

**GLAXOSMITHKLINE CONSUMER HEALTHCARE EUROPE -  
RESPONSE TO THE PUBLIC CONSULTATION PAPER ON  
COSMETICS DIRECTIVE 76/768**

**16 MARCH 2007**

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16 March 2007

**GLAXOSMITHKLINE'S RESPONSE TO THE PUBLIC CONSULTATION PAPER ON THE SIMPLIFICATION OF COSMETICS DIRECTIVE 76/768/EEC**

**Introduction**

GlaxoSmithKline Consumer Healthcare Europe ("GSK") appreciates the opportunity to participate in the public consultation which has as its aim the simplification of Directive 76/768/EEC on cosmetic products (the "Cosmetics Directive"). GSK develops and manufactures cosmetic products, particularly in the oral care area. The leading oral care products are toothpaste and mouthwash under the Aquafresh Odol, Sensodyne and Macleans brand names, and a range of toothbrushes. In addition, denture care products are available principally under the Polident, Poligrip and Corega brand names. GSK places its cosmetic products on all EU Member States' markets, and is an important stakeholder in the cosmetics sector, both within the EU and worldwide.

Headquartered in the UK, the GlaxoSmithKline group employs over a hundred thousand people and has more than 80 manufacturing sites in 37 countries, making almost 4 billion packs of medicines and healthcare products each year, with a turnover in 2006 of 23.2 billion pounds sterling. Of this, consumer healthcare products comprise 3.1 billion pounds sterling.

GSK is a member of COLIPA (The European Cosmetic Toiletry and Perfumery Association), and is supportive of COLIPA's response to the public consultation. In this response GSK puts forward its own views.

The public consultation is especially welcomed given that the Cosmetics Directive has already been amended 45 times. There is thus an element of legal uncertainty in the Cosmetics Directive's fragmented provisions, and it is hoped that the public consultation will lead to improved clarity, greater legal certainty and simplification.

GSK welcomes a recasting of the Cosmetics Directive if this is genuinely in line with the Commission's Action Plan which aims to simplify the regulatory environment. However, GSK is of the overall view that some of the current proposals do not appear to offer simplification but, rather, appear to aim for increased burdens on industry, and potentially also on the Member States' competent authorities, without any corresponding increases in protection for the consumer.

With reference to the legislative and political context outlined in the *Introduction* section of the Commission's consultation document, acknowledging that the aim of simplification is to create better regulation for growth and employment in the EU, it is indeed paramount for the EU industry to retain its global competitiveness, and meet the objectives of the Lisbon agenda. GSK agrees that this context is important when making proposed revisions to the Cosmetics Directive. For example, because of the 2009 ban on animal testing (pursuant to the Cosmetics Directive's seventh amendment), manufacturers should be permitted or even encouraged to use flexible approaches to safety assessment (as discussed in item 9 below).

GSK believes that given the recent legislative trends in the chemical substances sector, it would benefit industry and consumers alike if the Cosmetics Directive were reconciled with

the REACH requirements (e.g., encouraging valid alternatives to animal testing, which must be avoided). GSK's objective, in short, is to make the industry more competitive, obtain faster and more efficient market access for products, and create a regime that is favourable to innovation while ensuring appropriate consumer safety.

There appears to be a presumption in the public consultation's proposals that increased regulation of the content of safety assessments would enhance safety for the consumer. GSK disagrees with this. Rather, a greater enforcement of compliance via post-marketing surveillance and inspections under the current legislation would more effectively address the question of consumer safety.

This is, moreover, in line with the Commission's proposed introduction of *New Approach* elements, to improve operation of the cosmetics legislation. Under the *New Approach*, it is indeed more appropriate to shift the focus from increased regulation of safety assessments to the safety of cosmetic products that are on the market, based on the manufacturer's own responsibility and market surveillance by the Member States' enforcement authorities.

