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Nanotechnology in Cosmetics

Summary

Like other sectors, the cosmetics industry resorts to developments in the field of nanotechnologies. Encapsulation and carrier systems like liposomes, nanoemulsions, microemulsions or lipid nanoparticles serve to transport agents to deeper skin layers. Nano particles of titan dioxide and zinc oxide are used as UV filters in sunscreens. According to the producers, cosmetic products with nano minerals, nano-scaled gold and silver or fullerenes can be found on the market. While, according to our present state of knowledge, soluble or degradable nano materials are not considered critical for health, there are as yet no unambiguous results for the assessment of the potential toxic effects on humans and the ecosystem of non-soluble or non-degradable nano materials. Some studies, however, give hints of potential negative health effects. This needs to be studied in more detail within the framework of a comprehensive risk assessment – as insisted on by, among others, the EU Scientific Committee on Consumer Products (SCCP) and a number of environmental and consumer organisations.

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Introduction

EU Directive 76/768/EWG defines cosmetics as follows:

> *"A 'cosmetic product' shall mean any substance or mixture intended to be placed in contact with the various external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance and/or correcting body odours and/or protecting them or keeping them in good condition".*[1]

Unlike medicinal products, cosmetics do not serve to cure or prevent illnesses[2].

Nanotechnology[3] is most often described as the manufacture and manipulation of purpose-made structures which are at least smaller than 100 nm. Natural nanostructures are a coincidental by-product of processes which have been in use in the cosmetics industry for a long time, such as emulsifying[4]. Advances in technology however have made it possible to manufacture purpose-made nanostructured materials with pre-determined properties. These processes include, for example, high pressure homogenisation[5] and grinding larger raw materials into nanoparticles using special mills.

Cosmetics are a growth market. In Austria alone cosmetic products to the value of 1.3 billion Euros were bought in 2007, 3 % more than in 2006. A product's properties are an important factor in influencing the choice of purchase – more important even than the price[6]. The cosmetics industry is always looking to improve the properties of its products and hence is making more and more use of the developments in nanotechnology.

Nanomaterials are used in the manufacture of cosmetics in two important areas: as "encapsulation or carrier systems" to transport agents to deeper skin layers, and as optimal UV protective filters in sunscreens. According to the manufacturers other nanoscale materials can be found in cosmetic products such as nanoparticulate gold and silver, ceramic nanoparticles, pigments, minerals and fullerenes. In the USA the "Woodrow Wilson International Center for Scholars" has a database of nanoproducts (mostly those available on the US market) which lists, among others, 125 cosmetic products[7]. The German database nanoproducts.de has so far registered 9 cosmetic products[8].

Transporting agents into the skin

With an area of around 2 m^2 skin is our largest organ and it is constantly exposed to external influences. The outer layer (epidermis) acts as an essential protective barrier which at the same time performs the metabolic functions needed for vital skin. The outermost layer is composed of a protective layer of dead cells, the so-called horned layer (stratum corneum), which together with the skin's fat and acid mantle prevents most foreign substances and pathogens from entering the skin. Care products which are applied on the skin hence do not penetrate – or at most, only on a very small scale – to the deeper skin layers where cell regeneration takes place[9].

The cosmetics industry therefore uses nanodispersion "encapsulation or carrier systems", so that agents penetrate into deeper skin layers where they activate skin metabolism with the aim of improving the skin's appearance.

The functions and benefits of these "encapsulation and carrier systems" are:

- the controlled release and optimisation of the availability of cosmetic agents in certain skin layers
- the protection of sensitive agents
- longer shelf life and hence greater product effectiveness
- a reduction in the amount of agents and additives used in products

They include liposomes, nanoemulsions, microemulsions (micelles)[10] and lipid-nanoparticles which are soluble and biodegradable.

The use of liposomes, micelles and nanoemulsions in the food industry is described in Nano Trust Dossier No. 004. The following, therefore, is only a brief overview of these basic concepts in the context of "use in cosmetics".

