

Simplification cosmetics directive

DETIC asbl

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?

There is a need to clarify certain concepts in order to minimise legal uncertainty.

DETIC has the following observations:

1. Definition of a cosmetic product

Industry recognizes that the current definition of a cosmetic product has proven to be sufficiently flexible to adequately cover the development in product innovation.

It might be appropriate to reflect on the coverage of future product innovation by the existing definition, and on the connection with related legislation.

2. Poison control centres & frame formulae system

The Cosmetics Directive requires that appropriate and adequate information on substances used in cosmetic products be made available to the competent authorities for purposes of prompt and appropriate medical treatment in the event of difficulties, EU Member States have interpreted the requirements differently, leading to an increase in the administrative burden to cosmetic companies.

Not all Member States presently have a system of poison control centres. Of those that do, some require information based on the EAPCCT system of frame formulae of the European Association of Poison Control Centres and Clinical Toxicologists (EAPCCT), which was developed in association with the cosmetics industry. Others require the submission of full formula details for all products.

Faced with the above, DETIC considers that the poison control centre requirements should be harmonised across the EU. DETIC therefore calls on the European Commission to include in its legislative proposal a reference to the above-mentioned EAPCCT frame formulation system. Furthermore, DETIC pleads for one single European poison centre.

3. Interpretation of the “fields of application” colorants

This element, not part of the SLIM report and not covered either by other items of the public consultation document, is related to the lack of harmonised interpretation of the “fields of application” used in Annex IV of the Cosmetics Directive (use categories of colorants).

Other tools to tackle legal uncertainties

Notwithstanding the above observations, as indicated by the European Commission , “there are several tools which, in specific circumstances, can be used to achieve the objectives of the Treaty while simplifying lawmaking activities and legislation itself (co-regulation, self-regulation, voluntary sectoral agreements, open coordination method, financial interventions, information campaigns)”.

Against this framework, DETIC calls on the European Commission to make use of the above instruments also in the field of cosmetics, namely co-regulation and self-regulation for those cases where guidance is needed on the implementation of an unclear legal provision or either in those cases where, instead of legislation, a policy objective can be best achieved via a non-legislative instruments.

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 revision of the Cosmetics Directive must enhance international alignment, not hinder it.

The European Union remains the largest market for cosmetics & toiletries worldwide, as well as a leading region for Research & Development in the field of cosmetics. The European model of cosmetics regulation stimulates innovation, which allows the European cosmetics industry, in particular its dense network of Small and Medium Enterprises (SMEs), to successfully compete in world markets.

The Cosmetics Directive combines a wide definition of cosmetics with clear and comprehensive requirements on safety testing, ingredients and labelling, provides a good basis for achieving further alignment, demonstrated by the number of countries and regions already modelling their approach upon it”.

DETIC draws the attention to the European Commission of the fact that the operational aspects, definition of cosmetic products and the system of ingredient lists (negative, restrictive and positive lists) have been incorporated in many other regulatory frameworks (e.g. China, Latin America).

It is important that the proposed changes to the EU legislation should be viewed in a wider reality; as such regulatory changes would run counter the international trend towards the alignment of cosmetics regulations.

DETIC stands ready to support the European Commission in the impact assessment that will be carried out in preparation of the simplification of the Cosmetics Directive which, in DETIC’s views, should also encompass the repercussions for international trade.

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?**

An equal high level of consumer protection, a smooth functioning of the EU Single Market and the facilitation of international trade can be better ensured by the introduction of a clear and unambiguous Regulation.

Regardless of the legal instrument chosen, sufficient timelines for placing on the market of products are necessary to ensure effective implementation of new requirements.

The Cosmetics Directive is a piece of EC legislation based on Article 95 of the EC Treaty, which aims at the establishment and good functioning of the EC Internal Market by the approximation of regulations in the EU Member States.