GSK acknowledges that the Commission does not plan to amend the Cosmetics Directive's animal testing provisions. Nonetheless, clarity from the Commission over the scope of the seventh amendment (in Article 4 of the Cosmetics Directive), would be certainly welcome. Within such clarification there could be expressed the need for more flexibility in safety assessments as is recommended by the REACH Regulation, including acceptance of intelligent testing strategies. This would encourage innovation, and avoid conflicts between innovation and the ban on animal testing.

**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?*

In GSK's view, legal uncertainty sometimes arises due to the way the SCCP undertakes its role in response to mandates from DG Enterprise. The SCCP is required to be a risk assessor, but it tends at times to go beyond this by carrying out its role as a risk *manager* which can be potentially damaging to industry. It is GSK's understanding that responsibility for risk management lies with DG-Enterprise and Member State authorities.

Confusion in the manner in which the SCCP undertakes its role results in indecision, lack of transparency and delay in bringing products to the market.

No example better highlights this fact than the issue of tooth whitening products (TWP). In this matter, industry called for an increase to the acceptable limit of hydrogen peroxide in order to enable TWP to be placed on the market. The SCCP issued several Opinions on whether TWP could be made available as a cosmetic product for sale directly to the public. The Opinions were unable to arrive at a conclusive finding, even though the product was already available as a cosmetic product in the US, and other expert panels had concluded that there were no significant safety issues at stake.

To date, no conclusive decision has been made regarding TWP, and the matter remains pending. The case of TWP demonstrates the restrictions to market access because of indecision and legal uncertainty: industry in the EU is helpless to act and must continue suffering delays to market access, while the products are freely allowed on the US market.

The SCCP's involvement has not been helpful: its inconclusive Opinions have not only created legal uncertainty, but have increased costs for business, have had a negative effect on R&D, and this has proved damaging to the industry.

In sum, the role of the SCCP could be better defined. There should also be a realistic assumption that where there is a lack of certainty, it should be willing to take account of other experts' opinions. If it takes such other opinions into account but nonetheless decides to reject them, then it should provide, in a transparent fashion, the motivation for such decision.

Additionally, as it is not realistic for SCCP members to have expertise on all ingredients' fields of use, they should be positively encouraged, whenever necessary, to consult experts in those individual fields (e.g., dentists).

**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?*

International regulatory divergences decrease the competitiveness of the EU industry for cosmetics, and potentially create obstacles to trading in third countries. On the other hand, it is well documented that international alignment of regulatory requirements increases competitiveness. The Comparative Study (commissioned by DG Enterprise) on *Cosmetics Legislation in the EU and Other Principal Markets with Special Attention to so-called Borderline Products* (RPA, 2004) notes that cosmetics is a global industry, and that the EU is a major player. Because of the global nature of the industry, differences in regulatory frameworks have significant implications for stakeholders. Regulatory frameworks differ significantly, and are far from harmonised. This has the potential of negative impacts on the competitiveness and economic viability of the industry.

For example, the inability to sell similar products, or the requirement to change test methods, or formulations, can cause marketing delays, loss of sales and increased costs for the sector. The divergences do not only act as a barrier to trade, they also put a constraint on innovation. These are the areas which it would be useful to examine when considering alignment.

In particular, GSK strongly believes that a more flexible approach to accepting alternative sources of information (in addition to alternative methods) as regards safety assessments would be helpful for the industry, reducing costs while maintaining safety for the consumer (this is further amplified in item 9 below). Such a position is consistent with the REACH Regulation (see, e.g., its Article 13: "*Information on intrinsic properties of substances may be generated by means other than tests...*").

**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?*

It is indeed a likelihood that transforming the Directive into a Regulation may ensure consistency in implementation by the Member States, reducing legal uncertainty and national divergences within the Community, given the “direct effect” nature of EU Regulations. However, if it is turned into a Regulation, there should be an appropriate timeframe laid down to allow manufacturers to adjust to any of the new provisions.

GSK’s view is that annexes should not be turned into a Regulation, unless the updating of positive/negative lists were done via a quick-routed comitology procedure. Indeed, while an efficient and speedy procedure should be put into place for the *addition* of ingredients, this is not necessarily the case for the *removal* of ingredients, as industry needs to have an appropriate time period to change product formulations. GSK’s view is that these differences (on the one hand for the addition of ingredients and on the other hand for the removal of ingredients) are important in order to maintain the competitiveness of EU industry.

