ORGALIME

Position Paper

Brussels, 23 September 2016

COMMENTS ON DRAFT ECHA REACH GUIDANCE ON REQUIREMENTS FOR SUBSTANCES IN ARTICLES (VERSION 4.0)

Orgalime thanks the European Chemicals Agency (ECHA) for the opportunity to comment on its Draft Guidance Document on Requirements for Substances in Articles (version 4.0).

Orgalime acknowledges the complexity of the given task and the clear new remits stemming from the Ruling of the European Court of Justice (ECJ) regarding the interpretation and implementation of Articles 33 and 7.2 of the REACH Regulation.

Our industries are fully committed to comply with the requirements stemming from these legal provisions. However, we are seriously concerned that a proportionate and workable implementation of Article 33 REACH on the basis of the draft ECHA Guidance in its present form will be impossible for companies in our sector and its many SMEs in particular.

We hereby wish to provide our comments to support ECHA in improving the present Draft Guidance so that companies have at least a better understanding of Articles 7.2 and 33 REACH and at best a chance to demonstrate compliance with Article 33 REACH in its present form.

Orgalime believes that the new ECHA guidance can only be useful and reliable, for article manufacturers, importers and enforcement authorities alike, if it duly respects the **principle of proportionality** as established in Article 5 of the EU Lisbon Treaty.

The draft ECHA guidance in its present form in our view is not in line with this principle and currently **not proportionate, workable, feasible or reliable in terms of providing sufficient legal certainty to our sector for several reasons, including the following:**

- The **principle of proportionality** (Art. 5 EU Treaty) means that the measure is limited to what is necessary to achieve the given objective. The objective of the Article 33 REACH is to allow the safe use of articles. Sub-articles (components) of complex products are often deeply integrated, assembled or joint together into the final article with no exposure under reasonable and foreseeable conditions of use. **To allow the safe use**, it would therefore in our opinion **not** be **necessary to require a complete breakdown of a complex article into all of its components.**

- European engineering companies produce articles where even the simplest product has a complexity of several orders of magnitude greater than any of the provided examples. The draft guidance limits itself to articles with a rather limited degree of complexity, such as a bicycle or small printed circuit board (PCB) of less than 9 cm² size. Even for these (still rather simple) examples, the draft guidance does not break down the suggested methodology to each component but limits itself to some parts due to the complexity of the task (see page 112, lines 18-24).

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The suggested methodology is thus already being acknowledged burdensome for such articles, while it increases exponentially with ever more complex articles made of 100, 1000, 1.000.000 or even more components. The **draft guidance in its present form fails to address the difference between articles and complex articles and fails to provide any workable solution for companies producing complex articles.** It also fails to take into account the complexity of the supply chain, which involves several tiers of suppliers (who may therefore number in the many thousands) located in- and outside the EU). The present draft guidance does not sufficiently help SMEs to understand how to deal with complex articles.

- The given aim of the Article 33 REACH requires information to be simple, clear and easy to understand in practice. **Requesting a multiplication of documents on the final article and all articles included** in it, as the draft guidance suggests (such as aircraft skin fuselage panel example on page 79 lines 29-33), **risks leading to misunderstanding, confusion, mistakes and legal uncertainty**. In addition, this double/multiple layers of information providers raises the issue of **liability** in case of misinformation or non-compliance.

- Article 33 REACH requires that companies provide the name of the SVHCs above 0.1% to their customers, and the Draft ECHA Guidance stipulates that EU manufacturers should trust the information of EU suppliers. Apart from this, the draft guidance **goes beyond these legal requirements of Articles 7.2 and 33 of the REACH Regulation and the ECJ Ruling.** For example:
    - The requirement on manufacturers to request information from EU suppliers on components not manufactured in the EU if the given substance has already been notified (see for example Appendix 4 on page 84).
    - Example 2 “multi socket power strip” on page 87 (lines 1 to 3), for which the draft Guidance says that “*The importer needs now to determine the total amount of the Candidate List Substances 1 or 2 in all articles, assembled or joined together in the power strips, which contain more than 0.1% w/w of those substances*”: This requirement is not supported by the text of Article 7 and goes beyond the requirements of Article 33 REACH. It would not be proportionate for complex articles made of hundreds and thousands components and would have no added value for the recipient of the articles. The practical implementation is impossible for the importers. As stated in the ECJ September 2015 ruling, "'*sufficient information, available to the supplier, to allow safe use of the article [in question]' must include, as a minimum, the name of that substance*".
      In addition, the suggested approach risks that manufacturers would have to publish confidential business information, since a clear identification of all components of an article will only be possible by publishing the construction and other technical files. This would not be proportionate in terms of aim and purpose of the given REACH requirements and protection of European Intellectual Property Rights.
    - The requirement on article manufacturers to provide information on waste articles (see for example page 32, line 19): Article 33 REACH refers to information for the safe "use" of "articles", while the ECJ Ruling clarifies that an article ceases to be an article if it becomes waste. Also, the given REACH definition of "use" excludes disposal. Such an extension of the scope to the waste phase lacks an explicit legal provision in the REACH text (as e.g. made for notifications by Article 7.3, for transported isolated intermediates by Article 18.4, or for chemical safety assessments by Annex I.)"
    - The Draft Guidance promotes that article manufacturers should carry out chemical analysis (see pages 44 lines 6-12 and page 79 lines 29-33): Article 33 REACH, however, clearly indicates that the information to be communicated is the one "available to the supplier" of the article.

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- Manufacturing in Europe is highly dependent on sourcing articles (including components) and individual components globally. Due to the tremendous burden of the suggested methodology, non-EU suppliers of articles (including components) and individual components needed for EU manufacturers may well decide not to supply them to Europe. Another effect could be that such non-EU component suppliers transfer all REACH related costs to EU manufacturers thereby **negatively impacting the competitiveness of European industries**. This further substantiates the disproportionate nature of the present draft guidance.

