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 Proposal for Amendments concerning the proposed Regulation on Cosmetic Products (COM(2008)0049) Comments on the Draft Report of the European Parliament (22/07/08)

Amendment 30 :

Text proposed by European Commission :

Extract Article 2 – Definitions

« b) '**manufacturer**' means any natural or legal person who designs or manufactures a cosmetic product or who has such a product designed or manufactured, under his name or trademark »

Amendment proposed :

Apply the terminology that is already used by the profession, with the following definitions of the various existing reponsibilities, whilst respecting the objective of the European Commission to clarify the responsibilities :

1) Use the term "**Person responsible for placing of the product on the market**" to designate the person or entity that place the product on the market (the 1st availability of the product on the market, according to the definitions of the draft Regulation).

2) Use the following terms in order to describe the responsibilities of the different actors of the cosmetics industry :

- the term "**contract giver**" to designate the person or the company for the account of which operations of design, manufacture or packaging are carried out by a sub-contractor.
- the term "**sub-contractor**" to designate the company which design and/or manufactures and/or make the packaging of products for the account of an other company which is the contract giver. Specifications and/or a contract bind the contract giver with the sub-contractor
- the term "**formulator**" to designate the person or the company which design a product ; under his name or his mark, or on behalf of a contract giver.
- the term "**manufacturer**" to designate the person or the company which manufacture a product ; under his name or his mark, or on behalf of a contract giver.
- the term "**packer**" to designate the person or the company which carries out whole or part of the packaging of a bulk finished product ; under his name or his mark, or on behalf of a contract giver.
- the term "**distributor**" to designate the person or the company which buys and resells a product without modify nothing and has no property right on the mark.
- the term "**importer**" to designate the person or the company which buys a product from a third country and which resells it in a Member State of the European Community.

Justification :

Problem found : The term “Manufacturer” defined in the draft Regulation, has a completely different meaning in the professional language and is used for a situation other than that specified ! The use of this term can affect the understanding of the Regulation and actors responsibilities, and thus go against the major objectives of the Regulation.

Amendment 31 :

Text proposed by European Commission :	Amendment proposed :
Extracts Article 8 *– Product information file* « 1. The responsible person shall keep a product information file for the cosmetic product for which he is the responsible person. » « 3. The responsible person shall make the product information file readily accessible in electronic or other format at his address to the competent authority of the Member State where the file is kept. »	Item 1 : When subcontracting development and/or production activities, the responsibilities linked to the conservation of the product information file might be shared between the person responsible for placing the product on the market and the subcontractors by a written agreement. Item 3 : The person responsible for placing the product on the market ensures the existence of all data requested and is able to explain and justify to the authorities the places of detention of these information. The p*roduct information file* may contain references to information parts that are held in other places. Subcontractors are committed to rapidly transmit information to authorities.

Justification :

Problem found : In frequent cases where the person responsible for placing the product on the market, use subcontracting for the development and / or production of their cosmetic products, the product information file is often shared between the contract giver and its subcontractor for various reasons (update of informations, confidentiality, address labelling).
This situation faced by the cosmetics industry has never been taken into account nor described in the regulations.

Amendment 32 :

Text proposed by European Commission :	Amendment proposed :
Extracts Article 7 – Safety assessment « 1. The responsible person shall, prior to placing a cosmetic product on the market, ensure that the cosmetic product has undergone a safety assessment on the basis of the relevant information and that a cosmetic product safety report in accordance with Annex I is set up. The responsible person shall ensure that the cosmetic product safety report is kept up-to-date in view of additional relevant information generated subsequent to placing the product on the market. 2. The cosmetic product safety assessment, as set out in Part B of Annex I shall be carried out by a person in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognised as equivalent by a Member State, extending over a period of at least three years of theoretical and practical study in pharmacy, toxicology, medicine or a similar discipline. »	We propose that the person responsible for placing the product on the market may delegate the evaluation of the different risks to various competent persons (like the formulator, the manufacturer, the safety assessor,…) who would have every information and competence to judge. The conclusions issued by each of these persons will lead the person responsible for placing the product on the market to decide to put the product on the market or not.