Thus, with regulation of particular substances, there is in parallel a need for greater transparency and a focus on time periods – in order to avoid unnecessary costs and manage inventories.

In any event, GSK favours the publication of Guidelines in a number of areas and in particular for the safety assessment of products (which would, of course, take into account ingredients within products). It is noted that guidelines have already been published on other aspects of the Cosmetics Directive.

Guidelines are a very common feature of Community legislation. For example, guidelines are being extensively used in medicinal products and are being developed for certain aspects of the REACH Regulation. There is also DG-Enterprise’s very useful *Guide to the implementation of directives based on the New Approach and the Global Approach*; industry (in the sectors covered) has benefited, as have the Member States, from this Guide’s informative and harmonised nature.

Guidelines thus ensure that, as far as possible, manufacturers and enforcement authorities apply the law uniformly and with greater legal certainty. GSK discusses suitable guidelines for safety assessments in more detail under item 9 below.

**Item 4:** Which terms would need to be included in a set of definitions in order to make the *Cosmetics Directive* clearer?

GSK would welcome clear conditions for market surveillance: a definition describing the term *market surveillance* would assist in creating certainty as regards this term, with an indicative list of activities that comprise market surveillance. As an example, GSK draws the Commission's attention to the *RoHS Enforcement Guidance Document* (drawn up by the UK within the EU's network of RoHS enforcement authorities) which lists on page 4 the criteria for market surveillance activities, used by national enforcement authorities in their decision to carry out investigations for non-compliance on their respective markets. These include random selection; notification of concern from external parties; and notification of concern from other Member States. Such clarity would assist companies and ensure that Member State authorities do not act beyond defined limits.

In addition, GSK feels that there ought to be a clear definition of "placing on the market", consistent with existing Community legislation. It should be clarified that a product is placed on the market as from the date of manufacture in the Community, or, as regards imports, as from the date of customs clearance into the Community. Likewise, it should be ensured that the market is defined as the *Community* market, and that Member States do not have the option to define the term as their national market. If they were permitted to do so, there is a risk of legal uncertainty over the first placing of a product on the market.

**Items 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.

and

**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?

GSK believes that the current structure of the annexes can lead to confusion. Some consolidation and restructuring would be beneficial.

GSK understands that the positive lists have been drawn up to reflect groups of ingredients that may be of particular (high) toxicological concern because of their chemistry/activity. As such, positive lists provide for a common means of identifying ingredients which are appropriate for use.

It may be the case that, recognising that safety is independent of function, the current system of positive lists offers a convenient ready reference for those ingredients which are “authorised” for a specific purpose, which is helpful to industry and authorities alike. However if one accepts the principle that safety is the responsibility of the manufacturer, then these lists should certainly not be seen as “exhaustive/restrictive”; rather, should the manufacturer wish to use an ingredient not on a positive list, and taking into account ingredients listed in Annexes II and III, the safety of the product is entirely his responsibility.

In this respect, and in the interests of *simplification*, ingredients of particular concern should be managed solely through *negative or restrictive* lists. In addition, abolishing the positive lists would have the advantage of reducing the burden on the SCCP. This in turn would allow greater opportunity to focus on real safety concerns arising from, e.g., cosmetovigilance issues.

In short, therefore, GSK is in favour of abolishing positive lists, while for the sake of simplification maintaining a combined negative/restrictive list. If, however, the positive lists are finally to be maintained (whether as exhaustive or not), there needs to be greater transparency, clear timelines and criteria in adding/removing ingredients. Among such criteria, data requirements should take into account historic and in-use data as well as data from other sources (as explained in item 9 below). Thus, should such lists be maintained, a more collaborative system allowing for interaction between the SCCP and key stakeholders (including industry) would be beneficial.

The current annexes can be improved by presenting information in a consistent manner including INCI, EINECS and CAS numbers, as well as other internationally recognised

nomenclature such as pharmacopoeial names and/or CI numbers where relevant. An electronic version of the annexes which is searchable and could be manipulated placed on the Commission website would be beneficial in providing greater clarity.

