Anthony C. Dweck FLS FRSC FRSPH - Technical Editor

European Cosmetic Directive consolidated

The many amendments to the Council Directive 76/768/EEC of 27 July 1976 was leading to confusion and different interpretations by some member states. The unification of the regulations should be a good thing and Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (recast), Official Journal of the European Union L342/59 on 22 December 2009 is the universal hymn sheet from which we should all be singing.

Disappointment

There is no doubt that this new document is a mighty leap forward, but one has to say that this is not just a "recast" as it introduces new wrinkles that go far beyond the simple consolidation of the numerous amendments.

(1) *Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products 17 has been significantly amended on several occasions. Since further amendments are to be made, it should be recast as one single text in the interests of clarity.*

(2) *The recast aims at simplifying procedures and streamlining terminology thereby reducing administrative burden and ambiguities. Moreover, the recast strengthens certain elements of the regulatory framework for cosmetics, such as in-market control, with a view to ensuring a high level of protection of human health.*

(3) *A recast as a Regulation is the appropriate legal instrument as it imposes clear and detailed rules which do not give room for diverging transposition by Member States. Moreover, a Regulation ensures that legal requirements are implemented at the same time throughout the Community.*

In principle this is an excellent premise on which to clarify and ratify the regulations.

(7) *The assessment of whether a product is a cosmetic product has to be made on the basis of a case-by-case assessment, taking into account all characteristics of the product. Cosmetic products may include creams, emulsions, lotions, gels and oils for the skin, face masks, tinted bases (liquids, pastes, powders), make-up powders, after-bath powders, hygienic powders, toilet soaps, deodorant soaps, perfumes, toilet waters and eau de Cologne, bath and shower preparations (salts, foams, oils, gels),*

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depilatories, deodorants and antiperspirants, hair colorants, products for waving, straightening and fixing hair, hair-setting products, hair-cleansing products (lotions, powders, shampoos), hair-conditioning products (lotions, creams, oils), hairdressing products (lotions, lacquers, brilliantines), shaving products (creams, foams, lotions), make-up and products removing make-up, products intended for application to the lips, products for care of the teeth and the mouth, products for nail care and make-up, products for external intimate hygiene, sunbathing products, products for tanning without sun, skin-whitening products and anti-wrinkle products.

The definition of the cosmetic product is also clarified and acknowledges that a case by case basis may be required in borderline cases (this is similar to the approach taken by the MHRA on borderline products).

(11) *In order to establish clear responsibilities, each cosmetic product should be linked to a responsible person who is established within the Community.*

This statement has been modified to:

(11) *It is in particular necessary to determine who is the responsible person for cosmetic products which are sold directly to the consumer without recurring to an importer.*

Another key change is:

(19) *It should be made clear which information is to be made available to the competent authorities. That information should include all the necessary particulars relating to identity, quality, safety for human health and the effects claimed for the cosmetic product. In particular, this product information should include a cosmetic product safety report documenting that a safety assessment has been conducted.*

Notice that the safety assessment has been replaced by a far more comprehensive cosmetic product safety report. The need for the Product Information Pack (PIP) remains and the safety assessment was always a part of that requirement. The main difference is understood to be that far greater information is now required in the form of a summary report. The exact requirement is summarised in Annex I.

Annex I

Cosmetic product safety report

The cosmetic product safety report shall, as a minimum, contain the following:

Part A

Cosmetic product safety information

1. Quantitative and qualitative composition of the cosmetic product

The qualitative and quantitative composition of the cosmetic product, including chemical identity of the substances (incl. chemical name, INCI, CAS, EINECS/ELINCS, where possible) and their intended function. In the case of perfume and aromatic compositions, description of the name and code number of the composition and the identity of the supplier.

2. Physical/chemical characteristics and stability of the cosmetic product

The physical and chemical characteristics of the substances or mixtures, as well as the cosmetic product. The stability of the cosmetics product under reasonably foreseeable storage conditions.

3. Microbiological quality

The microbiological specifications of the substance or mixture and the cosmetic product. Particular attention shall be paid to cosmetics used around the eyes, on mucous membranes in general, on damaged skin, on children under three years of age, on elderly people and persons showing compromised immune responses. Results of preservation challenge test.

