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**The New
EC Cosmetics Regulation
1223/2009 –
Contents and
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EC-Cosmetics Regulation 1223/2009, Definitions Safety, Responsibility, Product Information File, Notification, Animal Testing, Market Surveillance

■ Introduction and Open Questions

On 22 December 2009 the European Cosmetics Regulation 1223/2009 was published in the Official Journal of the European Union (1). After tough negotiations between the European Commission, which had presented the first draft more than two years ago to the Member States and stakeholders, and the EC Council of Ministers and the European Parliament, the Regulation was signed on 30 November 2009 in Brussels by the Presidents of the European Parliament and the Council of Ministers. The new EC Cosmetics Regulation will completely replace the currently valid EC Cosmetics Directive 76/768 (2) and, by extension, most of the national provisions which are set out in the Food and Feed Code (LFGB) (3) and in the Cosmetics Ordinance in Germany (4).

Regulation 1223/2009 will only enter into force on 11 July 2013, with the exception of specific articles which already come into force on 1 December 2010 and 11 January 2013. This means that the European Community will have a harmonised legal regulation at its disposal. All the economic stakeholders and national legislators now have enough time to take the necessary steps or to make statutory amendments to national legislation. At the present time corresponding guidelines or explanations from the Commission are not yet available for many of the envisaged provisions. The main IT structures are nowhere near available in order to meet certain requirements already today (e.g. notification pursuant to the new Regulation).

The new Regulation 1223/2009 will render superfluous the provisions regarding

cosmetic products to be found in the national German Food and Feed Code (LFGB). The German Cosmetics Ordinance will only be needed in conjunction with the penalties imposed in cases of infringement of Regulation 1223/2009.

The German text of Regulation 1223/2009 contains some incorrect or at least misleading translations that must be corrected in the opinion of the authors. For instance in Article 6 para 1 the half sentence *»when making a product available on the market«* is incorrectly translated as *»wenn sie ein Produkt in Verkehr bringen«*. Instead this should read *»wenn sie ein Produkt auf dem Markt bereitstellen«*. In Article 13 para 4 *»Where a cosmetic product has been placed on the market before ... but is no longer placed on the market as from that date«* has been translated as *»Wird ein kosmetisches Mittel vor dem... in Verkehr gebracht, befindet es sich nach diesem Zeitpunkt aber nicht mehr auf dem Markt«*. What it should say is, *»Wird ein kosmetisches Mittel zwar vor dem..., aber nicht mehr nach diesem Zeitpunkt in Verkehr gebracht, ...«*. The English text clearly refers only to the (first) placing on the market. Finally, in the English version of Article 25 para 1 the competent authorities call on the responsible person in the event of non-compliance *»to take all appropriate measures«*. The term *»appropriate«* clearly expresses the fact here that of course only in individual cases are *»appropriate«* measures to be taken. Different from the term *»appropriate«* the translation *»alle geeigneten Maßnahmen«* does not render in the same way the constant need for compliance with the principle of proportionality.

Some recitals, individual chapters with their respective articles and specific an-

nexes are presented below. A short description is given along with any detailed comments from the authors available at the time.

■ Objectives of Regulation 1223/2009 – 3rd Recital

The objectives of the European Cosmetics Regulation are formulated in the 3rd Recital:

1. To simplify procedures and streamline terminology, thereby reducing the administrative burden and ambiguities (key word *»simplification«*).
2. To strengthen certain elements of the regulatory framework, such as in-market control, with a view to ensuring a high level of protection of human health.

■ »Simplification« and »New Approach«

Two terms *»Simplification«* and *»New Approach«* are repeatedly mentioned in conjunction with the new provisions in European cosmetics legislation.

The *»Simplification programme«* was elaborated by the European Commission in 2005 in order to put in place improved EU legislation by means of dismantling red tape, more structured and comprehensible legislation, improved administrative co-operation and the active involvement of all economic stakeholders. The objective was to promote more economic growth and jobs whilst maintaining consumer protection. In the context of *»Simplification«*

one initial comment is that the legal text of Regulation 1223/2009 is considerably longer than the Cosmetics Directive (roughly three to four times). The 11 recitals in the Directive have grown into 71. At first sight this does not look like simplification. However, on closer inspection the legislator's goal of simplification has indeed been achieved to a major degree in our opinion. The recitals are commentaries on the individual articles. Hence, they promote greater comprehensibility of the legal text. The 40 Articles – compared with the 15 in the Directive – have been clearly structured in 10 chapters. This also makes a major contribution to the clarity of the legal text:

1. Scope, Definitions (Articles 1-2)
2. Safety, Responsibility, Free movement of goods (Articles 3-9)
3. Safety assessment, Product information file, Notification (Articles 10-13)
4. Restrictions for specific substances (Articles 14-17)
5. Animal testing (Article 18)
6. Consumer information (Articles 19-21)
7. In-market control (Articles 22-24)
8. Non-compliance, Safeguard clause (Articles 25-28)
9. Co-operation between competent authorities (Articles 29-30)
10. Implementing measures, Final provisions (Articles 31-40)

»New Approach« is a term that was coined by the European legislator and European standardisation institutions (amongst others CEN). In this body of regulations the objective goal is formulated of improving consumer health protection and the free movement of goods through the creation of uniform standards within the EU. The term »New Approach« has been taken over into a few sub-aspects. In certain articles reference is made to the future importance of harmonised standards (cosmetics GMP, sampling, analytical methods).

■ New Contents

What changes have been made to contents compared with the Cosmetics Directive that go beyond the comments on the individual articles in the recitals and beyond the clear structuring of the comprehensive legal text? This is examined by taking a look at the individual articles and annexes. What can already be said about the annexes at this point is that the substance lists (list of prohibited substances, positive lists) have not been fundamentally revised. A structure similar to that of the articles would have contributed greatly to simplifying and clarifying the new Regulation given the lack of transparency of the comprehensive substance lists. No discussion is undertaken here of the contents because of the time concepts of the European institutions concerning the time of publication. The future will reveal the extent to which a simplification of the substance lists will be achieved within the framework of the work of the »Cosmetics« Standing Committee of the European Union.

1. Chapter I – Scope and Definitions

Chapter I regulates the **Scope and Definitions**: The previous **definition of cosmetic products** (Article 2) has been kept. Whereas in the German version the skin is still mentioned as an important site of application and action for cosmetic products, the narrower term »epidermis« is used in various language versions (for instance English, French, Italian, Spanish, and Portuguese). This incorrect name for the site of action which is disputed in expert circles was unfortunately taken over from the Cosmetics Directive. With the definition of exclusive or main purpose of use of a cosmetic product and the delimitations mentioned in the 6th Recital to the legal environment for medicinal products, medical devices and biocidal products, we are of the opinion that it is possible in the concrete individual case to sufficiently distinguish cosmetic products from these other products. As in the past there will still be serious cases of doubt for which commentaries to

a certain degree, e.g. in the form of guidelines of the European Commission (5) or publications (6) will serve as decision-making aids. The delimitation to food is not mentioned in the 6th Recital but given the clear legal situation in the basic Food Regulation 178/2002 this is not normally problematic. Here, too, commentaries can help in individual cases (7).

The 7th Recital contains, for instance, the categories of cosmetic products as currently named in Annex I to the Cosmetics Directive (e.g. skin care creams). The 8th Recital assigns the Commission the task in future of precisely defining these categories of cosmetic products. This will probably be done in a guideline.

New additions in Chapter 2 are the diverse definitions of terms which play a major role in other Articles. This constitutes a major improvement over the Directive.

1. Substance
2. Mixture
3. Manufacturer
4. Distributor
5. End user
6. Making available on the market
7. Placing on the market
8. Importer
9. Harmonised standard
10. Nanomaterial
11. Preservatives
12. Colorants
13. UV filters
14. Undesirable effects
15. Serious undesirable effects
16. Withdrawal
17. Recall
18. Frame formulation

Some terms are discussed in more detail in the following sections.