Justification :

Problem found : The Regulation proposes that the safety assessor is the only judge to certify the safety of the product. But he is not the most competent to take all decisions related to different risks for the product. He is especially competent to assess the toxicological risk, but he is not necessarily competent to evaluate all risk criteria that may present a cosmetic product (microbiological risk and control, stability…)

Amendment 33 :

Text proposed by European Commission :	Amendment proposed :
/	It would be preferable to speak about "users" instead of "consumers" in order to take into account the use of cosmetic products by professional users manipulating these products (beauticians, hairdressers….), who are not considered as consumers.

Justification :

Problem found : The draft Regulation refers mainly to consumers, and only mention professional use within the restrictions set out in the annexes.

Professional users are also concerned about the effectiveness of cosmetics, the degree of skin penetration and regulation of cosmetic ingredients.

Main comments about the EP Draft Report:

Main message : The rapporteur wants to strengthen the safety aspect to ensure the protection and health of all consumers.

➔ We fully agree with the principle of consumer protection.

However, we wish to draw attention to the fact that certain definitions and specific requirements of the Regulation, as defined in the draft of 05/02/08, may go against the safety of consumers (see our proposals for amendments), for example :

- The term "Manufacturer" whose definition is not industry practice,
- The safety assessment which is not led by those most competent to evaluate all risks.

So, we have made four additional proposals for amendments.

The draft report focuses on four aspects :

1) Safety assessment of cosmetic products :

a) *The rapporteur asks the Commission to adopt guidance that helps the responsible persons to produce the safety assessments and the product safety report of their products.*

➔ A guidance for the safety assessment could indeed be useful to SMEs.
➔ The SCCP could also bring its expertise to evaluate nanomaterials.

b) *The rapporteur therefore asks the Member States to perform adequate controls and in case of non-compliance to report back to the Commission*

➔ Nothing to report

2) The use of nanomaterials in cosmetic products :

a) *The rapporteur introduces a definition.*

➔ It seems useful to define what are nanomaterials since the Draft Regulation mentions them, and if possible, to do so at an international level.

But we do not agree with the definition proposed in the draft Report, for several reasons.

Indeed, according to the opinion adopted by the SCCP after the public consultation on the 14th plenary of 18 December 2007, a nanomaterial is not necessarily "intentionally manufactured". Nanoparticles can be found in their natural state, or make itself uncontrollably (during manufacturing processes, for example). The notion of "intentionally fabricated" reduces the definition given by the SCCP.

In addition, for example nanoemulsions fall into the category of nanomaterials and are not “solid”.

The definition given by the SCCP for a nanomaterial is : "*material with one or more external dimensions, or an internal structure, of the order of 100 nm or less, which could exhibit novel characteristics compared to the same material without nanoscale features”.*

b) An evaluation by the SCCP should be required for all products containing nanomaterials that are not covered in Annex IV, V and VI.

➔ The Draft Regulation already provides that when assessing the safety of a cosmetic product, “Particular consideration shall be given to any possible impacts on the toxicological profile due to particle sizes” (Annex 1, Part A, paragraph 8).

On the other hand, it does not seem useful to establish specific procedures for nanomaterials, as proposed in the draft Report. If the general procedures are not applicable today, their adaptation is necessary, and not the creation of a specific regime.

3) The use of CMR-substances in cosmetic products :

a) The rapporteur introduces the concept of global exposure from all routes and sources (food sector, cosmetics, other consumer products). This global exposure has to be taken into account by the SCCP when evaluating the safety of the CMR substance to be used in a cosmetic product.

➔ We agree with the fact that the authorization to use CMR 1 and 2 is exceptional.
It seems appropriate to assess the global exposure.

It seems difficult to consider certain vulnerable population goups since there is no concrete criteria to define them (notably the elderly, and Persons with weakened immune systems).

b) *The rapporteur asks the Commission to develop estimates for measuring global exposure.*

➔ It might be useful to establish guidance for evaluating the global exposure to substances.

4) The use of product claims for cosmetic products :

the CEN cannot be put in charge of a sensitive matter like product claims, where independent assessment would absolutely necessary. The rapporteur asks the Commission to review all product claims currently used.

