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## **Position of the Polish Union of Private Employers of Cosmetics Industry on the simplification of the Cosmetics Directive no. 76/768/EC**

The Polish Union of Private Employers of Cosmetics Industry presents its position concerning the simplification of the Cosmetics Directive 76/768/EC within the framework of the public consultations launched by the European Commission.

Comments presented in this document are the result of consultations carried out among members of the organisation, as well as of the standpoint elaborated during the work of the legislative working group and a discussion on individual proposals put by the European Commission.

The Union declares its willingness to further co-operate and participate in subsequent phases of the directive 76/768/EC simplification process. We hope that the current public consultations are an introduction to a further debate on the final shape of the future EU legislation in the field of cosmetic products. We also hope that the European Commission, having presented a detailed draft of the legal regulation, shall enable its public consultations. Simplification of the directive is the most important legislative project since the adoption of the 7th Amendment to the Cosmetics Directive. It is important to ensure that the introduced law should serve consumers, competent authorities and producers at its best, while staying workable, and was applied in a uniform manner in all EU Member States.

In the Union's view it is essential to implement new regulations subject to long enough transitional periods. The procedure for the directive simplification should be carried out in such a way as to be possible for execution for manufacturers, while avoiding retroactive nature of new regulations, which would force withdrawal cosmetic products legally placed on the market. Furthermore, impact of the new regulations on a functioning of small and medium enterprises should also be taken into account.

The draft of the directive 76/768/EC simplification gives an occasion to unify provisions which constitute barriers to the free movement of cosmetic products within the Community. Such barriers predominantly stem from different construction of the community law by legislators in individual Member States. A thorough analysis of the document submitted by the European Commission for the public consultations indicates, though, that certain proposals just reproduce requirements already existing in the REACH regulation and cause anxiety as to the possibility of their practical implementation by cosmetic manufacturers. Provisions and practical application of the Cosmetics Directive provide sufficient safety of cosmetic products. Therefore, amendments suggested in items 14 – 18 do not seem justifiable. The REACH regulation which is going to enter into force on 1 June 2007 will constitute an additional factor improving safety of the cosmetics ingredients. However, cosmetic products are not covered by the REACH regulation and introducing REACH-like provisions into the future legislation would have to involve amendment of appropriate REACH provisions, for example ones concerning the obligation to submit all research results to downstream users. Furthermore, certain Commission proposals seem to exert a potentially very unfavourable impact on the future innovations in the cosmetics industry. The industry, being extremely competitive, relies both upon safety and confidence of consumers, as well as upon innovations. Restricting innovations through a limitation of available components and introduction of additional time-consuming "admitting" procedures may result in a setback of the cosmetic industry development.

It is the Union's view that the procedure of the directive 76/768/EC simplification should lead to a complete harmonisation of the community law in the field of cosmetic products.

At present, such harmonisation is incomplete and insufficient. A good example of differences between domestic regulations and the directive 76/768/EC is the Polish legislation, namely the law on cosmetic products (Journal of Laws of 2001, no. 42, item 473) and administrative acts.

Remarks to individual proposals (items) considered by the European Commission in the document submitted for consultations are presented below.

**Item 1 considered by the Commission and submitted for public consultation:** 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?

#### Uncertainty concerning interpretation of legal provisions

Taking into account experience of the practical application of the Polish legislation in the field of cosmetic products, most uncertainties as to the interpretation of the directive provisions arise from rules concerning notification of cosmetic products (the main problem), management of reporting undesirable cases (cosmetovigilance), as well as issues relating to the scope and method of making available data which the competent authorities may require in order to begin treatment.

In most EU Member States legislators have differently interpreted legal regulations covering the mentioned issues, which has led to their different implementation into national legal systems. Interpretation doubts concerning the scope of data contained in the notification are reflected in decisions taken by the European Court of Justice, which has already ruled several times in cases concerning an improper transposition of the directive 76/768/EC into the national legislation (cases C-29/90 and C-246/91). The Cosmetics Directive 76/768/EC is of no minimum nature. This has also been underlined by the Court in its decisions (among others in cases C-150/88 and C-99/01).

It seems that interpretation differences might result from a different understanding of the directive article 7.3:

*“3. Furthermore, a Member State may, for purposes of prompt and appropriate medical treatment in the event of difficulties, require that appropriate and adequate information on substances used in cosmetic products be made available to the competent authority, which shall ensure that that information is used only for the purposes of such treatment.”*

The directive does not specify the practical meaning of the expression „to be made available to the competent authority”. It is differently interpreted by legislators and competent authorities (as an obligation to provide data by the manufacturer before a product is placed on the market) and by manufacturers (providing data to competent authorities and control bodies at their every request and without necessity of notification in the central register).