4. Impurities, traces, information about the packaging material

The purity of the substances and mixtures. In the case of traces of prohibited substances, evidence for their

technical unavoidability. The relevant characteristics of packaging material, in particular purity and stability.

5. Normal and reasonably foreseeable use

The normal and reasonably foreseeable use of the product. The reasoning shall be justified in particular in the light of warnings and other explanations in the product labelling.

6. Exposure to the cosmetic product

Data on the exposure to cosmetic product taking into consideration the findings under Section 5 in relation to

1) The site(s) of application;

2) The surface area(s) of application;

3) The amount of product applied;

4) The duration and frequency of use;

5) The normal and reasonably foreseeable exposure route(s);

6) The targeted (or exposed) population(s). ***Potential exposure of a specific population shall also be taken into account. The calculation of the exposure shall also take into consideration the toxicological effects to be considered (e.g. exposure might need to be calculated per unit area of skin or per unit of body weight).*** *The possibility of secondary exposure by routes other than those resulting from direct application should also be considered (e.g. non-intended inhalation of sprays, non-intended ingestion of lip products, etc.). Particular consideration shall be given to any possible impacts on exposure due to particle sizes.*

7. Exposure to the substances

Data on the exposure to the substances contained in the cosmetic product for the relevant toxicological endpoints taking into account the information under Section 6.

8. Toxicological profile of the substances

Without prejudice to Article 18, the toxicological profile of substance contained in the cosmetic product for all relevant toxicological endpoints. A particular focus on local toxicity evaluation (skin and eye irritation), skin sensitisation, and in the case of UV absorption photo-induced toxicity shall be made. ***All significant toxicological routes of absorption shall be considered as well as the systemic effects and margin of safety (MoS) based on a no observed adverse effects level (NOAEL) shall be calculated.*** *The absence of these considerations shall be duly justified. Particular consideration shall be given to any possible impacts on the toxicological profile due to*

– particle sizes, including nanomaterials,

– impurities of the substances and raw material used, and

– ***interaction of substances.***

Any read-across shall be duly substantiated and justified. The source of information shall be clearly identified.

9. Undesirable effects and serious undesirable effects

All available data on the undesirable effects and serious undesirable effects to the cosmetic product or, where relevant, other cosmetic products. This includes statistical data.

10. Information on the cosmetic product

Other relevant information, e.g. existing studies from human volunteers or the duly confirmed and substantiated findings of risk assessments carried out in other relevant areas.

Part B

Cosmetic product safety assessment

1. Assessment conclusion

Statement on the safety of the cosmetic product in relation to Article 3.

2. Labelled warnings and instructions of use

Statement on the need to label any particular warnings and instructions of use in accordance with Article 19(1)(d).

3. Reasoning

Explanation of the scientific reasoning leading to the assessment conclusion set out under Section 1 and the statement set out under Section 2. This explanation shall be based on the descriptions set out under Part A. Where relevant, margins of safety ***shall be assessed and discussed.*** *There shall be* inter alia *a specific assessment for cosmetic products intended for use on children under the age of three and for cosmetic products intended exclusively for use in external intimate hygiene. Possible interactions of the substances contained in the cosmetic product shall be assessed. The consideration and non-consideration of the different toxicological profiles shall be duly justified. Impacts of the stability on the safety of the cosmetic product shall be duly considered.*

4. Assessor's credentials and approval of part B

Name and address of the safety assessor.

Proof of qualification of safety assessor.

Date and signature of safety assessor.

The calculations required for the MoS and the NOAEL are (in a word) horrific. The calculations require LD_{50} values which by law are no longer available from animal tests and need to be determined from the alternative's *in vitro* methods which is no easy matter. The MSDS for a particular raw

Determination of the critical NOAEL

Basically the evaluation of the systemic risk is a key element in evaluating the safety of a given cosmetic ingredient. Difficulties result often from the fact that cosmetic ingredients are produced in small quantities and therefore exempt from the complete toxicological dossier needed for a complete notification of the chemical substances.

It is easy to understand the impossibility to determine a margin of safety without a full knowledge of possible target adverse effects and of the critical level below which they are not observed. Such studies have to be performed in sensitive species and should allow to cover the different potential toxic effects.

