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## **PUBLIC CONSULTATION ON THE SIMPLIFICATION OF THE COSMETICS DIRECTIVE**

**RESPONSE BY ICDA – March 16<sup>th</sup> 2007**

### **WHAT IS THE ICDA?**

The Irish Cosmetics, Detergents & Allied products Association (ICDA) is the trade association that represents the cosmetics industry in Ireland and is a member of COLIPA, the European Cosmetic, Toiletry and Perfumery Association.

ICDA fully supports the COLIPA response to the Commission consultation on the simplification of the Cosmetics Directive.

The membership of ICDA comprises large international companies as well as small and medium enterprises and welcomes the opportunity to provide a response which reflects the specific views of the member companies.

### **GENERAL REMARKS**

ICDA notes this is the first public consultation on initial proposals by the European Commission to simplify the Cosmetics Directive. The consultation opened on 12<sup>th</sup> January 2007 and closes on 16<sup>th</sup> March 2007. In such a short time it is not possible to represent the views of so many companies on so many separate points in depth; in particular, it is not possible to quantify the socio-economic impact of the proposals in such a time. Nevertheless, ICDA believes many significant and important points can be clearly made now so as better to direct detailed discussion between all stakeholders in the months ahead.

ICDA fully supports the basic premises of the Cosmetics Directive which seeks to achieve a high level of consumer protection by making the manufacturer, or more specifically the person responsible for placing a cosmetic product onto the European Community market, responsible for compliance with the provisions of the Cosmetics Directive coupled with in-market control by member states rather than pre-market approval.

ICDA considers that the “new approach” legislative framework is not suitable for regulating cosmetic products and understands that too is the view of the European Commission.

ICDA believes cosmetics legislation and subsequent regulatory decisions must be based on those fundamental principles that underpin all legislation in the European Community:

- risk-based, not hazard-based;
- non-discriminatory;
- minimum impact to achieve desired outcome.

## RESPONSES TO SPECIFIC ITEMS RAISED

### Item 1

Which elements in the Cosmetics Directive have given rise to particular legal uncertainty about application? Did this increase administrative costs, e.g. costs to get familiar and to understand the applicable legislation? Can these costs be quantified, e.g. by assessing the necessary man-hours? How can these administrative costs be reduced without compromising the safety of cosmetics placed on the market?

#### **Certain concepts could be clarified. Clarification would reduce legal uncertainty.**

Many concepts were identified and proposals made for their clarification in the SLIM exercise on the Cosmetics Directive which was reported in February 2004. Apart from those elements changed through the 7<sup>th</sup> Amendment, the original SLIM report and recommendations are still valid.

- Cosmetic product safety assessments cover, where appropriate, professional users as well as the ultimate consumer (SLIM recommendation 4).
- Certain labelling matters could usefully be clarified (SLIM recommendations 16, 17, 18, 19).
- Conditions of access to the product information could usefully be clarified (SLIM recommendations 26, 27).
- Currently, there are diverse interpretations by member states regarding information to be made available to “poison control centres”. In Ireland, and some other member states, a notification to national poison control centres is based around a “frame formula” system and has functioned effectively for many years. It has been the experience of ICDA that poison control centres do not want full formula disclosure – this is too much information for the most part – unless a product does not comply with the frame formula for its type. A formal reference to a harmonised European frame formula system would be beneficial; the system of the European Association of Poison Control Centres and Clinical Toxicologists (EAPCCT) already exists and was developed in association with the cosmetic industry at European level. This system has been adopted in many member states and its wider adoption is supported by the cosmetics industry.
- ICDA would like to see greater use of non-legislative means of achieving desired objectives through effective self-regulation, co-regulation, guidelines and recommendations to complement legislation.

## **Item 2**

Can you (roughly) estimate the costs stemming from international regulatory divergences? Which elements in the Cosmetics Directive should be reviewed in order to reach better international alignment? Can you estimate the savings this would bring about for European businesses?

**The cosmetics industry is a global industry and changes to the Cosmetics Directive must enhance international alignment and not hinder it.**

The European Commission understands the costs to industry of having diverse regulatory frameworks across the world. Such diversity does not simply add to the costs but acts as a disincentive to SMEs to consider expanding into export markets for fear of failing to comply fully with an unfamiliar legislative regime. For companies operating in Ireland access to global export markets is of paramount importance since the domestic market for all consumer products is small.