2. Chapter II – Safety, Responsibility, Free Movement of Goods

The **safety requirements** to be met by products have been reformulated in Article 3 of Chapter II (**Safety, Responsibility, Free Movement of Goods**). It stipulates that cosmetic products must be

safe when applied under normal or reasonably foreseeable conditions of use. There are two major differences compared with the Directive:

1. The requirement that a product must be safe is worded more strictly than in the previous provision which states that a cosmetic product may not cause damage to health.
2. The safety of cosmetic products explicitly includes – as was already the case but not mentioned in the Cosmetics Directive – the detailed provisions regarding confusion with food in accordance with Directive 87/357/EEC.

Article 4 gives a new definition of responsibilities. Article 5 lists the obligations of the responsible persons and Article 6 the responsibilities of distributors. Furthermore, Article 7 now stipulates identification within the supply chain (cf. on this subject 2.1).

Article 8 describes the requirements to be met in terms of good manufacturing practice (Cosmetics GMP). A later publication, envisaged pursuant to Regulation 1223/2009 in the Official Journal, will probably refer to DIN EN ISO 22716. IKW has published an additional brochure »Cosmetics GMP – DIN EN ISO 22716 with comments by the German Cosmetic, Toiletry, Perfumery and Detergent Association« (8). It encompasses both the standard and more in-depth explanations. Article 9 contains provisions on the free movement of goods within the EU, i.e. the Member States may not impede the marketing of cosmetic products when the products are in conformity with the Regulation. Hence, they may not lay down any national legal standards that go beyond this.

2.1 More in-depth explanations on definitions and responsibilities

Regulation 1223/2009 contains extensive provisions on responsibilities in conjunction with the production and making available of cosmetic products on the market. As the legislator attempted to regulate all conceivable constellations of responsibilities, the text in the Regula-

tion is in parts highly complicated. However, most of these provisions will not lead to any major changes in practice. Frequently, they seek to clarify existing practices or take over existing general provisions on product safety (in Germany in accordance with the Equipment and Product Safety Act, GPSG) into the special legal environment for cosmetic products.

Some new »language provisions« result from the following definitions in Article 2 of Regulation 1223/2009:

»Making available on the market« is deemed here to be the »any supply of a cosmetic product for distribution, consumption or use on the Community market in the course of a commercial activity, whether in return for payment or free of charge«.

The term »placing on the market« encompasses pursuant to Regulation 1223/2009 a one-off process only, i.e. the »first making available of a cosmetic product on the Community market«. Hence, a re-thinking of attitudes will be needed in conjunction with Regulation 1223/2009 as according to the current Food and Feed Code (LFGB), which is applicable to cosmetic products in Germany, the term »placing on the market« encompasses the supply on each distribution level including the mere »offering for sale«. This more comprehensive food law definition of placing on the market is regulated in the basic European Food Regulation 178/02.

According to Regulation 1223/2009 the manufacturer is »any natural or legal person who manufactures a cosmetic product or has such a product designed or manufactured, and markets that cosmetic product under his name or trade mark«. To the extent that this person has its registered office within the European Community, it is generally also the »responsible person« for the placing on the market of the cosmetic product (cf. also in more detail Article 4 para 3). A pure contract manufacturer is not, therefore, in principle deemed to be a »manufacturer« within the intendment of Regulation 1223/2009.

Distributor is, by contrast, the »person in the supply chain, other than the manufacturer or importer, who makes a cosmetic product available on the Commu-

nity market«. According to Regulation 1223/2009 a distributor can only become the responsible person in exceptional circumstances when he »modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected« (cf. also Article 4, para 6), i.e. for instance by adding elements to the label. Regarding the private labels of a commercial enterprise, it already regularly complies with the above-mentioned definition of manufacturer and is not, therefore, deemed to be a »distributor«.

Importer is »any natural or legal person established within the Community who places a cosmetic product from a third country on the Community market«.

The following »basic rules« continue to apply to the responsibilities of the persons defined here:

The »responsible person« indicated on the package with registered office within the European Community must guarantee compliance with all the safety and labelling requirements of the cosmetic product as well as compliance with the notification obligations and – inasmuch as this is necessary in individual cases – the taking of corrective measures (cf. in particular Article 5).

The responsibilities of the distributors exist in principle only in their actual sphere of influence. For instance, they must ensure – as was the case previously – that the labelling of ingredients at the point of sale, which is permissible by way of exception for small articles, is in fact present or that, where appropriate, the existing storage and transport requirements for cosmetic products are complied with. The explicitly regulated verification obligations of distributors concerning the cosmetic products made available by them are restricted to a few points which were already regularly verified up to now in the retail trade by way of random external verification. It is just as easy to verify the presence of the address of the responsible person, an INCI list and batch label as it is to check the required use of the respective national language for essential labelling elements, in particular warnings (cf. also Article 6). Besides the general obligation to cooperate with the competent surveillance authorities, the responsible persons and

distributors are already today – pursuant to the Directive on general product safety (17) – obliged to **notify the authorities** when a cosmetic product in an individual case constitutes a risk to human health. Article 5 paras 2 and 3 and Article 6 paras 3 and 5 of Regulation 1223/2009 now contain corresponding provisions. For **distributors** the obligation was merely **added** in Article 6 para 3 to immediately contact the person responsible for placing the cosmetic product on the market. This new provision is very useful as the responsible person in particular has the necessary technical knowledge in order to assess in an expert manner the actual risk situation in a – under certain circumstances only supposed – crisis and, in co-operation with the competent authority, to decide where appropriate on any required corrective measures.

The **new provisions concerning responsibilities** mainly concern the following points in the opinion of the authors:

1. The verification duties of distributors in future expressly include pursuant to Regulation 1223/2009 checking that the date of minimum durability on the label has not yet expired at the time of supply to the end user (see Article 6, para 2, third indent).
2. For all products which are initially exported from the territory of the European Community and then imported back into the Community, the importer is in principle always the »responsible person« (see Article 4, para 5). Hence in this case he had to assume all the obligations set out in Article 5.
3. Article 7 contains a new provision which aims to make it easier for the competent authorities to identify the persons involved in the supply chain of a cosmetic product. According to this article the responsible persons must be capable – at the request of a competent authority – of identifying those distributors to whom they supply the cosmetic product. At the same time, distributors must be able to name the responsible persons from whom they have obtained a cosmet-

ic product and, where appropriate, to likewise identify the distributors to whom they have passed on the cosmetic product. This obligation exists for a period of three years after the time when the last delivery of the respective cosmetic product was made available to the distributor. The Regulation does not contain any details about the form in which documents for the purpose of identification of the persons involved in the supply chain must be recorded and stored. This should be easily possible for instance with the help of delivery notes.

3. Chapter III – Safety Assessment, Product Information File, Product Sampling and Analysis, Notification

Chapter III, i.e. Articles 10–13, sets out the **requirements to be met by the Safety Assessment** (Article 10), the **Product Information File** (Article 11) and **Sampling and Analysis** (Article 12) and **Notification** of the products on the EU level (Article 13). The previous product information, which is now called the **Product Information File**, is basically the same although the safety assessment takes on greater importance. In future accessibility will be outlined more clearly: Article 11 (3) states that the responsible person shall make the information readily accessible at the address indicated on the label to the competent authority.

3.1 Requirements to be met by the safety assessment

The safety assessment requirements are described in far more detail than in the Cosmetics Directive. This reflects the strategy of the European legislator to supplement the previous form of comprehensive substance provisions (positive and negative lists) with greater manufacturer responsibility for each individual product and its ingredients. Whereas the Cosmetics Directive 76/768 merely envisaged a comprehensive negative list and various positive lists (restricted substances, colorants, preservatives and UV filters), the 6th Amendment to the Directive in 1993 introduced a safe-

ty assessment for each individual product. However, it is common knowledge that this provision is formulated in a very general manner (toxicological profile of the ingredients, chemical structure and level of exposure).

