Hogan Lovells

Cosmetics Liability and Safety Regulation: Retrospective and Prospective Perspectives

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Further information
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HOT TOPICS IN 2010 AND WHAT TO EXPECT IN 2011

Welcome to Hogan Lovells' first retrospective and prospective review of EU cosmetics liability and safety regulation with a specific focus on how such regulation was welcomed in France.

2011 promises to be a productive year in the cosmetics sector according to economic forecasts. Last year, it was one of the few industry branches which managed to beat the economic crisis. According to the French trade union for the chemical industries[1], the perfume, soap and body products sector should grow by 4% in 2011.

The cosmetics sector will, however, have to deal with a number of challenges in connection with the ever increasing risk of liability arising from an increase in consumerism, increased globalization of markets and, more importantly, changes in the regulatory environment in this field in Europe.

2011 will be another year of transition between Directive no. 76/768/EEC and the now famous new Regulation no. 1223/2009 on cosmetic products. These changes are giving rise to a number of difficult challenges for industry, for example: How can companies launch new products under the current regime when a few months later, once the new regime comes into force, they could be asked to remove them from the market? Indeed, for instance, since 1 December 2010, the CMR provisions of Regulation no. 1223/2009 on cosmetic products allow, on an exceptional basis, the use of CMR substances if several conditions are met. Manufacturers will therefore gain leeway. On the other hand, manufacturers will have to start anticipating controls of the use of nanomaterials and may even need to find alternative substances in case the Commission refuses to allow them because of any perceived shortcomings in the safety information manufactures will be required to produce.

Hence, although the purpose of Regulation no. 1223/2009 of 30 November 2009 on cosmetic products is to simplify the applicable legal regime in this field, a long period of uncertainty has started for manufacturers, suppliers and distributors. This uncertainty leads to extra costs, and new business risks. Indeed, the Regulation creates numerous new obligations for professionals in the cosmetics industry. Improved consumer safety protection product traceability and transparency are intended to be promoted the pillars of this industry in the coming years. This will come with the introduction of enhanced obligations and new concepts. These will be better ensured through a more detailed safety report and a strictly controlled use of CMR substances, through the appointment of a "*responsible person*" with enhanced obligations who will be in charge of gathering all necessary information on each product and who will be held liable for all defects, and through new labelling requirements.

The whole range of changes that this Regulation will bring and their exact impact are not yet clear (as the Commission has not published its guidelines). However, these changes, presented by the EU authorities as being for the best for consumers and the industry, will force the latter in many respects to make significant changes to the way in which they develop, produce and market their products. For instance, manufacturers will have to appoint a responsible person and modify their contracts with their sub-contractors to guarantee that the latter will share with them all the information needed for the safety report. Manufacturers will also have to notify the authorities a few months before introducing on the EU market products containing CMR substances or nanomaterials.

The impact of this Regulation is currently a central focus of the industry, not least because it may be the source of delays in the marketing of products if all the necessary steps are not implemented in due time. National authorities have, for this purpose, been asked to closely monitor the application of the Regulation even before its entry into force scheduled on 11 July 2013 (except for the rules relating to CMR substances, which apply since 1 December 2010 and the rules relating to nanomaterials which will apply as from 11 January 2013).

In light of the above, manufacturers, suppliers and distributors now must be focusing on the steps to be taken to comply with the Regulation in order to avoid any suspension of production, marketing or innovation because of regulatory problems.

French authorities (such as Afssaps[2]) have already started to encourage players in the cosmetics industry to enforce this new regulation, the objective being consumer safety and their trust in the safety of the market.

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1 "*Union des industries chimiques*".

2 French Health Products Safety Agency.

As Anne Dux, Director of Scientific and Regulatory Affairs of the FEBEA, stated on 4 November 2010: "*there are 676 working days before the mandatory implementation of the cosmetics regulation. For a catalogue featuring 50 products, this means that we need to upgrade a file produced every 13.5 days. Those who are waiting for 1 January 2013 to start with the task will only have two days per product!*".

So...on your marks, get set, go!

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In this booklet you will find a review of some of the hot topics of 2010 updated as at February 2011. This includes an overview of the new rules that will be introduced by Regulation no. 1223/2009 (page 3) and articles on the natural and organic products, which quite surprisingly remain a quite uncontrolled area, despite the brand new implementation of the new "Cosmos Organic" label. Indeed, Regulation no. 1223/2009 does not address them at all despite their growing importance in the sector (pages 8 and 14). You will also find an overview of the applicable rules relating to nanomaterials (page 19) and general guidance on how to cooperate with the DGCCRF and Afssaps in France (page 24), which tend to be increasingly demanding towards manufacturers, while in Italy, the Supreme Court rendered an important judgment in favour of manufacturers (page 29).

Looking ahead, you will also find a calendar of some of the legislative events and conferences that will occur in 2011 (pages 31 and 32).

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GLOSSARY

AFSSAPS: French Health Products Safety Agency

AFSSET: French Agency for Environmental and Occupational Health Safety

CMR substance: Carcinogenic, Mutagenic or toxic for Reproduction

DGCCRF: French General Directorate for Competition Policy, Consumer Affairs and Fraud Control

Nanomaterial: materials composed of elementary structures of which at least one of the dimensions is typically, but not exclusively, between 1 and 100 nanometres

Regulation no. 1223/2009 dated 30 November 2009: replaces Directive no. 76/768/EEC of 27 July 1976 on cosmetic products which currently governs the cosmetic industry. Unlike a Directive, a Regulation is directly applicable into the 27 Member States without any need to implement it.

SCCS: Scientific Committee for Consumer Safety

HOT TOPICS OF 2010

REGULATION NO. 1223/2009 ON COSMETIC PRODUCTS: HOW TO GET READY FOR 2013?

This article was published in the September 2010 issue of the European Product Liability Review and in the October 2010 issue of the Journal des Sociétés (in French).

Introduction

Directive 76/768/EEC on cosmetic products[3] has been the cornerstone of cosmetic law for more than thirty years. Its longevity is explained by the fact that it has been amended more than fifty times in order to adjust to scientific innovations in this constantly evolving sector. However, these numerous amendments resulted in a hardly understandable text, at the origin of incoherent national transpositions, complicating the work of more than 3,000 manufacturers.

This context explains that the adoption of Regulation 1223/2009 on cosmetic products[4] on 30 November 2009 has been welcomed by the manufacturers of the sector as well as by national authorities. The objective of the European authorities was clear and simple: to redraft the legislation in order to simplify it and enable its consistent application throughout the European Union[5]. The choice of adopting a Regulation rather than a new Directive and the statement made by Mr Verheugen, vice-president of the European Commission responsible for enterprise and industry, clearly prove this intention: "*The law on cosmetics is a good example of an EU legislation "ripe" for simplification. Working with 27 different transposition texts gives rise to unnecessary costs and work for the cosmetics industry. With today's proposal, we will be able to improve product safety while reducing administrative costs by replacing a superfluous legislation*"[6]. This approach is all the more justified since the European Union is the world leader in this sector and generates in this respect more than 65 billion Euros and 350,000 jobs. It can also be explained by the fact that cosmetic products directly affect the consumer's health and well-being.

Consumer safety, product traceability and the transparency of their composition thus became the major objectives of this new Regulation that substantially amends the existing rules and give rise, in the absence of European Commission guidelines, to numerous questions from cosmetic manufacturers. The latter must, indeed, get ready for the entry into force of such text, which main part will become effective as from 11 July 2013. For this purpose, cosmetic manufacturers will have to closely cooperate with national authorities (in France, in particular with the Afssaps[7]) that have been asked to encourage cosmetic manufacturers to already start to enforce this new text.

The impact of this Regulation and its limits still being unclear, this article intends to list the main new ideas implemented in order to achieve the three abovementioned goals.

REINFORCED CONSUMER SAFETY

Consumer safety was of course one of the objectives of Directive 76/768/EEC. The Regulation, by adding a certain number of new requirements or specifying the existing ones, has set it as its first objective, providing, in its Recital 4, for the need to ensure "*a high level of protection of human health*".

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3 Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products.

4 Regulation (EC) no. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

5 Recital 3 of the abovementioned Regulation.

6 "*New cosmetic regulation to strengthen product safety and to cut red tape*", Mr Verheugen, 5 February 2008, http://ec.europa.eu/luxembourg/news/frontpage_news/cosmetiques_fr.htm.

7 French Health Products Safety Agency.

Clarification of the information to be mentioned in the cosmetic products safety assessment

Pursuant to Directive 76/768/EEC, before placing a product on the market, it was necessary to carry out an "*assessment of the safety for human health of the finished product*"[8]. However, the information to be mentioned in this assessment had not been specified, such that the safety assessment never played the significant role that it was supposed to play[9].

Regulation 1223/2009 overcomes this problem and lays down, in its Annex I, a mandatory non-restrictive list of the information that must be mentioned in the "*safety report*".

This report shall include two parts that will require very close cooperation between the manufacturers of the finished products and their subcontractors, including the manufacturers of ingredients that will suddenly be subject to an increasing number of formalities, which manufacturers generally tend to avoid:

- a part relating to "*cosmetic product safety information*" that shall include the following elements: quantitative and qualitative composition of the cosmetic product, physical/chemical characteristics, stability of the cosmetic product, microbiological quality, impurities, traces, information about the packaging material, normal and reasonably foreseeable use, data relating to the exposure to the cosmetic product or to the substances contained in the cosmetic product, toxicological profile of the substances, undesirable effects and serious undesirable effects as well as any relevant information, and

- a part entitled "*cosmetic product safety assessment*" that shall be in line with the content of the first part and reflect any risk on the labelling, by means of instructions or precautions of use.

The controlled use of certain CMR substances

CMR substances (Carcinogenic, Mutagenic or toxic for Reproduction) are currently classified in three categories (1, 2 and 3) depending on the level of certainty of their carcinogenic, mutagenic or toxic for reproduction properties.

Pursuant to Directive 76/768/EEC, CMR substances of category 1 (substances known to be carcinogenic/mutagenic/toxic for human reproduction) and CMR substances of category 2 (substances that should be regarded as CMR substances of category 1 as there is a strong presumption that human exposure may result in the development of the indicated effects) are quite simply prohibited. On the contrary, CMR substances of category 3 (substances which cause concern for man owing to carcinogenic/mutagenic/toxic effects) may be used if they have been found acceptable for use in cosmetic products[10] after assessment by the Scientific Committee on Consumer Safety (SCCS).

