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LEGAL SERVICE

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OBJET: G		ECHÉANCE:	
LIBRE:			
DÉPART:		RÉGION:	
NOTE FOR THE ATTENTION OF			

Brussels, 9 July 2007

JUR (2007) 40472

*Opinion of the Legal Service**

61015921

Mr. Zourek, Director-General, DG ENTR
Mr. Carl, Director-General, DG ENV

SUBJECT: Article 7 and 33 of REACH: Substances present in articles above a concentration of 0.1%

Ref: Your note of 24/05/2007 (ENTR/G/1/OL/mm D (2007) 15921)

1. Your services requested the opinion of the Legal Service in the above mentioned note in relation to the interpretation of Article 7(2) of Regulation (EC) n° 1907/2006 (hereafter "REACH Regulation"). This provision obliges producers and importers to notify the presence of certain substances of very high concern in articles when those substances are found in the articles above a concentration of 0.1% weight by weight. The question is essentially whether in the case of "complex" articles made of different parts the concentration limit refers to the whole article or to each of the individual or homogeneous parts.
2. In practical terms, the interpretation of Article 7(2) is mainly important for articles that contain substances of very high concern that have not been manufactured in the Community and have not been registered under REACH for their use. The substances that are manufactured in the Community and are contained in an article (complex or not) are normally subject to the rules of REACH Regulation already at the stage of manufacture. In this regard, Article 7(6) of REACH Regulation provides that

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paragraphs 1 to 5 (of Article 7) shall not apply to substances that have already been registered for that use.

3. In REACH Regulation, the definition of "article" is found in Article 3 (n° 3): *"article" means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition.*

The obligation of Article 7(2) refers to "articles" as defined in Article 3. Nowhere else in the REACH Regulation more specific references or definitions of "complex articles" or "individual or homogeneous parts of articles" are found. Under those circumstances, a **grammatical or contextual interpretation** does not support the idea that Article 7(2) is applied to individual or homogeneous parts of an article rather (or in addition) to the whole article. Where the legislator intended to cover individual or homogeneous parts/materials in an article/product worded this under clear terms. One example mentioned in your note is Commission Decision 2005/618/EC of 18 August 2005 amending Directive 2002/95/EC of the European Parliament and of the Council for the purpose of establishing the maximum concentration values for certain hazardous substances in electrical and electronic equipment.

4. The **historic interpretation** of Article 7(2) indicates that "article" does not refer to individual or homogeneous parts. At least three attempts were made by the European Parliament, the Netherlands and Sweden to introduce a reference to homogeneous parts/materials. However, in the final wording of the provision the obligation refers only to "articles" without any further specification.

5. As you mention in your note, certain Member States argue that a **teleological interpretation** should lead to the conclusion that "article" covers individual or homogeneous parts in a complex article. However, given the number of modifications of the provision in question during the preparation of the Regulation and its final wording, it is very doubtful whether its purpose was to cover those parts of articles. Moreover, the arguments of Member States that point to certain difficulties in the applicability of Article 7(2), if accurate, highlight the shortcomings of this provision and certain negative consequences from its application. Those shortcomings might have to be addressed by a modification of Article 7(2). They are not justifying, however, an interpretation which has no basis on the text of REACH Regulation.

6. Having in mind that a modification of Article 7(2) could be one solution of this issue of interpretation, your services ask whether this modification can happen by using Article 7(8) of REACH Regulation which reads as follows: *"Any measures for the implementation of paragraphs 1 to 7 (of Article 7) shall be adopted in accordance with the procedure referred to in Article 133(3)"*. In the view of the Legal Service, a modification of Article 7(2) in order to add an obligation on notifying substances of very high concern in individual or homogeneous parts of an article is not part of the implementation of Article 7 paragraphs 1 to 7. It is a new obligation that can be introduced in a modification of the REACH Regulation in accordance with the relevant (co-decision) procedure. Moreover, such a modification will probably have to be accompanied by a definition of "individual or homogeneous parts of an article".

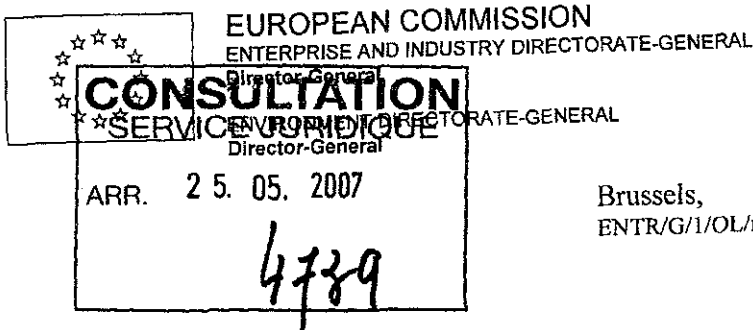
7. In conclusion, the Legal Service agrees with the views of your services that the 0.1% threshold applies to the article as produced/imported and not to components or homogeneous parts of articles.



Minas KONSTANTINIDIS



Eva KRUIKOVA



Brussels, 24 MAI 2007
ENTR/G/1/OL/mm D(2007) 15921

**NOTE FOR THE ATTENTION OF
M. MICHEL PETITE, DIRECTOR GENERAL, LEGAL SERVICE**

Subject: Article 7 and 33 of REACH: Substances present in articles above a concentration of 0.1 %

Following the adoption of Regulation (EC) No 1907/2006 (hereinafter "REACH"), DGs ENTR, ENV and JRC have been working together with stakeholders to prepare the guidance necessary for the application of the requirements established by REACH. In the course of this work, the following issue related to the interpretation of the legal text with respect to substances present in articles above a concentration of 0.1 % has been raised. We would like to obtain the Legal Service's opinion on this issue.

1. Legal text and its background

1.1 Article 7(2)

Article 7(2) of REACH obliges producers and importers of articles to file a notification in respect of certain substances of very high concern (hereinafter "SVHC") in articles in the following terms:

"2. Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:

(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;

(b) the substance is present in those articles above a concentration of 0,1% weight by weight."

Paragraphs 3 and 6 of Article 7 lay down exemptions from this obligation: no notification is required if exposure during normal or reasonably foreseeable conditions of use including