The transposition of changes to the Cosmetics Directive (to date, 7 Amendments and 40 Adaptations to Technical Progress) into 27 national legal frameworks presently gives rise to many issues:

- Additional national provisions may be added. For instance the addition of specific national notification requirements. These are permitted with the provision that they must not restrict the free circulation of goods and that they must be justified in the interests of public health.
- The transposition of the EU text into national laws may introduce errors or misunderstandings. In order to rectify this, a regulatory verification is required of the national text against the Cosmetics Directive and corrections to the national law then need to be undertaken by the national authorities.
- The Cosmetics Directive may be transposed into more than one piece of national legislation.
- Modifications to the articles and annexes of the Cosmetics Directive are transposed into national law with delays which vary from country to country. Thus, at any one given time, labelling and ingredient restrictions could differ. Such a situation is in a way contrary to the principle of the free circulation of goods within the EU.
- A lack of harmonization of regulated ingredients within the 27 Member States.

The above discrepancies could be resolved by the introduction of a single clear and unambiguous Regulation throughout the European Union.

Whatever legal instrument is chosen, DETIC calls on the European Commission to take into account the needs of the cosmetics industry of sufficient time for the implementation of new legal provisions, as well as updates of the Annexes (Adaptations to Technical Progress). In deciding the appropriate timeframe, a balance should be made between the socio-economic impacts and the nature of the risks involved.

Finally, DETIC also calls on the European Commission to link the implementation of new changes (both legal provisions in the text of the Directive and updates to the annexes) to the concept of “placing on the market”. Otherwise, the legitimate expectations of economic operators to sell cosmetic products to the final consumer of those products

already on the Community market would be jeopardised (See comments on item 4 for more details).

Item 4

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

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

DETIC 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.

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

Placing on the (Community) market:

DETIC 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.

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

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

DETIC 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).

General Observations on items 5, 6, 14, 16, 17, 18

Existing regulatory tools exist in the Cosmetics Directive that are adequate to specifically regulate substances of concern (or groups thereof). This includes the possibility of requiring pre-market clearance for identified groups of substances through positive lists. Other substances of concern are addressed through negative/restrictive list systems.

Rearranging and editing of the current Annexes to the Cosmetics Directive will increase clarity and user-friendliness and will facilitate substance management by companies as well as control activities by competent authorities

- 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?
- 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) have to be listed in the annex before they can be used as an ingredient in cosmetics.
- 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 to ensure this safety? If yes, what would be the socio-economic impact of these additional regulatory tools?
- Item 17
Apart from the positive list for hair-dyeing substances, the Cosmetics Directive could include a mandate for the Commission, as risk managers, 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 the safety assessment of cosmetic products? What would be the socio-economic impact?
- 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”.

Items 5, 6, 14, 17 and 18 all deal with positive lists, addressing fundamental principles as well as more specific administrative aspects. Given the overlap in scope of the questions, it is appropriate that some general principles are addressed in a general answer.

Beyond the general provisions of marketer safety responsibility / authorities in-market control, the EU Cosmetics Directive provides a clear frame for regulating substances of

particular concern. Substances considered as having specific risks, which need to be managed through a pre-market clearance of these substances, are subjected to a positive-list system.

To be of any practical use, identification of substances as candidates for listing must be in a clear and transparent manner for both the manufacturer/importer (to use) and the authority (to monitor).

In this context, the primary intended use is the clearest parameter, rather than the properties of substances. Any properties shown by a substance should be reviewed in the process of adding any material to the annex and so are in no way excluded from the safety review.

It is acknowledged that substances may have multiple functions within a cosmetic product, and the Cosmetics Directive provides the tools of negative lists (Annex II/III) which allow comprehensive substance regulation outside the scope of positive lists.

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, or the scope of existing positive lists be changed, in order to systematically cover this group of substances in a positive list approach.

In addition, to make the current system more effective, the system for addition or revision of new entries to positive lists should be enhanced. Proposals for this would include:

- Greater transparency on commitment to timings and where applications are currently in the review process.
- A more collaborative system that allows for interaction with the EU Scientific Committee for Consumer Products (SCCP) and key stakeholders (including industry) to better resolve developing issues at an earlier stage. This will help to ensure that concerns for human safety are resolved with the minimum of confusion and eliminate unnecessary testing which is key considering the restrictions included in the 7th Amendment.

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 principle approach on substance regulation is the simplest and most effective way of presenting reviewed and accepted materials in terms of their usual

function in a cosmetic product. It enables stakeholders easy access to relevant regulatory information and allows to monitor changes effectively.

