nanospecific provisions will apply to many products within the cosmetics industry. Environmental safety considerations will continue to be covered by the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) regulation that came into force in June 2007.

Cosmetics are defined to include, for example, creams, make-up products, toothpaste and sunscreens[1]. The initiative is also significant as it is inconsistent with the EU's statement in 2008 "that current legislation covers to a large extent risks in relation to nanomaterials and that risks can be dealt with under the current legislative framework."[5]

Under the regulation on cosmetics, anyone placing a new cosmetic product containing nanomaterials onto the EU market will be required to supply the European Commission with safety information six months before its planned entry onto the market. Manufacturers of nanoscale cosmetic products that are already on the market will be required similarly to notify and submit safety data to the Commission (ref. 1; article 16(3)). Should the European Commission have concerns about the safety of the nanomaterial in use, it is required to seek the opinion of the Scientific Committee for Consumer Safety, and any such opinion must be made publicly available (ref. 1; article 16(4)). The regulation also requires the European Commission to create a publicly available catalogue of "all nanomaterials used in cosmetic products placed on the market … and the reasonably foreseeable exposure conditions" (ref. 1; article 16(10)(a)). The lack of transparency about the presence of nanomaterials in consumer products was clearly a concern in the run-up to the regulation.

Products containing nanomaterials — which are defined as "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" (ref. 1; article 2(k)) — must indicate the presence of the nanomaterial(s) in the list of ingredients. This will be done by placing the word "nano" in brackets after the nanoscale ingredient (ref. 1; article 19(1)(g)). Importantly, the regulation does not set a minimum threshold for this labelling requirement, which suggests that the mere presence of any nanoparticles in the cosmetic will be enough to trigger this requirement.

The inclusion of nanospecific provisions evidently creates a further layer of legal obligations for companies wishing to gain a competitive edge through the inclusion of nanomaterials in their products. Unless the benefits of using nanomaterials outweigh these costs, it is possible that some companies may reformulate existing nanobased products so that the particles fall outside — even slightly — the size range specified in the regulation. In that respect, the definition of "nanomaterials" as referred to above may miss its target.

Different jurisdictions already take different approaches to the regulation of nanomaterials, and the introduction of nanospecific regulations in the EU has the potential to amplify these differences. However, with the EU now starting to regulate nanomaterials, other jurisdictions might also be encouraged to 'ratchet up' their own regulatory frameworks in the short-to-medium term. ❐

References

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