



**COUNCIL OF  
THE EUROPEAN UNION**

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from: General Secretariat of the Council  
to: Permanent Representatives Committee (part I)

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Subject: Proposal for a Regulation of the European Parliament and of the Council on cosmetic products (recast)  
– Preparation of an informal triologue

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**I. INTRODUCTION**

1. The Commission presented its proposal on 5 February 2008.
2. The European Parliament Environment Committee (ENVI) voted its report on 2 December 2008<sup>1</sup>.
3. The European Parliament will adopt its Opinion in first-reading in the plenary of 23-26 March 2009.

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<sup>1</sup> A6-0484/2008

## II. STATE OF PLAY

4. The Working Party on Technical Harmonisation (Cosmetics) has examined the proposal on 19 occasions during the Slovenian, French, and Czech Presidencies.
5. It should be noted that the report voted by ENVI on 2 December 2008 focuses on issues that were not previously examined in the Council Working Party such as nanomaterials and the fight against counterfeiting.
6. Following regular informal contacts, the Council and the European Parliament have reached a tentative common understanding of the proposal in a joint effort to reach agreement at first reading. In particular, the European Parliament could accept to align the text (in Articles 4a, 4b, 4c) to the New Approach framework, which allows for a clear repartition of the obligations of manufacturers, importers and distributors. The amendments relating to supply chain and sub-contractors (EP amendments 10 and 21 on Articles 2 and 8) could thus be abandoned. This is also the case for amendment 41 (Article 26) foreseeing Commission action in case of risks to the environment, which can now be streamlined with REACH (recital 8a).
7. The Presidency submits in the Annex to this note a compromise package to serve as basis for forthcoming negotiations with the European Parliament aiming at a first-reading agreement.
8. A number of issues are still open. The main outstanding issues are listed under III and the other issues under IV.

### III. MAIN OUTSTANDING ISSUES

- a) Compliance with Food law (Regulation 178/2002/EC) as a condition for derogating from the ban on CMR (carcinogenic, mutagenic or toxic for reproduction) substances (Article 12(2)) : A number of delegations pointed out that the food law criterion could exclude a number of substances which are safe for use in cosmetics. The Presidency compromise foresees additional criteria (safe history of use, known exposure and safety margins) when the food law criterion would not apply, while retaining the same high level of safety and the review by the Scientific Committee (SCCS).
- b) Nanomaterials (Articles 2, 10, 12a) (EP amendments 17, 20, 26, 27) : Apart from the positive lists in Annexes IV to VI dealing with colorants, preservatives and UV-filters, the Commission proposal does not regulate the use of nanomaterials in a specific regime. The European Parliament proposes a specific regime involving, amongst other elements, the opinion of the SCCS and a prior notification procedure. The system proposed by Parliament raises concerns on various grounds relating to legal certainty, the proper exercise of executive competences and compatibility with market surveillance and implementation; it would also require a heavy administration from the Commission.

The Presidency has presented a compromise to the Working Party which includes the basic elements of the Parliament amendments while ensuring a clearer application and a feasible administration by the Commission. Most delegations support the approach of the Presidency text.

An outstanding issue would be the choice between the notification by product or by nanomaterial (Article 12a). The compromise text of the Presidency proposes notification by nanomaterial (not by product) on the grounds that this would probably enable a better administration of group notifications and the notification by manufacturers.

- c) Counterfeit cosmetic products (recital (13bb)) ( EP amendments 16, 18, 38) : The European Parliament is proposing that the competent authorities of Member States trusted with market surveillance for cosmetic products should be charged with the identification and control of counterfeit cosmetic products. A broad majority of Delegations pointed out that these authorities are not best placed to deal with this aspect and that moreover the combating of

counterfeit is already provided for in other Community legal acts. The Presidency has proposed a recital (13bb) as a compromise to Parliament which mentions the potential of this Regulation to aid the fight against counterfeiting. Some delegations retain reservations on this last addition.

- d) Internet sales (Article 4(5)) : One delegation has a particular objection to the provision that requires a responsible person established within the Community for products coming directly to consumers from outside the Community, expressing doubts on the compatibility of this with WTO engagements.

#### **IV. OTHER OUTSTANDING ISSUES**

A number of technical issues remain outstanding. These are indicated in footnotes 35, 40, 42, 45, 57, 63, 64, 65, 68 and 84 of document 5895/2/09 REV 2.

#### **V. CONCLUSIONS**

**The Committee is invited to examine the main outstanding issues under section III and to endorse the attached Presidency's proposals on those issues with a view to forthcoming negotiations with the European Parliament for a first-reading agreement.**