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August 31, 2006

Comments on REACH Implementation Project 3.8
Draft Technical Guidance on Requirements for Substances in Articles
Submitted via email to reach.support@jrc.it

Dear Sir or Madam:

The United States Council for International Business (USCIB) welcomes the opportunity to submit the following comments on the draft technical guidance document on requirements for substances in articles being developed as part of the Registration, Evaluation, and Authorization of Chemicals (REACH) Implementation Project 3.8.

USCIB supports the protection of human health and the environment and the comments below aim to contribute to the workability of technical guidance for articles and the proposed legislation. We urge that further input into RIP 3.8 be considered and that the guidance be revised consistent with these comments. We also highlight the need to revisit RIP 3.8 to ensure that the technical guidance for articles does not go beyond the intent of the scope of the proposed REACH legislation.

USCIB promotes an open system of global commerce in which business can flourish and contribute to economic growth, human welfare and protection of the environment. Its membership includes some 300 leading U.S. companies, professional services firms and associations, representing companies from all industrial sectors. As the exclusive American affiliate of three key global business groups – the International Chamber of Commerce, the International Organisation of Employers, and the Business and Industry Advisory Committee to the OECD – USCIB provides business views to policy makers and regulatory authorities worldwide, and works to facilitate international trade.

Our specific comments on the RIP 3.8 Report and Draft Technical Guidance for Articles are as follows:

## I. 1.3.3: Time Scheme for Substances to be Notified

Section 1.3.3 of RIP 3.8 states that information on candidate list substances must be forwarded to the professional users of the article "directly" after a substance is included in the candidate list. Article 32(4) of the Common Position is cited for this proposition but that Article simply references Article 7(7), which in turn provides for Notification to the Agency no earlier than 3.5 years after Entry into Force, and, thereafter, within 6 months after a new

substance is added to the candidate list. Thus, the need to engage in a data collection effort in order to decide on whether there is an obligation to notify articles is not triggered immediately upon the listing of a candidate list substance. Clearly, communication to downstream users of the article should not precede the requirement to investigate the presence of a candidate list substance, as the TGD suggests. Moreover, the timing of downstream communications needs to take into consideration the flow of information through the supply chain. In the case of assemblers of imported article components, the trigger for the obligation to communicate down the supply chain should be no sooner then the time that the assembler first becomes aware that the component contains a candidate list substance.

Further, RIP 3.8 should clearly state whether articles already placed on the EU market by an importer are subject to Notification and Communication to Downstream User requirements whenever a new substance is added to the candidate list. If so, this would seem to require that the article importer engage in a constant and continuous review of substances in articles, an obligation that is not clearly envisioned by the REACH text. Moreover, the TDG should make clear that articles that have already been placed on the market prior to a listing decision are not subject to an Article 7(2) investigation or an Article 32(4) downstream user communication since the company is no longer an importer or producer of the article and is no longer under an obligation to examine the article for new candidate list substances.[1]

## II. Chapter 4: Checking if Registration is Required According to Article 7(1)

The "intent" requirement should be more carefully applied to the examples given in the TDG. The obligation to register substances contained in articles under REACH is carefully circumscribed by the text of REACH. Release of a substance during use is not a sufficient criterion; the release must be "intended". Similarly, exposure to the substance is not sufficient; again there must be an intended release. Finally, there must be the intent that the substance be released during the normal or reasonably foreseeable conditions of use.

Indeed, the concept of intent is the defining element in the decision on whether there is a need to Register. We submit that the three limitations expressly provided for in the text – release by design, exclusion of unintentionally released substances even in the case of exposure, and consideration only of releases that occur during normal or reasonably foreseeable use -- means that the release of the substance must be essential to the functioning of the article and the *primary reason* why the substance has been incorporated into the article in the first instance.

The above point is clearly understood in one definition of the concept of intended release that appears in the Annex I of the RIP 3.8 final report, May 26, 2006, on page 42. That definition provides: "A release of substances from articles is intended when: The release is essential for the end use of the article or vice versa, without the release of the substances, the article would not work sufficiently."

