UNION EUROPEENNE DE L'ARTISANAT ET DES PETITES ET MOYENNES ENTREPRISES
EUROPÄISCHE UNION DES HANDWERKS UND DER KLEIN- UND MITTELBETRIEBE
EUROPEAN ASSOCIATON OF CRAFT, SMALL AND MEDIUM-SIZED ENTERPRISES
UNIONE EUROPEA DELL' ARTIGIANATO E DELLE PICCOLE E MEDIE IMPRESE

UEAPME Analysis and Comments on the Opinion of the European Economic and Social Committee on the proposed Regulation on Cosmetic Products (COM(2008)0049)

1 - Context :

Under the recast of the Cosmetics Directive, the procedure provides that the European Economic Social Committee is consulted on the Draft Regulation.

This opinion was prepared by Mr KRAWCZYK.

2 - Comments about the Opinion :

2.1 – Conclusions and recommendations (see p. 1 of the opinion) :

The Committee points out that some of the new requirements (GMP, safety assessment, product information file, tests…) could cause considerable costs, particularly for SMEs.
Also, the Committee proposes to grant an additional period of 24 months to products already on the market in order to update their product information files, and to make an assessment of their security in accordance with new requirements.

➔ We totally agree with the observation made by the Committee, and fully support his proposal.

The Committee welcomes the fact that the evaluation of CMR is based on risk rather than on hazard.

➔ We totally agree with the Committee, and believe it is essential to base the safety assessment of ingredients on their risk (in particular related to the type of exposure) and not on their intrinsic hazard. This to make restrictions and / or prohibitions realistic in terms of consumer protection, without going to an excess of protection unnecessary for the consumer, and restrictive in terms of use of ingredients.

2.2 – Foreword (see p. 2 to 3 of the opinion) :

Mention of data on jobs and exports created by the cosmetics industry and the importance of SMEs within this industry.
This is to show the importance of taking into consideratino the interests and views of SMEs when analysing the impact of the Draft Regulation.

➔ We greatly appreciate that the Committee is concerned about the role of SMEs within the cosmetics industry.

2.3 – Introduction (see p. 3 to 5 of the opinion) :

Presentation of the key objectives and the key elements of the draft Regulation.

2.4 – General comments (see p. 5 to 8 of the opinion) :

Comment 1 :

The Committee endorses the aims and objectives of the draft regulation.

➔ Likewise, UEAPME approves the 3 objectives pursued under the simplification of the Directive 76/768/EEC, as mentioned in the preamble to the Draft Regulation.

Comment 2 :

The Committee welcomes the recast of the Directive 76/768/EEC as a regulation.

➔ Likewise, UEAPME approves the move from the Cosmetics Directive 76/768/EC to a Regulation in order to avoid differences in national implementation and highly appreciates the introduction of a single Community legislation by presenting a single, clear and coherent text. This simplification and clarification definitely contributes to reduce administrative costs for SMEs.

Comment 3 :

Despite the costs reduction related to administrative simplification, some new requirements may involve considerable costs for SMEs.

➔ We totally agree with the Committee. For example, UEAPME considers the centralization of the notification as an undeniable step forward, which will effectively reduce a large portion of administrative costs.

Comment 4 :

Comments about the fact that SMEs will be will be more affected than large enterprises, concerning the costs to undertake to comply with new requirements.

➔ We agree with the Committee.

Comment 5 :

Continuation of the previous comment with an example on the price of research reported to the quantity of products manufactured, which is much higher in an SME than in a large company.

➔ We agree with the Committee.

Comment 6 :

The Committee wishes to minimise the negative financial impact on SMEs, by proposing to grant an additional period of 24 months to products already on the market in order to update their product information files, and to make an assessment of their security in accordance with new requirements.

➔ We totally agree with the comment made by the Committee, and fully support his proposal.

Comment 7 :

The Committee welcomes the introduction of a set of definitions. However, it underlines the lack of updating the definition of "cosmetic" in relation to innovation and qualification of products, including borderline products.

➔ We agree with the Committee. Besides, we have a major remark about the definition of "manufacturer" because the proposed definition does not correspond to the wording used in the profession, so we proposed to use the terminology used in the profession.

Comment 8 :

The Committee welcomes the introduction of the concept of "a responsible person".

➔ We agree with the Committee.

Comment 9 :

The Committee considers that other concepts should also be defined, in particular the concepts of 'fragrance' and 'active ingredient'.

➔ We agree with the fact that other concepts could be defined in order to clarify certain issues. For example, the term "fragrance". But the concept of "active ingredient" is not used in the draft Regulation, we see no interest to define it.
On the other hand, we proposed to define the following terms : "bulk product" and "finished product" as defined by the standard ISO 22716.