The new Regulation slightly amended this pattern since it authorises, exceptionally, the use of certain CMR substances of category 1A or 1B[11], if several conditions are met, namely[12]:

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8 Article 7a, paragraph 1.

9 Extract from the Proposal for a Regulation of the European Parliament and of the Council presented by the European Commission on 25 February 2008.

10 Article 4b of Directive 76/768/EEC.

11 According to the classification of Annexe VI of Regulation 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

12 Article 15 of Regulation 1223/2009.

- these substances comply with the general principles and requirements of food law,

- there are no suitable alternative substances available,

- the application is made for a particular use of the product category with a known exposure,

- they have been assessed and found safe by the SCCS.

Due to this open door to use CMR substances some may have feared a "step backwards"[13] with respect to consumer protection but the rationale of this exemption is legitimate: to put an end to an inexplicable imbalance between the regime of cosmetics and food legislation that admitted, on the contrary, the use of these substances upon certain conditions. The European Commission decided that these new rules shall benefit from an early entry into force on 1st December 2010[14]. Manufacturers will have to ensure that their products, which contain such substances, meet all the requirements of the Regulation in order for them to protect themselves from any controls carried out by national authorities that may, in this case, be even more vigilant and interventionist.

TRACEABILITY AND MARKET SURVEILLANCE

As mentioned in Recital 12 of the Regulation, "*an efficient traceability system facilitates market surveillance authorities' task of tracing economic operators*". New definitions are introduced in this respect, manufacturers now having to designate their importer, the responsible person and their distributors, and each of them will have different responsibilities.

Identification of a "*responsible person*"

Identifying a responsible person is a crucial point which has the attention of all the professionals of the cosmetic industry. Article 4 of Regulation 1223/2009 now provides that, "*only cosmetic products for which a legal or natural person is designated within the Community as 'responsible person' shall be placed on the market*".

- To determine who the "responsible person" is, the Regulation sets forth several presumptions but leaves a lot of room for interpretation. Thus, the manufacturer established in the European Union is presumed to be the responsible person if the product is manufactured in the EU and not intended to be exported and then re-imported. If, on the contrary, the product is imported, the importer will be the responsible person. All these rules are only valid in the absence of express identification of a person established in the EU by means of a written mandate accepted by the latter.

- The obligations imposed on the responsible person are numerous since he/she must guarantee that the cosmetic product for which he/she is responsible complies with the safety requirements provided for by the Regulation. To this end, the responsible person will gather all the necessary information on the product (namely the safety report) in order to be able to inform the consumer as well as the relevant authorities of each Member State. This responsible person shall thus become the only contact within the European Union.

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[13] Information Report no. 958 of the French National Assembly on the texts submitted to the French National Assembly in accordance with Article 88-4 of the French Constitution from 25 April to 5 June 2008, document E3786.

[14] Article 40.2 of Regulation 1223/2009.

- If the identification of this person is already a delicate subject, numerous closely related questions arise such as the guarantee of the confidentiality of the composition and trade secrets that the subcontractors will not always want to share the transfer of liability in the event of non-conformity of an ingredient and the safety assessor's role. These questions are so sensitive that a new profession has come into existence in this sector: companies whose purpose will be to be the "responsible person" for the manufacturers.

Creating a central reporting system for cosmetic products

One of the other new ideas that will impact the cosmetic sector is the implementation of a unique and central reporting system for cosmetic products, which replaces the former system whereby the relevant authority of the Member State was informed of the place where the product was manufactured or first imported[15].

From now on, before a cosmetic product is placed on the market, the responsible person will have to "report" it, i.e. inform the European Commission through an electronic interface that would be handled by the latter. The gathered information will then be communicated to the relevant authorities in each Member State, to poison control centres and assimilated entities. The Regulation does not specify, however, if the consumer will have access to this portal, as it is currently the case with respect to the Community Rapid Information System for defective products implemented by the Directive on general product safety[16] (RAPEX).

Such portal should be effective on 11 January 2012[17]. In other words, as from such date and until 11 July 2013, both reporting systems mentioned above should coexist.

TRANSPARENCY

As well as improving consumer safety through controls before the introduction of the products on the European market, the authors of the Regulation wished to reinforce the consumer information requirements to enable them to choose their products freely. Labelling transparency is thus clearly required in this text, with respect to the price-quality-quantity ratio as well as the product composition[18].

Indication of nanomaterials in the list of ingredients

This new Regulation on cosmetics reinforces the legal regime of nanomaterials.

- The Regulation gives a uniform definition of a "nanomaterial": it means "an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm"[19].

- The Regulation defines a nanomaterial as an ingredient that shall be expressly mentioned in the list of ingredients. Article 19 thus provides that "all ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word ‘nano’ in brackets".

15 Article 7a 4) of Directive 76/768/EEC.

16 Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety.

17 Article 39, paragraph 2, of the abovementioned Regulation.

18 Recital 46 of the abovementioned Regulation.

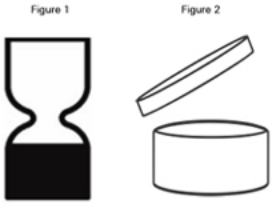
19 Article 2.1.k) of the abovementioned Regulation.

This new regulation shall also benefit from an early entry into force on 11 January 2013[20] and meets the national and European public authorities' intention to identify nanomaterials in order to protect consumers from the potentially harmful effects of these materials. The launch of a campaign to identify nanomaterials in consumer products in March 2010 by the French Agency for Environmental and Occupational Health Safety (Afsset) is the most recent example[21].

New labelling requirements

The labelling requirements relating to the packaging of a cosmetic product are not fundamentally different between the Regulation and the Directive[22], even though there are a few exceptions that should be highlighted.

- The name of the responsible person shall replace the name of the manufacturer or the person in charge of introducing the cosmetic product on the market. His/her address shall also be mentioned on the product in order to enable the consumers and the authorities to locate the cosmetic file.
- A new pictogram has been created to indicate the date of minimum durability, i.e. the "*date until which the cosmetic product, stored under appropriate conditions, will continue to fulfil its initial function and, in particular, will remain in conformity with Article 3*"[23]. This pictogram represents an hourglass (figure 1). Should the product be stable for more than 30 months, this pictogram will be replaced by the open cream jar pictogram, which already existed under the Directive (figure 2).



COMMENT

French authorities are already starting to ask manufacturers who place cosmetic products on the French market to apply the new Regulation 1223/2009 in order for them to be fully ready for 2013. Even if such a step often creates confusion in the manufacturers and distributors' minds as to whether what the French Authorities are asking them to do is compulsory, it is a straightforward message that French Authorities are planning to enforce the Regulation as soon as it comes into force. It is therefore recommended that companies start analysing this Regulation in depth and adapt their chain of production and supply accordingly, as well as their contracts with their sub-contractors and suppliers.

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[20] Article 40.2 of the abovementioned Regulation.

[21] Opinion of the French Agency for Environmental and Occupational Health Safety, "*Assessment of the risks associated to nanomaterials for the general population and the environment*", 17 March 2010.

[22] Article 6 of Directive 76/768/EEC.

[23] Article 19.1.c) of the abovementioned Regulation.

THE LEGAL REGIME OF ORGANIC COSMETICS

The following article was first published in the March 2010 issue of the European Product Liability Review.

Introduction

These last few months, the so-called "organic" cosmetics market has become one of the most profitable markets for players in the cosmetic industry due to the increasing interest of consumers in environmental protection and in the preservation of their health. Hence, most brands in the sector have an "organic" range of products.

Nevertheless, as for the so-called "natural" cosmetics[24], the legal regime for "organic" cosmetics is still fragmented creating space for disparate non-regulatory standards that should be standardised in the interest of consumers and in order to ensure legal certainty for the professionals of the sector.

TO THIS DAY: ABSENCE OF ANY SPECIFIC REGULATIONS

Unlike food products, cosmetics are not governed by any specific regulatory text, European or national, defining the conditions to use added-value labelling or advertising terms. An equivalent of the Regulation 834/2007/EC of 28 June 2007 on organic production and labelling of organic food products[25] does not exist for "organic" cosmetics.

The new cosmetic Regulation dated 30 November 2009[26] however, provides, in its Article 20, that the European Commission shall adopt, together with the Member States, a list of common criteria to be met by professionals when using advertising claims for their cosmetics. The Commission shall then establish a report indicating whether the criteria have indeed been met. If necessary, the Commission shall be entitled to specifically regulate the use of the claims. On September 2010, in response to a question asked by the EU Parliament, the EU Commission specified that the said criteria should be finalised by the second half of 2011 and be in force as from 2012.

As this process was only initiated recently, in the cosmetic industry, the only "organic" products that are regulated to this day are food products resulting from organic agriculture used as ingredients in the manufacturing of cosmetics.

MULTIPLICATION OF NON-REGULATORY SOURCES

Due to the legal vacuum in this field, numerous national and international standards, of manufacturers or certifying bodies, were established to attempt to control this growing market.

One can distinguish, amongst these sources, the documents issued by official institutions such as the Guidelines of the Expert Committee of the Council of Europe and those established by private institutions.

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[24] See Antoine de Brosses and Sylvie Gallage-Alwis, "The legal regime governing the marketing of "natural" cosmetics", *European Product Liability Review*, December 2009, p7; *International Law Office Publication*, February 2010

[25] EC Regulation no. 834/2007 of the Council dated 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91

[26] EC Regulation no. 1223/2009 of the European Parliament and of the Council dated 30 November 2009 on cosmetics

The fact of complying with these documents places the professional in a zone of relative legal security (presumption of conformity). To the contrary, should the professional not be compliant, he/she risks (presumption of non-conformity) that the national administrative authorities will question their labelling policy. French case law has indeed long acknowledged the principle according to which the works of standardisation bodies or advisory bodies could be taken into account as a reference in the assessment of the misleading nature of a claim or any other labelling or advertising terms. The courts have the same analysis with respect to professional codes of practice, which are documents by which professionals define, together with official services, the conditions of use of certain expressions or claims.

Private standards

The "*Cosmetics*" code of practice of December 2009 established by the French Professional Advertising Regulation Authority (ARPP)[27], which is a reference in this field, lists the rules relating to the use of claims when advertising a cosmetic product[28]. This code of practice states that a cosmetic product can only be characterised as "organic" if it meets at least one of the following requirements:

- "it contains 100% of certified ingredients resulting from organic agriculture;
- it has been certified as "organic" by a certifying body;
- proof can be provided that it has been established according to published specifications, with a level of requirements, in terms of composition and content of certified ingredients resulting from organic agriculture, that is identical to the level of requirement(s) required by certifying bodies".