The doubts concerning interpretation of the directive art. 7.3 are illustrated by the fact that manufacturers in individual EU Member States have been charged with very different obligations relating to the provision of certain data (quantitative or qualitative composition of each cosmetic product, place of storing its dossier etc.) within the framework of the product notification. As a result, there is no product notification on the EU common market. Products have to be notified separately in each EU Member State. From this point of view there are numerous distinct markets instead of a single community one. Many countries (like Poland) require a separate notification for each product instead of notifying the place of its production and first marketing, as provided for in article 7.3. A manufacturer that has already made notification in any EU Member State is additionally obliged to notify each product placed on

the Polish market. Since the scope of information provided in the process of notification in individual Member States differs, many products are subject to a multiple notification in separate countries.

Thus, it seems there is a need to settle this issue on the Community level in such a way as to embrace all EU Member States.

### Ambiguities as to the interpretation of legal provisions – the Polish versus Community legislation

#### Product notification

The Act on Cosmetic products of 30<sup>th</sup> March 2001 (Journal of Laws of 11<sup>th</sup> May 2001) is an example of the legislation according to which the scope of information provided in the process of notification exceeds requirements laid down in the directive 76/768/EC. According to art. 8.4 of the above act the following data should be submitted in order to notify a product: trade name and category of the cosmetic product, first name and surname of the manufacturer notifying the product, address of the place where the product dossier is made available, as well as any modifications of data referred to in paragraph 4 in relation to a cosmetic product being already on the market.

Manufacturers express their doubts as to the relevance of submitting such data, as being completely useless, during the notification process. Those data (as well as many others) are available on the product label, so they are accessible not only by competent authorities, but also by each and every consumer. Producing such data does not seem to facilitate supervision over the cosmetics' market, neither to affect consumer safety or the possibility to take up an immediate treatment referred to in art. 7.3 of the directive 76/768/EC. Instead, it means additional obligations and costs borne by entities marketing cosmetic products.

It seems to be of the high importance to harmonize the rules of notification within EU. Member States should not be allowed to introduce any individual, additional provisions as regards to notification.

The notification has also been examined under item 12.

#### Cosmetovigilance

Principles governing management of reporting undesirable cases are also a source of interpretation ambiguities in the Polish legislation. Provisions of the directive 76/768/EC in the field of the cosmetovigilance have been implemented in a fashion which prevents entrepreneurs in Poland from executing legal obligations concerning completion of the cosmetic dossier. According to art. 8.3 of the law on cosmetic products: „*A physician who diagnoses an illness being a result of a cosmetic product usage is obliged to immediately report such a case to the national system.*”

Later on, such cases are not verified by the manufacturer nor included in the product dossier since both physician and competent authorities have no legal obligation to inform manufacturer about the reported case.

An exact description of the problem may be found under item 11.

Since it is the Union's view that interpretation ambiguities and resulting therefrom differences in regulations concerning notification and cosmetovigilance are crucial issues requiring certain unification, they have also been discussed in paragraphs below. Other doubtful questions include the language of the cosmetics dossier, which has not been specified in detail in the Polish legal system. Furthermore, the law on cosmetic products lacks reference to trade secret and intellectual property rights.

#### Product Information File Language

An art. 7a p. 3 of the directive 76/768/EC has not been transposed into the Polish Act on Cosmetics. In art. 11. p. 1. 1-7 of the cosmetic act (defining the contain of product

information file) there is lack of the language of product file to be made available to competent authorities specified.

The cosmetic directive specifies the matter: “*The information referred to in paragraph 1 must be available in the national language or languages of the Member State concerned, or in a language readily understood by the competent authorities.*” Such as lack of specification could be a reason of different interpretation of regulation regarding producers and competent authorities (i.e. sanitary inspection) and therefore cause problems during control. According to the act on the Polish language (Journal of Laws of 1999 nr 90, item 999, amended) the sanitary inspection could require dossier to be made available prepare in Polish. That would be problematic if the majority of documentation (especially related to raw materials delivered by suppliers as well as scientific literature data) is prepared in English or other UE language. Translations (especially certified) of a large number of documents is time and cost consuming.

The Cosmetics Directive might contain more specific provisions as to the language in which the cosmetic product dossier could be made available. The dossier should be made available in the language of that Member State in which it is kept, yet the manufacturer should have the possibility to complete it in one of the official languages of the European Union (e.g. English).