90-day oral subchronic toxicity remains today the most practical approach to determine in the best conditions an adequate NOAEL (3). This supposes, of course, that the study provides at least a dose without any adverse effect which requires a great care in the choice of appropriate doses.

Oral hygiene and care products

The exposure of concern is the amount ingested. For a mouthwash, 10% of the amount used was considered as reasonable value and for toothpaste 17%. For other products such as lipsticks it is assumed that 100% of the dose ingested is absorbed.

Based on these considerations, Table 1 (see following page) shows global exposure to these cosmetic products.

Eye products

Since this category corresponds to sensitive products it has been considered that their dose of exposure corresponds directly to the dose applied. Table 2 shows global exposure estimates.

Non rinse off products

Since this category corresponds to products intended to be maintained in direct contact with the skin for long periods, it was relevant to consider that their dose of exposure corresponds directly to the dose applied. For hair care products such as hair styling and hair spray products, a partition coefficient of 10% is accepted. Table 3 shows the global exposure estimates.

Rinse off products

For rinse off products it was considered reasonable to assume a retention coefficient of 1%. For hair care products such as shampoos and conditioners which correspond to rinse off products, a partition coefficient of 10% was retained. Table 4 shows corresponding global exposure estimates.

From the estimates of exposure made for each of the four categories of products it can be extrapolated a maximalised global daily exposure:

- Total oral hygiene products 3.52 g
- Total eye products 0.05 g
- Total non rinse off products 13.50 g
- Total rinse off products 0.67 g
- Maximum global daily exposure 17.74 g

Table 1: Oral hygiene and care products.

Product type	Total amount ingested per application (grams)	Frequency of application per day	Exposure grams/day
Toothpaste	1.40	2	0.48
Mouthwash	10.00	3	3.00
Lipstick	0.01	4	0.04
Total			3.52

Table 2: Eye products.

Product type	Total amount ingested per application (grams)	Frequency of application per day	Exposure grams/day
Eye make-up	0.010	2	0.020
Mascara	0.025	1	0.025
Liner	0.005	1	0.005
Total			0.050

Table 3: Non rinse-off products.

Product type	Total amount ingested per application (grams)	Frequency of application per day	Exposure grams/day
Face cream	0.8	2	1.6
General purpose cream	1.2	2	2.4
Body Lotion	8.0	1	8.0
Anti-perspirant (roll-on)	0.5	1	0.05
Hair styling	5.0	2	1.0
Total			13.5

Table 4: Rinse-off products.

Product type	Total amount ingested per application (grams)	Frequency of application per day	Exposure grams/day
Make-up remover	2.5	2	0.50
Shower gel	5.0	2	0.05
Shampoo	8.0	1	0.08
Hair conditioner	14.0	0.28	0.05
Total			0.67

material often contains none of the toxicological information required for an accurate safety assessment and so the assessor is obliged to search deeply for CIR, SCCP and historic animal testing data.

We draw your attention to the work of Philippe Masson (EVIC, France) "How to approach the safety margin of cosmetic products". The text is taken from his paper presented at the PCIA Korea Conference, 2001. We have reproduced some of the critical information.

Thus the toxicology assessment now requires both a review of the product exposure alone and the potential global exposure.

(40) *The safety of cosmetic products and their ingredients may be ensured through the use of alternative methods which are not necessarily applicable to all uses of chemical ingredients. Therefore, the use of such methods by the whole cosmetic industry should be promoted and their adoption at Community level ensured, where such methods offer an equivalent level of protection to consumers.*

(41) *The safety of finished cosmetic products can already be ensured on the basis of knowledge of the safety of the ingredients that they contain. Provisions prohibiting animal testing of finished cosmetic products should therefore be laid down. The application, in particular by small and medium-sized enterprises, of both test methods and assessment procedures for relevant available data, including the use of read-across and weight-of-evidence approaches, which do not involve the use of animals for assessing the safety of finished cosmetic products could be facilitated by Commission guidelines.*

This is not a real world scenario for many assessors who do not have the benefit of decades of experience in the world of cosmetics and toiletries as formulators and compliance experts. We have seen many cases where the toxicologist has totally misunderstood and failed a product based on ignorance. In one example, an assessor thought that Rosa mosquetta oil was the irritant, rose musk, when in truth it was a safe and beneficial oil on the skin that has no harmful components at all.