Liposomes

Liposomes measure between 20 nm and several micrometers in diameter. The smallest are also called "nanosomes". They are contained within a shell of one or more bilayer membranes of the lipid phosphatidylcholine (lecithin)[11]. In their hydrophilic core they can encapsulate, amongst other substances, water-soluble agents such as vitamin C, grape seed extract[12] or phytohormones[13]. Liposomes can also absorb a small amount of liposoluble substances in the space between the bilayer membranes. Liposomes were first introduced on the cosmetics market in 1986.[14]

Liposomes fuse with the skin's barrier layer thus increasing the membranes' permeability locally and allowing the agents to penetrate into deeper skin layers. But even without the encapsulated agents, liposomes nurture the skin by feeding into it essential fatty acids and choline in bound form[16]. Liposomes are primarily used in skincare products but can also be found in shampoos and hair care products.

Nanoemulsions

Nanoemulsions are very fine emulsions of oil in water with a droplet size of approximately 50 to 1000 nm. Like liposomes they are produced by high pressure homogenisation with added phosphatidylcholine. However, the droplets' shell, unlike that of liposomes, only consists of one layer and inside they have a liquid, oily core. They can be used to transport liposoluble agents (vitamin A, vitamin E, evening primrose oil, coenzyme q10) to the skin.

The advantage of nanoemulsions is that they do not contain synthetic emulsifying agents (tensides)[18], which is why the skin's fatty components are not washed out with water. They are hence regarded as particularly suitable for sensitive skin. Nanoemulsions are transparent due to the droplets tiny size and they also remain stable for a longer period of time. They are mostly used in deodorants, sunscreens, shampoos, and skin and hair care products.

Microemulsions (micelles)

Microemulsions are a mixture of oil, water and a synthetic emulsifying agent (tenside). When a tenside is dissolved in water, droplet-shaped structures are formed which are called micelles, measuring between approximately 5 and 100 nm in diameter. Micelles enable non-water-soluble agents to be transported to deeper skin layers. The tenside content is mostly a disadvantage in skincare products because it retains its emulsifying properties when applied on the skin and the skin's fatty components can be washed out. In people with very sensitive skin some tensides can cause inflammation of the skin[19]. Microemulsions are used in some cosmetic products for skin cleansing.

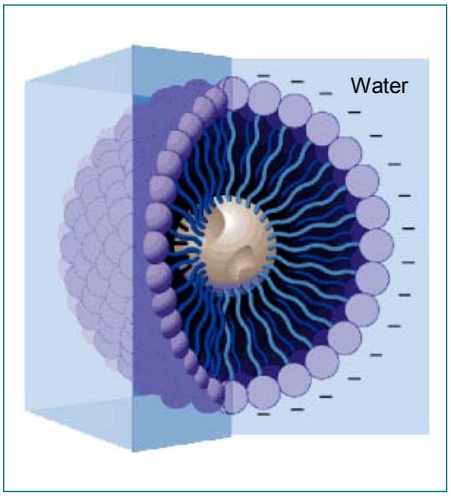

Figure 3: Micelles[20]

Lipid nanoparticles

Lipid nanoparticles of between 50 and 1000 nm in size likewise serve as agent carriers and are similar in both structure and function to nanoemulsions. They differ from the latter however in that they enclose a solid lipid core, in which the agents are enriched. A tiny amount of tenside is also added here to improve stability. Lipid nanoparticles are patented worldwide under the name "Lipopearls" or "Nanopearls".[21] They are currently being introduced on the market and are so far only to be found in a few anti-ageing skin care products.

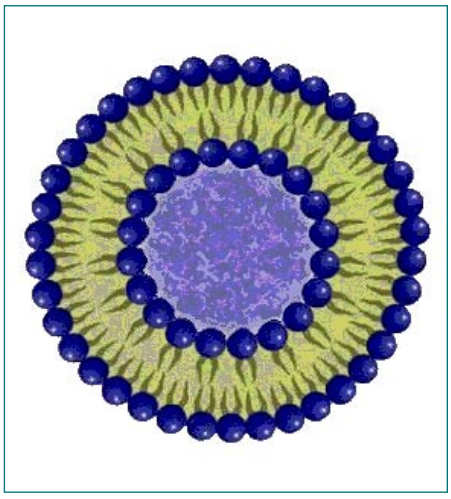

Figure 1:
Liposome with a bilayer membrane[15]