In the particular case of preservatives: it would be inappropriate to refer to these as '*anti-microbial*' since an ingredient may have anti-microbial properties and support anti-microbial claims without being a preservative. Terminology and definitions therefore need to be clear and precise.

It is also GSK's view that any attempt to draw up a positive list for all ingredients used in cosmetic products would: (a) stifle innovation (b) be burdensome on the SCCP and (c) undermine the basic philosophy that safety is the responsibility of the manufacturer.

**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?*

GSK supports the proposal for giving the Commission a more flexible mandate, which provides for establishing and updating an inventory (which is an indicative and not exhaustive list) without resort to the cumbersome legislative machinery. GSK supports a process by which the inventory can be updated in a timely manner.

However, a transparent process for agreeing timelines for implementation of new INCI names needs to be agreed, taking into account any potential safety issues.

**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.*

GSK's view is that all manufacturers must take their responsibilities seriously when placing products on the market particularly with respect to product safety. These responsibilities are clearly laid out in the current Directive.

**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?*

GSK points out at the outset that there is a difference between *ingredient (or substance)* assessments (as per REACH and the SCCP remit) and *product* assessments. This distinction is extremely important, as confusion can arise, blurring the distinction between the two.

The objective of product assessments is to ensure that products do not cause harm to human health, when they are used under reasonably foreseeable conditions. The assessment is thus carried out with regard to the finished product itself as well as the manufacturer’s knowledge of each ingredient contained within it, alone and in combination. The product assessment will take into account market experience either with the product’s own formulations or similar formulations, its presentation, and mode of use, thus including exposure to it. The assessment will look at the possibility of the product causing harm, and whether such possibility is acceptable: it is unrealistic to accept the absolute absence of risk in respect of any product that is placed on the market.

GSK emphasises that product assessments cannot be based on the SCCP guidelines, which cover ingredient assessments and not product assessments (once again: the distinction between the two is important and should not be blurred). Likewise, the REACH technical dossier and chemical safety report requirements are compilations of data on individual substances and not products.

However, it is also the case that manufacturers do assess the safety of the ingredients in the context of their product assessments. It is therefore very important, as already indicated in item 3, for the Commission to issue guidance on product assessments which would necessarily need to contain ingredient-related information in the context of the product assessment.

Furthermore, it is recommended that a transatlantic dialogue with the Commission’s counterparts in the US be encouraged on this issue.

Safety assessments should take into account historic data and data from other sources. Any increased technical documentation should not be based on SCCP guidelines. Rather, there should be a role for historic data, experience from established ingredients, data from the food or drug sectors, etc. Pragmatism and alternative types of data – as long as adequate safety is ensured – should be the order of the day. It is reiterated that under REACH, the “technical dossier” and the “chemical safety report” requirements therein are relevant only for individual substances; they are not appropriate for assessing the safety of products.

GSK respectfully submits its own proposed Intelligent Testing Strategy, which opts for an integrated approach comprising various evaluation methods. GSK is proposing this Strategy to the Partnership for Alternative Approaches to Animal Testing (EPAA), offering alternative approaches for the safety assessment of well-established ingredients, such as colorants, in light of the 2009 animal testing ban. In fact, GSK is committed to implementing the “3Rs” – *Reducing* the number of animals used for research, *Replacement* by non-animal methods whenever possible, and *Refinement* of the techniques used to eliminate or reduce animal suffering and improve animal welfare. GSK is very actively involved in initiatives and organisations for alternatives to animal testing, which include the European Partnership on Alternatives to Animal Testing (EPAA), among several others.