#### Public access to information vs. intellectual property rights

Art. 11.2a of the Act on Cosmetics, which concerns the “public access to information”, contains neither reference to trade secrets nor to intellectual property rights. In order to ensure a uniform interpretation of the expression “public access to information”, it is indispensable to have such a reference (appearing in art. 7a 1 h of the directive). Besides, there are doubts as to the specification of appropriate media through which the information should be made publicly available. The Act on Cosmetics contains their list: the post, telephone, electronic media, while the directive refers to all appropriate means of information. These are not significant differences, yet they indicate the possibility of different interpretations in individual countries as well as restrict future use of new means of communication.

It seems that the problem of the public access to information should be more precisely dealt with in the directive.

Certain interpretation ambiguities result from an inappropriate translation of the Cosmetics Directive into the Member States languages. The age limit for the use of borates and salicylic acid specified in the directive and the Polish legislation might serve as an example of this problem:

#### Borates and salicylic acid use for children - the age limit

There is an entry in the regulation of Minister of Health on the lists of substances (...) implementing annexes to the Cosmetics Directive (Journal of Laws of 2005 nr 42, item 642) under position 1 of annex 2 (boric acid, borates and tetraborates) as well as under position 3 of annex 4 (salicylic acid and its salts) defined, that the preparation containing the substance mentioned should “*not be used for children under third year of age*”. Due to the peculiarity of the Polish language and inappropriate translation into Polish this entry means, that such as preparations could not be used for children who has finished two years of age and has began third. The analogous entry in the annexes to directive 76/768/WE is as follows: “*Not to be used for children under 3 (three) years of age*”.

Such a mistake could result from a inappropriate translation of the Directive 76/768/EC itself. Polish language version of the of the directive contains the same discrepancy.

## Interpretation ambiguities concerning legal regulations within the framework of the Community market

Apart from the notification, interpretation ambiguities within the whole Community also relate to:

- the notion of placing on the market (examined in the further part of this standpoint) and the lack of a proper definition in the directive,
- using the mark "+/-" (or "may contain") on the list of components on the product label (art 6. 1 g of the directive),
- the requirement to carry out the safety assessment in accordance with the principles of a good laboratory practice (art. 7a 2 of the directive),
- the method of shortening information concerning the manufacturer seat, put on the product label (art 6.1.a),

### Using the mark +/- (may contain) on the list of components on the product label

Another dubious question within the Community law is the application of art. 6. 1(g) concerning the possibility to use the mark "+/-" ("may contain") in the list of ingredients on the cosmetic product.

According to the directive only substances listed in Annex IV could be listed after "+/-" or "may contain" wording. However, manufacturers are unable to place list of ingredients correctly. Due to the technical progress in cosmetics ingredients many raw materials are complex mixtures of many compounds. They contain additives, which does not affect the safety of the material but allow to obtain suitable shade or facilitate incorporation of a raw material into the formula. The ingredients in question are Mica, Tin Oxide (both used as opacifiers) and others. Using simple, one-substance-ingredients instead of modern, complex raw does not allow to achieve the same result (nor as regards to the required shade neither as regards to the easy incorporation into the cosmetic mass) in the in finished product. If such a complex raw material is used only in some of shades between hundreds of eye shadows or face powders, the idea of using one label for all shades could not be applied, since Mica can not be labeled after +/- sign. The practical result is that INCI labelling on most products present on European Market could not be properly applied.

It seems, that colour ingredients which do not have a CI number, but are closely associated with colour should be allowed to be listed under the "+/-" ("may contain") section of the ingredient listing. Otherwise, the idea of using one label for many shades does not make any sense.

### The requirement to carry out safety assessment in accordance with the principles of a good laboratory practice

The safety assessment of finished product is an intellectual exercise and not a laboratory procedure. It is performed on the basis of earlier tests of the finished product and its ingredients, literature data, material data sheets of the ingredients etc. Therefore, it does not seem justifiable to include in the directive a reference to the good laboratory practice in the field of the ready product safety assessment.

### The abbreviation of information concerning manufacturer, put on the product label

Information on the manufacturer (name and seat), put on the product label, may be abbreviated in so far as the abbreviation makes it generally possible to identify the undertaking. Such a wording arises doubts of both manufacturers and competent authorities: is it enough to place just a legible company logo or should some contact data, like phone number, postal code or website address, also be specified? Despite considerable usefulness of such a wording for manufacturers, information on the manufacturer's seat is rarely shortened in practice due to certain doubts as to the correctness of using the shortened marking.

### Costs of regulatory discrepancies

Costs generated by different interpretation of the directive 76/768/EC provisions and discrepancies between rules in the Member States and the directive itself are both costs borne by the public administration in individual Member States (maintaining notification systems like the National Registration System for Cosmetic Products in Poland) and costs borne by entrepreneurs in order to satisfy different requirements within the Community.

### Notification costs

In case of entrepreneurs which place cosmetic products on the Polish market these are primarily costs of the cosmetic products notification which discriminate entrepreneurs placing products on the Polish market in relation to products present in other EU Member States.