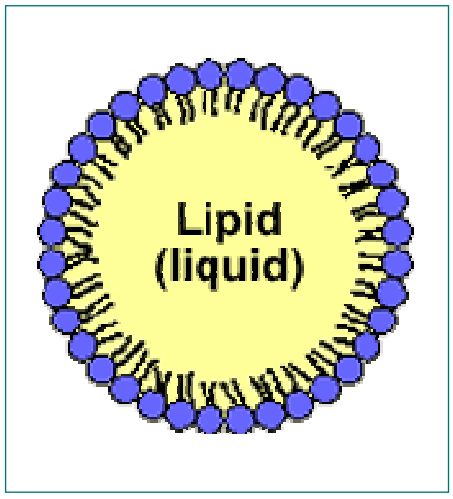

Figure 2:
Droplets in a nanoemulsion[17]

Nanoparticles as UV protective filters in sun screens

For many years now so-called microparticles of titanium dioxide and zinc oxide have been used in cosmetic products as UV filters. The substances were originally used as traditional white pigments in the micrometer sector. The resulting products however were comparatively thick, sticky pastes which were difficult to administer and were not widely adopted by consumers as they left a whitish film on the skin. By using nanoparticle-sized titanium dioxide and zinc oxide the substances are transparent to the human eye, can be applied more easily on the skin and leave a better skin feeling. In addition, protection against UV radiation has been radically improved as a result of the smaller-sized particles[22]. The primary size of the nanoparticles used as UV filters is approximately 40 nm. According to the German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW) titanium dioxide and zinc oxide are now only to be found in nanoparticle form in sunscreens, and products carry a notice advising of the titanium dioxide and zinc oxide content[23]. Currently only titanium oxide is listed as an authorised sunscreen filter on the EU Directive on cosmetics' list of permitted UV filters.

Examples of other application areas of nanomaterials in cosmetics

Some special tooth creams for the neck of sensitive teeth contain nanoscale calcium phosphate (apatite) which produces a thin layer similar to natural tooth enamel, which is thus supposed to reduce sensitivity to pain[24]. Tiny particles of nanometer-thin pigment can be found in make-up[25], and, according to manufacturers, nanoparticulate gold and silver is used in certain day and night creams to give the skin a fresher appearance[26]. Nanoparticles from volcanic ash are also in use in mascara[27], as are ceramic nanoparticles in nail varnish[28]. The range of cosmetic products using nanomaterials is broadened further by the inclusion of nanominerals (silicon, calcium, magnesium) in skin lotions, hair shampoos or massage oils.

Manufacturers also say that in a few ("anti-ageing") skin creams on the international market they use so-called fullerenes as antioxidants to combat free oxygen radicals which, together with other factors, contribute to wrinkle formation[29]. Fullerenes, the best known of which are also called "buckyballs" are spherical molecules of carbon atoms measuring about 1 nm in diameter. They are not biodegradable. Fullerol, on the other hand, is a water-soluble and degradable derivative of fullerene used in the cosmetics and other industries.

Potential health hazards of nanomaterials and nanoparticles in cosmetics

When consumers apply cosmetics they come into direct physical contact with nanomaterials and nanoparticles which may be absorbed by the body via the lungs, (from products in the form of sprays), the digestive organs (inadvertent swallowing of face or lip applications), eye membranes (inadvertent insertion of creams or sprays applied to the face; mascara) and the skin. Due to their tiny dimensions certain nanoparticles can penetrate cell membranes and thereby cause inflammation and/or cell damage as a result of oxidative stress (see Nano Trust Dossier No. 003). However, the threshold level at which the absorbed nanomaterials trigger an effect remains unknown.

For the purposes of risk assessment a distinction is made between nanomaterials which are soluble/degradable and those which are insoluble/non-degradable. The former, such as the carrier systems mentioned above (liposomes, nanoemulsions, lipid nanoparticles, microemulsions) break back down into their individual components when the active ingredient is released. Scientists currently believe that these nanomaterials are unlikely to have a toxic effect on humans or ecosystems that would be any different from the effect the larger particle form of the substances would have[30]. However, these carrier systems can change the bioavailability and the toxicological behaviour of the agents they transport. This needs to be taken into account when conducting safety tests on nanomaterials and/or the agents contained within them[31].