ICDA considers that up until the 7<sup>th</sup> Amendment, the Cosmetics Directive was seen by many authorities as a model on which to base cosmetics legislation. The 7<sup>th</sup> Amendment introduced elements that made the Cosmetics Directive a less desirable model and therefore led to divergence. In framing a revision of the Cosmetics Directive, the European Commission should consider the international dimensions such that new legislation further promotes the trend towards international alignment of cosmetics legislation.

## **Item 3**

Would it be preferable to regulate cosmetics by means of a Regulation (i.e. a directly applicable legal act, cf. Article 249(2) of the EC Treaty)? Two options could be considered:

*Option 1:* Turn the whole Cosmetics Directive into a Regulation;

*Option 2:* Turn only the annexes to the Cosmetics Directive into a Regulation.

What would be the socio-economic impact of these options?

**A high level of consumer protection, an effective functioning of the single market and facilitation of international trade can be achieved via a clear and unambiguous regulation.**

ICDA does not see the value in retaining a directive for the main body of the legislation whilst moving to a regulation for amendment to the annexes.

Currently, the requirement to transpose amendments to the Cosmetics Directive into national legislation gives rise to differences between member states through errors, misunderstandings, different time delays, additional national requirements and even transposition into more than one piece of national legislation. This situation is contrary to the principle of the free circulation of goods on the European Community market and adds to the uncertainty under which companies try to operate.

Regardless of the legal instrument chosen, the cost of compliance with new legislation is greatly affected by the time allowed both for the introduction of newly compliant products and for the legitimate sell-through of existing stocks.

Implementation of changes to the legislation must be linked to the concept of "placing on the market" being the first time the product is made available i.e. placed in stocks from point of

manufacture or importation for the first time in the European Community. Unless this is so, the legitimate expectation to be able to sell through to the final consumer those products already on the market would be put in jeopardy.

#### **Item 4**

Which terms would need to be included in a set of definitions in order to make the Cosmetics Directive clearer?

Guidance from the European Commission and collaboration between industry and competent authorities has enabled the Cosmetics Directive to function in the absence of clear definitions of many terms. However, this opportunity should be taken to incorporate those meanings into the legislation to avoid future difficulties which could arise either from future European Community legislation that imposes “horizontal” definitions wherever they do not exist already or from different interpretations being made in different member states or by non-European regulatory regimes.

“Placing on the market”, “person responsible for placing a product on the market” and other terms should be defined in the Cosmetics Directive.

ICDA agrees with the European Commission that the inclusion of certain definitions of key terms in the future EU cosmetics regulations would facilitate the interpretation of its provisions and therefore facilitate the free movement of cosmetic products within the EU Internal Market. This is all the more important taking into account the REACH Regulation and recent EC proposals for a new legislative approach on industrial products, where some general definitions are proposed, which may not be all suitable to the specificities of cosmetic products.

ICDA therefore recommends the following terms should be defined in the future EU cosmetics regulations:

#### **Placing on the (Community) market:**

ICDA considers it important to clarify that this concept refers to the *first time a product is put on the Community market*, and links it to the act of storage for the purpose of sale in the Community market.

Such is also the approach taken by the EC guidance document on the implementation of Directives based on the New Approach and the global approach and the EU Food Regulation.

The date of putting a product into the stocks and thus making it physically available, in most cases corresponds closely with the production date, which can be easily identified through the batch number. Therefore the interpretation that “placing on the market” means “putting into the stocks for sale” is practicable and easy to control.

Linking the moment of placing on the market to the act of storage for the purpose of sale in the Community market also covers situations where other approaches would not be consistent. In the case of direct marketing (catalogue sales) or outlet stores, products are offered to the public in a direct way out of the stocks, without being handed over to any retailers.

#### **Person responsible for placing the product on the (Community) market**

Recommendation n.6 of the SLIM report proposes adding a clear definition concerning the person(s) responsible for placing a cosmetic product on the Community market. For reasons of a harmonised interpretation of the Directive, it is necessary to clarify that “person” may not only refer to a physical person but also to a company.