Manufacturers do not deem the quantitative costs of the notification itself to be fundamental. The bureaucratic burden is much more important.

The number of products submitted to the National Registration System for Cosmetic Products amounts to some 178 700 item (February 2007). This is only the number of first submissions. If during the lifecycle of a product any submitted earlier data change (e.g. name of the product), the manufacturer is obliged to make a separate entry. On average, there are 2 or 3 such applications per product (which means that there are some 356 000 - 534 000 applications altogether). Change of the entrepreneur's address is the most controversial one. In such a case the manufacturer is obliged to report the change on separate forms for all products that were earlier submitted.

The biggest share in the notification costs falls to the National System notification confirmations for individual products. These documents are not required by the law. Since the Polish legal system does not provide for the feedback to the manufacturer after notification, most manufacturers are forced to obtain such confirmations because these documents are required by trading entities. A poll conducted among the Union members indicates that most (some 70%) manufacturers obtains such confirmations for all products in their offer. The cost of one confirmation amounts to PLN 20 (about EUR 5,1). Sometimes manufacturers order two language versions of the confirmation.

The notification costs also include maintenance of the National Registration System for Cosmetic Products – running a database, preparing confirmations, invoicing payments charged for issuing notification confirmations. Surely, these costs could be fully assessed only by competent authorities responsible for running the registration system for cosmetic products and undesirable cases.

Introducing one notification system within the Community would prevent similar situations and unnecessary multiplication of submissions. It seems that only regulation as a legal form offers an opportunity for simplification and full harmonisation of the notification procedures.

**Item 2 considered by the Commission and submitted for public consultation:** 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?

Striving for the harmonisation with legal systems on non-European markets seems quite natural in the process of the directive simplification. In its document submitted for public consultations, the European Commission has proposed a series of new concepts concerning, among others, regulations covering individual ingredients, range of obligatory tests for cosmetic components and scope of documents required in the cosmetic product dossier.

The Cosmetics Directive 76/768/EC constituted a model for numerous non-European legislative systems because of the credibility stemming from the scientific principles adopted as the basis for its provisions. Therefore, the process of the simplification should be

preceded by an analysis how the introduced amendments might influence on the harmonisation or differentiation of the EU rules in relation to non-European markets, thus affecting the trade in cosmetic products.

**Item 3 considered by the Commission and submitted for public consultation:** 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?

It is the Union's view that the unification of legal provisions concerning cosmetic products and their interpretation is one of the priorities in the simplification exercise. A uniform interpretation of legal rules contained in the directive is to be ensured by guidelines and recommendations published by the European Commission. Yet, these documents are not sources of law because they are not obligatory. Experience indicates there are still many issues for which no guidelines were published (placing on the market, using the mark "+/-" on the list of ingredients) and which raise doubts and are differently construed by individual Member States.

During consultations held among the Union members a significant majority of manufacturers opted for the adoption of a new cosmetic legislation in the form of a **regulation**. The Polish experience (notification, cosmetovigilance) explicitly indicate that differences in rules themselves or their interpretation generate real costs, hinder the free flow of cosmetic products within the Community, charge manufacturers with bureaucratic burden with no added value for the safety of cosmetic products (notification) or even hamper fulfilment of other legal obligations (cosmetovigilance). It seems that only adoption of a uniform legal system that can be ensured by a **regulation** would allow for the elimination of these discrepancies.

At present, the European Commission publishes several directives per year amending the directive 76/768/EC. Each of them has to be translated into all Member States languages. This generates certain costs, while translations contain language and technical errors. Additional administrative costs result from the necessity to implement each amendment. Short transitional periods determined by the European Commission are additionally shortened by the time necessary to implement the directive on the national level, as the directive is addressed to the Member States but manufacturers are obliged to fulfil national law provisions which are implemented at least several months later.

Irrespective of the results of the public consultations and the legal form that will be finally adopted (directive or regulation), harmonisation of legal rules and ensuring a uniform application of the law in all Member States are crucial issues.

**It is also important to lay down long enough transitional periods.** They should be agreed upon with the industry so as to make it possible for entrepreneurs to adjust to new requirements.

**Item 4 considered by the Commission and submitted for public consultation:** Which terms would need to be included in a set of definitions in order to make the Cosmetics Directive clearer?

The Union's view is that adoption of a coherent set of definitions will facilitate interpretation of the legal provisions.

Apart from the set of definitions it seems justifiable to specify the collection of requirements in the field of **product labelling**. Currently, there are no precise provisions regulating the way

of labelling cosmetics sets, promotion or collective packages, or sets containing cosmetic and other consumer products (i.e. a shaver and after shave balm). Problems concern labelling the ingredients, durability date and other elements. The term “external container” is also differently interpreted in case of sets by different authorities which control the labelling. Additionally, the method of information abbreviation concerning the manufacturer seat on the label might also be more precisely specified.