As from 1st March 2010, the advertisement should thus no longer include terms that suggest that the product has specific features whilst all the similar products have the same features or claims that may mislead, whether directly or indirectly, the consumer with respect to the reality of the advantages or environmental properties of the products as well as to the reality of the actions carried out by the advertiser for the protection of the environment.

Professional associations and certification bodies took even further steps in the attempt to establish rules on "organic" cosmetics, which took the shape of private standards and the attribution of "organic" logos. Moreover, they provide advice to professionals on how to promote their products. Thus, the Cosmos standard (*Cosmetic organic and natural standard*) provides for several rules concerning the "organic" claim. The product must contain the "Cosmos-Organic" logo. It must also mention the name of the certification or control body and identify the organic ingredients, included on the INCI list, with the wording "*from organic agriculture*". It may also specify the percentage of organic origin ingredients (by weight) in the total product without water or minerals, as defined in Articles 6.1.1 and 6.1.2. Article 10.2 also specifies that, for the products which "organic" percentage is below 95%, it is possible to include a reference to the organic products, for instance with the wording: "*shampoo with organic jojoba oil*".

Administrative legal writings

The official services in charge of the control of the loyalty of the labelling and advertising of cosmetics (in this case, the French General Directorate for Competition Policy, Consumer Affairs and Fraud Control ("DGCCRF") and the French Health Products

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[27] The ARPP report is available at the following address: http://www.arpp-pub.org/IMG/pdf/ARPPProdCosmetiques.pdf

[28] This code of practice also defines the "natural" cosmetic product. See footnote page no. 1

Safety Agency ("Afssaps")) closely control the conditions under which the claim "organic" can be used without, according to them, misleading the consumers[29].

Recently, certain certification bodies and associations considered that the criteria taken into account by the DGCCRF were too strict and unadapted. Thus, the association Cosmébio sounded the alarm when the DGCCRF declared that it understood the definition of Cosmébio according to which an "organic" cosmetic product must contain "*95% of natural ingredients or ingredients of a natural origin and at least 95% of the vegetable ingredients resulting from organic agriculture*" as meaning that the organic cosmetic product must contain 95% of certifiable organic ingredients. In December 2009, the business development director of Cosmébio indicated that it is impossible to reach such a percentage as water, which is the main ingredient in cosmetics, cannot be certified as "organic"[30].

This difference of opinions between the various players of the market and the administration proves the limit of the private standards and labels, which can be questioned at any time by the administration. Therefore, private standards and labels do not offer the same legal security to professionals that would be guaranteed by a regulation.

ABSENCE OF ANY STANDARDISED DEFINITION OF THE "ORGANIC" COSMETIC PRODUCT

The absence of specific laws on "organic" cosmetics also means that, to this day, there is no standardised definition of an "organic" cosmetic product. This is namely caused by the fact that the European Commission, together with manufacturers and associations, is currently drafting lists of criteria to define this kind of cosmetics[31] which should be finalised in the second half of 2011.

In the absence of any standardised definitions, there are as many definitions as there are labels or standards on the market. The main available standards, which show this difference, shall be presented hereafter.

The NaTrue standard

NaTrue (*International Natural & Organic Cosmetics Association*) places cosmetics in three categories: (i) "*natural*" cosmetics, (ii) "*natural cosmetics with organic ingredients*" and (iii) "*organic*" cosmetics, according to the quantity and quality of their ingredients.

"Natural" cosmetics[32] must meet all the strict requirements imposed on ingredients derived from nature. The processes that are authorised with respect to the manufacturing of these ingredients are limited to a strict minimum.

In "*natural cosmetics with organic ingredients*", "*at least 70 % of natural ingredients must stem from controlled organic production and/or controlled wild collection*", whilst for "organic" cosmetics this percentage reaches 95%.

Thus, to be identified as a "*natural cosmetic with organic ingredients*", the product must, in addition to the general requirements, contain "*at least 15 % chemically unmodified natural substances and maximum 15 % derived natural substances*".

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[29] Deceit is an offence that is punishable by a two years' prison sentence and a maximum fine of 37,500 Euros for an individual and 187,500 Euros for a legal entity. These sanctions may be doubled if the deceit can result in the use of the good being dangerous for one's health.

[30] "Cosmébio defends its cause", *Parfums cosmétiques actualités*, no. 210, December 2010

[31] This is also the case with respect to natural cosmetics

[32] See footnote page no. 1

The "organic" cosmetic product, in addition to the requirements for the "natural cosmetic with organic ingredients", must contain "at least 20% chemically unmodified vegetable or animal natural substances and maximum 15% derived natural substances".

The Cosmos standard

The new Cosmos-standard specifications published in May 2009[33] demonstrate, through their very existence, the necessity to standardise this sector. It indeed arises from the work of six different European associations: Bioform (Belgium), Ecocert and Cosmébio (France), BDIH (Germany), ICEA (Italy) and Soil Association (United Kingdom). Manufacturers have three years to comply with this new standard.

This standard requires that for "organic" cosmetics, at least 20% of the total product must be organic. This minimum percentage goes along with conditions concerning each category of ingredients that may be labelled: "*95% of the physically processed ingredients must be organically produced, and 30% of the chemically processed ingredients* ".

Cosmébio label

According to Cosmébio, "an "organic" ingredient is a natural or vegetable ingredient or an ingredient resulting from animal production (for instance, honey) that can be certified according to the production rules of organic agriculture". To obtain the label "organic"[34], the product must meet the following conditions:

- at least 95% of natural ingredients or ingredients of a natural origin,
- ingredients resulting from organic agriculture (at least 10% of the total of the ingredients),
- ingredients resulting from organic agriculture (at least 95% of the certifiable ingredients),
- a maximum of 5% of synthetic ingredients.

STRICT MANUFACTURING PROCESSES

Another consequence of the absence of standardised regulation in this field and of any definitions of an "organic" cosmetic product is the range of manufacturing processes that can be used by manufacturers in order for their products to be certified as "organic"; two are analysed more in depth hereafter.

The NaTrue standard

The Annexes of the NaTrue standard includes a list of the requirements imposed on "natural cosmetics with organic ingredients" (table 2) and "natural organic cosmetics" (table 3).

For each kind of cosmetic (oil/product without water, deodorant/antiperspirant, solar protection, emulsions (water/oil)/skin care), the standard specifies a minimum percentage of water, "natural substances", "nature-identical substances" and the maximum content of "derived natural substances".

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[33] COSMOS STANDARD- Cosmetic Organic and Natural Standard, May 2009.

[34] There is also an "Eco" label specifically for cosmetics

With respect to "natural cosmetics with organic ingredients", the standard lists, in Annex IV "*derived natural substances to be manufactured from raw materials certified as organic*".

The Cosmos standard

Cosmos recommends a principle of precaution at all the stages of the production and the use of non-polluting manufacturing and processing processes, incorporating the notion of "*Green chemistry*". It thus classifies the ingredients in five categories, each time specifying whether they can or not be certified as "organic":

- 1st and 2nd categories: water and mineral ingredients must be pure and natural but cannot be certified as "organic";
- 3rd category: physically processed agro-ingredients can be of a plant, animal or microbial origin. They can be certified as organic and are only authorised if they comply with the Convention on International Trade in Endangered Species of Wild Fauna and Flora. Agro-ingredients derived from plants or genetically modified and those extracted from living or slaughtered animals are prohibited;
- 4th category: chemically processed agro-ingredients shall meet the requirements of the 3rd category and meet the principles of "*Green chemistry*" to be certified. According to this standard, petrochemical solvents are not authorised for the production of ingredients certified as organic;
- 5th category: the other ingredients, mainly preservatives.

FRENCH AUTHORITIES, SATISFIED WITH THE QUALITY OF THE "ORGANIC" PRODUCTS AVAILABLE ON THE MARKET

Two studies have been carried out by the French authorities (DGCCRF and Afssaps) to analyse the quality and composition of the cosmetics sold on the French market under the claim "organic". Despite the absence of mandatory legal framework in this sector, the findings of these two studies were quite positive.

Thus, in 2006, the DGCCRF controlled 139 companies who presented themselves as manufacturers of "organic" cosmetics. This authority indicated that it was satisfied as only 6 of the 47 samples taken were, after the analysis, not compliant due to the presence of chemicals in their composition at higher dosages than those authorised[35]. It should be noted that most of the analysed products referred to a certification by an authorised body.

The Afssaps, in a report published in May 2009, notably noted that on a total of 30 analysed samples, "*a good microbiological quality of these products except for one*" had been observed, concluding that the analysed products meet the claims used on their packaging[36].

[35] Report "Le marché de la beauté", *Revue Concurrence et Consommation*, 2008, no. 157

[36] Surveillance of the market - cosmetics "without preservatives" with an "ORGANIC" label, Afssaps, March 2009

The specific vigilance of these authorities to control the "organic" cosmetics market today enables to overcome the absence of standardised definitions and regulations. Nevertheless, this absence means that the players of this sector depend on the assessment of these administrations who can, at any time, change their analysis criteria and impose prohibitions on manufacturers relating to the trade of products and even expose them to criminal disputes. The report of the European Commission as well as an "organic" European label for cosmetics, such as the ones that exist for food products, are thus still widely expected by the profession. The latter's patience seems to start being rewarded with the launch, in March 2011 of the new "Cosmos Organic" label which will be applicable worldwide:

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THE LEGAL REGIME GOVERNING THE MARKETING OF "NATURAL COSMETICS"

The following article was first published in the December 2009 version of the European Product Liability Review and on the International Law Office website.

INTRODUCTION

The so-called "natural" cosmetics market is constantly growing, just like the market of "organic" cosmetics, with which they are sometimes wrongfully confused.[37]

As always in such matters, the market precedes the regulation. Natural cosmetics are not an exception and are, for the time-being, only subject to disparate rules in France.