### **Other terms**

ICDA considers there is also a need to introduce definitions of certain other terms in the future EU cosmetics regulations, which would make its implementation easier and more harmonised (e.g. cosmetovigilance (see item 11), notification (see item 12), cosmetic ingredient, minimum durability, product information, preservative, UV filter).

### **Item 5**

Do you agree that objective criteria should apply for defining groups of substances, independent of the purpose for which a substance was added to a cosmetic product?

One example is the term “preservative”. At present, the definition of “preservative” refers to the intention of the manufacturer (“substances [...] added [...] for the primary purpose of inhibiting the development of micro-organisms in such products”, cf. preamble to Annex VI to the Cosmetics Directive). In order to avoid legal uncertainty it might be preferable to define a substance by referring to its *properties* (e.g. anti-microbial), independent of the *reason* why this substance was added to a cosmetic product.

**The current approach based on intended function is both easy to understand and simple to operate. It should be maintained.**

The alternative approach based on the properties of a substance (objective criteria) would differ fundamentally from the approach taken by other regulatory regimes, themselves often based on the Cosmetics Directive, leading to regulatory divergence and increasing complexity and costs for international companies. The point has already been made that regulatory divergence acts as a disincentive to SMEs in particular to consider expansion into other markets.

In practical terms, adopting objective criteria would increase the complexity of both creating the legislation and in operating it. Each of the criteria would require comprehensive definition as well as agreed testing methodologies adapted for each substance. There would also have to be exclusion criteria to allow the use of other substances that may possess such properties but are not used for that purpose. For example, aluminium chlorohydrate is used in antiperspirants because it acts to inhibit sweating; it also inhibits the growth of micro-organisms in the product but is not used for that function. In the proposed scheme, either aluminium chlorohydrate would have to be assessed because it has anti-microbial properties or it would require exemption because those properties are not used for the purpose of preservation of the product. This change would therefore increase complexity of the legislation and yet bring no compelling benefit.

### **Item 6**

An alternative approach could be to establish a single list of all regulated substances. With regard to positive lists, it could be specified that substances with specific properties (e.g. anti-microbial, colouring, UV-absorbing or UV-reflecting, etc.) have to be listed in the annex before they can be used as an ingredient in cosmetics.

Would this approach be preferable? Can you see any difficulties which this approach would pose?

What would be the impact on the safety of the products containing these substances? What would be the socio-economic impacts of this envisaged change? Are there alternative approaches to consider?

**The current approach of a negative list and several positive lists is well understood by authorities and by industry and it is readily appreciated by SMEs for its clarity; it is of proven effectiveness.**

The current annexes could certainly benefit from re-organisation, editing and comprehensive cross-referencing (particularly to INCI names) to increase clarity to all users but to compile a single list of all regulated substances would not seem to improve the user-friendliness of the annexes.

On occasions ICDA have to discuss the regulation of cosmetic products with the media. After explaining that there is a Cosmetics Directive whose main purpose is safeguarding human health, people are reassured by the straightforward and clear principles of having a banned list (Annex II), a restricted list (Annex III) and positive lists for key classes of ingredients: colours (Annex IV), preservatives (Annex VI) and UV filters (Annex VII).

Nevertheless, if it is envisaged that a single positive list of the current Annexes III, IV, VI and VII should be considered so that all the relevant restrictions regarding a single substance are consolidated into a single entry, that must be done in such a way that the underlying reasoning for positive listing is not obscured and that there is no divergence of essential requirements from other international regimes based on the EU Cosmetics Directive as a model. Electronic documents may make this feasible, however.

There are opportunities to improve the current process by which substances are evaluated for listing in one of the annexes to the Cosmetics Directive. ICDA believes the placing of substances into one of the annexes should be based on sound science and requires a full evaluation of the available data by the Scientific Committee on Consumer Products (SCCP), but recognises the current application of the process is not functioning well enough. To make the process more effective, ICDA would like to see introduced greater transparency and commitment to timings when substances are progressing through the review process and a more collaborative system that allows industry interaction with the SCCP.

### **Item 7**

To remedy this situation the Commission could be given a more flexible mandate, which allows for establishing and updating a publicly-available inventory without legislative procedure. Would this approach be preferable? Can you see any difficulties with this approach? What would be the socio-economic impact of this envisaged change? Are there alternative approaches to consider?