It seems justified to lay down the following definitions in the directive:

- placing on the market
- public access to information
- colouring agent
- preservative
- sunscreen (UV filter)
- aroma
- perfume
- undesirable event
- serious undesirable event
- cosmetic product (change of the current definition)

#### Placing on the market

The most important definition the directive currently lacks is „placing on the market”. Lack of this definition in the directive 76/768/EC led several times to disruptions in the free flow of cosmetic products.

For instance, Polish Act on Cosmetics contains definition of placing on the market, which is imprecise and ambiguous:

*2) placing on the market – payable or free of charge first delivery of a cosmetic product by the manufacturer to the user or entrepreneur participating in the supply chain,*

Delivery to the entrepreneur participating in the supply chain and delivery to the consumer are two different phases in the supply chain, often quite distant in time. It seems that placing on the market should refer to the point in time when a product (ready to be delivered to the consumer) leaves the production phase and is handed over to a stock. Delivery to the consumer usually takes place somewhat later. Therefore, expressions „placing on the market” and „delivery to the consumer” should not be identified.

In case of new regulations being introduced subject to a transitional period, it is fundamental for entrepreneurs whether such a period refers to the delivery from the production phase to the stock (meaning de facto placing on the market) or delivery to the consumer. If the transitional period concerns delivery to the consumer, the manufacturer has significantly less time for adjusting products. Quite often it means retroactive legislation: products delivered to the stockroom (that is products legally placed on the market) or to subsequent links of the delivery chain have to be withdrawn from the market before they are delivered to the consumer. Interpretation of the expression „placing on the market” exerts direct influence on the length of the transitional period manufacturers have in order to adjust to new regulations. Thus, differences in this interpretation result in a situation in which a product placed on the market of one Member State is not accepted in another Member State.

Individual EU Member states apply different definitions of placing on the market: in some cases this means the first delivery of the product from the production and conditioning phase to the stock, in others delivering each and every batch of the product from the production line to the stock.

The Union proposes the following definition of “placing on the market”:

- **Placing on the market** – *the first delivery of the cosmetic product in a ready-to-sale form from the production phase to the stock with a view of its sale or distribution within the Community*

Additionally, the Union suggests changing definition of the cosmetic product to ensure more transparency, also from the point of view of problems involving bordering products. The current definition of the cosmetic product is ambiguous with respect to the interpretation of terms „function” and „purpose”.

While the currently used definition of cosmetics products is quite well understood, The Union proposes to consider the following definition of the “cosmetic product” in order to clarify the “application site” and “purpose” of cosmetic product:

*A “cosmetic product” shall mean any substance or preparation intended exclusively or mainly to be placed in contact with the skin and its appendages, the lips and external genital organs, or the teeth and the mucous membranes of the oral cavity, with a view to maintaining them in good condition and/or contributing to well-being.*

*This may be achieved notably by cleaning them, perfuming them, changing their appearance and/or correcting body odours and/ or protecting them”.*

**Item 5 considered by the Commission and submitted for public consultation:** 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.

It seems that current criteria of placing substances on lists are quite clear and understandable, and they should not be essentially modified. Also, assessment of the safety of particular ingredients by the SCCP is usually carried out for specific uses of the cosmetic product.

Applying objective criteria for placing ingredients of the cosmetic products on cosmetic products’ ingredient lists would result in a lesser transparency of such lists and would have a negative impact on innovations. For instance, certain preservatives are used as active substances also in bigger concentrations and for other purposes than preserving the product. Objective criteria would make this impossible because of the legal considerations, while not increasing the consumer safety. On the other hand, there are numerous active substances (e.g. having anti micro-organism effects) which are not placed on the lists (for instance many natural ethereal oils). Adoption of the objective criteria (the list of allowed bacteriostatic substances) would mean necessity to include such substances and extension of the lists, otherwise these substances could not be used.

**Item 6 considered by the Commission and submitted for public consultation:** 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?

It seems that the currently used system of lists is well understood by industry and competent authorities. Establishing of single lists of regulated substances could make using it more difficult as it is in case of list of substances which must not form part of the composition of cosmetic products. This list is long and searching for specific substances is time consuming and not user-friendly. The substances are placed on the list in order they were added to the list (chronologically) not in alphabetical or CAS number order.

Legibility of the lists should be improved through supplementing tables with CAS, EINECS/ELINCS numbers, as well as INCI names of the substances used in the cosmetic products. Such a system would facilitate usage of the lists also in case of consumers since the cosmetic label contains only INCI names and not chemical or traditional names of ingredients which are currently stated in the tables.