[1] We refer to the article numbering scheme used in the Common Position as opposed to the article numbering scheme used in the RIP 3.8 Technical Guidance Document, which is based on the earlier version of the Council text.

Consistent with that definition, we believe all parties would agree that ink in pens and correction fluid in correction rollers are classic examples of substances where the release of the ink or correction fluid, respectively, is essential to the functioning of the article. Similarly, we believe there is no disagreement that substances in packaging materials are not intended to be released from the packaging. There may be some incidental or potential migration of a substance into the materials contained within the package but it can not be said that the migration is essential to the end use functioning of the packaging material.

The alternative definition of "intended release" that appears on page 43 of the TDG is inconsistent with the above analyses and includes cases where "[t]he release contributes to a quality or minor function of the article… which is not directly connected to the end use function." One can not decide that the release must be "essential" to end use, on the one hand, as is clear from the text of REACH, and in the same breath decide that the release need only contribute to a "quality or minor function" not directly connected to end use. We submit that the later definition is inconsistent with the proposed REACH legislation.

Read in the above light, it is clear that some of the examples given in Table 2 of the TDG involve products where the release is only incidental rather than essential to function and those examples should be deleted from the TDG. In particular, we view the entire category of "Textile, films and sheets with a layer of adhesive" as not meeting the intended release criterion. For example, we are hard pressed to see how the adhesive on the back of adhesive tape is intended to be released. Indeed, the adhesive is specially designed to remain affixed to the tape. Yes, there may be some release when the adhesive tape is removed from an item, but it can not be said that the release is essential to function.

In sum, we request that the examples in the TGD be reconsidered. We also ask that each example be given a careful analysis taking into consideration the narrowly tailored Registration obligation envisioned by Article 7(1) of REACH.

**Chapter 5: Checking Whether Communication of Information Under Article 32(4) and Notification Under Article 7(2) Are Required**

**5.4: Determining Whether the Article Contains Substances of Very High Concern (SVHC)**

The workability and proportionality of REACH is a central concern raised by both the Commission and the Council, but the Technical Guidance for articles is neither workable nor proportionate.

The Guidance poses disproportionate burdens on article importers and is thus contrary to Paragraph 3 of the recitations in the preamble to REACH. There will be many situations in which article importers will not be able to obtain information on the presence of candidate list substances using the guidance provided in this section. Specifically,

**5.4.1** – Obtaining product information from non-EU suppliers will be a considerable challenge in situations where such information is protected as confidential or trade secret information under national regulation or norms. Suppliers may even refuse to provide this information if their country regulations do not require it of them. This puts article importers in a different position from EU manufacturers that source article components from EU suppliers. Additionally, obtaining SVHC information for complex or multi-component articles is particularly difficult because there are numerous suppliers located around the world responsible for the individual components that make up an article. Further, the supply chains for multi-component articles are typically very complex. In many cases it may not even be possible to identify all the component suppliers for a given article let alone obtain information from them. For the above reasons, article importers are disproportionately burdened with this problem.

**5.4.2** – Chemical analysis of articles is not feasible. It is estimated that some 1200 to 1500 chemicals will be added to the candidate list. There is no methodology of which we are aware that would allow for the screening of thousands of diverse chemicals at trace concentrations. Assessing all articles for the presence of this number of chemical substances is not feasible. Moreover, chemical analyses will not distinguish between "substances" that are subject to Notification and the impurities and stabilizers associated with the substance that are not subject to Notification leading to over reporting.

The principles of workability and proportionality are best accommodated by Guidance which requires that article manufacturers and importers undertake "due diligence", consistent with the general duty of care, to obtain information about the presence of SVHCs in articles.