To date, no suitable methods have been found for conducting a comprehensive risk assessment of insoluble/non-degradable nanomaterials and as a result there are still considerable gaps in our knowledge of this area. Following a report by its "Scientific Committee on Consumer Products" (SCCP) the European Commission prohibited the use of **zinc oxide** as a UV filter[32]. The SCCP criticised the fact that the risk assessment data submitted to it was largely out of date and that there were no studies into whether nanoform zinc oxide could penetrate cells via the skin and enter the blood stream[33].

There have also been some studies which have examined the potential effects of **titanium dioxide** on health when it is used as a UV filter. The EU NANODERM project, for example, concluded that the application of nano-titanium dioxide on healthy skin was unlikely to have a harmful effect on health since the particles could not penetrate the skin. At present there are no studies available on skin disorders (e.g. neurodermatitis) or damaged skin, so that the penetration of nanoparticles into cells or the blood stream via the skin barrier cannot currently be ruled out. Massage or mechanical flexion (bending a joint) can assist the penetration into deeper skin layers[34]. Here too there is still a need for appropriate studies.

The question whether nanoscale titanium dioxide can penetrate through the skin's barrier into living cells is of special importance in assessing its potential danger because titanium dioxide exhibits photocatalytic properties. In other words, where UV radiation and water are present it forms free oxygen radicals which are known to cause cell damage. In such instances titanium dioxide shows greater activity in nanoform than in its larger form. The crucial factor is which form of TiO_2 crystal structure is used. Rutile titanium dioxide[35] demonstrates far less photocatalytic activity than anatase TiO_2. By the same token, the photocatalytic activity can also be prevented by coating the nanoparticles[36] without a resulting loss in their effectiveness as a UV filter. Hence, by using the less photoactive form or coated nanoparticles, sunscreen manufacturers can reduce or prevent the photocatalytic activity in their products. As manufacturers are not currently required to identify substances which have been incorporated in the cosmetic in nanoform, it is not obvious to the consumer which form of UV filter has been used in a product.

The EU's "Scientific Committee on Consumer Products" (SCCP) recommends a re-evaluation of titanium dioxide[37] so that unresolved questions are answered.

There are likewise only a few investigations into the potential health hazards of non-soluble **fullerenes**. Studies show however that

they can penetrate the skin due to their tiny size and that in tests on bacteria they had a phototoxic[38] and genotoxic effect[39]. Here too, a considerable amount of research needs to be conducted in order to evaluate the potential danger[40].

In a recent German survey of experts (a "Delphi method" analysis) on the subject of nanotechnology, those questioned were very critical of the use of fullerenes. 87 % said that their use in cosmetics was likely to have a harmful effect on health and categorised them as having "moderate toxic potential"[41]. In Austria there are currently no cosmetic products available which are known to contain fullerenes.

The stance of environmental and consumer organisations

The United States organisation "Environmental Working Group" (EWG) has analysed around 400 studies which deal with the potential health hazards of nanoparticulate UV filters and concludes that sunscreens with titanium dioxide and zinc oxide are among the most effective and safest on the market. Unlike products with chemical UV filters they guarantee greater UV protection and contain fewer harmful ingredients[42].

In a report in 2006 the environment and consumer organisation "Friends of the Earth" (Australia and USA) pointed to the potential risks of nanomaterials in cosmetics, criticised the fact that there was no requirement to label nano-products and even called for a moratorium[43]. In August 2007 "Friends of the Earth" published a brochure on sunscreens containing nanoparticles which highlighted vividly the risks they pose[44].

The Berlin branch of the Federation of German Consumer Organisations likewise calls for, among other things, compulsory product labelling, more information, a comprehensive risk assessment and special protection for children from the as yet unpredictable effects of nanotechnology[45].