An official, electronic version of the lists should be developed to facilitate using the lists and search desired compound.

**Item 7 considered by the Commission and submitted for public consultation:** 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?

Introducing a system allowing for updating on an on-going basis the list of ingredients seems to be justifiable and desirable. The European Commission should receive an appropriate mandate for this. Currently, the list is permanently incomplete and out of date. The delay in updating rises to at least several years. Manufacturers have often doubts how they should denote an ingredient not included in the list.

An additional problem consists in the translation of a several hundred pages long document into all languages of the Member States. This is a time-consuming and costly procedure. Besides, translations are not sufficiently verified and contain language and content-related errors.

**Item 8 considered by the Commission and submitted for public consultation:** 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.

The fact that a person placing a product on the Community market is fully responsible for the compliance with the directive (therefore also for the product safety) seems quite obvious and did not rise any doubts in the past. Such a responsibility is enforced by establishing a system of the market surveillance by competent authorities in each Member State. Therefore, it does not seem necessary to introduce a separate provision into the directive.

**Item 9 considered by the Commission and submitted for public consultation:** 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 product safety assessment has been regulated in the directive quite shortly. There are no guidelines or manuals by the European Commission which would determine how the person assessing the cosmetic product safety should come to the final conclusions. Perhaps including such guidelines into the Cosmetics Directive 76/768/EC would prove helpful, also for the entrepreneurs. The Cosmetics Directive could contain a more detailed specification of basic competences (education and skills) with relation to the safety assessor.

The safety assessment is a complex exercise which final conclusions depend on the quantity and the method of applying the product, profile of the consumer to which the product is addressed, or an interactions of ingredients applied in the formula. Thus, the product assessment cannot be reduced to a simple review of characteristics safety data sheets or other data concerning safety of particular ingredients. Therefore, it does not seem expedient to include the proposed range of documents (safety assessment of ingredients according to SCCP or REACH) as obligatory element of the cosmetic product dossier.

**Item 10 considered by the Commission and submitted for public consultation:**

The Cosmetics Directive could provide for clear response mechanisms in the event of noncompliance 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?

It seems that the currently existing provisions of the directive are quite sufficient to ensure an effective control over the compliance of the cosmetic products with the directive requirements.

It is a fact that the efficiency of the surveillance carried out by competent authorities over the cosmetic market is not sufficient. Yet, it does not stem from the lack of appropriate provisions in the directive 76/768/EC itself. Competent authorities have no legal or administrative instruments aimed at counteracting trade in counterfeits and an appropriate control over sale of products which do not satisfy requirement of the directive 76/768/EC via internet. It does not seem possible, though, that the Cosmetics Directive could contain detailed principles governing administrative proceedings and internet trade, since these issues are subject to a separate legislation.

On the other hand, it is justifiable to have clear and precise rules for the cooperation between competent authorities of individual Member States in the field of the market surveillance. This requires rather some coordination activities among the Member States instead of additional restrictions in the directive. The system should be also clear from the point of view of the cosmetic manufacturers.

**Item 11 considered by the Commission and submitted for public consultation:**

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?

Surveillance over the safety of cosmetic products - „cosmetovigilance” – covers in principle two separate aspects: monitoring undesirable events resulting from the application of cosmetic products and ensuring that cosmetic products regarded as dangerous (for instance those containing substances not permitted for the use in cosmetic products) should not be available on the market. The latter is already covered by RAPEX system.

As concerns monitoring of undesirable cases resulting from the application of the cosmetic products, legal rules oblige manufacturers to include appropriate data in the cosmetic dossier, as well as to make them available to competent authorities and to the public opinion at the request of consumers. In order to ensure credibility and adequacy of the created data the manufacturer must have the possibility to assess and verify them. In 2006 Colipa published a very useful guide, which indicates how manufacturers may prepare data concerning undesirable events.

The Union of the position that it would be justified to introduce one European monitoring system of serious undesirable events.

The basic assumption of that system should be assessment and verification of undesirable cases by the manufacturer (for instance in cooperation with a dermatologist), and then submission of the information to the central register should the undesirable cases be a grave one. The system should be harmonised and compliant with the earlier industry initiatives based on self-regulation (e.g. “Colipa guidelines on the management of undesirable events reports” published in 2005). It should cover exclusively serious undesirable events. Information concerning other cases (other, than serious) would be included in the cosmetic product dossier and made available to competent authorities and consumers according to the currently binding provisions of the Cosmetics Directive.