Due diligence should include the following:

- A data collection program under which a producer/importer requests that suppliers provide information on the presence of substances within an article.
- An understanding that a supplier can provide estimated data based on MSDS information or other knowledge regarding the substance content of an article, such as available information from resources listed in Annex 7 of the TGD for Articles, where applicable.
- A further understanding that a producer/importer is entitled to rely on the estimated information provided by a supplier, absent very clear indications that the supplier's information may be faulty.

The following should not be required for due diligence:

- Analytical testing, except possibly in very limited circumstances. The sheer volume of substances within some articles will make analytical testing time consuming and costly, assuming a producer/importer is actually able to impose a testing requirement on its suppliers.

**5.8 and Chapter 6: Checking Whether a Substance in an Article Has Been Registered for that Specific Use**

We recommend that the Article 7(6) exclusion for already registered substances should be properly stated in the technical guidance. Article 7(6) of the Common Position text provides that "Paragraphs 1 to 4 shall not apply to substances that have already been registered *for that use*." The text does not explain whether the concept of use is broad or narrow. For example, sound arguments could be made that the prior registration of a substance for use in articles generally, or for broad categories of articles such as consumer goods, would be sufficient for the exclusion of Article 7(6) to come into play. We submit that this question is outside the scope of RIP 3.8, a point the drafters have conceded by noting that use identifiers need still to be developed under RIP 3.2. See p. 38 of RIP 3.8. Nonetheless, we note that RIP 3.8 has recast the text of Article 7(6) in most instances where it appears by making reference to substances in articles already registered for a "*specific use*," which is not the term used in Common Position text. See, e.g. Section 5.8, Chapter 6. We recommend that the word "specific" be deleted wherever reference is made to the "use" referred to in Article 7(6) of the REACH text.

**5.10: Checking if Exposure can be Excluded During Normal or Reasonably Foreseeable Conditions**

We understand that RIP 3.2-2 will provide guidance on the exemption from Notification for substances in articles where exposure during normal or reasonably foreseeable conditions of use can be excluded. RIP 3.8 states that exposure to humans or the environment can be excluded if there is "*no* release of substance of concern." We are concerned that this statement prejudges the outcome of the RIP 3.2-2 deliberative process. We suggest that Section 5.10 of the RIP 3.8 not comment on the degree of exposure that is permissible under the Article 7(3) exclusion until RIP 3.2-2 has issued.

Moreover, we are concerned the limited guidance provided on the Article 7(3) exemption seems to go beyond the REACH proposed regulation. REACH Article 7(3) provides:

> "Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article in accordance with Article 32(4)."

The guidance in the draft TGD seems to make it very difficult to ever exclude exposure. Even handling a belt buckle which contains 0.3% lead is theorized as presenting an exposure hazard to the lead in the buckle. *See* page 87 of the RIP 3.8 TGD draft, which states in pertinent part:

> "Potential for emission during use(s) and disposal – Look at the routes of exposure: The routes of exposure in the case of metallic lead are by inhalation and by ingestion.

> Inhalation can be discounted in this case. However, it is within the realms of possibility that lead may be transferred from the buckle to the hands of the consumer and subsequently ingested."

The above excerpt is problematic with respect to the use of an unworkable "realm[] of possibility" standard for making exposure judgments. Again the issue of whether *de minimis* exposure satisfies the Article 7(3) criteria is a matter that should be reserved for the RIP 3.2-2 guidance.

**5.10.3: Exposure of Humans and the Environment**

We recommend that the section 5.10.3 guidance be expanded and provide examples of disposal practices that meet the criteria for excluding human and environmental exposures. Recycling or reclamation in our view should meet the criterion.

USCIB members, which do business globally, maintain significant investment and employment in Europe and serve European consumers and communities. We are eager to work with you to ensure that the technical guidance for REACH requirements for substances in articles is both workable and consistent with the intent of the proposed legislation.

Please do not hesitate to call on us if we can be of further assistance (rgoldberg@uscib.org / +1 212 703 5047). Thank you again for this opportunity to comment.

Sincerely,

Ronnie L. Goldberg
Executive Vice President & Senior Policy Officer