The International Society of Doctors for the Environment (ISDE), Eco Counselling Austria ("die umweltberatung" Österreich), the Austrian Institute of Ecology and the Consumers Association of Austria (VKI) are asking for the precautionary principle to be applied, more financial support for research into risks and, in common with the two organisations cited above, the compulsory labelling of products containing nanoparticles. Current legislation in respect of chemicals is criticised as being inadequate for the regulation of synthetic nanomaterials[46].

"Which?" (UK), Europe's biggest consumer organisation, is calling for an independent group of experts to be set up which can advise the government on the advantages and risks of sunscreens containing nanoparticles. At the same time it is asking the government to require companies to disclose the use of synthetic nanomaterials and to withdraw potentially unsafe cosmetic products from the market. It also wants new guidelines for cosmetics containing a list of the nanomaterials which are permitted for use in cosmetics on the basis of independent risk assessments. A recent consumer conference held by "Which?" showed that consumers want more information and the labelling of cosmetics with synthetic nanomaterials[47].

Conclusions

Producers of cosmetics that contain nano materials and nano particles claim that according to current legal requirements their products have to be submitted to a security assessment and are therefore safe. However, it is debatable whether the applied testing and analytical methods, in particular for non-soluble and non-degradable nano particles, are suitable for determining the specific risk relevant-properties of nano particles. Adequate in vivo and in vitro testing methods are currently being developed. Of specific importance is the establishment of meaningful dose-effect relationship, because we do not as yet know the threshold levels that trigger an effect.

Notes and References

1 Council Directive dated 27 July 1976 on the approximation of the laws of the member states relating to cosmetics (76/768/EEC).

2 On the definition of a medical product see Directive 2001/83/EC of the European Parliament and the Council and the Austrian Pharmaceuticals Act (Official Journal, 2 March 1983, on the production and putting into circulation of pharmaceuticals).

3 See also NanoTrust Dossier No. 1/May 2008: On the definition of nanotechnology.

4 Emulgation is the production of an emulsion, i.e. a finely distributed mixture of two liquids that can normally not be mixed, such as oil and water, without any apparent separation. Examples of emulsions include many cosmetics and mayonnaise.

5 In high pressure homogenisation – put simply – a liquid (pre-emulsion) is pressed at high pressure through a narrow slit, creating gas bubbles that implode when the liquid emerges from the slit. This releases high forces that break up the emulsion drops or the solid particles, thereby making them smaller (based on Jacobs Claudia [2004]: Neue Nanosuspensionsformulierungen für verschiedene Applikationsformen; Dissertation; Freie Universität Berlin).

6 Kosmetik transparent, press release dated April 2008.

7 www.nanotechproject.org.

8 The two databases accessed on 18.9.08.

9 See also NanoTrust Dossier No. 003en, "How do nanoparticles enter the human body and what do they do there?" epub.oeaw.ac.at/ita/nanotrust-dossiers/dossier003en.pdf.

10 For an overciew of encapsulation and carrier systems (liposomes, nanoemulsions, microemulsions) see: www.dermaviduals.de/deutsch/publikationen/spezielle-wirkstoffe/ (accessed on 16.10.08) Dr. Hans Lautenschläger, Kosmetik Konzept KOKO GmbH & Co KG.

11 Lecithin is the classical name for a group of chemical compounds known as phosphatidylcholins. They are lipids, or to be more precise phospholipids, composed of fatty acides, glycerine, phosphoric acid and choline. Lecithins are a part of cell membranes of animals and plants. They accompany fats and fatty oils and are found in particularly large quantities in egg yoke and plant seed cells. de.wikipedia.org/wiki/Lecithin (accessed 13.10.08).

12 Grape seed extracts contain oligomeric procyanides (OPC), which have an antioxidising effect and protect against free radicals, thus reducing the formation of wrinkles. In addition, grape seed extracts are said to encourage the production of collagen in the skin.

13 Phytohormones are vegetable substances usually obtained from soy and red clover and have the same effect as the female hormone oestrogen. In the field of cosmetics, they are used for skin problems associated with an oestrogen deficiency (such as during the menopause), such as early ageing of the skin or hormonal skin impurities.

14 Gleiche M., Hoffschulz H. and Lenhert S. (2006): Nanotechnology in Consumer Products. Nanoforum Report. www.nanoforum.org (accessed 16.10.08).