The **contents of the safety assessment** are described in detail in **Annex I**. Here the legislator acknowledges the fact that an inestimable number of cosmetic raw materials are available (roughly tens of thousands) and that the number of new active ingredients, raw materials and subsidiary materials in the very innovative field of cosmetic products is very high. The state regulation of all these substances does not make sense and is not possible. Hence, the complicated procedure of negative and positive lists should only be used for the most important substances from the angle of consumer protection. Annex 1 contains many points of the basic elements of the »Safety Assessment« working group published in 2005 by the German Society for Scientific and Applied Cosmetics (DGK) (9) and also the published minimum requirements of the national official cosmetic experts in Germany (10). The European Commission is to set up a working group to elaborate a guide for the preparation and structure of safety assessments which will be of assistance in particular to small and medium-sized enterprises. This guide should of course contain all the available information.

Article 10 (2) stipulates that the safety assessment must be carried out by a person in possession of a diploma or other evidence of formal qualifications awarded on completion of a university course of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline, or a course of study recognised as equivalent by a Member State. The authors are of the opinion that a qualification of this kind is not enough in order to be able to carry out a sound expert safety assessment. What are required are additional technical further training courses. The German Society for Scientific and Applied Cosmetics (DGK) and IKW have co-operated closely in staging further training courses for safety assessors for 10 years now. In the new European Cosmetics Regulation a robust safety assessment of cosmetic products

will assume even greater importance in future. The IKW/DGK courses offer experts with the relevant basic knowledge from the cosmetic industry and official surveillance authorities an opportunity to undergo further comprehensive training in the field of safety assessment. The courses are unique in Europe but are frequently not very well known outside German-speaking areas. The new contents are explained in detail at seminars tailored specifically to safety assessors (11).

Already today it can be observed that in Germany many safety assessments already meet the requirements set out in Annex I and do not, therefore, require any revision.

3.2. Sampling and Analysis

Article 12 refers from the angle of the »New Approach« to **existing and future standards for the sampling and analysis of cosmetic products** which are elaborated and published by European standardisation authorities. These are harmonised test methods and standard operating procedures which are to be made available both to official cosmetic surveillance authorities and cosmetic manufacturers for the in-house control of their products. The 20th Recital comments on the fact that sampling and analysis should be carried out in a reproducible and standardised manner to ensure the uniform application and control of the restrictions for substances. Article 25 para 1 d makes clear the fact that this not only refers to analyses within the framework of in-market control but also to a company's in-house controls. It addresses the situation of non-compliance by the responsible person with the sampling and analysis standards. At this point it must, of course, be stressed that a manufacturer can routinely check as a rule the proof or non-proof of certain substances in the formulation within the framework of cosmetic GMP (e.g. via weighing protocols). Of course, analytical methods are also used in internal quality assurance. What is needed here are reliable, reproducible methods. They need not, however, necessarily be internationally standardised methods. So-called multi-methods which combine

the analysis of several substances in one class within one method are only routinely used by manufacturers in their in-house controls in rare cases.

In order in future to meet the requirement of uniform standardisation within the indentment of Regulation 1223/2009 – also with a view to Europe-wide harmonised, reliable surveillance – the authors are of the opinion that efficient and, if possible, unbureaucratic standards must be available for the sampling and analysis of cosmetic products. They should correspond to the best available analytical methods, which means that they have to be efficiently updated. This was not the case in the past.

What is the legal situation?

The Cosmetics Directive does not deal in a concrete manner with harmonised methods. Article 8 of the Directive merely states that the European Commission is responsible for the necessary analytical methods. On this point the European Commission published between 1980 and 1996 a total of seven Directives as official methods in the Official Journal of the European Union. They look in more detail at the sampling and specific analytical methods for cosmetic products. All seven Directives have been published in a volume of the European Commission (12). One example is Directive 80/1335/EEC which sets out the general criteria for the sampling and analysis of substances, amongst others oxalic acid in hair care products or chloroform in toothpaste.

§ 5 e in the German Cosmetics Ordinance clearly states that the analytical methods are to be used which are listed in the Official Collection of Test Methods pursuant to § 64 para 1 of the Food and Feed Code. In § 5e 20 European methods are listed (examples from the Cosmetics Regulation: K 84.006 (EC) status November 1982 or K 84.0024 (EC) status November 1996).

These methods were developed in the 1980s and 1990s in national working groups (in Germany, for instance in the § 35 Act on Food and Articles in Everyday Use [LMBG] working group), in the »Cosmetic Products« working group of the Member States or under the aegis of the Joint Research Centre of the Euro-

pean Commission. They were published by the European Commission as directives in the Official Journal of the European Union and finally taken over into § 5 e of the Cosmetics Regulation. The working group was disbanded eight years ago because the European Commission had recognised that standardisation work can be undertaken more effectively on the CEN level or in national bodies (DIN in Germany) or even internationally on the ISO level (»New Approach«). The published official methods frequently no longer reflect the state of the art. However, in principle no deviations may be undertaken from test methods which are bindingly laid down in legal provisions. The authors are of the opinion that this dilemma can be resolved in the following way: the official European methods should be revoked by the publication as soon as possible of a corresponding directive. They will gradually be replaced by harmonised standards on the ISO/CEN and DIN level which, because of the rules of these standardisation institutes, will be subject to a strict updating modus which is still cumbersome but perhaps more purpose-specific than the procedure so far. Unfortunately in recent years – above all in conjunction with ISO approaches – the option of international standardisation which is so promising for everyone has proved to be problematic. For instance limit values were laid down across the world for heavy metal levels in toothpaste which were higher than the limit values recommended in Germany. Examples of this kind reveal the weakness of international standardisation. Shortcomings of this kind must be avoided at all costs in future.

What is the current situation?

A few years ago the national working group § 64 Food and Feed Code (LFGB) »Analysis of cosmetic products« was set up within the Federal Office of Consumer Protection and Food Safety (BVL). In this group cosmetic experts from control offices in Germany, Austria and Switzerland as well as laboratories of the cosmetics industry and larger commercial laboratories develop modern analytical methods and publish them as § 64 LFGB methods (13).

On 1 October 2009 the CEN working group TC/392 »Cosmetics« was set up on the European level. This working group consists of four sub-groups which are involved in the standardisation of the following methods:

- WG1: Analytical methods (active ingredients, restricted or prohibited substances)
- WG2: Microbiological methods
- WG 3: Proof of efficacy, for instance UV protection
- WG 4: Skin compatibility

On 24 November 2009 the national entity was set up within DIN (NA 057-07-01 AA »Cosmetic Products«). The activities of the § 64 working group have been incorporated into this new working group and the next step is to make them available as CEN Standards.

3.3 EU-wide notification method

In order to avoid different national notification methods, an EU-wide two-track notification method is to be introduced in future in accordance with Article 13. The notification of specific information about each product on the market must be undertaken prior to the placing of the product on the market. The following information is to be notified about the product (name, category) when the product information is accessible, the country of origin (in the case of imports from third countries), the Member State, in which the product is placed on the market, any nanomaterials or CMR substances as well as the framework formulation for the product. The European Commission informs all competent authorities about the notification whereby there are differing responsibilities for the information.

The information about the framework formulation is intended solely for the poison control centres so that they can take quick and suitable action for treatment of poisoning incidents. The other notification data, by contrast, are only intended for the competent national authorities in Germany and, by extension,

the numerous regional and municipal levels in the individual federal states.