TO THIS DAY: ABSENCE OF CONSISTENT REGULATION

Regulation

Unlike food products,[38] cosmetics are not governed by any specific regulations defining the conditions that must be met in order for “added-value” labelling or advertising claims to be made about the product. There is, to this day, still no community or national text in this field, although this position might change in the near future. Indeed, the new cosmetic regulation dated 30 November 2009[39] (the “Regulation”), which replaces Directive 76/768/EEC, provides, in its Article 20, that the European Commission shall, firstly, adopt a list of common criteria with which professionals will have to comply when using advertising claims for their cosmetics. On September 2010, in response to a question asked by the EU Parliament, the EU Commission specified that the said criteria should be finalised by the second half of 2011 and be in force as from 2012. Secondly, the Commission shall establish a report indicating whether these criteria have been complied with. If they have not, the Commission shall be entitled to take the appropriate measures, in other words, regulate the use of the claims.

However, there is no regulation[40] that specifically defines the legal regime of the claim "natural" for a cosmetic. The Regulation only sets general rules, such as a prohibition to mislead as well as an obligation to justify the truthfulness of each claim used.

These general obligations result both from the Regulation and from laws applicable to products generally, such as those on unfair commercial practices[41] or that relating to the obligations of the first person introducing a product onto the market.[42]

Other non-regulatory sources

Other sources of law, that are not mandatory ("soft law") can be mentioned.

One can distinguish amongst these sources between the documents issued by official institutions (for example the Guidelines of the Expert Committee of the Council of Europe) and those established by private institutions.

The fact of complying with these documents places the professional in a zone of relative legal security (presumption of conformity). To the contrary, should the professional not be compliant, he/she takes a risk (presumption of non-conformity).

French case law has indeed long acknowledged the principle according to which the works of standardisation bodies[43] or advisory bodies[44] could be taken into account as a reference in the assessment of the misleading nature of a claim or any other labelling or advertising terms.

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[37] An organic cosmetic is inevitably natural; the reverse is not true: a natural cosmetic can include substances that do not result from organic farming, but from conventional farming.

[38] Food resulting from organic farming is governed by Council Regulation 834/2007/EC of 28 June 2007; food products that wish to use a nutritional or health claim must comply with the provisions of Council Regulation 1924/2006 of 28 January 2006.

[39] Regulation 1223/2009 of 30 November 2009 on cosmetic products.

[40] Although Article 16 of Regulation 1334/2008/EC, which defines the conditions under which flavouring used in a food product can be qualified as natural, seems to be transposable to cosmetics: French administration had in fact applied the rules of natural flavourings to "natural" additives used in food products, by reasoning by analogy.

[41] Directive no. 2005-29 and Article L 121-1 and following of the French Consumer Code.

[42] Article L 212-1 of the French Consumer Code.

[43] Crim 7 February 1994, no. 92-80561; Crim 10 April 1997, RJDA 8-9/1997, no. 1133; Crim 10 June 1998, RJDA 12/1998, no. 1428.

[44] The French Supreme Court thus confirmed the conditions of use of the qualitative “fresh” defined by a Notice of an advisory body, the National Consumer Council (Com 12 January 1999, no. 97-13801).

The courts have the same analysis with respect to professional codes of practice, which are documents by which professionals define, together with official services, the conditions of use of certain expressions or claims.[45]

With respect to cosmetics, the Council of Europe has issued guidelines on the conditions of use of a claim of naturalness.[46] Currently, the cosmetics industry has not adopted any code of practice of this kind for natural cosmetics.[47]

The recommendations of the French Professional Advertising Regulation Authority (ARPP) have a legal value that is equivalent to those of professional codes of practice: in either case, they are self-discipline rules established by consensus by the profession. The "Health and Beauty" recommendation of the ARPP, which covers cosmetics, thus defines rules on the use of the claim "natural" for a cosmetic product.

The most significant efforts in the establishment of rules on natural cosmetics were provided by the professional associations and the certification bodies, which took the shape of private standards.[48] Two in particular are worth noting: the Cosmos standard (Cosmetic organic and natural standard) and NaTrue (International Natural & Organic Cosmetics Association).

Case law

It is the courts' responsibility, in the last resort, to determine whether a product that qualifies itself as "natural" can do so or if the claim is misleading. There are relatively few decisions in this field. However, two decisions of the European Court of Justice ("ECJ"), which concern either food products or cosmetics, are worth mentioning.

In the first case, the ECJ considered that a Member State could not force an industrialist to indicate on the labelling of its cosmetics whether the flavourings and fragrances used had a natural or synthetic origin. For the ECJ, the communication on the naturalness of an ingredient or of a cosmetic can thus not be imposed: it is voluntary.[49]

The ECJ also ruled that the accidental presence of contaminants (heavy metals) could not prohibit an industrialist in the jam sector from using the claim "purely natural".[50] We believe that this solution could be transposed to cosmetics.

French case law on the naturalness of products is more significant and specific. It concerns both food products[51] and cosmetics.[52]

The French General Directorate for Competition Policy, Consumer Affairs and Fraud Control's guidelines

The official services in charge of the control of the loyalty of the labelling and advertising of cosmetics (in this case, the French General Directorate for Competition Policy, Consumer Affairs and Fraud Control ("DGCCRF")) sometimes issue notices on the conditions under which certain claims are, according to them, not misleading. Complying with the instructions of these official notices places the professionals in an interesting legal position with respect to the risk of incurring criminal liability.[53] Such a professional might have an argument, in the event of criminal proceedings, to advance an argument that there has been a mistake of law,[54] which constitutes a justification that enables exoneration from criminal liability.

The DGCCRF has adopted a general information notice, which defines, with a certain level of detail, the conditions under which a food product can be qualified as natural.[55] This notice could be transposed to cosmetics.

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[45] There are a number of professional codes of practice in the food sector (for example, codes of practice for cooked meat, rice, minced meat, and so on).

[46] Natural cosmetics; guidelines approved by the Expert Committee of cosmetics of the Council of Europe (September 2000).

[47] The European Cosmetics Association (COLIPA) has, for the moment, only noted that the interpretation of the term "natural" varied from one State to another, due to the existence of different rules. It is however working on adopting a code of practice on naturalness.

[48] These standards cannot be compared to the official quality guarantees (for example, Label rouge, Eco-label), acknowledged by the regulation.

[49] ECJ, 7 March 2002, case C-365/00.

[50] ECJ, 4 April 2000, case C-465/98.

[51] Paris Commercial Court, 25 September 2008, Panzani v. Heinz; Crim 1 February 2000, Juris-data no. 2000-001149.

[52] Paris Court of Appeal, 31st Chamber A, no. 99-07165; Paris Court of Appeal, 13th Chamber, 24 January 1992, Juris-Data no. 1992-020201.

[53] If a term that is used in the labelling and/or advertising is considered as misleading, the professional in question can be criminally sued for misleading advertising (Article L 121-1 of the French Consumer Code) and/or for deceit (Article L 213-1 of the French Consumer Code).

[54] Article 122-3 of the French Criminal Code.

[55] DGCCRF information notice no. 2009-136 dated 18 August 2009.

Moreover, the DGCCRF adopted certain individual notices on the naturalness of cosmetics, notably with respect to the use of the term "natural"[56] or natural extracts.[57]

Nonetheless, the guidelines established by the professionals with the DGCCRF on the conditions to justify the claims of cosmetics do not seem relevant here as they concern the content of the scientific files to justify the effect of a cosmetic. Yet, a claim of naturalness does not require any scientific file: to the contrary, it implies presenting a cosmetic product as using substances that can be found in nature.

COMPARATIVE STUDY OF THE MAIN REQUIREMENTS ON NATURAL COSMETICS

Definition of a natural cosmetic

There are various definitions of natural cosmetics that are all rather similar.

The guidelines of the Council of Europe

These guidelines define a natural cosmetic as a product that consists of natural substances of botanical, mineral or animal origin, exclusively obtained through physical, microbiological or enzymatic methods, with certain exceptions for fragrances and preservatives.

The Cosmos standard

This standard does not include any formal definition of a natural cosmetic. However, it sets a number of rules and guidelines which should be complied with when manufacturing a cosmetic product in order for this product to obtain the Cosmos certification on its packaging.

The NaTrue standard

According to this text, natural cosmetics are products exclusively manufactured from "*natural substances*". Natural substances are substances of botanic, inorganic-mineral or animal origin (except for dead vertebrates) or substances resulting from mixtures and reactions with each other. These substances have to be obtained or processed using the authorised manufacturing processes.

Natural cosmetics can also contain under specific conditions, "*natural-identical substances*" (set out in Annex 2a of the standard), "*nature-identical inorganic pigments and minerals*" (set out in Annex 2b of the standard) and "*nearly natural substances*", i.e. substances which are not natural but manufactured using processes which are modelled on physiological mechanisms.

The health and beauty recommendation of the ARPP

According to this recommendation, published at the end of December 2009, natural cosmetics are products which contain at least 95% "*natural ingredients*" or "*natural origin ingredients*" as understood under the relevant national or European law.

The manufacturing processes

The processes that are compatible with naturalness

The guidelines of the Council of Europe specify that natural ingredients can only have been obtained by way of physical methods (for example extrusion or filtration) or microbiological or enzymatic methods.

The Cosmos standard includes, in its Annexes I and II, a list of authorised physical methods for natural cosmetics.

According to the NaTrue standard, with respect to the recovery and processing of natural substances, only physical processes and extraction methods using purifying agents (extraction and cleaning/purification) listed in Annex 1a as well as the pH-adjusting agents listed in Annex 1b, are authorised. Moreover, the enzymatic or microbiological processes are permitted as long as they use only naturally occurring enzymes or micro-organisms.

With respect to Genetically Modified Organisms, the natural raw materials, enzymes and micro-organisms must meet the requirements of Regulation 834/2007/EC on organic farming.

The processes that are incompatible with naturalness

[56] DGCCRF notice no. 87-086, no. 89-303, no. 91-207.

[57] DGCCRF opinion no. 98-180.

The Cosmos standard includes a non-exhaustive list of prohibited methods in its Annex III.

According to NaTrue, raw materials (of plant or animal origin) cannot be subjected to ionising radiation. The use of chlorine (sodium hypochlorite) is not permitted for bleaching purposes.

Specific cases

Additives

In order to be used in natural cosmetics, additives must firstly be included in the positive lists defined by the Regulation and comply with their conditions of use.[58]

Unlike for food products, the use of certain additives does not seem to be incompatible with the fact that a cosmetic uses a claim of naturalness. For instance, this is the case of nature-identical preservatives, of certain emulsifiers or colouring. The use of synthetic substances is generally prohibited.[59] The use of these additives however entails the obligation to provide the consumer with additional information on the labelling, informing them that these chemical substances have been used.

