



## **COMMENTS ON CARACAL WORKING DOCUMENT: “REACH AND DIRECTIVE 2011/65/EU (RoHS) – A COMMON UNDERSTANDING”**

Brussels, 7 February 2014

ORGALIME, EUROMETAUX and Cefic highly appreciate and fully support the Commission’s initiative to develop a Common Understanding on the implementation of the REACH Regulation and Directive 2011/65/EU concerning the restriction of certain hazardous substances in electrical and electronic equipment (RoHS).

### **1. Why should a Common Understanding be developed?**

Such a **Common Understanding is urgently needed** by the European industry, considering the increasing overlaps and inconsistencies arising from an insufficiently coordinated implementation of the horizontal REACH Regulation and the sector specific RoHS Directive today. For example:

- Inconsistency of entry 23(7) annex XVII REACH and entry 8b RoHS annex III regarding exemption of cadmium from restrictions in electrical contacts have been identified during the REACH review.
- Three Phthalates (DEHP, DBP, BBP) are on annex XIV REACH list of substances subject to authorisation (sunset date: February 2015), while RoHS examines and suggests new restrictions of these substances in EEE on the basis of a new substance evaluation methodology that is not aligned with REACH. Following a negative opinion of REACH scientific bodies (RAC and SEAC) on a Danish annex XV restriction proposal for these phthalates, Denmark introduced a national restriction.
- Sweden has proposed an annex XV dossier to restrict the use of lead and its compounds in consumer articles, which can be placed in the mouth by children, and which are made available for consumers or intended for consumer use. This initiative does not explicitly exclude electrical and electronic equipment, while RoHS already restricts the use of lead for EEE since 1 July 2006. The recent REACH RAC opinion and SEAC draft opinion confirm this overlap and recommend derogating articles already regulated under existing Community legislation, in particular, excluding EEE in scope of RoHS from the newly proposed REACH restriction.
- Lead compounds are considered for identification as substance of very high concern and cadmium and cadmium oxide are already on the REACH candidate list, even though cadmium and lead have been restricted in EEE since 1 July 2006.

The current lack of a Common Understanding on the interface between REACH and RoHS and the fact that they both cover the use of substances in electrical and electronic equipment (EEE) puts significant administrative and regulatory burden on the affected European industry and gives rise to legal uncertainty.

In addition to the multiplication of costs and work - as files and test reports have to be prepared under both legal frameworks - there is an increasing risk of conflicting new restriction and authorisation requirements, which will negatively impact the commitment of this industry to ensure timely and proper compliance with all legal requirements.

Developing a Common Understanding is in our view both necessary and beneficial for Member States as well, since legal inconsistencies and conflicting requirements will also hinder **proper implementation and enforcement at national level**.

Finally, the objective of **environment and human health protection** will be strengthened by a holistic evaluation of any substance targeted for risk management as the basis for a clear, coordinated and mutually reinforcing implementation of RoHS and REACH.

***We therefore consider it vital to develop a Common Understanding for a better interaction between REACH and RoHS in order to ensure consistent judgements and decisions that will ease preparations for compliance, the implementation and enforcement of both legal instruments in respect of their objectives to protect human health and the environment.***

## **2. What should the Common Understanding address?**

We welcome the Commission working document as proposed at the CARACAL meeting of 28.11.2013 as a means to increase legal certainty for companies and minimise overlaps and inconsistencies between REACH and RoHS. In our view, it draws a fair picture of the current situation and identifies the remaining challenges.

**The document generally builds on the proposal to exempt EEE from the scope of REACH (restriction or authorisation) where RoHS takes into account the protection of human health and the environment at all stages. This constitutes a very welcome big step forward.**

However, the working document also confirms that the current draft Methodology for Identification and Assessment of Substances for Inclusion in Annex II to RoHS ('RoHS Methodology') (as developed by the Austrian UBA on behalf of DG Environment, cf. <http://www.umweltbundesamt.at/rohs2>) is not addressing all stages of the life cycle in its proposed risk assessment, but focuses on hazardous substances and concerns solely related to their waste phase. Therefore, in practice, **overlaps and inconsistencies will not be resolved if the working document's concept was to be applied without modifying the draft RoHS Methodology.**

The **first main element** of any effective solution would therefore be to **ensure that REACH risk assessment procedures are fully taken up in the draft RoHS Methodology** that is currently under preparation, as hinted by the working document. ORGALIME, EUROMETAUX and Cefic call upon regulators to shape the current draft RoHS Methodology in this way.

In our view, this is not only legally possible but necessary in the light of the explicit requirement of Article 6 of RoHS stating that the RoHS Directive's substance evaluation methodology "*shall be coherent with REACH*".

This step also appears relevant to us in the light of the recent ruling of the European Court of Justice annulling the tightening of the restriction on cadmium pigments in plastics and obliging regulators to carry out a thorough risk assessment when setting substance restrictions (please cf. [herese http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62011TJ0456:EN:NOT](http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62011TJ0456:EN:NOT)).

**Shaping the draft RoHS methodology in a way that it is aligned with REACH risk assessment procedures ruling should thus constitute a first step. Further elements that should in our view be taken up in the Commission’s working document on a Common Understanding are the following:**

- Setting in place a structured, continuous, transparent communication exchange between the REACH and RoHS officials of the European Commission involved in both legislations, preferably with the involvement of the affected stakeholders. Any potential new conflict zone or area that may require further clarification and/or Common Understanding should in our opinion be regularly discussed and decided upon in CARACAL.
- The RoHS Methodology should be risk based, assess substances and their alternatives from a life cycle perspective, take socio-economic aspects into consideration, use the CLP definition of “hazardous substances” and use REACH and CLP as its main information source.
- Regarding the Swedish restriction proposal for lead, if adopted, EEE should be excluded from its scope.
- Regarding phthalates, should RoHS set new restrictions, Article 58.2 of REACH should be applied where RoHS grants exemptions.
- The Commission has explicitly stated on earlier occasions that RoHS is not the vehicle to combat illegal waste management practices, as other, more suitable pieces of legislation need to be strictly enforced to handle these problems. We fully support this and kindly request this to be spelled out explicitly in the future guidance document on a Common Understanding of REACH and RoHS.
- Finally, from a wider perspective, this debate ties in with the debate on Risk Management Options (RMO) analysis as currently held under REACH and the identification of the best (legal) measure to address potential risks for human health or the environment. The Common Understanding developed for RoHS and REACH should therefore be taken into account in the future activities on RMOs.