It is proposed to continue the current principle approach on specific substance lists as the simplest and most effective way of presenting reviewed and accepted materials in terms of their usual function in a cosmetic product. In particular, SMEs and control authorities in the EU as well as third countries are more likely to find the listing easier to use, and to be able to monitor changes effectively.

One substance may have distinct properties for which it can be used in a cosmetic product. It may even have more than one property for which it is used in the same product. As way of an example, salicylic acid may be added to cosmetic products as a preservative, as an antidandruff agent (microbial property) or as an exfoliant (keratolytic property). In other cosmetic products, it may exhibit other distinct properties/functions.

Furthermore, the current form of listing is in keeping with similar EU legislation (e.g. biocides) as well as with most international regulations on cosmetics, some of which were themselves developed based on the current EU structure. With such a system the possibility always exists for international alignment on ingredients and subsequent benefits to trade. If major changes are made to the structure the opposite effect, and subsequent costs to Industry, are possible.

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 fundamental approach of specific substance regulation is well understood by industry and authorities and has proven its effectiveness.

Rearranging and editing of the current Annexes to the Cosmetics Directive will increase clarity and user-friendliness and will facilitate substance management by companies as well as control activities by competent authorities.

It is proposed to continue the regulation of specific substances in Annexes to the Cosmetics Directive. The simplest and most effective way of presenting reviewed and accepted materials is in terms of their usual function in a cosmetic product.

This fundamental approach is transparent and well understood by both industry and competent authorities and creates an appropriate basis for consumer confidence. This form of listing is also in line with similar EU legislation (e.g. biocides) as well as with

most international regulations on cosmetics, some of which were themselves developed based on the current EU structure.

However, the present set of negative (annex II), restrictive (annex III) and positive lists (annexes IV, VI and VII) should be reviewed and clarified for readability and accessibility.

Confusion may arise in some cases from the fact that the same substance can be regulated simultaneously in several Annexes of the Cosmetics Directive. Indeed, one substance may exhibit different distinct properties for which it can be used in a cosmetic product. It may even have more than one property for which it is used in the same product. As way of an example, salicylic acid may be added to cosmetic products as a preservative, as an antidandruff agent (microbial property) or as an exfoliant (keratolytic property). In other cosmetic products, it may exhibit other distinct properties/functions.

It should be considered to regroup and edit the existing annexes in a manner that for substances that may be used only under specific restrictions, all relevant information can be found in a single place. Such rearrangement of the annexes would not change their essential nature and should not therefore pose problems with third countries who have adopted the EU annexes.

The development and use of an electronic version of substance lists must be considered. Industry and control authorities in the EU as well as third countries are likely to find electronic listing easier to use, in particular for monitoring changes effectively.

Placing of an ingredient in an annex should remain to be scientifically founded and should be preceded by a full evaluation by the SCCP. To make the current system more effective, the system for addition or revision of new entries to Annexes should be enhanced. Proposals for this would include:

- Greater transparency and commitment to timings where applications are currently in the review process.
- A more collaborative system that allows for interaction with SCCP and key stakeholders (including Industry) to better resolve developing issues at an earlier stage. This will help to ensure that concerns for human safety are resolved with the minimum of confusion and eliminate unnecessary testing which is key considering the restrictions included in the 7th Amendment.

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?

DETIC supports simplification of the existing procedures for regular updating of the EU Inventory.

Industry is in favour of a simplification of the existing procedure to ensure availability of up-to-date information on INCI names to all stakeholders.

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.

The current framework works but can be clarified.

DETIC considers it is important that the person placing the products on the market is responsible for compliance with the requirements of the Cosmetics Directive.

DETIC considers this aspect has not given rise to misunderstanding in its application.

In parallel, Article 3 requires Member States to put in place an adequate system of in-market control, which DETIC strongly supports.

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?

DETIC proposes to provide a more detailed description on the aim and approach for product safety assessments, setting out of minimum standards, including a requirement for a reasoned argument as to how the safety assessor reached his/her conclusion.

Clearer definitions on the role and qualification of the safety assessor would improve consistent interpretation.