The legislation has another helpful clarification:

(50) *In the safety assessment of a cosmetic product it should be possible to take into account results of risk assessments that have been carried out in other relevant areas. The use of such data should be duly substantiated and justified.*

This is a wonderful idea in principle but many of us perform hundreds of assessments per year and among those assessments there will be similar formulae that differ only in perfume and colour. How one might retrieve previous assessments and compare those historic formulae which could go back decades is a challenge yet to be solved. In the past, safety assessments were based on good old-fashioned experience which was backed up with substantial toxicology files collected over decades. To our knowledge this method never failed.

The Directive has more guidance after the pre-ambles:

Chapter II
Article 4
Responsible person

1. Only cosmetic products for which a legal or natural person is designated within the Community as "responsible person" shall be placed on the market.

2. For each cosmetic product placed on the market, ***the responsible person shall ensure compliance*** *with the relevant obligations set out in this Regulation.*

3. For a cosmetic product manufactured within the Community, and not subsequently exported and imported back into the Community, the manufacturer established within the Community shall be the responsible person. The ***manufacturer may designate, by written mandate, a person established within the Community as the responsible person who shall accept in writing.***

4. Where, for a cosmetic product manufactured within the Community, and not subsequently exported and imported back into the Community, the manufacturer is established outside the Community, he shall designate, by written mandate, a person established within the Community as the responsible person who shall accept in writing.

5. For an imported cosmetic product, each importer shall be the responsible person for the specific cosmetic product he places on the market. The ***importer may, by written mandate, designate a person established within the Community as the***

responsible person who shall accept in writing.
6. The distributor shall be the responsible person where he places a cosmetic product on the market under his name or trademark or modifies a product already placed on the market in such a way that compliance with the applicable requirements may be affected.
The translation of information relating to a cosmetic product already placed on the market shall not be considered as a modification of that product of such a nature that compliance with the applicable requirements of this Regulation may be affected.

All of these carry new wording and pull together, in concise form, information that was previously less succinct in the original Directive.

Article 5

Obligations of responsible persons

1. Responsible persons shall ensure compliance with Articles 3 , 8 , 10 , 11 , 12 , 13 , 14 , 15 , 16 , 17, 18 , Article 19(1),(2) and (5) , as well as Articles 20 , 21 , 23 and 24 .
2. Responsible persons who consider or have reason to believe that a cosmetic product which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that product into conformity, withdraw it or recall it, as appropriate. Furthermore, where the cosmetic product presents a risk to human health, responsible persons shall immediately inform the competent national authorities of the Member States in which they made the product available and of the Member State in which the product information file is readily accessible, giving details, in particular, of the non-compliance and of the corrective measures taken.

This requirement is very similar to the system used with drugs and medicines. In the old days there was no guidance on the topic of product recall.

3. Responsible persons shall cooperate with these authorities, at the request of the latter, on any action to eliminate the risks posed by cosmetic products which they have made available on the market. In particular, responsible persons shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of specific aspects of the product, in a language which can be easily understood by that authority.

Chapter III

Safety assessment, product information file, notification

Article 10

Safety assessment

1. In order to demonstrate that a cosmetic product complies with Article 3, the responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report is set up in accordance with Annex I.
The responsible person shall ensure that:
(a) the intended use of the cosmetic product and the anticipated systemic exposure to individual ingredients in a final formulation are taken into account in the safety assessment;
(b) an appropriate weight-of-evidence approach is used in the safety assessment for reviewing data from all existing sources;
(c) the cosmetic product safety report is kept up to date in view of additional relevant information generated subsequent to placing the product on the market. The first subparagraph shall also apply to cosmetic products that have been notified under Directive 76/768/EEC. The Commission, in close cooperation with all stakeholders, shall adopt appropriate guidelines to enable undertakings, in particular small and medium-sized enterprises, to comply with the requirements laid down in Annex I. Those guidelines shall be adopted in accordance with the regulatory procedure referred to in Article 32(2).
2. The cosmetic product safety assessment, as set out in Part B of Annex I shall 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 recognised as equivalent by a Member State.