The system of framework formulations was already elaborated in conjunction with the adoption of the Sixth Amendment to the EC Cosmetics Directive. Both the notification system and also the framework formulations were published in Germany in the Bundesanzeiger. In Germany a multi-lingual notification system **SYSDECOS** (System for the Declaration of Frame Formulations of Cosmetic Products to European Poison Control Centres) was elaborated which makes notification easier for companies.

The Commission is currently preparing a corresponding mask for future notifications. All notifications (category, name, address of the responsible person, country of origin for products from third countries, Member State responsible for placing on the market, information on the natural person for contact purposes, information about nanomaterials, CAS No. for CMR 1 substances, original label, photo of packaging) should be undertaken electronically and managed centrally. As soon as the system has been introduced, there will be no further need for national notifications. Only those products must be notified which are still being placed on the market when Article 13 comes into force.

In order to offer advice for products notified prior to the new EU Regulation, too, the national systems must be maintained up to 11 July 2020. The product information file must be kept for 10 years after the last batch of the product has been placed on the market.

4. Chapter IV – Restrictions for Specific Substances

Chapter IV contains the **substance regulations**. Article 14 specifies the **restrictions** for the substances listed in the **Annexes**. Article 15 focuses on the substances classified in chemical legislation within the EU as **CMR substances**. Article 16 looks at nanomaterials and Article 17 regulates the **traces of prohibited substances**.

In the development of the new EC Cosmetics Regulation it was clear from the very outset that no new provisions were

envisaged concerning the substances in a first stage but that existing provisions were merely to be consolidated. For legal reasons, however, the substance-related part was kept on the level of the end of 2007 during the preparation of this Regulation as this was the version that was available at the beginning of the legislative process of the European bodies (Parliament, Council) and was approved by them.

This has important consequences: The substance provisions in the Annexes to Regulation 1223/2009 are to be gradually updated and only apply from 11 July 2013. This means that **the substance provisions in Annexes II to VII of the Cosmetics Directive 76/768 apply up to then**. Up to that time the necessary adjustments are to be made to the provisions in the Cosmetics Directive, like for instance recently for hair colorants. The source of information for provisions in the Annexes on cosmetic legislation is, therefore, until further notice the valid version of the previous EC Cosmetics Directive or the corresponding national transposition, in our case the German Cosmetics Ordinance. The current status of the substance provisions can be checked until further notice on the following website of the European Commission (consolidated version of Directive 76/768 up to a specified point in time and in later Amendment Directives based thereon):

http://ec.europa.eu/enterprise/sectors/cosmetics/documents/directive/index_en.htm

In future the following substance provisions will be set out in Regulation 1223/2009. They mainly reflect the content of the provisions in the prior EC Cosmetics Directive. These provisions have still to be adopted in the Steering Committee of the European Commission within the framework of the co-determination procedure in the Member States:

1. Substance provisions of Annexes II-VI (up to now Annexes II-VII in Directive 76/768).
2. CMR substances – (Article 15) – in principle updating of previous practice. What is new and prudent is the option of envisaging the use of specific CMR substances of natural ori-

gin after evaluation and support by the SCCS in cosmetics.

3. Traces of undesirable/prohibited substances (Article 17 in conjunction with Annex I – Safety assessment).
4. Statements on substances with suspected endocrine-disrupting action (Article 15) – new in this form but merely a declaration of intent by the European Commission.

4.1 Annexes on the new Regulation

In the new Regulation the substance-related provisions are in detail:

1. Article 2: amongst other things definitions of colorant, preservative, UV filter

- f) »Face product«
(for the skin of the face)
- g) »Nail product«
- h) »Oral product«
- i) »Product applied on mucous membranes« (oral cavity, rim of the eyes, external genital organs)
- j) »Eye product«
(in the vicinity of the eyes)
- k) »Professional use«

Changes in the Annexes of Regulation 1223/2009 will, in future, stipulate amongst other things that:

1. For each entry INCI designations and in some cases EU names, EC-numbers and CAS-numbers are listed pursuant to chemicals legislation.

entries are correct and complete. The INCI designations and EU numbers are not to be seen as definitive provisions but as a way of facilitating work.

Annex II, List of prohibited substances.

In this text in the Regulation the entries end at number 1328. The legal text which is valid today with regard to the still relevant EC Cosmetics Directive is Annex II up to entry 1371.

Several updates are still necessary to the **restricted substances in the Annex (Annex III)**. For instance hydroquinone has not yet been deleted as a hair colorant; the numbers 102 up to 214 are still missing.

Annex on colorants (Annex IV). In future this Annex will also include hair colorants or precursors of oxidative hair colorants (so far this has merely been a declaration of intent of the European Commission). From the definition of colorants pursuant to Article 2 para 1m) it is clear that colorants are also deemed to be precursors of oxidative hair colorants. The active principle of a colorant within the intendment of the Regulation explicitly only encompasses the absorption and the reflection of visible light but not photoluminescence, interference or colorant action based on a chemical reaction (27th Recital and Article 2 para 1 m). This clarified the fact that, for instance, optical brighteners are not colorants within the intendment of cosmetic legislation and hence do not have to be approved for inclusion in the positive list of colorants. For E-colorants (food colorants) reference is made to the purity criteria in accordance with Directive 95/45/EC although it has since been replaced by Directive 2008/128/EC. This will likewise have to be corrected when updating the Annexes of Regulation 1223/2009. The substances covered in the Regulation are identical with the colorants regulated up to now in cosmetics legislation.

Annex on preservatives (Annex V). The preamble to the Annex for preservatives has been shortened. For preservatives there is no longer any explicit reference to substances which have no primary action as preservatives (essential oils, alcohols...). The definition of preservatives pursuant to Article 2 para 2 I) indicates

Regulated substance group	Annex in Regulation 1223/2009	Annex in Directive RL 76/768
Prohibited substances	Annex II	Annex II
Restricted substances	Annex III	Annex III
Colorants	Annex IV	Annex IV
(Certain strontium compounds in a separate list)	Provision in special Annex deleted, specific provisions in Annexes II, III and IV are unchanged	Annex V
Preservatives	Annex V	Annex VI
UV filters	Annex VI	Annex VII

2. Previous Annexes II-VII are now Annexes II-VI (new)

The preambles to Annexes II to VI have now been merged, some new definitions have been added, the names of which take some getting used to. However, a uniform definition is welcome as in the past there were often different interpretations of the substance provisions:

- a) »Rinse-off product«
- b) »Leave-on product that remains on the skin/hair«
- c) »Hair product« (hair of head or face with the exception of eyelashes, e.g. thioglycol-containing eyelash dyes will no longer be admissible in future)
- d) »Skin product«
- e) »Lip product«

2. Some definitions must be mentioned for the first time in the preamble or concretised (see above).

3. In the list of prohibited substances in Annex II now CAS numbers, EC numbers are listed throughout. However, some of these entries are still very incomplete; particularly in the case of compound entries (e.g. substance X and its salts and esters) often only one entry can be found although there should in fact be several entries.

4. Methyl eugenol was moved from Annex II to Annex III.

5. In Annexes III to VI there are columns throughout for INCI designations, CAS numbers/EU numbers – this permits improved identification as long as the

that preservatives mainly or only inhibit the development of micro organisms in cosmetic products. Hence, it can be concluded here that on the other hand there are substances which possess subordinate preservative action without being deemed to be preservatives within the intendment of cosmetics legislation.

Annex VI contains the approved **UV filters**. The function of a UV filter within the intendment of this Regulation is limited through the definition in Article 2 to the exclusive or main protection of the skin against UV radiation. The regulated substances are largely identical with the UV filters covered up to now in cosmetics legislation. The only exception is PABA; this UV filter was banned at the end of 2008 in cosmetics legislation. However, this Amendment has not yet been taken into account in the new EC Cosmetics Regulation for the reasons outlined above.