The guidelines of the Council of Europe provide a restrictive list of nature-identical preservatives[60] that can be used in natural cosmetics. Natural cosmetics that use one of these preservatives must clearly mention the words "*preserved with*", with the name of the preservative next to the terms "*natural cosmetic*".

These guidelines also authorise the use in natural cosmetics of a list of emulsifiers obtained from natural substances by hydrolysis, esterification or reesterification. No additional labelling requirements are provided for in this case.

In Germany, the fact that a nature-identical preservative has been used as well as its name must be clearly mentioned on the product, next to the claim "*natural cosmetic*".[61]

The Cosmos standard includes three lists (Annexes IV, V and VI) regarding the additives and other substances that are authorised in natural cosmetics. For instance, it accepts five preservatives authorised by Annex VI of Directive 76/768/EEC.[62]

The NaTrue text includes, in its Annexe 2a, a list of the nature-identical preservatives that can be used in natural cosmetics and indicates that the use of these substances should be mentioned on the packaging. This NaTrue standard also includes, in its Annexe B, a list of the nature-identical inorganic pigments and minerals approved for the manufacturing of natural cosmetics. It uses practically the same preservatives as the Cosmos standard.[63]

In France, the DGCCRF permits the use of certain additives in natural products, when they have been manufactured from natural substances through appropriate physical processes. Appropriate wording must be used to explain the use of additives, for example "*natural preservative*".[64]

Fragrances

The NaTrue standard provides that only natural fragrances (essential oils) defined by the standard ISO 9035 are permitted in natural cosmetics. Isolates of essential oils exclusively reconstructed from them are also permitted. The synthetic fragrances and chemically modified natural fragrances are prohibited in natural cosmetics.

Surfactants

The NaTrue standard specifies that the surfactants used should be entirely biodegradable, according to the terms of Regulation 648/2004/EC on detergents.

Other requirements

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[58] These conditions relate to the maximum authorised concentration, the limitations, requirements and conditions of use and warnings to be printed on the labelling.

[59] The Ecocert standard includes an exception for floral water, which can use phenoxyethanol and parabens up to a maximum of 0.2%.

[60] This is a substance that is identical to a natural substance, but obtained synthetically.

[61] Recommendations of the Federal Ministry of Health on requests on natural cosmetics.

[62] These substances are benzoic acid and its salts, benzyl alcohol, dehydroacetic acid and its salts, salicylic acid and its salts and sorbic acid and its salts.

[63] The NaTrue standard however replaced dehydroacetic acid and its salts by formic acid, propionic acid and its salts.

[64] DGCCRF notice no. 95-337 and 96-246.

The different standards (such as Cosmos and NaTrue) also prohibit certain other matters that would be incompatible with natural cosmetics, such as the use of GMO or nanomaterials, irradiation processes, animal testing. They also impose the use of certain materials (for example recyclable packaging).

The various claims of naturalness

It is possible to distinguish at least three different categories of claims of naturalness, whose conditions of use are not the same.

The standards and guidelines on natural cosmetics only define the conditions under which they can be qualified as natural, without specifying how the claim should be worded. This is the case, for instance, of the guidelines of the Expert Committee of the Council of Europe, Cosmos[65] and NaTrue. The wording to be used for the claims is only mentioned in administrative notices (for example the DGCCRF).

The claim "natural" concerns the entire cosmetic

This is the case when the wording "*natural cosmetic*" is used. The guidelines of the Council of Europe accept the use of this wording when the product meets all its requirements.

The claim "natural" only concerns one or several ingredients

For instance, this is the case of the wording "*100% natural extracts*". This means that the entire cosmetic does not meet the requirements of naturalness, but only certain ingredients. The ingredients in question will have to meet the conditions of naturalness.

The claim mentions a "reduced" naturalness

This is the case of the wording "*natural preservative*". It means that the entire product does not meet the criteria of naturalness, and that the ingredient in question is not natural, but has a natural origin.

COMMENT

The absence of specific regulation and the disparities between the private standards and administrative interpretations on natural cosmetics create a legal insecurity for the industrialists of the cosmetics sector, especially for those that market their products in several countries. These disparities impose, in theory, on the industrialists to check in each country[66] the conditions of use of a "*natural*" claim and thus to adapt the composition of their product or their marketing language accordingly.

Several possible solutions exist: the adoption announced by the European Commission of common criteria relating to natural claims, that of a regulation, of an official community standard or lastly of a Code of Practice by the European cosmetics association (COLIPA). COLIPA was used in another field, for tea-based products, by the *European Tea Committee*. This solution is the one that can the most quickly succeed if the profession wishes to be governed by specific rules on natural cosmetics.[67]

In the absence of will from the manufacturers to apply common rules on a voluntary basis, the Regulation or the courts will need to step in to make the rules clearer.[68]

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[65] The Cosmos standard only provides that the labelling and advertising must be clear and must not mislead the consumer (Article 10.1).

[66] Subject to the principle of mutual recognition.

[67] COLIPA would currently be working on the establishment of professional codes of practice for natural cosmetics.

[68] This is what happened in the food sector where, faced with the confusion of nutritional communications, the community authorities adopted Regulation 1924/2006/EC of 28 January 2006, on nutritional and health claims.

NANOTECHNOLOGIES AND COSMETIC PRODUCTS: NEW OBLIGATIONS AND LEGAL UNCERTAINTIES TO BE EXPECTED

The following article was first published in the December 2010 issue of the European Product Liability Review and on the International Law Office website.

Introduction

Nanomaterials are defined by the French Agency for Environmental and Occupational Health Safety (Afsset) as materials "composed of elementary structures of which at least one of the dimensions is typically, but not exclusively, between 1 and 100 nanometres"[69].

As highlighted in our September 2008 edition[70], nano-sized structures are not new. They were simply not assessable before due to difficulties in measuring them. The knowledge of their use in products for the general public is therefore quite recent and keeps on increasing. The Afsset, in its report of 17 March 2010, identified nanomaterials in a number of everyday life products such as "sun protection cream, textiles, foodstuffs, transport" in "sectors as diverse as building, automotive, packaging, chemical, environmental, energy and health"[71].

This reality was revealed together with the fear that nanotechnologies may be at the origin of asbestos-like illnesses in the future and warnings that both workers and consumers should be protected from them. This explains why nanomaterials are today the central focus of abundant research projects all around the world. Professor Bengt Fadeel, Vice chairman at the institute of environmental medicine at Karolinska Institutet[72] and coordinator of the project NANOMMUNE created by the European Commission to study the hazardous effects of engineered materials on the immune system, hence warned that "*when you shrink material down to nanoscale, you change their properties and we still don't really understand which properties are hazardous*"[73]. France makes no exception to this concern. The Afsset, which carried out a national level research on nanomaterials this year, indeed considers this field as being "***the** booming area of scientific and technical research*"[74].

The cosmetics industry is known as one of the industries using the highest level of nanomaterials as they offer innovative solutions to manufacturers and producers. Consequently, the Regulation 1223/2009 on cosmetic products (hereafter "the Regulation"), scheduled to enter into force on 11 July 2013, explicitly and specifically regulates the use of nanomaterials and acknowledges the existing uncertainties regarding their hazardous properties. Even more, this Regulation provides for an earlier entry into force for the provisions on nanotechnologies, i.e. on 11 January 2013.

Nanomaterials, which are said to be surrounding all of us, should therefore be considered by manufacturers and suppliers from the cosmetics industry, as a factor which will increase risk liability in the near future, especially in France where Afsset has decided to monitor their use very closely.

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[69] Opinion of the French Agency for Environmental and Occupational Health Safety: "*Assessment of the risks associated to nanomaterials for the general population and the environment*", 17 March 2010, p1.

[70] See Marion Palmer, "Science Feature - Nanotechnonolgy: recent interest", *European Product Liability Review* September 2008, Issue 32, p2.

[71] See Opinion of the Afsset referred to under footnote no. 1, p2.

[72] The Karolinska Institutet is one of the leading medical universities in Europe. It is also Sweden's largest centre for medical education and research.

[73] See http://ki.se/ki/jsp/polopoly.jsp?a=67485&d=3297&l=en&newsdep=3297

[74] See footnote no.1.

NEW SPECIFIC NOTIFICATION AND LABELLING OBLIGATIONS

In order to ensure traceability and transparency regarding the use of nanotechnologies in cosmetic products, the Regulation creates a distinct set of obligations, specific to nanomaterials[75].

Pursuant to Article 16-3, the "*responsible person*"[76] shall notify the Commission six months prior to placing on the market a product containing nanomaterials. Willing to prevent manufacturers from placing on the market numerous products before the entry into force of the Regulation, the latter further states that products that are placed on the market before the entry into force of the Regulation should fulfil the notification requirement between 11 January 2013 and 11 July 2013[77].

The notification to the Commission shall be made by electronic means and should contain, "*at least*": [78]

- "the identification of the nanomaterial, including its chemical name (IUPAC) and other descriptors (...)";
- "the specification of the nanomaterial including size of particles, physical and chemical properties";
- "an estimate of the quantity of nanomaterial contained in cosmetic products intended to be placed on the market per year";
- "the toxicological profile of the nanomaterial";
- "the safety data of the nanomaterial relating to the category of cosmetic product, as used in such product";
- "the reasonably foreseeable exposure conditions".[79]

Identification, assessments and tests will therefore be required in order to ascertain the data necessary to conform to the notification requirements. Manufacturers and producers will have to plan ahead in order not to have their manufacturing and selling process blocked for a number of months because of a lack of notification in due time.

Additionally, Article 19 establishes new labelling requirements for products containing nanomaterials. "*All ingredients present in the form of nanomaterials shall be clearly indicated in the list of ingredients. The names of such ingredients shall be followed by the word "nano" in brackets*".[80] Current practices of labelling will therefore have to also be reviewed in order to comply with the provisions of the Regulation.

SCALABLE RULES

The availability of the information on the boom of the industrial use of nanomaterials being quite recent, their effects on human health are yet to be assessed. Along these lines, Professor Bengt Fadeel asserted that "*there are great many studies on cells and animals suggesting that nanomaterials can have damaging effects on the health and the environment*".[81]

The Regulation acknowledges these potential risks, as Recital 30 recognises the fact that the current information on the risks associated to nanomaterials is "*inadequate*". In addition, Article 16-1 provides that "*for every cosmetic that contains nanomaterials, a high level of protection of human health shall be ensured*".