➔ We endorse the procedure chosen by the European Commission, to ask the CEN for establish harmonized standards, because it allowed to involve all stakeholders :

- Competent authorities
- Representatives of consumers
- Representatives of industrial producers of cosmetics
- Doctors, Dermatologists
- Representatives of tests centres

This in order to establish relevant harmonized standards, particularly concerning claims (Article 16, draft Regulation), sampling and analysis of cosmetic products (Article 9, draft Regulation), and also in order to make a reference to relevant standards already existing at european or international level, especially on GMP (Article 5, draft Regulation).

Detailed comments about the proposed amendments :

Amendment 1 :

Proposal made in the report :

New recital (No. 25a) :
Develop a uniform definition of nanomaterials at international level, for the development of this technology.

UEAPME comment :

It seems useful to define what are nanomaterials since the Draft Regulation mentions them, and if possible, to do so at an international level.

Amendment 2 :

Proposal made in the report :

New recital (No. 25b) :
On nanomaterials not yet included in Annex III to VI, a specific assessment of their security should be made by the SCCP.

UEAPME comment :

The Draft Regulation already provides that when assessing the safety of a cosmetic product, “Particular consideration shall be given to any possible impacts on the toxicological profile due to particle sizes” (Annex 1, Part A, paragraph 8).

On the other hand, it does not seem useful to establish specific procedures for nanomaterials. If the general procedures are not applicable today, their adaptation is necessary, and not the creation of a specific regime.

Amendment 3 :

Proposal made in the report :

New recital (No. 25c) :
The SCCP should develop testing methods specific to nanomaterials in order to take into account their specific characteristics.

UEAPME comment :

The SCCP could indeed bring its expertise to evaluate nanomaterials.

Amendment 4 :

Proposal made in the report :

New recital (No. 25d) :
The Commission should regularly review the data on nanomaterials, in the light of scientific progress.

UEAPME comment :

This is the approach adopted by the European Commission for all substances used in cosmetics.
The Draft Regulation already provides for a regular review of data, in particular in article7, paragraph1.

Amendment 5 :

Proposal made in the report :

New recital (No. 26a) :
The safety assessment of substances, especially CMR 1 and 2, should take into account the overall exposure to these substances (including sources other than cosmetic products).
Thus, for the achievement of security assessments, it would be appropriate that relevant stakeholders (including the EC, the SCCP, ECHA, AESA…) develop guidelines for obtaining and using estimates of the overall exposure.

UEAPME comment :

It might be useful to establish guidance for evaluating the global exposure to substances.

Amendment 6 :

Proposal made in the report :

New recital (No. 39a) :

In evaluating the safety of substances, it should be possible to take into account the results of risk assessments carried out in other areas, only if it is relevant.

UEAPME comment :

Nothing to report.

Amendment 7 :

Proposal made in the report :

Modification of recital No. 40 :
Refusal to have harmonised standards for certain cosmetics claims.
To assess the validity of certain claims, the Commission should submit a report on the use of these claims and proof given for them and, where necessary, propose appropriate measures to resolve any problems found.

UEAPME comment :

We endorse the procedure chosen by the European Commission, to ask the CEN for establish harmonized standards, because it allowed to involve all stakeholders :

- Competent authorities
- Representatives of consumers
- Representatives of industrial producers of cosmetics
- Doctors, Dermatologists
- Representatives of tests centres

Amendment 8 :

Proposal made in the report :

New recital (No. 44a) :
Member States should provide their market surveillance authorities with the necessary powers, resources and knowledge so that they can carry out their missions.

UEAPME comment :

Nothing to report.

Amendment 9 :

Proposal made in the report :

Amendment of Article 2 “Definitions”, Section 1, paragraph f - "harmonised standard" : Remove the definition of "harmonized standard”.

UEAPME comment :

We endorse the procedure chosen by the European Commission, to ask the CEN for establish harmonised standards, because this allowed :

- To involve all stakeholders to establish relevant harmonized standards, particularly concerning claims (Article 16), sampling and analysis of cosmetic products (Article 9).
- To make a reference to relevant standards already existing at european or international level, especially on GMP (Article 5).