The table hereunder specifies these general comments for the different scenarios described in the Commission working document:

SCENARIO OF COMMISSION WORKING DOCUMENT	ORGALIME – EUROMETAUX - Cefic REMARKS
<b>RESTRICTION</b>	
<p><b><u>Scenario 1 [Restriction proposed under REACH for a substance already in RoHS Annex II]</u></b></p>	<p>We support the proposal to exclude EEE within the scope of RoHS from the scope of a proposed REACH restriction also covering EEE, as was the case for entry 45 of Annex XVII REACH. To ensure a coherent and systematic implementation of this solution, the draft RoHS Methodology should be aligned with REACH risk assessment procedures, as highlighted on page 2 and 4 of the suggested Common Understanding, in order to ensure that RoHS qualifies against the REACH criterion of adequately controlling the risks presented by a substance in EEE throughout the lifecycle.</p> <p>The overall objective should be to have one holistic assessment for a substance used in EEE to be used for the implementation of both, RoHS and REACH.</p> <p>The alignment of the RoHS methodology with REACH risk assessment procedures is a precondition for consistent judgments and decision under both policy tools.</p>

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<p><b><u>Scenario 2 [Restriction in place under REACH when a new substance is proposed for inclusion in RoHS]</u></b></p>	<p>We support the suggested understanding that if REACH already restricts the use of a substance, RoHS should no longer look at this substance. In principle, the situation described in the working document (decision to establish more stringent measures for EEE under RoHS despite the existing REACH restriction already covering EEE) should not arise, as the risk assessment performed under REACH already covers the waste management stage. If the Commission or Member States propose to tighten the conditions of an existing REACH restriction covering EEE, the REACH risk assessment should be updated as a first step. The RMO analysis shall assess the best risk management option for the given case at the given time.</p>
<p><b><u>Scenario 3 [Annex XV proposal for a restriction under REACH for a substance used in EEE but not yet restricted under RoHS]:</u></b></p>	<p>We support the second alternative given in the working document, namely to start the restriction procedure under REACH, and if RAC and SEAC confirm that a restriction of a substance in EEE is justified and proportionate, to implement it under RoHS (see p. 5).</p> <p>The option of setting a REACH restriction first and amending it at a later stage when the substance is in RoHS Annex II creates, in our view, confusion and legal uncertainty.</p>
<p><b>AUTHORISATION</b></p>	
<p><b><u>Scenario 1 [Substance proposed for inclusion in REACH Annex XIV which is already restricted under RoHS Annex II]</u></b></p>	<p>The working document highlights the possibility of using Art. 58(2) REACH to exempt the uses covered by the RoHS restriction (including the applications exempted under RoHS) from the authorisation requirement, provided the risk is properly controlled under RoHS. We support this solution, as it would</p> <ul style="list-style-type: none"> <li>(i) relieve companies that already applied for and obtained an exemption under RoHS to apply for authorisation under REACH for the same application (and subsequently apply for renewal under both frameworks);</li> <li>(ii) avoid putting EU manufacturers at a disadvantage versus non-EU manufacturers selling EEE in the EU, since REACH authorisation requirements would not apply to EEE imported from outside the EU.</li> </ul> <p>We therefore support this suggested way forward. We remind of the need to align the draft RoHS Methodology with REACH risk assessment procedures.</p>
<p><b><u>Scenario 2 [Substance already in REACH Annex XIV when it is proposed for being restricted under RoHS Annex II]:</u></b></p>	<p>In line with our comments on Authorisation Scenario 1, where it is proposed to restrict under RoHS with exemptions, Art. 58(2) REACH should be used to exempt the relevant uses regulated under RoHS (both restricted and exempted) from the authorisation requirement.</p>

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	We remind the need to align the draft RoHS Methodology with REACH risk assessment procedures.
<b><u>Scenario 3 [Substance not yet included in REACH Annex XIV or RoHS Annex II]:</u></b>	A case by case approach may be needed that should be determined during the RMO analysis. We remind of the need to align the draft RoHS Methodology with REACH risk assessment procedures.

### 3. Conclusions

We conclude that there are the following key issues for the Common Understanding on the RoHS-REACH Interface in order to ensure legal certainty and facilitate preparations for compliance and enforcement:

- 1) REACH risk assessment procedures need to be taken up for RoHS implementation in order to provide for one holistic commonly accepted scientific and technical substance evaluation method that should be valid under both legal acts.  
The REACH Regulation should be the primary vehicle to gather information on substances. The RoHS methodology should specify what information needs to be gathered for a proper implementation of the RoHS Directive.
- 2) The RMO analysis under REACH needs to fully take into account existing legal measures and objectively choose the best legal instrument in case additional risk management is necessary.

In the interest of a mutually reinforced implementation of both, RoHS and REACH, ORGALIME, EUROMETAUX and Cefic kindly seek your support for these comments and recommendations.

Our more detailed views are available here:

[Joint PP RoHS Methodology](#)

[Orgalime PP Complementarity RohS-REACH](#)