### **ICDA supports simplification of the existing procedures for regularly updating the inventory of cosmetic ingredients.**

The INCI system of ingredient labelling has been a significant step towards helping consumers know which products they can use and which they may wish to avoid, whether for reasons of allergy or simple consumer choice. Its success is shown by its wider adoption by regulatory regimes in other, non-EU, countries.

The key requirement for the effective functioning of the INCI system of ingredient labelling is that companies should have ready access to an up-to-date list of INCI names accurately assigned to chemical substances (by chemical name, CAS, EINECS, ELINCS, INN or other descriptor). All other information is superfluous as is the need for its translation into all EU languages and publication in paper format. These additional elements in the inventory hinder the process of updating. Electronic documentation would greatly benefit this process.

ICDA would support a reconsideration of the Cosmetics Directive requirements with regard to the inventory of cosmetic ingredients, remembering always that the inventory is not “closed” and that

appearance in the inventory is not a prerequisite to the use of a substance as a cosmetic ingredient.

### **Item 8**

The Cosmetics Directive could clearly stipulate that the person responsible for placing the product on the Community market is responsible for compliance with the Directive, i.e. for the safety of the product.

**It would be beneficial to clarify that the person placing the cosmetic product onto the European community market is responsible for compliance with the requirements of the Cosmetics Directive.**

Although ICDA does not believe this aspect has given rise to misunderstandings in the past, for the sake of legal certainty this responsibility could indeed be stated clearly, perhaps in Article 3 as stated in SLIM recommendation 3.

ICDA also supports an adequate system of in-market control by competent authorities as already required under Article 3.

### **Item 9**

The Cosmetics Directive could specify more clearly the information to be made available in the product information file requested via in-market controls to prove the safety of the product. The extent and content of the information required could be based on:

- the SCCP guidelines for safety evaluation of cosmetic ingredients; and/or
- the “technical dossier” and “chemical safety report” requirements in the REACH Regulation 1907/2006 as far as human health risks are concerned.

Which concrete information (including safety data) would the product information file need to contain to allow for more efficient in-market controls of the safety of the products/their substances? How does this information compare with what is usually available in product information files today? Would this mean an increase in information as compared to today? What would be the socio-economic impacts of these envisaged changes?

**The safety assessment of cosmetic products is fundamental to the trust the consumer places in reputable brands and companies. ICDA believes there are opportunities to demonstrate how safety assessments operate to underpin that trust and to ensure all companies are fully aware of their obligations.**

ICDA believes the process of cosmetic safety assessment and its aims could be better described, including the need for a reasoned argument in addition to a statement of conclusion by the safety assessor. Indeed, ICDA is aware that the wording of the Cosmetics Directive on the qualifications required of a safety assessor has been interpreted very differently in different member states.

In view of this, ICDA believes the role, responsibility, qualifications and experience required of the safety assessor could be defined more clearly.

However, there is a need to distinguish between two very different aspects of safety assessment addressed in the Cosmetics Directive which are based on different legal provisions, have different primary objectives and, necessarily, led to a difference in approach:

- product safety assessments are the responsibility of the industry (specifically, the person responsible for placing the product on the market) and will include an assessment of the safety of each of the ingredients under the specific circumstances of their use in that product;
- substance evaluations for the purpose of listing in one or other annex to the Cosmetics Directive are the responsibility of the SCCP, the European Commission and the member states collectively.

In the case of substance evaluations, the SCCP has issued guidelines regarding the information it expects to see to enable it to prepare risk assessment opinion on the risk posed by that substance. Risk management proposals for that substance will be developed by the European Commission in discussion with the member states.

Product safety assessment is carried out prior to placing a cosmetic product on the market and is aimed at ensuring the product will not cause harm to human health under normal or reasonably foreseeable conditions of use. It comprises an expert assessment carried out by a duly qualified professional on the basis of their knowledge, experience and judgement; it will incorporate information from many sources to look at whether or not in the opinion of the assessor the product is capable of causing harm to human health; it is far more complex than a single compilation of toxicological data on ingredients according to a pre-defined list. Remembering that the safety assessor signs the assessment in a personal capacity shows the weight of responsibility they bear.