It is essential to distinguish between two different aspects of safety assessment addressed in the Cosmetics Directive which are based on different legal provisions, have different primary objectives and, necessarily, lead to a difference in approach :

- product safety assessments (including, but not limited to, the assessment of the safety of the ingredients as used in the product) are under the main responsibility of the industry

- substance evaluations for the purpose of listing in the Annexes of the Cosmetics Directive are under the responsibility of the SCCP/ European Commission).

Safety assessment for human health of a cosmetic product, prior to placing it on the market, aims at evaluating and ensuring that it does not cause damage to the human health under normal and reasonably foreseeable conditions of use.

Safety assessment consists of an expertise conducted by a competent professional safety assessor. It has to cover the safety assessment of ingredients or combination of ingredients based upon evaluation of their human exposure in the finished product, their chemical structure, their analytical profile, and their general toxicological profile established from all available sources of information. In its reasoning, safety assessment also includes confirmatory safety information on the finished product and post marketing safety experience with this and/or similar formulations, its presentation and mode of use.

Safety assessment of cosmetic products and their ingredients is a much more complex expertise than the simple compilation of a predefined list of toxicological data on ingredients. In-market control of the safety of cosmetic products and their ingredients would not benefit from a rigid list of obligatory tests on each individual ingredient in the product information file. The nature of data that is necessary to conduct the safety assessment of ingredients and combination of ingredients greatly depends on chemical and physical properties, concentration in the finished product, product type, presentation and target population. In this sense, the 'technical dossier' and 'chemical safety report' under REACH are data compilations on single substances. They are not intended and do not seem appropriate as a basis for constituting or controlling the safety assessment of cosmetic products and/or their ingredients. In addition, the mandatory requirement for animal testing, as currently recommended in the SCCP guidelines, on each single ingredient would not be consistent with the bans outlined in the 7th Amendment. Consistency in the quality and standards to which safety assessments for finished products are carried out is of paramount importance. The current wording of the Cosmetics Directive in this respect is very general and does not reflect the complexity of the present expertise.

The best guarantee of safe cosmetic products is the quality, training and experience of the safety assessor in combination with more consistent and formalized safety assessments to allow for more efficient in-market controls.

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 system, supported by good administrative cooperation, already provides adequate tools.

DETIC believes this question refers to two different aspects: the first concerns the situations of non-compliance with the Directive and the second relates to the cooperation between competent authorities in the EU in the in-market control of cosmetic products.

Non-compliance with the Directive

DETIC considers the existing EU regulatory framework (Cosmetics Directive and the General Product Safety Directive) provides for sufficient clarity as of the consequences when products which are put on the market are not compliant with the law. Member States, in the framework of their competence to set up their own systems of in-market control, set up the necessary implementation measures to ensure compliance with the EU regulatory framework. This also includes the imposition of fines, and the prohibition of placing a non-compliant product on the market, where appropriate.

Administrative cooperation

DETIC supports the principle that access to the product information should be confined to one single location within the European Union. Whereas the concept of a unique location for product information is already incorporated into Article 7a(d), DETIC considers that the text of the Directive should clearly specify that this concept should apply to all of Article 7a. DETIC also considers that the concept of underlining of the address where the product information is held (if multiple addresses), which is already a standard practice applied throughout the EU, should be explicitly stated in Article 6.1(a). Within this context, DETIC considers that, in the case where the product information is located in a Member State other than in the one where the control takes place, the competent authorities controlling the market should contact the concerned competent authorities having access to the product information.

Once contacted, the latter should then carry out the necessary enquiry and inform the requesting competent authority of the results obtained. Together, the two competent authorities should then agree to a corrective action, if this is thought necessary.

In the case where the findings reveal clear problems for public health, the European Commission and other Member States should be alerted, using the existing mechanism

already foreseen in EU legislation. However, DETIC considers this action would be inappropriate when the inspection has revealed no such issues.

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?

DETIC supports that the Commission should co-ordinate national activities in the area of “cosmetovigilance” to ensure any system is harmonised across the EU. Industry is ready to play its role to support such a system.

DETIC recognises the intention of some EU Member States to create “cosmetovigilance” systems. Industry is ready to collaborate with the Commission and Member States to ensure that any system of “cosmetovigilance” is harmonised across the EU.