Based on these potential and yet uncertain risks for human health, the Regulation has built a flexible scheme that will be adjusted according to the findings of ongoing and future scientific research. In effect, the current definition of nanomaterials is provisional and the list of allowed nanomaterials is deemed to change.

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[75] Please note that these obligations do not apply to nanomaterials used as colorants, UV-filters or preservatives, which are explicitly regulated as restricted substances under Article 14 of the Regulation.

[76] The responsible person is designated pursuant to Article 4 of the Regulation. Article 16-3 of the Regulation provides that for nanomaterials it can be "*another legal or natural person designated by the responsible person by written mandate for the notification of nanomaterials, if the Commission is informed*".

[77] Article 16-3, para.2; Article 40-2, para.2. However, pursuant to Article 16-3, para. 3, this notification requirement does not apply to cosmetic products containing nanomaterials that conform to the restrictions set out in Annex III (list of substances which cosmetic products should not contain except subject to the restrictions laid down).

[78] Article 16-3 para. 4 of the Regulation.

[79] Article 16-3 (a) to (f) of the Regulation.

[80] Article 19-1 (g) (ii) of the Regulation.

[81] See http://130.237.98.166/ki/jsp/polopoly.jsp?d=24253&a=108524&l=en&newsdep=24253.

Provisional definition of nanomaterial

Nanomaterials are currently defined by the Regulation as being "*an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on a scale from 1 to 100 nm*".[82]

As previously mentioned, this definition will be subject to changes. Indeed, Recital 29 addresses the necessity to establish a definition of nanomaterials at an international level and adds that "*should such an agreement be reached, the definition of nanomaterials in this Regulation should be adapted accordingly*".

In addition, Article 2-3 states that the definition of nanomaterials will be adapted by the Commission, "*in view of the various definitions of nanomaterials published by different bodies and the constant technological and scientific development in the field of nanotechnologies, the Commission shall adjust and adapt point (k) of paragraph 1 to technical and scientific progress and to definitions subsequently agreed at international level*".[83]

Finally, the Commission will publish by 11 January 2014 a catalogue of all nanomaterials used in cosmetic products placed on the market. This catalogue will be public and regularly updated afterwards.[84]

Flexible list of authorised nanomaterials

The provisions allowing the use of nanomaterials may be adapted based on the progress of the understanding about the possible hazards of nanomaterials. Article 16-11 provides that "*the Commission shall regularly review the provisions of this Regulation concerning nanomaterials in the light of scientific progress and shall, where necessary, propose suitable amendments to those provisions*". The first review is scheduled to be undertaken by 11 July 2018,[85] i.e. only five years after the entry into force of the Regulation.

Moreover, if the Commission has concerns regarding the safety of a nanomaterial, it must, "*without delay*" request the Scientific Committee for Consumer Safety (SCCS)[86] to give its opinion on the safety of such nanomaterial. This information shall be made public by the Commission. If the SCCS considers that "*any necessary data is lacking*", it will have to request the responsible person to provide the data necessary for the inquiry "*within an explicitly stated reasonable time*", with no extension possible. The SCCS should deliver a final public opinion within six months.[87]

Based on the result of this inquiry, the Commission will have the power to amend the list of prohibited and restricted products in order to include a nanomaterial if there is a "*potential risk to human health, including where there is insufficient data*".[88] The precautionary principle finds an important application here and creates great uncertainties for manufacturers and suppliers as some ingredients may be suddenly prohibited from being used when they were, at first, allowed.

COMMENT

It is recommended that companies start adapting their chain of production and supply as well as their contracts with their sub-contractors in order to take into account the new obligations as well as the uncertainties originating from the Regulation concerning nanomaterials. When doing so, manufacturers should bear in mind the fact that research is likely to force them to find new ingredients within a short time scale as some nanomaterials may be prohibited when they were first allowed.

This reality is also true outside the scope of the cosmetic industry as highlighted by the Afsset which identified 246 products on the French market within the census that was carried out which contain nanomaterials. Indeed, while the effects of nanomaterials on human health are yet to be ascertained, some risks are already being studied very seriously. For example, Professor Bengt Fadeel asserted that "*there are serious fears that carbon nanotubes might have the same harmful properties as asbestos fibres*".[89]

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82 Article 2-1 (k) of the Regulation.

83 Article 2-3 of the Regulation.

84 Article 16-10 (a) of the Regulation.

85 Article 16-11 of the Regulation.

86 This Committee was established by the Commission Decision 2008/721/EC of 5 August 2008 to provide the Commission with scientific advice in evaluating scientific risks related to consumer safety, public health and the environment.

87 Article 16-4 of the Regulation.

88 Article 16-6 of the Regulation.

89 See http://130.237.98.166/ki/jsp/polopoly.jsp?d=24253&a=108524&l=en&newsdep=24253.

Nanomaterials being presented as the "future asbestos", the potential discovery of their hazardous properties, whether used in the cosmetics field or any other industry, may increase the liability of manufacturers and producers not only towards consumers, but also towards their employees who are in contact with nanomaterials and even perhaps towards the populations living nearby manufacturing plants. We may indeed see former employees suing their employers, claiming their liability based on the negligent exposure to a hazardous substance or for gross negligence should they develop an occupational illness. Serious questions should therefore be raised today about notably the insurance coverage of such risks. Indeed, for instance in France, it is very rare to find companies which are covered for asbestos-related risks, leading most of them into great financial difficulties. Another approach may be preferable for nanotechnologies. Manufacturers, producers and suppliers should start focusing on such questions.

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GOING FURTHER

PRODUCT SAFETY IN FRANCE: CURRENT TRENDS AND KEY POINTS FOR SUCCESSFUL COOPERATION WITH THE FRENCH AUTHORITIES

Introduction

In compliance with EU legislation, in France, manufacturers and distributors may place on the national market only those products which are safe for consumers.[90] The General Directorate for Competition policy, Consumer affairs and Fraud control (*Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes* - DGCCRF) is the authority in charge of ensuring such safety in France. Each year, the DGCCRF sends a report of its actions to the European Commission to show that it has been duly applying the EU legislation to protect French consumers.

2010 has been characterised by a desire of both the European and national authorities to reinforce through appropriate controls the safety of consumer products placed on the EU market. On 26 January 2010, the Commission published new guidelines for the management of the "RAPEX" system[91] and of the notification procedure established under Article 11 of the General Product Safety Directive (GPSD),[92] asking national authorities to intrude even further into the activities of manufacturers and distributors. Also in January 2010, the DGCCRF published its first national orientation rules (*Directive Nationale d'Orientation* - DNO)[93] to structure its actions.

These two texts have brought about a real change for manufacturers and distributors who place consumer products on the French market. We have already observed since the beginning of the year that the DGCCRF has increased the number of its controls and no longer hesitates to question the relevancy of corrective measures that are implemented when safety issues arise and to report such issues to the Commission through the RAPEX system.

Cooperation with the DGCCRF is, therefore, and now more than ever, a key point on which manufacturers and their distributors need to focus. Knowing how the DGCCRF is organised is also of fundamental importance given that different types of agents may now take actions.

THE NEW ORGANISATION OF THE DGCCRF

Missions of the DGCCRF

The DGCCRF, created in 1907, has three principal missions. It must

- ensure that the various players on the French market comply with market competition regulations,
- ensure consumers' economic protection and
- ensure consumers' safety.

As for the latter mission, which is the subject matter of this article, the DGCCRF carries out both preventive and in-field verification actions.

Preventive actions consist of carrying out risk assessments, informing consumers about dangerous products or precautions to be taken when using a product, referring products to experts to test their safety/compliance if necessary and reporting dangerous products through the RAPEX system.

Field verifications consist of controlling the packaging, labelling and first marketing of products and inspecting the manufacturing sites (eg their hygiene for food or cosmetic products, the traceability of the products, the transport conditions).

To carry out these missions in the most effective manner, the DGCCRF focuses on

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90 Article L. 221-1 of the French Consumer Code.

91 The Rapid Alert System for Dangerous Consumer Products.

92 Commission Decision no. 2010/15/EU of 16 December 2009 laying down guidelines for the management of the Community Rapid Information System 'RAPEX' established under Article 12 and of the notification procedure established under Article 11 of Directive 2001/95/EC (the General Product Safety Directive).

93 *Directive Nationale d'Orientation* for 2010, 4 January 2010, http://www.economie.gouv.fr/directions_services/dgccrf/ dgccrf/dno/dno_2010.pdf.

- those manufacturers who have, in the past, been reported to the Commission (either by the DGCCRF or by other national authorities)
- manufacturers of products that are considered to be "sensitive" eg toys, cosmetics, cars and household products and
- manufacturers of innovative products.

The DNO states that such controls should be reinforced in order for French consumers to have even more faith in the quality of the products that are offered to them: "*consumers' trust constitutes a major pillar of the economic support... Trust in the economy depends on confidence in a safer daily life. The security of products largely contributes to it*". Product safety has therefore become one of the primary tools for the French Government to revive the national economy.

New organisation within the DGCCRF

To carry out the increased controls mentioned above, the structure of the DGCCRF has been reorganised.

Until recently, product safety was ensured at two main levels

- the national agency (DGCCRF) was in charge of the dispatch of product safety notifications or complaints received within the different local agencies and of communication with the Commission and other national authorities
- the local agencies (DRCCRF - *Direction Régionale de la Concurrence de la Consommation et de la Répression des Fraudes*[94] - at the regional level and DDCCRF - *Direction Départementale de la Concurrence de la Consommation et de la Répression des Fraudes*[95] - at the departmental level) were in charge of the field investigations and of the assessment of the effectiveness of corrective measures implemented by manufacturers when a safety issue arose.

A Decree dated 10 November 2009,[96] in force since 1 July 2010, reorganised this two-fold structure. The DGCCRF's central services have been maintained, and their supervisory role as well. On the other hand, the organisation and the role of the local agencies, both at the regional and departmental levels, have changed. Since 1 July 2010, the DRCCRF and the DDCCRF have disappeared. In their place, 23 regional agencies, known as Regional Directorates for Companies, Competition policy, Consumer affairs, Labour and Employment (*Directions Régionales des Entreprises, de la Concurrence, de la Consommation, du Travail et de l'Emploi* - DIRECCTE) were created. All of these agencies are placed under the authority of their respective "regional prefect". As their name indicates, these regional agencies are in charge of more than simply ensuring product safety in the French market. However, a specific unit dedicated to product safety exists in each DIRECCTE. This unit will instruct the agencies which are at the departmental level and gather all the information needed to then report to the DGCCRF.