Because the “chemical safety report” and “technical dossier” under REACH and the dossier compiled for SCCP evaluation are for single substances and are not intended for product safety assessments they would seem to be inappropriate as a basis for controlling the adequacy of a product safety assessment. In addition, the requirement for data from animal tests as currently mandated in the SCCP guidelines for single substance evaluation would not be consistent with the bans introduced by the 7<sup>th</sup> Amendment.

The best guarantee of safe cosmetic products is the quality, training and experience of the safety assessor and the standards to which safety assessment are carried out. The current wording of the Cosmetics Directive in this respect is very general and does not reflect the complexity of the requirement, but any clarification should not lead to obligatory compilation of extensive reports which would not benefit the consumer yet would increase regulatory burden significantly.

### **Item 10**

The Cosmetics Directive could provide for clear response mechanisms in the event of non-compliance with the Directive (including rules on product withdrawal). In addition, the Cosmetics Directive could contain rules on the procedure which would apply for the cases where the product information file is available in another Member State than the one where the in-market control took place.

What is your view on this? What would be the socio-economic impact of such an envisaged mechanism?

**The current legal provisions, supported by good administrative co-operation by the member states, are already adequate in this respect.**

This item covers two separate elements: where there is non-compliance with the Cosmetics Directive; and rules concerning administrative co-operation for access to the product information.

Regarding the first element, the member states are required to set up their own systems of in-market controls including punishment regimes of fines in case of non-compliance as appropriate.

This element is very much under the competency of national governments and authorities and ICDA believes the current provisions are adequate.

Regarding the second element, that of administrative co-operation, ICDA supports the principle that product information should be accessible through one single location in the EU. Whereas this principle is already incorporated into Article 7a (d), ICDA believes this should clearly apply to all the information referred to in Article 7a. Also, ICDA believes the accepted practice of underlining the address on the product label through which product information can be accessed should be explicitly stated in Article 6.1(a).

In the case of a competent authority outside Ireland having a question regarding the product information accessible through an address in Ireland, ICDA believes the other competent authority should contact the Irish authority (the Dept of Health and Children) who would then inspect on behalf of the enquirer. It would not be appropriate or practicable for a non-Irish authority to inspect Irish based product information. Such practice should form the basis of administrative co-operation between competent authorities of the member states.

### **Item 11**

The Cosmetics Directive could include a mandate for the Commission to assist in coordinating cooperation between the Member States in the field of “cosmetovigilance”.

What is your view on this? How would this information flow need to be organized to ensure an efficient surveillance of the safety of the products? What would be the socio-economic impact?

**If a system of “cosmetovigilance” is to be introduced, and it should be recognised this represents an additional regulatory requirement not in the current Cosmetics Directive, it is essential the European Commission should co-ordinate activities to prevent a plethora of different systems operating at national level and thereby the European Commission must act to minimise the impact of this additional burden.**

The Cosmetics Directive requires companies to record adverse events associated with the use of cosmetic products. In 2005, Colipa (the European Cosmetic, Toiletry and Perfumery Association) issued guidelines on handling adverse event reports as a tool for harmonising industry practice and ICDA has carried out training for members in their use. However, the Cosmetics Directive does not require any form of “cosmetovigilance” to be established and ICDA does not, at this time, see the value of establishing such a system at national or European level. Even so, some member states wish to set up national “cosmetovigilance” systems of their own, though the details of their proposals are not clear at this time.

Companies conduct their own post-market surveillance system on the basis of their data and contacts to company helplines etc. which allows companies to react very rapidly should any product fail to be acceptable to the consumer. In view of this, ICDA is not clear how a “cosmetovigilance” system might operate and what added value it might bring.

ICDA calls upon the European Commission to take the lead in this debate to determine whether there is indeed an added value to be gained from a cosmetovigilance system and, if not, to suppress the creation of national systems that would act to the detriment of the industry.

If there is an added value to be gained from a system of “cosmetovigilance”, ICDA calls upon the European Commission to co-ordinate matters to ensure such a system:

- is based on a single EU-wide model;

- uses common definitions and tools;
- has an appropriate scope to ensure it remains manageable;
- defines roles and responsibilities clearly;
- uses high quality data;
- is based on a clear and common understanding of how the information will be used, by whom and for what purpose;
- has minimal cost impact upon individual companies.

## **Item 12**

Would clarification of the rules on notification help to improve market surveillance? What elements should notification cover? What would this mean in terms of socio-economic impact?