Comment 10 :

The Committee welcomes the introduction of the electronic notification.

➔ We totally agree with the Committee. UEAPME considers the centralization of the notification as an undeniable step forward, which will effectively reduce a large portion of administrative costs.

Comment 11 :

The Committee endorses the application of harmonised standards. However, consumer health and safety issues must be regulated by the relevant regulations.

➔ We totally agree with the Committee.

Comment 12 :

The Committee welcomes the reference to harmonised standards for product claims, and pointed out that these standards should address methods of assessment applied to prove the claims, not to the claims themselves.

➔ We totally agree with the Committee.

Comment 13 :

The Committee welcomes the introduction of a differentiated regime based on the risk assessment of CMR. However, the draft Regulation excludes any application of a substance which is non-compliant with the requirements related to food safety, whereas the substance could be considered safe for use in cosmetics.

➔ We totally agree with the Committee.

Comment 14 :

The Committee recommends a further transition period of 24 months for products already on the market in order to update their product information files, and to make an assessment of their security in accordance with new requirements.

➔ We totally agree with the proposal made by the Committee

2.5 – Specific comments (see p. 8 to 10 of the opinion) :

Comment 1 :

The Committee is aware of certain new provisions which could be difficult to fulfil, in particular the scope of data required for the product information files and safety assessment.

➔ We totally agree with the Committee.

Comment 2 :

The safety assessment must be carried out by an independent third party, i.e. from outside the company in question.

➔ We do not understand this interpretation of article 7 made by the Committee. For us, the Safety Assessor can be external or internal to the company.

Comment 3 :

The term "non-clinical safety studies" is unclear and is interpreted differently by various Member States.
According to Directive 2004/10/EC, the provisions on good laboratory practices are not applicable to the tests involving the participation of humans.

➔ This term could be defined.
In France, this term is not a problem of interpretation, it is not restricted to drugs, Afssaps, for example, has prepared a guide for Security Studies conducted on non-clinical cosmetics.

Comment 4 :

The draft Regulation requires that all toxicological tests and analysis necessary for the safety assessment be performed in accordance with the principles of good laboratory practice, which prevents the use of most data included in toxicological databases and scientific publications.

➔ Not all toxicological tests and analyses necessary for the safety assessment have to be carried out according to BPL, but only non-clinical safety studies.
For these non-clinical safety studies that must be carried out according to BPL, we agree with the Committee, so far, few studies have been conducted with BPL.

Comment 5 :

Some data are not readily available because there is no commonly available and recognised methodology to obtain it, concerning notably the assessment of the purity and stability of packaging material, the evaluation of interactions between the compounds, the evaluation of the influence of product stability on its safety, and the specification of the "period-after-opening".

➔ We agree with the Committee.

Comment 5.1 :

The Committee welcomes the content of the Cosmetic Product Safety Report, which will improve the quality of the dossier, facilitate market surveillance and therefore contribute to consumer safety.

➔ We agree with the Committee.

Comment 6 :

The Committee pointed out that, in order to determine the NOAEL, value required, it will be necessary to conduct animal tests that contravenes the provisions of Article 14 (Animal testing).

➔ We fully agree with the Committee.

Comment 6.1 :

New legislation should therefore clearly specify which tests manufacturers are to carry out on substances used in cosmetics.

➔ Nothing to report.

Comment 7 :

The Committee does not accept that the list of ingredients may be indicated on the packaging alone, rather, if possible, it should be indicated on the product.

➔ It is true that for the consumer, it is more useful that the list of ingredients be listed on the product itself.

Comment 8 :

The Committee considers that cosmetic products must carry special warnings regarding their use by children, stating a minimum age and that they must be kept out of the reach of children.

➔ The draft Regulation stipulates already that cosmetics have to be labelled with any indication or information so that they are safe for human health. This covers the cases for which products should not be used by children, or according to particular conditions.

Comment 9 :

According to the Committee cosmetic products sold via distance-selling should bear exactly the same type of information on labels and packaging than cosmetic products sold in shops.

➔ We agree with the Committee.

Comment 10 :

The Committee endorses the administrative collaboration between the competent authorities, and the application of the good administrative practices.

➔ We agree with the Committee.

Comment 11 :

The Committee welcomes the addition of CAS / EINECS N° and INCI names, into lists of prohibited, restricted and allowed substances, and the creation of an electronic inventory of cosmetic ingredients.

➔ We fully agree with the Committee.

Comment 12 :

The Committee welcomes the withdrawal of the former Annex on product categories, as arbitrary, repetitive, and not mentioning the new categories of existing products.

➔ We quite agree with the Committee.

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