Such system should:

- be based on an EU wide model
- use a set of common definitions and tools to be used by participants
- have an appropriate scope that keeps the system manageable (e.g. restricted to active reporting of serious adverse effects)
- define clear roles and responsibilities, ensuring information exchange between all relevant stakeholders
- utilise only standardized data of high quality
- be based on a common understanding on how, and for what purpose, the information generated within the system will be used.

Industry is ready to play its role to support such a system. Indeed, Colipa has recently issued "Guidelines on Handling of Adverse Event Reports" (Colipa, 2005) as a tool for harmonizing industry practice with regard to the 6th Amendment Product Information requirements regarding the collection of adverse event reports. These guidelines provide a good basis for determining the scope of a practicable “cosmetovigilance” scheme, as well as the type of data that would be included.

An efficient post market surveillance of cosmetic product safety should be based on active reporting of Serious Undesirable Events (Undesirable events which have caused permanent or significant disability /incapacity, hospitalisation, congenital anomalies, immediate vital risk or death) by cosmetic industrialists and health professionals but also by continuous monitoring of incidence of genuine and attributable Undesirable Events performed by the cosmetic industrialists on their respective product categories and made available to the competent Authorities when a significant signal is detected.

The European Commission should play an active role in the field of “cosmetovigilance” in supporting and coordinating EU Member States’ initiatives but most importantly in evaluating alerts from EU Member States through a dedicated centralised entity, before any risk management decision is taken at the European level.

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?

A simple EU notification system would be more effective than current practice and would reduce red tape.

DETIC agrees with the European Commission that clarification of the rules of notification would help improve market surveillance, in particular by better enabling Member States to trace products on the market.

The objective of this clarification should be, in DETIC’s view, the facilitation of administrative cooperation between Member States and, at the same time, reduce the administrative costs and red tape for cosmetics companies.

Such system should however not be contradictory to the principle that the person placing the product on the market is responsible for ensuring compliance with the requirements of the Cosmetics Directive.

The current situation creates significant administrative burden:

- The Cosmetic Directive requires notification of the address of the place of manufacture or of initial importation to the competent authority of the corresponding Member State (See Article 7a.4).
- In practice, this provision is generally transposed in national terms, which lead to the obligation of multiple notifications.
- Moreover, requirements for notification vary greatly between Member States and some of them require, in addition to the address, detailed product by product information and to pay for the administrative requirement.

A simplification of the current practices could be achieved by introducing a single and simple system at EU level, preferably based on electronic notification.

DETIC fully supports the efforts by the European Commission to fight against the counterfeiting of cosmetic products, which represents a threat to the economic expectations of legitimate right-holders, as well as a threat to the safety of consumers. However, DETIC considers notification systems will not help competent authorities to identify counterfeited goods. Persons placing counterfeited goods on the market are not likely to pro-actively meet the notification requirements and therefore never appear “on record”.

DETIC considers an effective control of counterfeited products can only be done through an effective control of those goods sold to the final consumer, in close cooperation between customs authorities, police and right-holders.

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).

Industry is happy to discuss how existing ingredient review mechanisms at EU level can be modified to work more effectively.

Product safety assessments aim at ensuring that the product in question does not cause damage to human health when applied under normal or reasonably foreseeable conditions of use. Such specific product assessments are not intended to justify the use of a particular ingredient across a wide range of cosmetic products.

Inadequacy of a specific product safety assessment can justify appropriate action against this product. It should not, however, be the basis for decisions, either at national or EU level, about the wider use of an ingredient in cosmetics.

If wider questions on the safety of a specific ingredient arise from controls of product safety assessments, there is already a mechanism at EU level to handle this.

Industry is happy to discuss how this mechanism can be modified to work more effectively, and to ensure that the scientific review process at the European Commission is reserved for consumer safety matters that are significant from an EU perspective.

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 as such does not indicate concerns for safety and should not form the basis for product categorisation.

The principal elements of the Cosmetics Directive (general and specific safety provisions), 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 the years.

Innovation should not only be associated with new ingredients but can also be the result of a change in an ingredient's concentration, delivery system or application regimen. Furthermore, a new ingredient in cosmetics is not necessarily a new ingredient in other sectors and adequate safety information may already exist from these uses.