4.2. Traces of prohibited substances

The non-intended presence of traces of prohibited substances in products is permitted in exceptional cases pursuant to Article 17 if the cosmetic products are safe. These traces can be heavy and transitional metals, CMR substances, polycyclic aromatic hydrocarbons, pesticides, 1,4-dioxane, ethylene oxide, nitrosamines etc., i.e. either impurities or residues of natural or synthetic starting materials or traces that occur during production or storage or migration from packaging. In the new EC Cosmetics Regulation this provision applies as it did in the past to prohibited substances in cosmetics legislation. These traces must be technically unavoidable and toxicologically safe in conjunction with the observance of good manufacturing practice (Cosmetics GMP). In this context Annex I No. 4 explicitly mentions for the first time proof of technical unavoidability as a component of the safety report.

4.3. Substances with suspected endocrine-disrupting action

The following passage has been added to Article 15 para 4: *»When Community or internationally agreed criteria for identifying substances with endocrine-dis-*

rupting properties are available, or at the latest on 11 January 2015, the Commission shall review this Regulation with regard to substances with endocrine-disrupting properties«.

So far no uniform criteria are available either internationally or within the EU. In this context substances with endocrine-disrupting action (according to the Weybridge definition from 1996 and the definition of the International Programme for Chemical Safety (IPCS) from 2002) are defined as follows: an *»endocrine disruptor«... is an (exogenous) substance that causes adverse health effects in an intact organism, or its progeny, secondary to changes in endocrine function«.*

In fact the hormonal effects of highly potent substances have been prohibited for a long time in Annex II in cosmetics legislation like, for instance, substances with androgenic effect (No. 37), anti-androgens of steroidal structure (No. 390), progestogens (No. 194) and oestrogens (No. 260). Recently, a few substances with potentially weak endocrine-disrupting action, which may be used in cosmetic products, have also been included in official lists of suspected substances. In the case of a risk assessment, which takes into account the concentration used and exposure, by the competent authorities or bodies – like the National Cosmetics Committee or the Scientific Committee for Consumer Safety (FCCS), these substances were not identified as posing a risk to human health by BfR (Federal Institute for Risk Assessment).

4.4 Substances classified as CMR substances

CMR substances are covered in Article 15 of the new Regulation. In principle this is a continuation of previous practice for the individual substance provisions. CMR substances have been covered by cosmetic legislation since 2004. In the past reference was made to chemicals legislation, Directive 67/548. Now reference is made to the GHS Regulation 1272/2008 (Global Harmonised System of Classification and Labelling of Chemicals) or the first Amendment Regulation 790/2009.

In hazardous substance legislation a CMR substance is classified as carcinogenic

(C), mutagenic (M) or toxic for reproduction (R).

In Directive 67/548 substances of this kind were designated in chemical legislation and where appropriate in the safety data sheet as CARC. Cat 1,2,3, Muta. Cat 1,2,3 or Repr. Cat 1,2,3, in the new GHS Regulation as Carc. Muta, Repr (1A, 1B, 2). Particularly as a consequence of the change in the nomenclature, it must always be clarified which statutory reference applies.

The categories for CMR substances are (simplified in accordance with GHS criteria 1272/2008):

- CAT 1 A (formerly 1): Classification on the basis of effects in humans (epidemiological data);
- CAT 1 B (formerly 2): Classification based on effects from animal testing (two animal species or other strict criteria);
- CAT 2 (formerly 3): Classification based on findings from animal testing. Either unclear data situation, which cannot be improved through further studies either; or inadequate data – further clarification necessary.

Many natural substances are or would be CMR substances based on the criteria from chemicals legislation.

According to Regulation 1223/2009 substances classified as CMR 1 A and 1 B may be used in exceptional cases in cosmetic products when the following requirements are met:

- Food safety requirements pursuant to Regulation 178/2002 must be met.
- Analysis of the alternatives: no suitable replacement substances available.
- Use for a specific application with known exposure.
- Assessment by the Scientific Committee for Consumer Safety (SCCS) of the European Commission: safe bearing in mind total exposure from other sources and vulnerable groups in the population.
- If appropriate special labelling in order to prevent misuse.

- Re-evaluation by SCCS: every five years to the extent that no safety concerns have been raised.

Substances classified as CMR 2 substances (pursuant to Regulation 1272/2008) can be approved, as was the case in the past, on the basis of the submission of a dossier and assessment by the Scientific Committee for Consumer Safety (SCCS) (prior or similar procedure for CMR 3 classification pursuant to Regulation 67/548). In order to establish whether substances are explicitly regulated in cosmetics legislation (already approved or prohibited CMR substances, too), the Annexes of the previous EC Cosmetics Directive 76/768 must continue to be used as the legal source of information for the time being.

For almost all substance provisions the EC Regulation indicates a deadline of 11 July 2013. There are plans for the corresponding provisions to be adapted up to that point in time 1:1 in the Regulation. Public authorities and industry are currently examining the Annexes of the Regulation and providing support for the ongoing up-dating and correction process.

Important exception:

There are earlier deadlines for **CMR substances which have been newly classified in chemicals legislation or have not been further defended**, which are to be prohibited in cosmetics legislation. The Regulation envisages a deadline of 1 December 2010. For these substances it was already the case in the past that they had to be regulated within a period of 12 months in cosmetics legislation or their use banned.

4.5 Nanomaterials

Article 16 contains very comprehensive new requirements to be met by nanomaterials or products containing nanomaterials. Nanomaterials are, therefore, explicitly regulated for the first time in cosmetics legislation. Article 2 para 1 k) currently defines a nanomaterial as an *»insoluble or bio-persistent and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to*

100 nanometres«. At the present time efforts are underway on various levels to establish a uniform definition for *»nanomaterial«*. Hence, this is a provisional definition which will be adapted to the state of the art as soon as a uniform European or international definition is available (Article 2, para 3).

The definition already indicates now that the requirements do not apply to soluble nanoscale systems or nanoscale systems which are unstable under physiological conditions like, for instance, nanoemulsions, liposomes, nanosomes or niosomes.

The presence of nanomaterials must be notified separately within the framework of the general notification obligation for cosmetic products. In this context the substance(s) concerned must be identified and the reasonably foreseeable exposure conditions must be indicated.

Article 16 also contains a specific notification obligation for all cosmetic products containing nanomaterials. This must be done six months prior to placing on the market and mainly concerns the toxicological data on the nanomaterials. The following information must be notified:

- Identity of the substances concerned
- Physico-chemical specifications
- Estimate of the volume to be marketed every year
- Toxicological profile of the nanomaterial
- Safety assessment of the nanomaterial for the concrete product
- Exposure conditions

Nanomaterials which are regulated in Annexes IV, V and VI (Article 14 – Positive lists) and substances regulated in Annex III are exempt from this notification.

Products, which are placed on the market before 11 January 2013, must only be notified within six months from 11 January 2013 onwards, i.e. up to 11 July 2013.

After notification the European Commission can ask SCCS to assess a substance if there are concerns about its use.

All questions and answers are published. SCCS must submit an initial opinion at the latest after six months. Manufacturers may submit data later. This later submission is, however, only possible once – within a stipulated period. This deadline cannot be extended either. The final assessment by SCCS must again be available at the latest after six months. After that the nanomaterial may be covered by Annex III or II.

Pursuant to Article 16 the European Commission is also bound to publish a catalogue of all nanomaterials used in cosmetics by 11 January 2014. This is likewise to include substances from Annexes IV to VI. For the substances, the respective product categories in which the nanomaterials are used and the exposure conditions are to be indicated. Furthermore, the European Commission must submit an annual expert report to the Council and Parliament which must be completed for the first time by 11 July 2014.

Article 19 para 1 g) also envisages that nanomaterials must be separately labelled in the INCI designations. To this end, all INCI designations of nanomaterials contained in a product must bear the suffix *»(Nano)«*, for instance *»Titanium Dioxide (Nano)«* in the list of ingredients.