In outline, GSK’s proposed Intelligent Testing Strategy comprises the use of (i) human exposure data, which relies on the long history of safe use of ingredients in cosmetic products worldwide, thus attesting to the safety of these ingredients; (ii) data from other sources – combining existing human exposure data with existing data from other sectors (such as the food or drug sector, or data from Japanese, or US agencies (including the Food & Drug Administration – FDA)); (iii) toxicological risk assessments whereby the actual exposure to the substance in question is negligible and therefore does not represent a health risk. Potential exposures as well as potential hazard of the specific ingredient are key elements in this risk assessment process; low toxicity and low exposure for a specific ingredient results in a favorable toxicological risk assessment. Toxicological risk assessment can also be conducted using similar chemical structures.

GSK reiterates that to ensure appropriate standards and harmonisation of product safety assessments, comprehensive guidelines are issued and training provided. GSK would welcome the opportunity to participate in the development of such guidelines.

It is relevant that in the US, the safety of cosmetics is the responsibility of the manufacturer. There is an industry-driven code, the *CTFA Consumer Commitment Code*, under which the industry polices itself on safety (the CTFA is the *Cosmetic, Toiletry & Fragrance Association*). The Code contains valuable guidance related to safety assessments.

Although aspects of the US system are aligned to the EU’s, the CTFA guidance (or similar) would be a very welcome standardised document that industry could use. GSK would be happy to assist the Commission further with respect to formulating any such guidance.

The issuing of guidance for the benefit of the industry but also of enforcement authorities is moreover in line with the *New Approach*, as already outlined under item 3 above.

In any event, whatever approach is decided upon pursuant to the public consultation process, it must be both sustainable in terms of safety, and economically viable and sustainable in terms of avoiding excessive costs for industry.

This will become especially relevant in view of the seventh amendment ban on animal testing, and provisions in the REACH Regulation concerning avoidance of animal testing (e.g., Article 13).

It is additionally added that simply increasing the technical documentation *per se* will not increase the safety for the consumer. Rather, there needs to be greater enforcement of compliance and collaboration by industry against agreed guidelines.

**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 Commission already recognises that where there are any gaps in product-specific legislation as concerns product safety, then the provisions of Directive 2001/95/EC on general product safety will automatically apply in order to fill such gaps (see: the Commission's *Guidance document on the Relationship Between the General Product Safety Directive (GPSD) and Certain Sector Directives with Provisions on Product Safety* – via the following link, at page 31 onwards:

[http://ec.europa.eu/consumers/cons\\_safe/prod\\_safe/gpsd/guidance\\_gpsd\\_en.pdf](http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/guidance_gpsd_en.pdf))

As such, the rules on withdrawal, recall and notification of dangerous products, and other response mechanisms contained in the Directive on general product safety, would apply to cosmetic products. In consequence, it is GSK's view that adding such provisions to the Cosmetics Directive is not necessary as they would be, in effect, a duplication of already-applicable legislation.

Indeed, the addition of such provisions in the Cosmetics Directive would only increase the bureaucracy within the Commission and Member States' authorities, leading to unnecessary additional costs.

Instead, cooperation over market surveillance could be increased between the relevant authorities, as is already envisaged in Directive 2001/95/EC on general product safety.

**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?*

GSK takes its responsibilities seriously for ensuring product safety through both pre-market safety assessments and post-marketing safety data. It endorses the Guidelines on cosmetovigilance drawn up by Colipa: “*Guidelines on Handling of Adverse Event Reports (Colipa 2005)*”. These Guidelines, if used by industry, can form a harmonised integral basis for European industry practice.

Indeed, any reporting mechanism must be consistently applied across all the Member States; given the free movement of goods principle, it is also reasonable that this is managed through one system that can be shared with/accessed by individual Member States.

It is also necessary that there is alignment between industry, the Commission and the Member States on what will be done with the data and how it will be managed. No attempt should be made to collate information across products and assign causality to specific ingredients. Therefore, the authorities should be clearly informed about what to do with the information. Additionally, confidentiality is a very important consideration.

**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?*

Today, different processes exist in different Member States for notification of cosmetic products that are placed on the market. GSK would therefore be in favour of one single central notification system/database accessible by the Commission, the Member States and where appropriate Poison Centres (or equivalent). Such a system could hold information on product names, qualitative or frame formulae (which may be useful for managing urgent safety issues), manufacturing sites and location of Product Information Files.