Establishment of the system without such a crucial element as the case assessment by the manufacturer might lead to incompatibilities with provisions regulating inclusion of data on undesirable cases in the cosmetic dossier and making them available, thus resulting in an inefficient and useless system. Such a system has been introduced in Poland by the law on cosmetic products whose art. 8.3 stipulates that *„A physician who diagnoses an illness being a result of a cosmetic product usage is obliged to immediately report such a case to the national system.”*

The system does not provide for submitting any piece of information by the physician or the National Registration System for Cosmetic Products to the manufacturer. As a result, the manufacturer has no possibilities to verify these cases or to include data to the cosmetic product dossier or make them publicly available. Therefore, there is no possibility to fulfil legal obligations laid down in the directive 76/768/EC relating to the management of reports concerning undesirable cases. Thus, provisions of the Act on Cosmetic products governing the central register and the management of reports concerning undesirable events by the manufacturer seem to be contradictory. Additionally, it is not known who benefits from such system. It also seems that a dermatologist is not always the most competent person to assess the composition and effects of a cosmetic product, so it should be the manufacturer who would verify reported cases in cooperation with the dermatologist.

**Item 12 considered by the Commission and submitted for public consultation:** 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 Union is of the opinion that harmonization of the notification procedures remains a matter of priority. A single, European system of notification should be developed. Such system should be harmonized and simplified in comparison to current procedures applied by various Member States. Possibly, the system should be based on electronic form of submission.

It seems that it is not the directive which requires more precision in the field of the notification but ensuring that rules in this area will be implemented by all Member States in the same way. At present, each country applies different procedures for the product notification requiring data exceeding those specified in the directive 76/768/EC. However the directive provisions has no minimum character, what was mentioned several times in European Court of Justice Judgments. Many states, like Poland, require a separate notification for each product. Since the scope of data submitted in the process of the notification varies depending on the Member State, one cannot practically speak about placing on the Community market. The cosmetic product is separately placed on the market of each country. It seems to be contradictory to the spirit of the directive and its basic assumption: harmonisation of national regulations governing cosmetic products within the European Union. The European Court of Justice ruled several times in this field pointing to the obligation of the Member States to harmonise laws.

**Item 13 considered by the Commission and submitted for public consultation:**

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 above proposal seems to be a complete challenge of the principle of the manufacturer responsibility for the safety of products, which has been stressed by the Commission in item 8 of the document submitted for consultations. It is also an attempt to introduce a „pre-market control” inconsistent with the spirit of the directive 76/768/EC.

Furthermore, safety of the cosmetic products’ ingredients – chemical substances – is governed by the REACH regulation. Chemical substances compliant with the REACH shall be assessed by an agency which will verify the quality of the dossier of every substance. The agency means huge financial outlays, including expenses for training experts. Yet, this institution assesses one dossier created during one registration of the product.

It is quite difficult to picture how, when (during a standard control?) and which authorities would be supposed to assess safety of the cosmetic products’ ingredients. Administration bodies seem to be currently unprepared for this. Securing appropriate resources in order to carry out the proposed assessment would mean enormous costs, unjustified by the consumer safety. Assessment of the cosmetic products’ ingredients safety by competent authorities would mean a significant duplication of the safety assessment laid down in the REACH and a multiple assessment of the same substance, which seems to be illogical.

Besides, the above proposal by the Commission does not seem to be feasible without introducing appropriate amendments into the REACH, which would give the cosmetic manufacturers a full access to data concerning the toxicology of ingredients.

Additionally, delegating the assessment of ingredients' safety to the authorities of individual Member States would result in the necessity to develop internal guidelines by the bodies of each country. This always leads to interpretation discrepancies and disrupts the free flow of goods. It is very probable that some authorities might treat a given ingredient as safe one, while other could question it. Therefore, the Commission proposal under item 13 seems to be contradictory to the idea of harmonisation.

**Item 14 considered by the Commission and submitted for public consultation:** 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?

In the Union's view the directive 76/768/EC ensures safety of all ingredients and cosmetic products, including innovative ones. It does not seem justified to distinguish a separate category of "innovative" ingredients.

Every new ingredient of the cosmetic product has to be registered according to the REACH provisions, which means that it has to be put under tests in accordance with the regulation. Duplicating such tests seems neither purposeful nor justified.

The cosmetic industry relies upon innovations, both in the field of application properties of the cosmetic products and their effects, including application of innovative ingredients. The Commission proposals introducing particular restrictions in relation to the innovative ingredients may have an adverse influence on the industry.

**Item 15 considered by the Commission and submitted for public consultation:** 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?