5. Chapter V – Animal Testing/ Alternatives

Chapter V, Article 19 addresses **animal testing** whereby no changes were made compared to the provisions in the Cosmetics Directive including the existing deadlines. Given the clear scientific facts and forecasts concerning the achievability of the ambitious goals, the authors believe it will be difficult to meet the deadlines. The Scientific Committee for Consumer Safety of the European Commission also voices this opinion in a memorandum published on 26 January 2010 (15).

Alternative methods to animal testing are deemed to be *in vitro methods* (*in vitro* = [Latin] in the glass), i.e. methods which can be conducted outside living organisms – in the test tube – for instance using cell cultures.

The German cosmetics industry has voluntarily foregone animal testing for **finished cosmetic products** since 1989. Furthermore, the German Animal Welfare Act has stipulated since 1998 that the animal testing of cosmetics is prohibited. In the meantime – since 11 September 2004 – these animal experiments have been banned throughout the EU. Furthermore, it is prohibited to market cosmetic products that have been tested in animals.

The safety of the **raw materials** used in cosmetic products still has to be proven. This is done by meeting the requirements of the relevant chemicals legislation. The tests required here are normally conducted by the manufacturer who supplies substances or are commissioned. Some of these safety tests can currently only be carried out in conjunction with animal experiments. At this point it must be stressed that very few substances are only used in cosmetic products. Most of the raw materials are substances that are also or mainly used in other areas (medicinal products, food, detergents and cleaning agents).

The dilemma here is that in the field of chemical legislation the animal testing of raw materials is stipulated by law whereas in cosmetics legislation with the publication of the 7th Amendment to the EC Cosmetics Directive the concrete goal is to prohibit animal testing in order to meet the requirements of this Directive. The ban is to enter into force in two phases: the date 11 March 2013 is to apply for the toxicological end points 'sensitisation (allergenicity)', 'toxicity in conjunction with repeated administration', 'reproductive toxicity' and 'toxicokinetics'. All other animal testing for the purposes of meeting the provisions of the EC Cosmetics Directive was already banned from 11 March 2009.

In co-operation with all interested circles like for instance industry, public authorities, for example ECVAM (European Centre for the Validation of Alternative Methods), the European Commission and also other sectors of industry, diverse efforts have been undertaken to develop alternative methods for the individual toxicological end points. At the present time there is particular emphasis on the end points which are important for ensuring the safety of cosmetic products.

They include tests for skin and eye irritation, skin sensitisation and genotoxicity. Furthermore, work focuses on novel risk assessment methods which can likewise help to reduce the number of animal experiments.

In November 2004 the European Commission founded the »European Partnership on Alternative Approaches to Animal Testing« (EPAA). With this initiative the European Commission involves other important stakeholders like, for instance, animal welfare organisations in its activities. In August 2009 the European Commission and the cosmetics industry announced a comprehensive € 50 million programme to develop alternative methods within the framework of the 7th EU Framework Programme for Research of the European Commission.

Nonetheless, the development of reliable alternatives to animal experiments constitutes an enormous scientific challenge. It must be guaranteed that the alternative test systems reliably predict the complex reactions of an entire organism to the potentially harmful effect of foreign substances. The replacement of a single animal experiment normally requires a combination of several alternative *in vitro* methods.

Thanks to the considerable efforts of numerous research groups with the major support of the cosmetics industry, a substantial number of validated test methods for skin and eye irritation are already available today. Furthermore, a series of promising alternative methods for testing for allergenic effects is available. However, there are other end points for which the complete replacement of animal experiments is not yet foreseeable by the deadline 11 March 2013.

Moreover, the developed test methods must be recognised by the competent authorities. The essential precondition for official recognition is comprehensive validation, for instance within the framework of the test guideline programme of the OECD (Organisation for Economic Co-operation and Development). Here each alternative method is examined in comprehensive interlaboratory trials for reproducibility (in the same laboratory) and comparability of results (between different laboratories).

In Article 18 two further definitions have been introduced, the terms »finished cosmetic product« and »prototype« (*»the first model or design that has not been produced in batches, and from which the finished cosmetic product is copied or finally developed«*). Both terms also apply to Article 20 (product claims).

6. Chapter VI – Consumer Information

Consumer information is described in Chapter VI. Article 19 draws together the **previous labelling requirements**. One new feature is the **hourglass symbol**, which can now be used as an alternative to the *»best used before the end of...«* and the EU-wide obligation to state *»Made in...«* for products manufactured outside the EU whereby *»Made in...«* doesn't have to be translated into the national languages. Article 20 addresses **product claims** and Article 21 deals with access to information for the public.

6.1 Hourglass symbol

Article 19 (1) c) in the EU Cosmetics Regulation envisages that with immediate effect pursuant to Article 39 instead of using the wording *»Best used before the end of...«* the new hourglass symbol in



Annex VII No. 3 can now be used in the national language versions in order to avoid translations into the various languages of those countries in which the product is marketed. Continued use of *»best used before the end of...«* is, of course, also possible.

In order to facilitate use of the new symbol, IKW has produced various graphic formats for the hourglass which can be downloaded from the IKW website.

In future, the hourglass symbol can be used instead of the wording *»best used before the end of...«*. The previous fundamental requirements governing the indication of the durability of cosmetic products have not, however, been amended by the new EU Cosmetics Regulation.

6.2. Durability after opening

Indication of the minimum durability date is not prescribed either, as was the case so far, for products which can be stored for more than 30 months. In these cases the indication of durability after opening is still required (symbol of the open jar). In the new Regulation explicit reference is made to the fact that the concept of durability after opening is not relevant if no damage to the health of consumers is expected. The European Commission had already published a guideline on this topic with regard to the previous Cosmetics Directive in which it states for which products the indication durability after opening is not relevant. It can be accessed on the following link: http://ec.europa.eu/enterprise/sectors/cosmetics/documents/guidelines/labelling/index_en.htm

6.3. Batch number

The previous provision has been taken over here whereby the batch number need only be indicated on the packaging and not on the container of a cosmetic product if, for practical reasons, this is not possible because of the small dimensions of the cosmetic product. In principle, this derogation is not plausible although it only plays a subordinate role for consumer protection. Nonetheless, the indication of a batch number on the primary packaging always serves the purposes of protecting both the manufacturer and the consumer should the product turn out to constitute a risk.

6.4. List of ingredients

As in the past an ingredient is each substance or mixture which is intentionally used in the manufacturing process of a cosmetic product. The only exceptions now are impurities of raw materials used and subsidiary technical substances which are used in the mixture but are no longer present in the finished product. The previous derogation that solvents or carriers for perfumes and aromatic ingredients do not have to be declared either has been deleted. The CosIng database of the European Commission can be used as a source for INCI designations as can the International Cosmetic Ingredient Dic-

tionary of the Personal Care Products Council (14).

In 2008 the European Commission published a new Internet database on ingredients of cosmetic products, the »CosIng« database. (<http://ec.europa.eu/enterprise/cosmetics/cosing/>).

This database is to replace the customary practice up to then of the irregular publication of an inventory of cosmetic ingredients in the Official Journal of the European Union. The database contains all INCI designations of cosmetic ingredients of relevance for the EU. In August 2009 it was updated in line with the data status of the 12th edition of the International Cosmetic Ingredient Dictionary (ICID, 2008). The 13th edition of the ICID has since been published (14) which is likewise available as a database.

Besides the INCI designations from the inventory of cosmetic ingredients, all other substances listed in EU cosmetics legislation – including the prohibited substances – are recorded and correspondingly labelled in the CosIng database. Furthermore, it also contains references to all currently available assessments of SCCS (Scientific Committee on Consumer Safety) or its precursor bodies SCCP and SCCNFP on the Internet.