How can the registration requirement best contribute to combating importation of counterfeit goods?

**The current requirements of the Cosmetics Directive are very simple and very clear. However, many member states have added requirements of their own. A simple EU notification system would be more effective than the current practice provided it does not involve unnecessary elements.**

The Cosmetics Directive currently requires notification of the place of manufacturer or of initial importation to the competent authority of the corresponding member state. This allows for both inspection of manufacturing sites throughout the EU and inspection of product information. Thus the current requirement is both understandable and reasonable. Notification of the same information to a single point in the EU, for onward transmission to the member states' competent authorities, can then be facilitated by that single point and thereby improve the basis for administrative co-operation.

However, ICDA emphasises that notification of any additional information (such as product names, market launch dates, formula details) would represent an additional requirement over and above that currently required under the Cosmetics Directive and cannot therefore be considered a simplification measure.

The fight against counterfeit goods is important and ICDA fully supports measures by the European Commission in this area. However, neither the current nor an enhanced notification system will assist in that regard. Persons placing counterfeit goods on the market are unlikely to notify their presence; also, counterfeits now are often so good that it would require a company expert to detect them; a simple list of products expected to be on the market would be of little practical value in identifying counterfeits.

Effective control of counterfeit goods depends on the vigilance of customs, excise and police authorities working in close co-operation with the companies that have the legitimate rights over the products.

### **Item 13**

The safety of ingredients in cosmetics would be assessed by the competent authorities on the basis of the product information file. Only if the competent authorities of different Member States disagree with this assessment they should refer the matter to the Commission (including the SCCP).

**The existing ingredient review process could be made to operate more effectively to ensure the existing full scientific review process involving the SCCP, the European Commission and member states is reserved for consumer safety matters that are significant from an EU perspective.**

However, the product safety assessments are intended to assess whether a specific cosmetic product is suitable for placing on the market i.e. is not going to cause harm to human health under normal or reasonably foreseeable conditions of use. A product-specific safety assessment is not intended to justify the use of any particular ingredient across a wide range of cosmetic products. It would be wholly inappropriate to try to use the information from a product safety assessment in such a fashion.

If, during an inspection of a product safety assessment, a concern arises regarding the wider use of any ingredient, there is already a mechanism at EU level to address such a situation.

### **Item 14**

Which elements of the Cosmetics Directive need to be strengthened to ensure the safety of innovative products in the future? Are additional regulatory tools required in order to ensure this safety? If yes, what would be the socioeconomic impact of these additional regulatory tools?

**Innovation *per se* does not raise special concerns for product safety and should not form the basis for specific activity. The principle elements of the Cosmetics Directive (general and specific safety requirements) apply equally to all cosmetic products whether or not “innovative”. These various elements, if clearly described, complied with and enforced, are well suited to ensuring the safety of all cosmetic products including the many innovative products already introduced over many years.**

The scope of the question is unclear as there are references in the text to both novel ingredients and innovative products. Innovation does not rely on the development of novel ingredients but can take many forms, including new uses in cosmetics for substances widely used elsewhere.

The challenge is in the efficient implementation of existing requirements for the safety assessment of all cosmetic products rather than attempting to create additional regulatory tools to be applied under circumstances that would prove difficult to define.

In this regard, ICDA has already stated that the roles, responsibilities, qualifications and experience of the safety assessor should be clarified along with a clearer description of the scope and extent of the safety assessment itself.

### **Item 15**

Clarification could be achieved by explaining and defining the concept of “uncompromised safety”. What is your view on this clarification? What would be the socio-economic impact?

**The concept of uncompromised safety does not exist in the cosmetics sector and is not referred to in the Cosmetics Directive. There is no need for a new term.**

However, it is accepted that the separate concept of a risk-benefit analysis, as it applies in the regulation of medicinal products, does not apply to cosmetics. Instead, the legal concept of a “high level of consumer protection” enshrined in Article 95.3 of the Treaty Establishing the European Community is already clearly incorporated into the Cosmetics Directive in Article 2.

Article 2 requires cosmetic products not to cause harm to human health when applied under normal or reasonably foreseeable conditions of use. However, Article 7a(1)h refers to existing data on undesirable effects, thus acknowledging that cosmetic products may produce undesirable effects that fall short of harm to human health. The Cosmetics Directive recognises established concepts in European Community laws such that in achieving a high level of consumer protection, zero risk is unattainable and that legislation should be based on risk- not hazard- assessment.