Amendment 10 :

Proposal made in the report :

New definition (ja) in Article 2 “Definitions”, Section 1 :
Definition based on an opinion of SCCP : “nanomaterial means a solid and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale of 100 nm or less”

UEAPME comment :

We do not agree with this definition for several reasons.

Indeed, according to the opinion adopted by the SCCP after the public consultation on the 14th plenary of 18 December 2007, a nanomaterial is not necessarily "intentionally manufactured". Nanoparticles can be found in their natural state, or make itself uncontrollably (during manufacturing processes, for example). The notion of "intentionally fabricated" reduces the definition given by the SCCP.

In addition, for example nanoemulsions fall into the category of nanomaterials and are not “solid”.

The definition given by the SCCP for a nanomaterial is : "*material with one or more external dimensions, or an internal structure, of the order of 100 nm or less, which could exhibit novel characteristics compared to the same material without nanoscale features”.*

Amendment 11 :

Proposal made in the report :

New definition (la) in Article 2 “Definitions”, Section 1:
“vulnerable population groups means children under three years of age, elderly people and persons showing compromised immune responses”

UEAPME comment :

There are no concrete criteria for defining the following population groups :

- The elderly,
- Persons with weakened immune systems.

We believe that only children under 3 years and pregnant or lactating women should be taken into account for cosmetics. The other cases are pathological and are the responsibility of the attending physician.

Amendment 12 :

Proposal made in the report :

New point (2 a) in Article 2 “Definitions”, § 2 :
The EC should amend the definition of " nanomaterial " according to the evolution of knowledge.

UEAPME comment :

Instead of adding a new paragraph 2a, mention this sentence after the definition of “Nanomaterial”, to the point (j a).

Amendment 13 :

Proposal made in the report :

Amendment of Article 7 " safety assessment," § 1:
Add 2 sentences :

1) Particular consideration shall be given to particle size and more specifically to 'nanomaterials' as defined in Article 2.

2) The Commission, in close cooperation with all stakeholders, shall adopt appropriate guidance to enable enterprises, in particular SMEs, to comply with the requirements laid down in Annex I (safety assessment).

UEAPME comment :

About first sentence added :
The Draft Regulation already provides that when assessing the safety of a cosmetic product, “Particular consideration shall be given to any possible impacts on the toxicological profile due to particle sizes” (Annex 1, Part A, paragraph 8).

About second sentence added :
A guidance for the safety assessment could indeed be useful to SMEs.

Amendment 14 :

Proposal made in the report :

Amendment of Article 8 "Product Information File" § 2, point d :
Request deletion of part of the sentence underlined : “where justified by the nature or the effect of the cosmetic product, proof of the effect claimed for the cosmetic product”

UEAPME comment :

The deleted part of the sentence was indeed unclear.

Amendment 15 :

Proposal made in the report :

Amendment of Article 10 "Notification", Section 1, paragraph c :
Regarding the name of the Member State in which the product is marketed, specify that this is the 1st Member State in which the product is placed on the market.

UEAPME comment :

The justification given for this proposal is not correct. Indeed, the notification has not to be done in a Member State, but to the European Commission, which will then forward this information to Member States.

It does not seem useful mentioning in the notification only the first country in which the product is placed on the market, it seems more useful to mention all the countries in which the product is placed on the market.

Also, we make another proposal :
"The Members States where the cosmetic product is placed on the market."

Amendment 16 :

Proposal made in the report :

Amendment of Article 10 "Notification", Section 1, paragraph e :
Notify the presence of all substances in the form of nanomaterial, not just those which are not listed in Annex III to VI as envisaged in the Draft Regulation.

UEAPME comment :

It does not seem useful to notify nanomaterials whose security has already been evaluated by the SCCP and are therefore listed in Annex III to VI.

Amendment 17 :

Proposal made in the report :

New point (ha) in Article 11 "Restrictions", § 1:
The products should not contain substances in the form of nanomaterials other than those listed in Annex IV, V, VI and VIa, nor substances in the form of nanomaterials that are not used within the restrictions set out in the annexes.