The database likewise contains information on the history of the regulation status of individual substances – together with the corresponding transitional periods. The legal references in this database do not, however, negate the need to consult the valid version of EU cosmetics legislation.

In future, all ingredients in the form of nanomaterials must be clearly stated in the list of ingredients. The name of these ingredients must be followed by the word »Nanox« in brackets (cf. also 4.5).

Concerning the +/- rule for colorants, it was clarified that colorants, which are used to dye hair, are exempted from this.

6.5. Product claims

Article 20 stipulates that the European Commission must draw up a report on the use of advertising claims for cosmetic products by 11 July 2016. To this end, the European Commission is to initially define criteria, together with the Member States that could be used as the

basis for claims about cosmetic products. In this context the basic requirements of advertising claims for cosmetic products apply, i.e. they may not, of course, mislead the consumer. Hence according to Article 20 para 1 of the Regulation 1223/2009 »in the labelling, making available on the market and advertising of cosmetic products, text, names, trademarks, pictures and figurative or other signs shall not be used to imply that these products have characteristics or functions which they do not have«.

Furthermore, in the area of advertising the more detailed ban on misleading consumers in the Act against Unfair Competition (UWG) must also be borne in mind for the protection of consumers, as already required today.

6.6. Public access to specific information

Article 21 regulates access of the general public to specific information. This requirement already existed in the EU Cosmetics Directive (known under »public access«) and is restricted to hazardous substances within the intendment of Regulation 1272/2008. In the interests of the consumers industry suggested an EU-wide uniform procedure detailing the form in which manufacturers can pass on information to interested consumers: ([http://www.ikw.org/pdf/broschueren/7_Aenderungsrichtlinie_neu04\(i\).pdf](http://www.ikw.org/pdf/broschueren/7_Aenderungsrichtlinie_neu04(i).pdf)).

7. Chapter VII – Market Surveillance

A new addition is Chapter VII on **in-market surveillance**. Articles 22–24 stipulate how surveillance is to be undertaken.

7.1. In-market control

Article 22 stipulates that in-market control by official cosmetics surveillance draws on the three following components:

- i. Analytical laboratory tests of an unstipulated number of samples (»appropriate«)
- ii. Verification of the product documentation (including safety assessment)
- iii. Verification of good manufacturing practice (GMP)

The Member States undertake to equip the competent authorities for the pursuit of their tasks and, in future, to check and assess the way in which they carry out their surveillance activities at least every four years.

7.2 Notification of serious undesirable effects

In Article 23 manufacturers undertake to notify all **serious undesirable effects** to the competent authorities.

According to the definition in Article 2 (1) p) a serious undesirable effect is *»an undesirable effect which results in temporary or permanent functional incapacity, disability, hospitalisation, congenital anomalies or an immediate vital risk or death«*. The competent authorities will be indicated in a list that is still to be published by the European Commission. Furthermore, the European Commission will develop a guideline on this Europe-wide *»Cosmetovigilance«* system which describes this procedure in detail. Industry already recommended a few years ago the establishment of a uniform system for dealing with intolerances. The brochure with the corresponding explanations (16) can be accessed on the following link:

http://www.ikw.org/pdf/broschueren/Leitfaden_Unvertraeglichkeiten.pdf.

What is important when it comes to the appearance of a *»serious undesirable effect«* is that there is a causal relationship, i.e. the link between the occurrence of the *»serious undesirable effect«* and the use of the cosmetic product must be plausible.

7.3. Information about substances

Article 24 regulates information about substances in cosmetic products which must be communicated by the responsible person to the competent authority when serious doubts arise about the safety of this concrete substance in cosmetic products. Here, it is theoretically about substances that do not attract attention until the marketing of the products as a consequence of the increased incidence of serious undesirable effects and which had not been known to be unsafe during the safety assessment. This

provision goes beyond access to the product documentation of a cosmetic because here all cosmetic products containing the substance must be named by the manufacturer in the case of reasonable grounds for concern. In urgent cases the competent authority can derive consumer information from this or even issue national safeguard clauses (cf. also Chapter 8) pursuant to Article 27 after indentifying a serious risk. The decision to inform consumers about cases of this kind must, of course, be carefully weighed up. Consumer information should, therefore, always be provided in close consultation between all stakeholders and only in cases where it is also actually justified (e.g. when it still makes sense to provide the information when the manufacturer has already disclosed details to the public at large).

8. Chapter VIII – Non-Compliance, Safeguard Clause

Articles 25-28 in Chapter VIII regulate questions linked to **non-compliance with the Regulation** and also outline the option for Member States to use the safeguard clause in special cases.

Article 25 describes all the possible cases of non-compliance with the provisions of Regulation 1223/2009 by the responsible person and the related measures of the competent authorities. The individual elements are good manufacturing practice, safety assessment, the requirements for the product information file, the provisions on sampling and analysis, the notification requirements, the restrictions for substances, animal testing requirements, the labelling requirements, the product claims requirements, the access to information for the general public, the communication of serious undesirable effects and the information requirements on substances. Para 4 of Article 25 mentions for the first time the term *»serious risks to human health«*. Several discussions took place about whether this term should be included in the definitions in Regulation 1223/2009 as is the case for instance in the basic food Regulation 178/2002. The taking of action in conjunction with a serious risk is, however, directly linked –

pursuant to para 7 of Article 25 – to the Directive on general product safety 2001/1995 (17). Product notifications in conjunction with serious health risks are published according to this in the EU Rapid Alert System for Dangerous Consumer Products (RAPEX) (18). This applies not only to cosmetic products but also to other consumer products (but not to food, feed consumer products = RAFFS). In parallel to the discussions about the European Cosmetics Regulation, the Directorate General SANCO of the European Commission – which coordinates the RAPEX system – has focused on drawing up a guideline for identifying a serious risk in respect of these products and involved all stakeholders in this process using the tool of a public hearing. As one goal of this guideline was to give a comprehensive explanation of the term *»serious risk«*, the European legislator did not include a definition of this term in Regulation 1223/2009. Instead the Commission is called on in the 59th Recital *»to provide information on the uniform interpretation and use of the term of the serious risk in order to facilitate the coherent use of the Regulation«*.

On 16 December 2009 the European Commission published an updated RAPEX guideline which stipulates that the assessment of a serious risk is to be undertaken by the competent authorities (19). This decision is indeed seen as a legal act with no statutory character. It will, however, in future be an extremely important guideline in the daily practice of the competent authorities in the Member States. It replaces an earlier, somewhat more general guideline which was also intended for the Member States. It is based on the determination of the serious risk of a product following the assessment of the injury scenario, the foreseeable group of persons affected and the likelihood of injury. On this basis a decision is taken by the public authorities on the appropriate further procedure and, if necessary, the type of RAPEX notification (Article 12 alert notification = public RAPEX notification, Article 11 = non-public exchange of information).

The guideline is highly complex as it seeks to take into account all product categories (from toys over tools, computers, household cleaning agents down to cos-

metics). It would go beyond the remit of this publication to examine in any detail the resulting problems in practice. In Germany experts will explain the application of the guideline with regard to cosmetic products and, where appropriate, endeavour to improve it regarding the assessment of the serious risk of a cosmetic product.

The **safeguard provision** in Article 27 has not changed vis a vis the Cosmetic Directive. It deals with the case where a cosmetic product complies with Regulation 1223/2009 but the competent authority has reasonable grounds for concern that the product probably constitutes a serious risk. A recent example was the ban handed down in France on vitamin K1-containing cosmetics which were legally on the market but which had attracted attention because of the occurrence of numerous serious undesirable effects. A national ban of this kind must be notified to the European Commission. Vitamin K1 has since been added to the list of prohibited substances in the Cosmetics Directive. Fortunately, incidents of this kind involving cosmetic products are extremely rare.