- Last but not least, **we also question the enforceability of the system as designed in the draft Guidance**. Enforcing Article 33 REACH would mean that enforcement authorities would have to carry out a complete test of any article for all (today) 169 SVHCs or otherwise arbitrarily select certain products. We see particular enforcement challenges arising, such as for example if it turns out after such a test that the article contains one or more SVHC of above 0.1% and that the supplier to the controlled company is located outside the EU. We are also concerned if authorities would be in a position to dedicate sufficient enforcement resources, as they seem to be already absorbed by enforcing for example Annex XVII of REACH.

  Even more problematic would be the enforcement of Article 7.2 REACH. A system that cannot be enforced in practice represents a huge burden for serious companies and represents an unfair advantage for free-riders.

We call for the future guidance to adopt all the practical solutions required to ensure a real enforceability of the provisions of Articles 7.2 and 33 REACH. In particular, we call on ECHA to shape the draft guidance in the following respects:

- Considering the high complexity of this issue, **start the guidance with a chapter explaining the relation between the legal texts of Articles 7.2 and 33 REACH and the ECJ Ruling** - in particular, the understanding and consequences of the last paragraph with the actual interpretation of Articles 7.2 and 33 REACH (see ANNEX I) should be explained.

- **Better clarify the definitions of "article" and "component"**, since, in our view, many uncertainties exist in this field: for example, a European manufacturer (company A) integrates electronic parts (such as a capacitator, resistors, etc.) in a product circuit board (PCB). Company A considers the PCB to be an article and all electronic parts to be components. Its European supplier (company B) however, considers electronic parts as articles. Therefore, an electric component would be the smallest article. Company A can alternatively import the same PCB from a supplier outside the EU (company C). As a result, the information about SVHC's from company B can be presented at component level and from non-European supplier C at article level thereby leading to different quality and reliability levels in the given information.

- **Align the draft guidance with the principle of proportionality** by limiting it to the necessary and appropriate level of detail to implement the objective of Article 33 of REACH. This should be done through **identifying appropriate cut-off criteria reflecting the risks involved for human health and the environment** stemming from the use of an article.

- **Include concrete examples of complex articles and their cut-off** criteria in the final guidance:

In order to identify them, ECHA should first present an example on how communication of information for complex articles consisting of thousands of components on the basis of the suggested methodology would be supposed to work. Possible examples could be a typical laptop, a complex set top box, a TV set, etc.

As a next step, ECHA should present how the methodology could be further extrapolated to super complex articles made of hundreds of thousands of components (such as medical imaging devices or industrial machinery).

In particular, these examples should provide a clear indication on how the information collected from the supply chain at the level of each single individual article (including components) would have to be transmitted to the next actor in the supply chain.
The typical article should contain thousands of components of which:

- a given percentage (but at least a few hundred components) contains SVHC above the concentration limit of 0,1%
- a given percentage has an unknown content, since information has not been provided yet by the supply chain
- glues, paint, plating, sealing, dielectric liquids and other substances are present in subassemblies and a given percentage contains SVHC above the threshold limit of 0,1%
- none of the articles and/or components has been accompanied by safe use instructions.

The ECHA example for the same article should contain two scenarios:

- Scenario 1: an article manufactured in the EU with a large amount of components imported from outside the EU
- Scenario 2: an imported article with a large amount of components

- **Provide further "simplification" by clarifying that:**
  - An (electronic) component supplied on its own represents the smallest article to be considered.
  - Components that are integrated (soldered, welded, glued, etc.) together become one single article.
  - Articles that cannot be disjointed without destroying the functionality are one single article.
  - Only information on articles (including components) where there is a risk for final users or consumers to be exposed to SVHC has to be communicated down the supply chain.

- **Remove interpretations from the draft guidance that go beyond the legal requirements** of the REACH regulation and the Ruling of the European Court of Justice.

We provide detailed comments in the enclosed Excel table.

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ANNEX I

Extract of REACH Regulation (1907/2006)

- **Article 7(2)** - Registration and notification of substances in articles:
  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:
  the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;
  the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

- **Article 33** - Duty to communicate information on substances in articles:
  1. Any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the recipient of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.
  2. On request by a consumer any supplier of an article containing a substance meeting the criteria in Article 57 and identified in accordance with Article 59(1) in a concentration above 0,1 % weight by weight (w/w) shall provide the consumer with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of that substance.
  The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

Extract of European Court of Justice Ruling – 10th September 2015 - Case C-106/14

84 Since these proceedings are, for the parties to the main proceedings, a step in the action pending before the national court, the decision on costs is a matter for that court. Costs incurred in submitting observations to the Court, other than the costs of those parties, are not recoverable.
On those grounds, the Court (Third Chamber) hereby rules:

- ***Article 7(2)*** *of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, as amended by Commission Regulation (EU) No 366/2011 of 14 April 2011, must be interpreted as meaning that, for the purposes of application of that provision, it is for the producer to determine whether a substance of very high concern identified in accordance with Article 59(1) of that regulation, as amended, is present in a concentration above 0.1% weight by weight of any article it produces and, for the importer of a product made up of more than one article, to determine for each article whether such a substance is present in a concentration above 0.1% weight by weight of that article.*

- ***Article 33*** *of Regulation No 1907/2006, as amended, must be interpreted as meaning that, for the purposes of application of that provision, it is for the supplier of a product one or more constituent articles of which contain(s) a substance of very high concern identified in accordance with Article 59(1) of that regulation in a concentration above 0.1% weight by weight of that article, to inform the recipient and, on request, the consumer, of the presence of that substance by providing them, as a minimum, with the name of the substance in question."*