The chartered chemist and chartered biologist are still recognised as qualified assessors in this description.

3. Non-clinical safety studies referred to in the safety assessment according to paragraph 1 and carried out after 30 June 1988 for the purpose of assessing the safety of a cosmetic product shall comply with Community legislation on the principles of good laboratory practice, as applicable at the time of performance of the study, or with other international standards recognised as being equivalent by the Commission or the ECHA.

Article 11

Product information file

1. When a cosmetic product is placed on the market, the responsible person shall keep a product information file for it. The product information file shall be kept for a period of ten years following the date on which the last batch of the cosmetic product was placed on the market.

This is a very long period of time when one considers that tax accounts only need to be kept for six years. This will require excellent data retrieval and careful electronic file management to ensure easy retrieval in an emergency.

2. The product information file shall contain the following information and data which shall be updated as necessary:
(a) a description of the cosmetic product which enables the product information file to be clearly attributed to the cosmetic product;
(b) the cosmetic product safety report referred to in Article 10(1);
(c) a description of the method of manufacturing and a statement on compliance with good manufacturing practice referred to in Article 8;
(d) where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product;
(e) data on any animal testing performed by the manufacturer, his agents or suppliers, relating to the development or safety assessment of the cosmetic product or its ingredients, including any animal testing performed to meet the legislative or regulatory requirements of third countries.
3. The responsible person shall make the product information file readily accessible in electronic or other format at his address indicated on the label to the competent authority of the Member State in which the file is kept. The information contained in the product information file shall be available in a language which can be easily understood by the competent authorities of the Member State.
4. The requirements provided in paragraphs 1 to 3 of this Article shall also apply to cosmetic products that have been notified under Directive 76/768/EEC.

The next part of the law is often overlooked by many companies but now states:

(23) In order to allow for rapid and appropriate medical treatment in the event of difficulties, the necessary information about the product formulation should be submitted to poison control centres and assimilated entities, where such centres have been established by Member States to that end.

The current system for France is the 'green card' notification which is both cumbersome and difficult, if for no other reason than it is not always easy to get hold of the green cards themselves!

(24) In order to keep administrative burdens to a minimum, the notified information for competent authorities, poison control centres and assimilated entities should be submitted centrally for the Community by way of an electronic interface.

This will either be the best idea ever or another bureaucratic nightmare. Will the information be supplied in a consistent simple format like the "frame formulations" established many years ago? Some clarification is given in the Directive in addition to the pre-amble.

s) "frame formulation" means a formulation which lists the category or function of ingredients and their maximum concentration in the cosmetic product or gives relevant quantitative and qualitative information whenever a cosmetic product is not covered or only partially covered by such a formula. The Commission shall provide indications permitting the establishment of the frame formulation and adapt them regularly to technical and scientific progress.

We looked for this document and found a version of the January 2000 document at www.colipa.eu/downloads/99.html. Once again the start up of this system is going to take time as people familiarise themselves

with the complexity of this 142 page document.

Article 13

Notification

*1. Prior to placing the cosmetic product on the market the **responsible person** shall submit, by **electronic means**, the following information to the Commission:*

(a) the category of cosmetic product and its name or names, enabling its specific identification;

(b) the name and address of the responsible person where the product information file is made readily accessible;

(c) the country of origin in the case of import;

(d) the Member State in which the cosmetic product is to be placed on the market;

(e) the contact details of a physical person to contact in the case of necessity;

*(f) the **presence of substances in the form of nanomaterials** and:*

*(i) **their identification** including the chemical name (IUPAC) and other descriptors as specified in point 2 of the Preamble to Annexes II to VI to this Regulation;*

*(ii) the **reasonably foreseeable exposure conditions**;*

*(g) the name and the Chemicals Abstracts Service **(CAS) or EC** number of substances **classified as carcinogenic, mutagenic or toxic for reproduction (CMR)**, of category 1A or 1B, under Part 3 of Annex VI to Regulation (EC) No 1272/2008;*

*(h) the **frame formulation** allowing for prompt and appropriate medical treatment in the event of difficulties. The first subparagraph shall also apply to cosmetic products notified under Directive 76/768/EEC.*

This is a great deal of information to submit electronically. There has already been a complaint to the Commission on the introduction of specific conditions relating to nanomaterials. This was the subject of a memorandum [Interinstitutional file: 2008/0035 (COD) 17 November 2009].