UEAPME comment :

It does not seem useful to add this sentence.

Amendment 18 :

Proposal made in the report :

Amendment of Article 12 "CMR substances," § 2, under Section 2 and 1st indent :
Permission to use CMR 1 and 2 should be exceptional.
The SCCP should assess the safe use of CMR 1 and 2 :

- Depending on the overall exposure to these substances (including sources other than cosmetic products).
- And taking into consideration the vulnerable population groups.

UEAPME comment :

We agree with the fact that the authorization to use CMR 1 and 2 is exceptional. It seems appropriate to assess the global exposure.
It seems difficult to consider certain vulnerable population goups since there is no concrete criteria to define them.

Amendment 19 :

Proposal made in the report :

New paragraph (2 a) Article 12 " CMR substances " :

The EC must ensure, within 2 years after publication of the Regulation, that procedures and guidelines are established to estimate the overall exposure to the CMR.

UEAPME comment :

Nothing to report.

Amendment 20 :

Proposal made in the report :

Amendment of Article 16 "Claims", § 1, sub-§ 2:

Refusal to have harmonized standards for cosmetic claims.

UEAPME comment :

We endorse the procedure chosen by the European Commission, to ask the CEN for establish harmonized standards, because it allowed to involve all relevant stakeholders.

Amendment 21 :

Proposal made in the report :

New paragraph (2 a) Article 16 "Claims" :

The EC shall, within 5 years after publication of the Regulation, present a report on claims used, and how these have been proved. If necessary, the EC will make a proposal on harmonized requirements for product claims.

UEAPME comment :

We endorse the procedure chosen by the European Commission, to ask the CEN for establish harmonized standards, because it allowed to involve all relevant stakeholders.

Amendment 22 :

Proposal made in the report :

Amendment of Article 17 "Public access to information," § 1:

Clarifying that public access to information must be facilitated.

UEAPME comment :

Nothing to report.

Amendment 23 :

Proposal made in the report :

Amendment of Article 18 " market control"
Adding two sentences :

a) Member States shall perform controls at an appropriate level by assessing the available documentation and, if necessary, by conducting physical and laboratory tests products.
b) Member States shall report to the EC annually, on the controls performed for surveying compliance with this Regulation and on the main non-conformities observed.

UEAPME comment :

Nothing to report.

Amendment 24 :

Proposal made in the report :

Amendment of Article 21 "Non-compliance", Section 1 :

In case of non-compliance, asked to act without delay (corrective action or withdrawal), while the Draft Regulation provides for a reasonable time, proportional to the nature of risk.

UEAPME comment :

We do not consider it useful to act without delay according to the risk caused by the non-compliance.

Amendment 25 :

Proposal made in the report :

Amendment of Article 26 "Amendment of annexes", § 1, sub-§ 1 :

Amend the annexes to the Regulation not only in case of risk to human health, but also in cases of risk to the environment, after consulting the SCHER (Scientific Committee on Human and Environmental Risks) if necessary.

UEAPME comment :

This proposal goes in the continuity of the REACH Regulation.

Amendment 26 :

Proposal made in the report :

Amendment of Article 26 "Amendment of annexes", § 2, under Section 2 :

When the EC consults the SCCP, it shall give its opinion within 6 months.

UEAPME comment : Nothing to report.

Amendment 27 :

Proposal made in the report :

Amendment of Article 31 "formal objection against the harmonised standards":

Removing this article : refusal to have harmonized standards for cosmetic allegations.

UEAPME comment :

We endorse the procedure chosen by the European Commission, to ask the CEN for establish harmonized standards, on various subjects such as claims, but also sampling and analysis, GMP.

Amendment 28 :

Proposal made in the report :

New paragraph (2 a) Article 34 "Entry into force":

Adding a transition period of 2 years for the compliance of products containing nanomaterials unregulated by Annexes to the date of entry into force of the Regulation.

UEAPME comment : Nothing to report.

Amendment 29 :

Proposal made in the report :

New Annex (VI): « List of permitted nanomaterials other than those included in Annex III, IV, V or VI »

UEAPME comment : Nothing to report.

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