9. chapter IX – Administrative co-operation

Chapter IX regulates **administrative co-operation**. Article 29 calls for **administrative co-operation between the competent authorities responsible for cosmetic surveillance** in the individual Member States in order to guarantee the correct application and implementation of Regulation 1223/2009. In this context the Commission has the task of co-ordinating and promoting communication within the framework of the PEMSAC working group (Platform of European Market Surveillance Authorities for Cosmetics). This working group jointly develops surveillance programmes and engages in the exchange of specific surveillance strategies (cosmetics GMP, safety assessment, analytical methods).

Article 30 describes the co-operation procedure between the competent authorities of two Member States in the **verification of the product information file** when a Member State has doubts that a cosmetic product on its market is safe

but the product information file is located in a second Member State. In this case the competent authority of the first Member State can, on the basis of reasonable grounds for suspicion (e.g. consumer complaint, analytical finding, distributor information), ask the competent authority of the second Member State for administrative assistance to verify the product information file and then notify it whether the cosmetic product is safe. Depending on the degree of emergency this verification must be undertaken immediately. The cases of administrative assistance are, however, restricted to verifying the safety of products that have attracted attention. Practice will show what additional efforts will be required by the competent authorities or the cosmetic experts in the surveillance institutions as a consequence of this provision.

10. Chapter X – Implementing Measures, Final Provisions

The **implementing provisions** are regulated in Chapter X. Article 31 lays down the procedure for **amendments to the Annexes**, Article 32 the **committee procedure** («Cosmetic Products steering committee»).

In Article 34 the Member States are called on to indicate their **competent authorities** and poison control centres which will then be published by the European Commission.

Article 35 obliges the European Commission to submit an **annual report on progress in the development of alternative methods to animal testing**.

Article 36 gives the Member States or the European Commission an opportunity to lodge **formal objections against harmonised standards** which means that under certain circumstances these standards can also be withdrawn

Article 37 stipulates that effective, proportionate and dissuasive **penalties for infringements must be imposed on the national level**. The national provisions must be notified to the European Commission by 11 July 2013.

Article 38 regulates the **repeal of the EC Cosmetics Directive (11 July 2013)**. Certain information must be kept available

by the competent authorities even after the entry into force of the Regulation, e.g. product information which is elaborated after the Directive must be readily accessible up to 11 July 2020.

10.1 Glossary of common ingredient names

Article 33 refers to the **Glossary of common ingredient names** (up to now inventory) which is the basis for INCI labelling. The Amendment was made as the inventory was frequently misinterpreted as a list of approved substances.

10.2 Transitional provisions

The **transitional provisions** are regulated in Article 39. Article 40 stipulates the **entry into force (11 January 2010) and date of application** of the Regulation. The Regulation applies **in principle from 11 July 2013**. The following areas enter into force prior to that:

1. **Regulations concerning CMR substances: 1 December 2010** (after that CMR substances classified as 1A or 1B may be used subject to strict requirements).
2. The **notification concerning nanomaterials applies from 11 January 2013**.
The European Commission is already working on the EU-wide notification procedure. As soon as this system is ready, at the latest however by **11 January 2012**, companies can immediately send their notifications to Brussels and no longer have to carry out any national notifications.

Further deadlines:

1. The **Annexes of the Regulation concerning substance provisions** are valid only **from 11 July 2013**, i.e. up to that date the substance Annexes of the EC Cosmetics Directive still apply.
2. The European Commission must submit the **report on the use of product claims** to Parliament and Council by **11 July 2016**.
3. In order to also facilitate advice for products notified prior to the new EU

Regulation, the national systems (like for instance the German BVL database for the poison control centres) must still be available up to 11 July 2020.

4. In the same way the product details for cosmetic products, which are still on the market but have not (for the first time) been placed on the market after 11 July 2013, must be kept by the responsible persons up to 11 July 2020.

According to the transitional provision in Article 39 cosmetic products, which correspond to the EC Cosmetics Regulation, even if they deviate from the still valid Cosmetics Directive, can already be placed on the market before 11 July 2013. This is relevant in the short-term for instance for the option already available now of using the »hourglass« symbol instead of indicating a minimum durability date with the wording »best used before the end of...«.

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References

- (1) Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast) – text of importance for the EEA (Official Journal of the European Union L 342/59, 22 December 2009)
- (2) EC Cosmetics Directive of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products (76/768/EEC) (OJ L 262, 27.9.1976, p. 169)
- (3) Food, Commodities and Feed Code (LFBG) and Food and Feed Code (LFGB), 27 April 2006 (BGBl. I, 20, p. 947)
- (4) Cosmetics Ordinance in the version published on 7 October 1997 (BGBl. I p. 2410), which was last amended by Regulation of 13 October 2009 (BGBl. I p. 3662)
- (5) Guidance Document on the demarcation between the Cosmetic Products Directive 76/768 and the Medicinal Products Directive 2001/83 as agreed between the Commission services and the competent authorities of the Member States
- (6) Kratz E. et al., »Abgrenzung kosmetische Mittel/Arzneimittel«, StoffR 2, 90 (2007)
- (7) Keck-Wilhelm A. et al. »Kaugummi – Kau dragee – Drops – Bonbon mit zahnpflegenden Eigenschaften – Lebensmittel oder kosmetisches Mittel?« StoffR 1, 37 (2008)
- (8) Cosmetics GMP – DIN EN ISO 22716, commented by the German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW), available from Verlag für chemische Industrie (www.sofw.de). The English version of International Standard DIN EN ISO 22716 is available via Beuth Verlag in Berlin, Germany www.beuth.de, via ISO at www.iso.org or at any national Standard Organisation Office
- (9) Rossow U. et al., »DGK-Vorschlag zu Kernelementen einer Sicherheitsbewertung«, SOFW-Journal 131, 8, S. 41 (2005)
- (10) Mildau G. et al., »Basisanforderungen an Sicherheitsbewertungen kosmetischer Mittel«, SOFW-Journal 133, 6, 16 (2007)
- (11) Motitschke L. Ten Years of Training for Safety Assessors, IFSCC-Magazine, (Vol. 11, No.3/2008 p. 255)
- (12) The rules governing cosmetic products in the European Union 1999 Volume 2, Cosmetic products, Methods of analysis, http://ec.europa.eu/enterprise/sectors/cosmetics/files/pdf/vol_2en_en.pdf
- (13) Amtliche Sammlung von Verfahren zur Probenahme und Untersuchung, website des BVL http://www.bvl.bund.de/nn_1095650/DE/09__Laboratorien/04__amtliche__sammlung/methodensammlung__node.html_nnn=true
- (14) International Cosmetic Ingredient Dictionary & Handbook, 13th Edition, 2010, available from Verlag für Chemische Industrie in Germany or Personal Care Products Council in the US/ International <http://www.personalcarecouncil.org/>
- (15) SCCS: Memorandum »Alternative Test Methods in Human Health Safety Assessment of Cosmetic Ingredients in the European Union«, adopted 8 December 09 (SCCS/1294/10)
- (16) Leitlinien zur Handhabung von Berichten über Unverträglichkeitsreaktionen im Zusammenhang mit der Verwendung von kosmetischen Mitteln, Broschüre IKW, Oktober 2004
- (17) DIRECTIVE 2001/95/EC OF THE EUROPEAN PARLIAMENT AND THE COUNCIL of 3 December 2001 on general product safety, Official Journal of the European Communities of 15 January 2002, L11/4
- (18) RAPEX – Rapid Information System of the European Union, http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_de.cfm
- (19) Guidelines of the European Commission for the management of the Community Rapid Information System »RAPEX« in accordance with Article 12 and the notification procedure in accordance with Article 11 of Directive 2001/95/EC on general product safety, Official Journal of the European Communities, 26 January 2010, L22/1

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