The Council would refer to the second paragraph of point 4 of the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts (hereinafter referred to as "the IIA of 28 November 2001"):

"A new legal act shall not constitute a recast act if, with the exception of standardised provisions or wordings, it makes substantive amendments to all the provisions of the earlier act, which it replaces and repeals."

In view of Article 249 of the Treaty, the Council considers that, in principle and by definition, the use of the recasting technique for a legal act which consists of the conversion of the provisions of one or more Directives into a Regulation ''makes substantive amendments to all the provisions of the earlier act which it replaces and repeals''. In the case in point, because of the advanced stage reached in negotiations, including those with the European Parliament, it did not appear possible to break off the discussions under way at the Council and the Parliament. However, this cannot under any circumstances be taken as a precedent. The Council reserves the right in future to reject any proposal which does not comply with the IIA of 28 November 2001.

Statement for the minutes by the Federal Republic of Germany on the proposal for a Regulation of the European Parliament and of the Council on cosmetic products

With regard to the introduction of labelling for nano particles in cosmetic products (Article 19(1)(g)), it cannot in Germany's view be excluded that the general mention on labels of nano-scale materials in cosmetic products using the term "nano" might be misunderstood by consumers as a warning. Because of the general safety requirements for cosmetics, it is in any case only safe products that are allowed on the market. This applies also to cosmetics which are produced using nanotechnology. Germany believes that information on nano-scale materials may be important for consumers where the particle size results in altered properties.

4. Transitional provisions and dates of application of the Regulation

The Commission will draft an explanatory note regarding transitional provisions and dates of application of the Regulation (in particular in view of Articles 10 (Safety Assessment), 11 (Product Information File), 13 (Notification) and 16 (Nanomaterials).

5. Definition of nanomaterials

The Commission notes that work towards a common definition of nanomaterials is still evolving. The Commission therefore confirms that in future Community legislation progress on the common definition should be taken into account and notes that the Comitology procedures contained within this proposal also allow for the updating of the definition within this proposal.

In addition to all of these requirements which are stacking to an ever increasing burden, there are further requirements:

*2. When the cosmetic product is placed on the market, **the responsible person** shall notify to the Commission the **original labelling**, and, where reasonably legible, a **photograph** of the corresponding packaging.*

3. As from ..., a distributor who makes available in a Member State a cosmetic product already placed on the market in another Member State and translates, on his own initiative, any element of the labelling of that product in order to comply with national law, shall **submit, by electronic means**, the following information to the Commission:*

**OJ: 42 months after the date of entry into force of this Regulation.*

(a) the category of cosmetic product, its name in the Member State of dispatch and its name in the Member State in which it is made available, enabling its specific identification;

(b) the Member State in which the cosmetic product is made available;

(c) his name and address;

(d) the name and address of the responsible person where the product information file is made readily accessible..

4. Where a cosmetic product has been placed on the

market before ... but is no longer placed on the market as from that date, and a distributor introduces that product in a Member State after that date, that distributor shall communicate the following to the responsible person:*

**OJ: 42 months after the date of entry into force of this Regulation.*

(a) the category of cosmetic product, its name in the Member State of dispatch and its name in the Member State in which it is made available, enabling its specific identification;

(b) the Member State in which the cosmetic product is made available;

(c) his name and address.

On the basis of that communication, ***the responsible person*** *shall submit to the Commission,* ***by electronic means****, the information referred to in paragraph 1 of this Article, where notifications according to Article 7(3) and Article 7a (4) of Directive 76/768/EEC have not been carried out in the Member State in which the cosmetic product is made available.*

5. The Commission shall, without delay, make the information referred to in points (a) to (g) of paragraph 1, and in paragraphs 2 and 3 available electronically to all competent authorities. That information may be used by competent authorities only for the purposes of market surveillance, market analysis, evaluation and consumer information in the context of Articles 25, 26 and 27.

6. The Commission shall, without delay, make the information referred to in paragraphs 1, 2 and 3 available electronically to poison centres or similar bodies, where such centres or bodies have been established by Member States. That information may be used by those bodies only for the purposes of medical treatment.

