



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 17 November 2009

**Interinstitutional file :
2008/0035 (COD)**

**12682/09
ADD 1 REV 1**

**CODEC 1044
MI 303
ENT 167
CONSOM 163
SAN 211
ECO 111
ENV 524
CHIMIE 66**

ADDENDUM TO "I/A" ITEM NOTE

from : General Secretariat of the Council

to : COREPER/COUNCIL

N° Cion prop.: 6725/1/08 REV1 MI 71 ENT 40 CONSOM 25 SAN 37 ECO 27 ENV 109
CHIMIE 7 CODEC 240

Subject : Proposal for a Regulation of the European Parliament and of the Council on
cosmetic products (recast) **[first reading]**
– Adoption of the legislative act (LA + D)
Statements

COUNCIL STATEMENT

The Council would refer to the second paragraph of point 4 of the Interinstitutional Agreement of 28 November 2001 on a more structured use of the recasting technique for legal acts¹ (hereinafter referred to as "*the IIA of 28 November 2001*"):

"A new legal act shall not constitute a recast act if, with the exception of standardised provisions or wordings, it makes substantive amendments to all the provisions of the earlier act, which it replaces and repeals."

¹ OJ C 77, 28.3.2002, p. 1.

In view of Article 249 of the Treaty, the Council considers that, in principle and by definition, the use of the recasting technique for a legal act which consists of the conversion of the provisions of one or more Directives into a Regulation "*makes substantive amendments to all the provisions of the earlier act which it replaces and repeals*".

In the case in point, because of the advanced stage reached in negotiations, including those with the European Parliament, it did not appear possible to break off the discussions under way at the Council and the Parliament. However, this cannot under any circumstances be taken as a precedent.

The Council reserves the right in future to reject any proposal which does not comply with the IIA of 28 November 2001.

Statement for the minutes by the Federal Republic of Germany on the proposal for a Regulation of the European Parliament and of the Council on cosmetic products

With regard to the introduction of labelling for nano particles in cosmetic products (Article 19(1)(g)), it cannot in Germany's view be excluded that the general mention on labels of nano-scale materials in cosmetic products using the term "nano" might be misunderstood by consumers as a warning. Because of the general safety requirements for cosmetics, it is in any case only safe products that are allowed on the market. This applies also to cosmetics which are produced using nanotechnology. Germany believes that information on nano-scale materials may be important for consumers where the particle size results in altered properties.

Statements by the Commission

1. *Recast (agreed in December)*

The Commission takes note of the concerns of Member States on the recasting of directives into regulations.

The Commission considers that where the existing provisions of a directive are sufficiently clear, precise and detailed they may be capable of conversion into directly applicable provisions in a regulation by way of recasting. This is true more particularly where the provisions at issue are of a technical nature and have already been fully transposed into national law by all Member States.

The Commission accepts, in the light of the different opinions expressed, that the specific case of the Cosmetics Regulation will not be used as a precedent for the interpretation of the Interinstitutional Agreement on this point.

2. *Internet sales*

The Commission commits to clarifying the situation regarding internet sales of cosmetic products prior to the date of application of the Regulation.

3. *Counterfeiting*

Like the European Parliament, the Commission is concerned by the fact that the cosmetic sector may be affected by counterfeiting which may increase risk for human health. Therefore the Commission will take actions in order to enhance the cooperation between national competent authorities in order to fight counterfeiting.

4. *Transitional provisions and dates of application of the Regulation*

The Commission will draft an explanatory note regarding transitional provisions and dates of application of the Regulation (in particular in view of Articles 10 (Safety Assessment), 11 (Product Information File), 13 (Notification) and 16 (Nanomaterials))¹.

¹ Previously Articles 7, 8, 10 and 12a, as it appears from the original oral statement given on 24 March 2009.

5. *Definition of nanomaterials*

The Commission notes that work towards a common definition of nanomaterials is still evolving. The Commission therefore confirms that in future Community legislation progress on the common definition should be taken into account and notes that the Comitology procedures contained within this proposal also allow for the updating of the definition within this proposal.