A second Decree, dated 3 December 2009,[97] created 101 Departmental Directorates for Protection of the Populations *(Directions Départementales de Protection de la Population* - DDPP) also called Departmental Directorates for Social Cohesion and Protection of the Population (*Directions Départementales de Cohésion Sociale et de Protection de la Population* - DDCSPP). These agencies are the result of a merger between the previous DDCCRF and the Departmental Veterinary Services agencies. They now carry out the missions they are given by their respective DIRECCTE. They mostly investigate in the field and should be the new points of contact for manufacturers and distributors. These local agencies are placed under the authority of the "prefect" of their respective department. They are each organised as follows

- a general secretariat which manages notifications and complaints on a daily basis. The agents working in this secretariat are now the direct points of contact for manufacturers and distributors. The secretariat is divided into four units: food, economic protection, animal health and the environment
- a unit specialised in receiving safety alerts sent by consumers and in reporting safety issues at national level and
- a unit specialised in controlling the exportation of animals and products.

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94 Regional Directorates for Competition policy, Consumer affairs and Fraud control.

95 Departmental Directorates for Competition policy, Consumer affairs and Fraud control.

96 Decree no. 2009-1377 of 10 November 2009 on the organisation and missions of the Regional Directorates for Companies, Competition policy, Consumer affairs, Labour and Employment.

97 Decree no. 2009-1484 of 3 December 2009 on Departmental Directorates for Protection of the Populations.

Other regional and departmental units have been created to manage specific areas, such as the Competition Policy, Consumer Affairs, Fraud Control and Metrology pole[98] in charge of controlling issues relating to notably the economic safety of the

consumers, the loyalty and transparency of the market and the methods of measurement used. On the other hand, the service in charge of investigating competition issues is now transferred to the High Competition Authority.

The new organisation described above is supposed to ensure that only highly specialised and trained agents will be in charge of product safety issues. This should be a positive outcome for both consumers and manufacturers as their contacts with the French authorities will bring more effective results. Having said that, although all levels will, in the end, have to follow the broad guidelines and objectives decided at national level, this new organisation is said to give more flexibility to each local authority in order to contribute to the safety of the French market through decisions which would be adapted to the local environment in question. This will surely raise difficulties in terms of equality of treatment of manufacturers according to the department/region they are in.

KEYS TO A SUCCESSFUL VOLUNTARY REPLACEMENT PROGRAMME OR RECALL IN FRANCE

A few figures

On 1 June 2010, the DGCCRF published its report relating to its activities in 2009. According to this report, in 2009 the DGCCRF

- carried out 900,132 controls
- visited 164,872 sites
- took 37,660 samples of products for analysis and
- controlled 7,353 websites selling products in France.

Following these actions, the DGCCRF issued 120,000 warnings, followed in 50% of cases by a second control, seized products in 800 instances and requested that criminal proceedings be launched against manufacturers in 16,000 cases.

The DGCCRF mentions that, concerning pure safety issues, it has focused its attention in 2009 on "*products for children (toys and childcare products), leisure products (lawn mowers, Christmas lights), products used on a daily basis and eco-products*". It also carried out specific industry sector investigations on cosmetic products (it controlled 256 products in 131 sites and detected dangerous substances in 30% of the products analysed), on automatic smoke detectors (it analysed 22 models and noticed that 12 models were not offering the expected level of safety) and on telephone cards sold on the internet (it seized 793,000 counterfeited cards).

During the first quarter of 2010, the DGCCRF registered 27,127 complaints from consumers.

Manufacturers' new points of contact within the DGCCRF

Since the reorganisation of the DGCCRF, manufacturers will have two points of contact

- the DGCCRF, at national level, when a manufacturer needs to inform the French authorities of a safety issue,
- the relevant DDPP at local level, ie the DDPP of the department in which the head office or the concerned subsidiary of the manufacturer is established, during the investigation that will be carried out following a notification or a complaint from a consumer. It is to the DDPP that manufacturers will have to prove that the corrective measures they have implemented are effective enough.

The DGCCRF's changing behaviour towards manufacturers and distributors

Since January 2010, we have experienced a change in the behaviour of the DGCCRF and its local agencies towards manufacturers and distributors.

First, the DGCCRF now reports safety issues to the Commission through the RAPEX system more systematically. France was known, until now, as one of the EU member states that reported to the Commission only on a very rare basis. It seems that this has changed as the DGCCRF no longer hesitates to report without even contacting the manufacturer beforehand to discuss the safety issue.

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[98] *Pôle C "concurrence, consommation, répression des fraudes et métrologie"*.

Second, when simply informing the DGCCRF of a potential or low safety risk, ie a risk which should not, under the GPSD, be notified or reported to the Commission, the DGCCRF will insist that the manufacturer nevertheless fills in the Business Application reporting form, even though that form is supposed to be submitted only when the risk assessment reveals a reportable risk.[99] It is becoming increasingly difficult to convince the DGCCRF that such an application should not be completed, especially as most of its agents argue that this application allows them better to manage their cases. Experience has shown that submitting the Business Application directly without contacting the DGCCRF beforehand, through an informative letter, makes it difficult to know, in particular, which agent will be in charge of the case and will therefore control the corrective action plan and publicity in the marketplace, as well as the confidentiality of the data sent. We do, therefore, advise that the DGCCRF first be informed of a safety issue through a format chosen by the manufacturer and only then, once the case is allocated to a specific agent and only if the latter insists, use the Business Application.

Furthermore, although the DGCCRF is usually satisfied with the corrective measures suggested by manufacturers (as long as all the distributors and end users are informed in an effective manner), it now requests regular updates in order to assess the effectiveness of such measures. Before 2010, the DGCCRF would usually ask for only one update, a month after having received the initial information. The DGCCRF is also even more intrusive when it is not satisfied with the effectiveness of the implemented corrective actions. It frequently asks for press releases to be published in consumer association publications such as "*UFC Que Choisir*" or "*60 millions de consommateurs*".

Finally, the DGCCRF is no longer satisfied when it receives mere information with no corrective actions suggested. In the past, the DGCCRF would accept information about a mere potential risk without any corrective actions taken. This was a way for manufacturers to inform the DGCCRF at a very preliminary stage, just in case an injury was to occur while further testing was being carried out. It is no longer advised to take such a step as there is a real risk that the DGCCRF will treat such information as a notification and require the manufacturer to implement corrective measures even though no actual risk is evidenced.

Steps to be considered when launching a voluntary replacement programme/recall

When deciding to recall or voluntarily replace products that are already on the market, the main issue for many manufacturers is to ensure that such a recall or replacement is quickly and effectively handled and that there is a minimum of additional publicity around the recall or replacement. As shown above, the DGCCRF is increasingly inclined to report to the Commission or to order the publication of press releases, making such exercises even more difficult to handle.

Without going into the details of the Commission's guidelines relating to the assessment of a safety risk,[100] it is important to note that in France, as in the rest of the EU, the manufacturer is supposed to inform the DGCCRF "immediately" should a safety risk come to its attention.[101] However, contrary to the law of most member states, French law does not provide for any specific sanction for breach of the obligation to notify the DGCCRF. Having said that, if the DGCCRF is informed by a consumer of the existence of such a risk, the manufacturer will find it difficult to justify the absence of notification and may, if a consumer is injured, face criminal liability.

Attention should therefore be given to the way in which the notification or information sent to the authority is drafted. In particular, the DGCCRF will focus mainly on the following points

- the number of incidents/accidents, the percentage they represent out of the total number of products marketed worldwide and the worst case scenario that could happen. The information written in the section of the notification relating to "information on the risk" is therefore crucial
- the question of whether or not the product is traceable to the end user
- the evidence provided to show that the manufacturer's distributors/installers and end users have been effectively informed. The DGCCRF always asks to be provided with a copy of the letters sent to the distributors/installers and a copy of the letters sent to the end users or, if the product in question is not traceable, a copy of the web announcements or press release published and
- how many products are on the French market and whether a batch of defective products was identified by the manufacturer.

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[99] For more details, see by Rod Freeman and Heather Gagen, "The Business Application: a new way forward for notification of safety risk?", *European Product Liability Review* 35 (June 2009) p5.

[100] See newsflash by Rod Freeman and Claire Taylor "European Commission announces important new Guidelines for Product Recalls and Risk Assessments", 27 January 2010.

[101] Articles L. 221-1 and following of the French Consumer Code.

Manufacturers should be ready to send on any information requested by the agent in charge of their case and especially to provide evidence that all the players who need to be informed have been effectively informed. Manufacturers should also be ready to meet with the agent on several occasions on their site as agents like to have face-to-face meetings. It is advised never to refuse such meetings as this would send the message that the safety issue in question is not the company's priority, when it should be. Such meetings will provide opportunities to inform the DGCCRF of how the other national authorities are handling the same safety issue. Experience has shown that when other national authorities consider that the risk is low or under control and that the corrective measures implemented are effective, the DGCCRF tends to follow their lead.

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ITALY - SUPREME COURT OF CASSATION - JUDGEMENT OF 13 DECEMBER 2010, NO. 25116

INTRODUCTION

In a recent decision, the Supreme Court, ruling on a case concerning the alleged liability of the manufacturer of a tanning lotion, has interpreted the specific regulation on cosmetic products in light of the general provisions on product liability. In particular, the Supreme Court ruled out the liability of the manufacturer as the product had been used under abnormal and unforeseeable conditions.

BACKGROUND

In Italy cosmetic products are governed by Law no. 713/1986[102] (and subsequent amendments). In particular, section 7 of Law No. 713/1986 provides that cosmetic products must not be harmful under normal or foreseeable conditions of use.[103]

The provisions set forth by Law no. 713/1986 on defectiveness of the product are similar to those provided for under Presidential Decree No. 224/1988 concerning liability for defective products[104], currently encompassed into the Consumer Code.[105] Particularly, section 5 of Presidential Decree no. 224/1988, now transposed on section 117 of the Consumer Code, sets forth the circumstances under which a product can be considered defective (*i.e.* the way in which the product was marketed and presented; the product information and warnings; the expected use; the time when the product was put into circulation). [106]

The Supreme Court has interpreted the above provisions, covering a number of interesting issues relating to the liability of the manufacturer of cosmetic products.