Problem of the relative safety already applies to the cosmetic products and is unanimously interpreted by all manufacturers. Unlike medical products, no risk and benefits analysis is carried out in case of cosmetic products. A cosmetic product must not have any side effects or intended undesirable effects. It seems that this issue has not evoked interpretation doubts until now. Inserting such a definition in the directive will have little impact on the consumer safety. Instead, there is a concern whether introducing a separate definition will result in an over-interpretation by e.g. control bodies. One should remember that there is always a group of oversensitive persons and undesirable effects affecting part of the population are the result of personal reactions which cannot be foreseen. Expressions „undesirable cases" and health hazards refer in particular to such unpredictable reactions that are hard to avoid. Similarly, there are many people allergic to food ingredients – strawberries or tomatoes – such reactions cannot be eliminated.

**Item 16 considered by the Commission and submitted for public consultation:** 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?

It seems that the proposal presented under item 16 is an attempt to introduce into the directive the principle "no data - no market" used in the REACH, whereas the current basic principle of the Cosmetics Directive seems to be "no product safety assessment – no market" rather.

One should remember that the REACH is addressed to the manufacturers of substances who register such substances and own the results of tests. On the other hand, the Cosmetics Directive is addressed to the manufacturers of finished products who have no legally guaranteed access to all data created within the framework of the REACH. The cosmetic manufacturer assesses the finished product on the basis of existing data instead of running and completing tests of individual ingredients. The product safety assessment is not just a simple verification of toxicological data for individual ingredients, either.

As in the case of items above (13, 14), which are proposed by the Commission, adoption of the view presented under item 16 would mean duplication of requirements already existing under the REACH.

So far, the approach „no data - no market” has been applied exclusively in case of substances which pose a risk or substances for which existing data on the safety of application are inconsistent, like hair dye components, and in such cases it is justified.

Adopting the approach “no data – no market” in case of the cosmetic products’ ingredients may result in a drastic limitation of the cosmetic raw materials available on the market and a negative impact on the innovations in the industry, unjustified by safety reasons. It’s hard to punish the cosmetic manufacturer for the lack of tests concerning certain toxicological parameters of a given ingredient if such data are not currently available.

**Item 17 considered by the Commission and submitted for public consultation:** 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?

So far, the complex assessment of the cosmetic products’ ingredients carried out by the SCCP has been applied exclusively in case of hazardous substances or substances for which existing data on the safety of application are inconsistent, like hair dye components. Imposing these requirements on all cosmetic ingredients seems to be neither reasonable nor justified by the consumer safety. It is hard to imagine how the SCCP would be able to assess some 10 000 cosmetic ingredients so that only those components which were assessed by the Committee could be used in the cosmetic products. Besides, such an approach does not seem desirable in case of substances whose properties are known, which have been used for decades, and for which not all tests recommended by the SCCP might have been carried out strictly in accordance with the Committee guidelines. Imposing additional obligations on the industry in the form of the whole set of tests in accordance with the SCCP recommendations and completion of the dossier would probably end in resignation from the production of numerous substances, and thus in a limitation of the number of available ingredients, leading to the suppression of innovations.

Ensuring efficient and prompt assessment of all cosmetic ingredients seems to be hardly feasible without significant administrative outlays (employing experts, appropriate trainings, costs of assessment of individual dossiers etc.), which are not adequate to the needs in the field of the ingredients safety. Additionally, such a proposal again seems to duplicate the REACH requirements.

The positive lists contain ingredients for which specific conditions of use should be determined in order to guarantee their safe usage. The Cosmetics Directive 76/768/EC provides sufficient instruments which enable creation of new “positive lists” and introduction of the prohibition to use certain substances in the cosmetic products in justified cases.

The concept of creating a list of “ingredients allowed for the use in the cosmetic products” seems to be contradictory to the Commission’s general remarks: it is the Commission’s view that the lists of ingredients should not be treated by the industry and competent authorities as a “cook book”, where the manufacturer is confined to complying with the list provisions and attaches lesser importance to the safety of the finished product. Covering all cosmetic ingredients by the list aims at strengthening the treatment of positive lists of substances as a “cook book”. Therefore, the two concepts seem to be inconsistent with each other.

**Item 18 considered by the Commission and submitted for public consultation:** 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?

It seems that the current provisions of the Cosmetics Directive 76/768/EC are sufficient and provide for the possibility to anew examine relevance of the presence of individual substances on the lists at any given moment. So far, the procedures were applied only in case of hazardous substances or substances for which new data concerning their usage appeared.

A repeated examination should be dictated exclusively by the safety reasons, and not by imposed arrangements and deadlines.

Adoption of the proposal presented under item 18 (as well as items 13 and 17) would probably result in the limitation of the portfolio of the ingredients available on the market.

Furthermore, it seems that any additional mandates for the Commission and the SCCP should require a more precise determination of the procedures for the exchange of information between the Commission, the Committee and the industry.

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