15 Source: www.uni-magdeburg.de/imos/mea_sen/docs_de/gebiete.html (accessed 16.10.08).

16 Phospholipids, such as phosphatidylcholin (lecithin) as used in cosmetics, regulate cell metabolism of the skin and have an effect on softness and suppleness. They also regulate the skin's pH value and have a greasing effect.

[17] Source: http://www.azonano.com/details.asp?ArticleID=1244 (Accessed 18.12.08).

[18] Emulsifiers are also referred to as surfactants and are used to enable two liquids that are otherwise not capable of being mixed (e.g. oil in water) to mix to create an emulsion. There are a number of artificial surfactants (such as soap) used in cosmetics. A natural emulsifier is phosphatidylcholin (lecithin). Surfactants are also the detergent substances used in washing powders, dishwasher powders and shampoos. See also "Emulgatoren in der Kosmetik", www.kosmetikportal.net/kosmetik-info/kosmetiklexikon/emulgatoren.html and de.wikipedia.org/wiki/Tenside (Accessed 14.10.08).

[19] Emulgatoren – Alternativen gesucht. Kosmetik Konzept KOKO GmbH & Co KG, Dr. Hans Lautenschläger, www.dermaviduals.com (Accessed 13.10.08).

[20] Source: www.uic.edu/classes/bios/bios100/lecturesf04am/lect02.htm (Accessed 16.10.08).

[21] Daniels R. (2001): Galenische Prinzipien moderner Hautpflegeprodukte. Skin Care Forum, 25th issue, April 2001. www.scf-online.com/german/25_d/25_d_dr/galenik_25_d_dr.htm (Accessed 16.10.08).

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[23] Stakeholder-Dialog Kosmetik. Thema: Nanopartikel in kosmetischen Mitteln. Industrieverband Körperpflege and Waschmittel e.V., Frankfurt am Main, November 2007.

[24] E.g. Theramed S.O.S. sensitiv, Henkel; www.nanit-active.de (Accessed 15.10.08).

[25] E.g. ESTÉE LAUDER Double Wear Light Stay-in-Place Makeup SPF 10; Deutsches Museum Munich, special exhibition on "Nano im Alltag".

[26] E.g. JOYONA Micro Silk® Nano Gold Complex Cream, JOYONA; www.joyona.de (Accessed 15.10.08).

[27] MANHATTAN Volcano Mascara, Dr. Scheller Cosmetics; www.cosmoty.de/news/1060/ (Accessed 15.10.08).

[28] Misslyn FRENCH NAILS CERAMIC, Interco Cosmetics; www.misslyn.de (Accessed 15.10.08).

[29] Dr. Brandt "laser lightning" skin care series; www.dr.brandtskincare.com (Accessed 29.10.08).

[30] CONANO Final Report (2007): Comparative Challenge of Nanomaterials – A Stakeholder Dialogue Project. Comparative use-risk analyses of degradable and non-degradable nano-delivery systems and conventional micro-delivery systems in pharmaceutical and cosmetic applications.

[31] Scientific Committee on Consumer Products (SCCP): Opinion on safety of nanomaterials in cosmetic products. 18 December 2007.

[32] Cosmetic products and "nanotechnology". ec.europa.eu/enterprise/cosmetics/html/nanotechnology_en.htm (Accessed 16.10.08).

[33] Scientific Committee on Cosmetic Products and Non-Food-Products Intended for Consumers SCCNFP/0649/03,final: Opinion concerning Zinc Oxide, Juni 2003.

[34] NANODERM (2007) – Quality of Skin as a Barrier to ultra-fine particles. Final Report.

[35] Titanium dioxide occurs in nature in three different crystalline forms, Rutil, Anatas and Brookit. Only Rutil and Anatas are used as pigments.

[36] Barker P.J. and Branch A. (2008): The interaction of modern sunscreen formulations with surface coatings. Progress in Organic Coatings 62:313-320.

[37] Scientific Committee on Consumer Products (SCCP): Opinion on safety of nanomaterials in cosmetic products. 18 December 2007.