FACTS

The case was brought against the manufacturer of a tanning lotion[107] by a woman claiming compensation for damages suffered following second and third degree burns with permanent after-effects, allegedly due to the use of the cosmetic.

On 30 June 2000 the first instance court upheld the claim for damages stating that claimant had successfully proved the causal link between the use of the product and the alleged damages suffered.

The first instance decision was overturned by the Court of Appeal of Catania based on the following grounds.

i) The evidence submitted in Court confirmed the use of the product by the claimant and her exposure to the sun during the morning hours, but did not prove causation between the use of the tanning lotion and the alleged sunburns.

ii) The fact that the tanning lotion allegedly used by the claimant was not submitted in Court did not allow for chemical tests to be carried out to assess whether the product could have been altered as a consequence of incorrect packaging or due to other defects.

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102 Law no. 713/1986 implemented Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic product.

103 Under section 7 of Law No. 713/1986 states that: "*A cosmetic product must be manufactured, put on the market within the Community must not cause damage to human health when applied under normal or reasonably foreseeable conditions of use, taking account, in particular, of the product's presentation, its labelling, any instructions for its use and disposal as well as any other indication or information provided by the manufacturer or his authorized agent or by any other person responsible for placing the product on the Community market. The provision of such warnings shall not, in any event, exempt any person from compliance with the other requirements laid down in this Law*".

104 Presidential Decree No. 224/1988, implementing the Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products.

105 Legislative Decree No. 206 of 6 September 2005.

106 Section 5 of Presidential Decree No. 224/1988 provides that: "*A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:*
(a) the way in which the product has been put into circulation, its presentation, its tangible features as well as the instructions and warnings provided with the product;
(b) the use to which it could reasonably be expected that the product would be put and the behaviors that may reasonably be expected in connection thereto;
(c) the time when the product was put into circulation.
A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.
A product is defective if it fails to offer the degree of safety that is normally offered by other items of the same range".

107 Included among the cosmetics listed in annex I of Law no. 713/86.

iii) As regards dosage and the time of exposure to the sun, the claimant did not regard the cautionary warning, which was required on the basis of the product information provided by the manufacturer.

The decision of the Court of Appeal was challenged by the claimant before the Supreme Court on grounds that: (i) section 7 of Law no. 713/1986 was incorrectly applied (ii) the Court of Appeal failed to examine the evidence submitted in Court (iii) the producer had the burden of proving that the cosmetic was compliant with regulatory and statutory requirements relating to the manufacturing and marketing of the product.

THE SUPREME COURT DECISION

The Supreme Court reviewed the second instance decision and referred the case to a different panel of Judges of the Court of Appeal for them to reconsider the evidence submitted by the consumer in previous stages of the proceedings in light of the following principles stated by the Supreme Court.

Section 7 of Law No. 723/1986, as interpreted according to the general provisions on product liability[108], does not establish an absolute strict liability of the manufacturer of cosmetic products. Indeed, according to section 7 of Law No. 723/1986, the cosmetic product shall be considered defective - with consequent possible liability of the manufacturer - when such product is considered as harmful for human health under the normal conditions of use. To the contrary, the manufacturer's liability shall be excluded in case of 'abnormal use' of the product, which occurs not only when the product is used under abnormal and unlawful conditions, but also in the event of occurrence of highly anomalous circumstances - albeit not directly ascribable to the consumer - leading the harmless product to become capable of causing health injuries. Said circumstances include the consumer's health conditions - even when temporary - during the use of the product.

Finally, the Supreme Court found that, even when the product is used under normal conditions, the damage per se does not prove the dangerous nature of the product, which is not sufficient per se to establish the manufacturer's liability, unless it is ascertained that the product does not comply with the standards of safety prescribed by law or that users can legitimately expect.

COMMENT

The interpretation given by the Supreme Court appears to be in line with the recent case law, according to which the health damage occurred to consumers as a consequence of the use of a cosmetic product is not sufficient to prove the dangerousness of the product and hence the manufacturer's liability.[109]

In assessing the manufacturer's liability the Judge shall consider the way in which the product was used; no liability can be ascribed to the manufacturer in case of abnormal use of the product by the consumer.

In light of the above mentioned approach followed by Supreme Court, the manufacturer can only be held liable when the consumer proves i) that the product was used under normal conditions; ii) the product did not comply with the standards of reliability legitimately expected by users or prescribed by law iii) causation between the use of the product and the damage allegedly suffered is substantiated.

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[108] The Supreme Court stated that, under section 5 of Presidential Decree No. 224/1988, a product is deemed defective when it does not provide the safety that the consumer is entitled to expect, with reference to all circumstances provided by the same provision to any other elements to be specifically considered (among which the safety standards possibly required by the specific regulation which is provided by Law no. 723/1986 as regards cosmetics).

[109] *Inter alia*, Supreme Court of Cassation, 15 March 2007, No. 6007.

LEGISLATIVE CALENDAR FOR THE COMING YEARS

Date	Legislative event
March 2011	New International Cosmos Organic label for organic and natural cosmetics
Spring 2011	Russia will issue a technical regulation on perfumes and cosmetics
1 April 2011	Entry into force of the new registration procedure of cosmetic products imported in India
Second half of 2011	Publication of the EU common criteria for "natural" and "organic" claims pursuant to Article 20 of Regulation no. 1223/2009 on cosmetic products
11 January 2012	Deadline for the new electronic notification procedure (Articles 13 and 39 of Regulation no. 1223/2009 on cosmetic products)
11 January 2013	Entry into force of the provisions relating to the use of nanomaterials (Article 16 of Regulation no. 1223/2009 on cosmetic products)
11 March 2013	The prohibition to market in the European Community, finished cosmetic products and ingredients which were tested on animals will entry into force on 11 March 2013 (this deadline may be postponed)
11 July 2013	Entry into force of Regulation no 1223/2009 on cosmetic products

MAIN EVENTS IN THE COSMETICS FIELD SCHEDULED IN 2011

Date	Events	Contact
26-28 February	International Fair of Cosmetic & Wellness (Spain - Barcelona)	http://www.cosmobelleza.com/es/feria/info/events/estetica/congresoesteticacosmo
12-14 March	Worldwide Spa & Beauty Fair (France - Paris)	http://www.msbparis.com/
17 March	2nd Technical Regulatory Information Day (Belgium - Brussels)	COLIPA
18-21 March	Cosmoprof (Italy - Bologna)	http://www.cosmoprof.com/
24 March	The 11th Cosmed Regulatory Meeting (France - Marseille)[110]	COSMED (Professional association of small businesses of the cosmetic industry), www.cosmed.fr
29 March	Conference on the responsible person (France - Paris)	FEBEA
29/31 March	In-Cosmetics (Italy - Milan)	www.in-cosmetics.com
3/4 April	Natural & Organics Product Europe (UK - London)	http://www.naturalproducts.co.uk/
10/11 May	Supplier's Day Fair (USA - New York)	http://www.nyscc.org/suppliersday.html
16/18 May	Beauty World Japan Fair (Japan - Tokyo)	http://www.beautyworldjapan.com/en/east/
17 - 20 May	Biomakers World Europe (UK - London)	http://www.healthnetworkcommunications.com/2011/biomarkerseur/
24-26 May	Beauty World Middle East (UAE - Dubai) FCE Pharma & Cosmetics (Brasil - Sao Paulo)	http://www.gulfbeautyexpo.com/ www.lyon.cci.fr/site/document/...0/MISSION-BRESIL-MAI-2011.pdf
15-17 June	COLIPA's General Assembly	COLIPA
16 June	The 11th Cosmed Regulatory Meeting (France - Paris)	COSMED
23/24 June	Make up in Paris (France - Paris)	http://www.makeup-in-paris.com/Inspiration,60.html
12/14 September	Beyond Beauty Paris (France - Paris)	www.beyondbeautyparis.com
6/7 October	Natural beauty Summit (USA - New-York)	www.naturalbeautysummit.com
2-4 November	In Cosmetics Asia (Thailand - Bangkok)	http://www.in-cosmeticsasia.com/
9-11 November	Cosmoprof Asia (Hong Kong)	http://www.cosmoprof-asia.com/

[110] Sylvie Gallage-Alwis from Hogan Lovells will make a presentation on "*Contracts - how to protect yourself effectively*?" at both the Marseille and Paris sessions.

EXPERTISE OF HOGAN LOVELLS IN COSMETICS LITIGATION

Hogan Lovells has the largest and most **highly regarded product liability practices in Europe**. The network comprises over 100 lawyers who are able to advise on all aspects of product safety, risk management, regulation, litigation and other forms of dispute resolution.

Our European Product Liability Network of specialist practitioners enables us to **provide a co-ordinated, multi-jurisdictional service using the best expertise in each jurisdiction at a competitive cost**. It also provides a forum for innovation and best practice ensuring that clients receive a consistently high standard of service.

As market leaders in product liability matters, we have developed **good working relationships with national and EU authorities**. At an EU level, we are recognised within the European Commission as leading experts in this field, and are invited by the Commission to speak at Commission-organised public seminars as well as at training sessions for Commission staff.

Our lawyers regularly work with national investigating, enforcement and product safety authorities. **We assist our clients in liaising with lawmakers and enforcement authorities on matters relevant to product liability and product safety laws**. Our reputation in the marketplace helps to ensure our views on such matters are heard and respected.

The Hogan Lovells Cosmetics Group

The Hogan Lovells Cosmetics Group was founded to assist clients to resolve these increasing legal problems. The members of the Group are in regular contact with national and international regulatory authorities, and they work closely with experts, in a variety of legal contexts.

The Hogan Lovells Cosmetics Group has pooled specific expertise in the cosmetics industry and related suppliers in the EU and around the world. The Cosmetics Group works closely with clients to understand their business, the technical aspects of their products and their commercial concerns. The members of the Cosmetics Group are ready to assist, whatever issues clients face.

The Science Unit

The Hogan Lovells Science Unit, founded in 1996, has worked on matters relating to a variety of industries including, in particular, the life sciences industry. The scientists' advice has proved valuable in a variety of legal contexts including regulatory issues, product liability and personal injury litigation, advertising claims patent infringement and revocation actions, due diligence exercises, and insurance cases.

The members of the Unit have carried out and published original scientific research so are familiar with the processes involved in data collection and analysis, publication and peer review of scientific research. They continue to publish articles on subjects of scientific interest and have presented at seminars and conferences.

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