The introduction of a new term, uncompromised safety, is unnecessary and potentially misleading, increasing rather than decreasing legal uncertainty, as it suggests a desire to achieve zero risk and does not adequately convey the intended concept surrounding risk-benefit assessments and the fact that such assessments are not part of cosmetic product safety assessments.

### **Item 16**

The Cosmetics Directive could make it clear that, as a consequence of the responsibility of the manufacturer, if data are missing the substance in question will be presumed unsafe.

What is your view on this clarification? Are there alternative approaches to ensure the safety of products? Do you think this clarification would have a socio-economic impact? How?

**The Cosmetics Directive already has a clear requirement for mandatory product safety assessments as a prerequisite for the marketing of cosmetic products. An adequate ingredient assessment is a necessary part of a product safety assessment but, as part of this, specific data on ingredients can justifiably be waived on the basis of a reasoned argument. Thus, the absence of data do not mean that either the product or the ingredient are unsafe.**

The current basic principle of the Cosmetics Directive is “no product safety assessment – no market”. There is no scientific justification for presuming that the absence of certain data from a pre-determined set of toxicological studies indicates either the ingredient or the product in which it is found may be unsafe.

The best guarantee of safe cosmetic products is through a combination of the quality, training and professional experience of the safety assessor, a consistent and robust safety assessment and post-market surveillance by the company.

### **Item 17**

Apart from a positive list for hair-dyeing substances, the Cosmetics Directive could include a mandate for the Commission, as risk-manager, to compile new positive lists for groups of substances. This would allow it to ensure that only substances which have undergone a safety assessment by the SCCP can be used as ingredients in cosmetics.

What is your view on this? How would this impact on the safety of cosmetic products? What would be the socio-economic impact?

**The Cosmetics Directive already provides a mechanism for creating new positive lists when deemed necessary. In the interim period, until a new list is constituted, substances can be managed by use of the existing Annex II (banned) and Annex III (restricted) system. Thus, there is no need for the European Commission to assume a new mandate to allow it to compile new positive lists.**

Currently there is an absolute requirement for the manufacturer to ensure product safety prior to marketing regardless of the ingredients in the product. If any substance raises concerns, the present Cosmetics Directive allows for that substance to be evaluated by the SCCP and for risk management measures to be proposed by the European Commission as appropriate depending on the SCCP's opinion.

Similarly, if a class of substances united by function raises concerns, as did hair dyes, there already exists a mechanism by which a new positive list may be created after due discussion in Council and in European Parliament. During those discussions individual substances within that class may be controlled through the existing Annex II and Annex III system.

### **Item 18**

The Cosmetics Directive could provide for a mechanism placing an obligation on the regulator to reconsider the listing of a substance on a "positive list".

What is your view on this? How would this impact on the safety of cosmetic products? What would be the socio-economic impact?

**There is no need for a specific, time-related mechanism for the automatic re-review of substances on positive lists. Re-evaluation of substances can be triggered at any time but should be based on the availability of new, relevant information and not by the expiry of a period of time.**

The current Cosmetics Directive allows systematic or case-by-case re-evaluation of substances on positive lists at any time, whether as a result of new information or new questions. It is important that such re-review of substances on positive lists should be based on the availability of new and relevant safety findings that could affect the conclusions of the existing safety assessments: re-review should not be triggered by a simple time limitation or a simple unwillingness to accept the initial opinion.

An automatic, time-triggered re-evaluation would create an unnecessary and burdensome obligation on both industry and authorities; indeed, it might even be counter-productive in having new information shelved until some future review date rather than being considered at the time.

Clarification could be made in the Cosmetics Directive to reinforce the premise that the positive listing of a substance does not take away the responsibility to consider recent scientific findings on substances in the product safety assessment.

## **CONCLUSIONS**

ICDA, speaking for and on behalf of the Irish cosmetics industry, broadly welcomes the proposal to simplify the Cosmetics Directive to ensure it can continue to provide a high level of consumer safety without imposing unnecessary regulatory burdens on a successful and responsible industry that is recognised as the global leader.

**Submitted by:**            **Dr James Ring**  
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**16/3/07**