[38] Phototoxy is a characteristic of pharmaceutical and chemical substances. It describes the strength of toxic effects caused on the skin by a substance in combination with sunlight. If sunlight does not change the chemical structure of the substance, it is qualified as photostable. de.wikipedia.org/wiki/Phototoxie (Accessed 22.10.08).

[39] Genotoxicity or mutagenicity refers to the effects of chemical substances that cause changes in the genetic material of cells. The term is a purely experimental consideration of how substances behave in experiments *(in vitro* or *in vivo)*. Substances that are tested genotoxically positive need not however be mutagenic or carcinogenic. The determination of the genotoxicity of a substance is part of the determination of its toxicity. de.wikipedia.org/wiki/Genotoxizit%C3%A4t" (Accessed 22.10.08).

[40] Scientific Committee on Consumer Products (SCCP): Opinion on safety of nanomaterials in cosmetic products. 18 December 2007.

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[47] Small Wonder? Nanotechnology and Cosmetics. Which?, London, November 2008.

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nano trust dossiers

Ergänzung zu Dossier Nr. 008, Stand: Dezember 2010

Seit 1. Jänner 2010 ist die neue Kosmetikverordnung in Kraft[1]. Die Neuerungen, die größtenteils 2013 in Geltung treten werden, reichen von einer Vereinfachung und Neuregelung der Vermarktung über eine weitgehende Herstellerverantwortung bis hin zu einer hoheitlich organisierten Marktkontrolle. Die Verordnung beinhaltet nicht zuletzt aufgrund des nachhaltigen Drucks des EU-Parlaments umfassende Bestimmungen im Hinblick auf Nanotechnologien und -materialien[2]. So dürfen Nanomaterialien nur dann verwendet werden, wenn sie sicher sind. Kosmetika mit bestimmten Nanomaterialien müssen darüber hinaus mit dem Beisatz „Nano" gekennzeichnet werden (Art. 19) und zusätzlich besteht eine Anzeigepflicht (Art. 16). Schließlich enthält die Verordnung erstmals eine Legaldefinition von Nanomaterialien. Nach Art. 2 Abs. 1 lit. k sind Nanomaterialien „unlösliches oder biologisches beständiges und absichtlich hergestelltes Material mit einer oder mehreren äußeren Abmessungen oder einer inneren Struktur in einer Größenordnung von 1 bis 100 Nanometern". Diese Definition kann von der Kommission unter Einbeziehung eines Ausschusses jederzeit an den Stand der Wissenschaft und Technik sowie an internationale Entwicklungen angepasst werden.[3]

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[1] Verordnung EG 1223/2009

[2] Siehe dazu KOM (2008) 49 sowie die 1. Lesung des EU-Parlaments (23.-26.3.2009).

[3] Allgemein zur EU-Rechtslage siehe insbesondere NanoTrust-Dossier 017 epub.oeaw.ac.at/ita/nanotrust-dossiers/dossier017.pdf.

Addendum for Dossier No. 008, Version: December 2010

The new regulation on cosmetic products entered into force on 1 January 2010.[1] The innovations, largely not applicable until 2013, range from the simplification and revision of how a product may be placed on the market, the responsibility of manufacturers for product safety, to market surveillance conducted by each member state. Partly as a result of prolonged pressure from the European Parliament, the regulation contains comprehensive provisions in relation to nanotechnologies and nanomaterials.[2] First, nanomaterials may only be used if they are safe. Secondly, ingredients in nano-form must be indicated in the list of ingredients and followed by the word "nano" in brackets (Art. 19). Thirdly, manufacturers are also obliged to notify the Commission of cosmetics containing nanomaterials (Art. 16). Finally, the regulation contains for the first time a legal definition of nanomaterials. Art. 2. para. 1, section k defines "nanomaterial" 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." The Commission, in cooperation with a committee, may adapt this definition at any time to technical and scientific progress and international developments (Art. 3 para. 3).[3]

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[1] Directive EC 1223/2009.

[2] On this point, see COM (2008) 49 and the first reading in the European Parliament (23-26.3.2009).

[3] On EU regulation in general see in particular NanoTrust Dossier 017 at epub.oeaw.ac.at/ita/nanotrust-dossiers/dossier017en.pdf.