Most importantly the safety of a cosmetic product, innovative or long established, is not only determined by the intrinsic properties of its ingredients but also by the final formulation and intended use.

No additional regulatory tools are necessary. Currently, the person responsible for placing a product on the market has the duty to ensure product safety as described in Art. 2 of the Cosmetics Directive and cannot pass that responsibility on to another party or authority.

The industry realises that the challenge will be in efficient implementation of regulation rather than in creation of new requirements and stands ready to discuss proposals in this area which adequately match the process of product innovation.

For instance, there may be opportunities to clarify the appropriate requirements of training and experience for persons entrusted to carry out the product safety assessments (see question 9).

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 implementation of the safety provisions of the Cosmetics Directive already ensures a high level of consumer protection. The legal concept of “high level of consumer protection” is enshrined in the EC Treaty and defined in case law. Hence there is no need of a new legal concept.

DETIC observes the established concepts in EU legislation and case law of the European Court of Justice, such as “high level of consumer protection” and the difference between hazard and risk, and the acknowledgement that that “risk zero” does not exist for any consumer product, as laid down by the Communication of the Commission on the Precautionary Principle and the relevant case law of the European Court of Justice.

The introduction of a new concept would create rather than reduce legal uncertainty, without an advantage for consumers.

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 marketing of cosmetic products.

Adequate ingredient assessment is a necessary part of a product safety assessment. As part of this, specific data on ingredients can justifiably be waived on the basis of a reasoned argument. This does not mean that either the product or the ingredient is unsafe.

The Cosmetics Directive provides a strict requirement for assessing product safety under the responsibility of a qualified safety assessor prior to marketing. Accordingly, there is already a provision in the Cosmetics Directive that places on the industry the burden of proof of the safety assessment of finished products including their ingredients and/or combinations of ingredients. The current basic principle of the Cosmetics Directive is thus “no product safety assessment – no market”.

Safety assessment of ingredients or combination of ingredients for a specific use consists of an expertise conducted by a qualified safety assessor often based on a unique combination of data in relation to human exposure in finished products under normal and foreseeable condition of use, structure-toxicity relationships using computer modeling, analytical profile, general toxicological profile established from all available sources and type of data and confirmatory in-vitro and/or clinical safety data (i.e. data from human volunteer studies) on the finished product and/or similar formulations.

There is no scientific justification to presume unsafe ingredients and/or combinations of ingredients on the basis of missing data from a predefined set of toxicological studies. The safety assessment of ingredients or combination of ingredients can be supported by other relevant and valid scientific data.

The best guarantee of safe cosmetic products is through a combination of:

- the quality, training and experience of the safety assessor;
- more consistent and formalized safety assessments to allow for more efficient in-market controls;
- a robust post market surveillance system by companies.

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 the creation of new positive lists when deemed necessary. In the interim, until a new list is formally constituted, substances / groups of substances can be managed by virtue of the existing Annex II (banned) and Annex III (restricted).

Beyond the general principles addressed above (general observations on items 5, 6, 14, 16, 17, 18), there are several specific reasons why it is not necessary to change the current process for the creation of new positive lists.

Currently, there is an absolute requirement for the manufacturer to ensure product safety regardless of the ingredients in the product. If any substance raises general concerns, the present Directive allows for that substance to be evaluated by the SCCP and then discussed and regulated by the member states.

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 by Council and European Parliament; during those discussions, individual substances within that class are controlled by virtue of the existing Annex II (banned) and Annex III (restricted).

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 mechanism. Re-evaluation of substances can already now be decided at any time. Such action should however be triggered by new relevant safety information rather than by time limitations.

The current Cosmetics Directive allows systematic or case-by-case re-evaluation of substances on positive lists at any given time, whether as a result of new information or new questions.

This provision could be made more explicit, also as a reminder to companies that positive listing status of a substance does not take away the responsibility to consider recent scientific findings on substances in their safety assessments.

It is important, however, that regulatory substance (re)-review on positive lists should be based on new and relevant safety findings that could affect the conclusions of the existing safety assessment and should not be triggered by a simple time limitation.

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

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