7. Where any of the information set out in paragraphs 1, 3 and 4 changes, the responsible person or the distributor shall provide an update without delay.

8. The Commission may, taking into account technical and scientific progress and specific needs related to market surveillance, amend paragraphs 1 to 7 by adding requirements. Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 32(3).

It will be interesting to see how all of these schemes will be enforced and enabled, but having seen other electronic systems of this magnitude struggle, we are not optimistic for the immediate future.

The pre-amble also mentions other duties that will need to be fulfilled in relation to the product purchased by the consumer.

(53) *In addition to the labelled information, consumers should be given the possibility to* ***request certain product-related information from the responsible person*** *in order to make informed product choices.*

We are not quite sure how this could be implemented. It could be in the form of a glossary (electronic or hard copy) that explains and details every single raw material

listed on the product as an INCI name, or it could be access to a web-based site that details the ingredients in each product. A number of household product manufacturers give detailed explanations of their product composition and also have an MSDS type document for public consumption available at an internet address. Article 21 gives further clarification.

Without prejudice to the protection, in particular, of commercial secrecy and of intellectual property rights, the responsible person shall ensure that the qualitative and quantitative composition of the cosmetic product and, in the case of perfume compositions and perfumes, the name and code number of the composition and the identity of the supplier, as well as existing data on undesirable effects and serious undesirable effects resulting from use of the cosmetic product is made easily accessible to the public by any appropriate means.

The quantitative information regarding composition of the cosmetic product required to be made publicly accessible shall be limited to hazardous substances in accordance with Article 3 of Regulation (EC) No 1272/2008.

(54) *An effective market surveillance is necessary in order to ensure that the provisions of this Regulation are respected. To this end, serious undesirable effects should be notified and competent authorities should have a possibility to request from the responsible person a list of cosmetic products containing substances which have raised serious doubts in terms of safety.*

This sounds simple, but the small enterprise that is selling products from a contract manufacturer or importing a brand is going to find this extremely complicated and may not have a technical resource that is capable of scanning vast numbers of ingredient lists to find products that contain a dubious substance. The same comment applies even more strongly to a distributor.

Many smaller enterprises retain the services of a technical consultant who stores on their behalf this information and is often the safety assessor, who receives (in strict confidence) the full PIP and compiles the safety assessment and new product safety report. However, this consultant is not necessarily the responsible person described in the legislation and is not at the address shown on the product label. It is also true that the consultant is unlikely to be the person who makes the electronic product registration and so the point of contact by the competent authority. Ironically it is this consultant who would be the best point of contact since he/she holds all of the information, is capable of interpreting the request and most likely capable of sourcing all the product reports to filter out affected products.

Conclusions

We have only looked at certain key elements of the legislation, there is plenty more to ponder in the area of hair dyes for example.

The spirit of the legislation is to be applauded, but the implementation is going to be complicated, take considerably longer to implement per product and so prove more costly. At current market rates a safety assessment that complies with the old legislation will cost around £100 (€115) but in view of the additional calculations relating to total daily exposure and the specific effect of the product alone, and the need for a discussion on these results in the new product safety report, we would anticipate this cost to double.

The law of economics has a very clear concept of supply versus demand. When demand exceeds supply then costs will rise. The number of competent safety assessors and toxicologists we suspect will not be sufficient to fulfill this demand and we wonder whether this is the reason for changing the classification of who can be a safety assessor. Many organisations that perform safety assessments use software that is not geared up to the new requirements of this legislation and we suspect that some users of these systems have never worked in the cosmetic industry and have little understanding of the real effects of skin care products.

The toxicological information for new materials is not in the universally understood form of LD_{50} values for rat, mouse, guinea pig, rabbit, cat or dog. The Draize eye test and dermal test (rabbit) was extremely informative and we need to compare these old results to the new *in vitro* results in order to make sense of them. We do not condone animal testing, but have to point out that for the purpose of safety assessments it is quite useful to perform the calculations using the same parameters and yardsticks.

Finally, we have severe reservations and concerns about the electronic system of registration. If there is going to be a standard format, then please can we have it sooner rather than later, because many manufacturers are starting to implement the new legislation today because it is retrospective and all products on the market will have to comply eventually. PC