In connection with the foregoing, consideration needs to be given to confidentiality and to how the information being held centrally would be used. E.g., proactive communication to companies on issues concerning ingredients could be beneficial.

Such a notification system should not be regarded as a pre-market registration/pre-approval requirement and any ingredient listing arising from such a database should not be regarded as an “approved” or “authorised” list.

Such notification system could be a voluntary system to begin with as in the US.

US/European similarities would support public health and encourage competitiveness of the industry.

**Item 13:** *The safety of ingredients in cosmetics would be assessed by the competent authorities on the basis of the product information file. Only if the competent authorities of different Member States disagree with this assessment they should refer the matter to the Commission (including the SCCP).*

The product information file relates to the safety of the product taking into account its intended use. However, in reality, a product safety assessment does not (and rightly so) necessarily include all data according to SCCP Guidelines on each ingredient. It does not take into account the justification for the use of any single substance as an ingredient in a range of cosmetic products.

Should a particular product give rise to a safety concern, the Cosmetics Directive could include a statement that, if the issue cannot be resolved with industry, following review of the Product Information File, then the relevant authority in the Member State concerned should request an SCCP Opinion on the use of that ingredient in the context of its intended use but only as a last resort. However, as noted under item 1 above, such Opinion should not be indecisive and lead to delays in the marketing of products.

In addition, it is important that the aforementioned SCCP Opinion take into account alternative sources of information, as GSK proposes, as part of its Intelligent Testing Strategy, under item 9 above.

GSK therefore endorses that referral to the Commission (and SCCP) should be the exception rather than the rule.

Additionally, the circumstances under which market surveillance are carried out should also be clarified, as this will become an important tool vis-à-vis non-compliance, as part of the *New Approach* elements.

**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 socio-economic impact of these additional regulatory tools?*

In GSK's view, no additional regulatory tools are deemed necessary. Article 2 already places an obligation on producers to ensure that products have to be safe before they are placed on the market. In addition, any gaps in the Cosmetics Directive as regards safety are filled by Directive 2001/95/EC on general product safety.

GSK favours manufacturer responsibility, based on self-assessment, in combination with the legislative requirement that only safe products shall be placed on the market. All these elements already exist in the Cosmetics Directive. Effective market surveillance would enhance these elements, without increasing the regulatory burden.

Should the Cosmetics Directive contain more and burdensome regulatory tools in the future, this would harm the competitiveness of the EU industry. Given that this industry works in a global sphere, its competitiveness should be enhanced; more regulatory tools will constrain innovation, whereas it should be actively encouraged.

If the Commission nonetheless feels, despite the above, that a strengthening of the Cosmetics Directive is required, then the Cosmetics Directive could provide (only if deemed absolutely necessary) for the presumption of conformity and self-declarations of conformity by manufacturers, as already exist in other Community legislation, in combination with efficient market surveillance by the enforcement authorities. However, this should not mean increasing the technical documentation required of manufacturers, who already keep product information files attesting to the safety of their products.

In any event, GSK favours product safety assessment guidelines as already discussed under items 3 and 9 above, as a valuable additional regulatory tool.

**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 term “uncompromised safety” would be novel to EU legislation as regards product safety if it were introduced. As such its meaning would inevitably require interpretation by the ECJ before which time manufacturers would be left uncertain as to the level of safety required in the cosmetics they place on the market. It is also recalled that none of the *New Approach* directives contain this term. Thus GSK does not endorse the use of this additional terminology.

Moreover the interpretation of safety in product safety and “liability” legislation, although high, is not “uncompromised safety”. In the Directives that deal with the safety of consumer goods and liability for failure to ensure that only safe goods are placed on the market (e.g., Directive 2001/95/EC on general product safety and Directive 85/374/EEC concerning liability for defective products), safety is assessed while taking into account surrounding factors. Thus, it is not “absolute” or even “uncompromised”. Please see the relevant requirements of safety in the following “liability” legislation:

#### *FIRSTLY*

In Council Directive 85/374/EEC concerning liability for defective products, Article 6 states as follows:

*A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:*

- (a) the presentation of the product;*
- (b) the use to which it could reasonably be expected that the product would be put;*
- (c) the time when the product was put into circulation.*

*2. A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.*

The preamble of the above Directive states as follows:

*Whereas, to protect the physical well-being and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect; whereas the safety is assessed by excluding any misuse of the product not reasonable under the circumstances.*

#### *SECONDLY*

In Directive 2001/95/EC on general product safety, Article 1 states that “*The purpose of this Directive is to ensure that products placed on the market are safe.*”

The term safe product is defined in Article 2(b) as follows:

*‘Safe product’ shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product’s use, considered to be acceptable and consistent with a high*

*level of protection for the safety and health of persons, taking into account the following points in particular:*

*(i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;*

*(ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products;*

*(iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;*

*(iv) the categories of consumers at risk when using the product, in particular children and the elderly.*

*The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be 'dangerous'.*

In sum, while the level of safety under the above-mentioned Directives is a high one, it cannot be equated to "uncompromised safety". Even the EC Treaty itself does not speak of uncompromised safety, but rather a "high level" of protection and safety (for example, Article 95).

Rather than use the term "uncompromised safety", the Commission and Member States should ensure consistency in approach with concepts of consumer protection as already established in other directives dealing with product safety.

**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?*

Under the Cosmetics Directive, the producer is responsible for the safety assessment of his products. Missing data should not automatically or necessarily be equated with a lack of safety information. In other words, if the word “data” in the question posed above is data according to SCCP guidelines, then GSK does not agree that the substance should be presumed unsafe.

Indeed, there is a conflict between the SCCP requirements and the need for animal testing. The conflict arises due to the tick-box approach and the list of tests which the SCCP want performed in order to ensure the safety of an ingredient, for which animal testing is currently required. The SCCP will not take account of historic data or in-market experience but will examine only definitive toxicological studies according to current laboratory practice to prove safety, without taking into account evidence from other areas.

If, however, specific data are missing on individual ingredients, the manufacturer should be given the opportunity to collect adequate information on safety of the product. This would be efficiently enhanced, including in a cost effective manner, by taking into account all the different sources of information – including historic data, and other sources that are listed under item 9 above as part of GSK’s Intelligent Testing Strategy.

GSK endorses the view that rather than declaring individual substances unsafe for want of data, national authorities should concentrate on ensuring compliance with the Cosmetics Directive as regards product safety, recognising the validity of different types of information on the products such as confirmatory safety studies, experience from safe-use histories, etc.

The taking into account of all the different sources is moreover endorsed under the REACH Regulation, Article 13. This Article states that “*information on intrinsic properties of substances may be generated by means other than tests [...]. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, **through the use of alternative methods** [...].*” (emphasis added).

**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?*

GSK is, in principle, opposed to positive lists (see, also, GSK's comments under items 5 and 6 above). In any event, the Cosmetics Directive already contains a mechanism for the compilation of new positive lists when deemed to be necessary. Substances are also already controlled by means of the Annex II (banned) and Annex III (restricted) lists.

If maintained, positive lists should be restricted to only those substances which are of serious concern. At present, if any substance raises serious concerns, the Commission can request the SCCP for an Opinion; the substance can thus be appropriately evaluated and regulated under the existing procedure. Any other system would be completely disproportionate and impose unjustified burdens on industry, reducing its competitiveness on the global market. Indeed, if the SCCP were to review all new substances, this would not only be overly burdensome: it would also stifle innovation and result in unwarranted marketing delays.

In short, GSK is not supportive of a mandate for the Commission to compile new positive lists and only allow substances which have undergone an SCCP safety assessment to be used as ingredients in cosmetics.

**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?*

GSK is not in favour of a “sunset” provision, whereby the regulator must reconsider the listing of all substances on a positive list. Re-evaluation should only be considered on the basis of new information which would change the original assessment of safety, or place it under suspicion, thus, on a case-by-case basis.

Basing reconsiderations simply on a time-mechanism would be unduly burdensome and costly for industry, and would intolerably increase the burden on Member States’ authorities.

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