Preliminary comments on the revision of Annex II of the RoHS Directive
Joint submission from Cefic, Eurometaux, Orgalime and PlasticsEurope
June 13, 2013

1 – Preliminary remarks

The undersigned acknowledge that the updated Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances under the RoHS2 Directive ("RoHS Methodology") as presented during the 2nd stakeholder meeting and described in the Draft Manual released by the Austrian UBA on 7 May has integrated some of the issues raised during the second consultation:

- References to the REACH Regulation where the assessment of substances is concerned
- Reference to chapter R.18 of the ECHA guidance on exposure scenario building for the waste life phase
- Clearer decision trees and improved criteria for prioritisation

However, we believe that the methodology should be further improved in order to ensure that the implementation of the RoHS2 directive achieves maximum coherence and efficiency in dealing with its main remit, which is the restriction of hazardous substances used in electrical and electronic equipment ("EEE"). More emphasis is therefore needed on the assessment, including the waste phase, rather than on the production volume as is the case in the Draft Manual.

We would therefore like to offer some constructive comments and suggestions.

2 - General views on the revision Annex II of the RoHS Directive

- The methodology and the policy should be fully risk-based and based on the whole life cycle of the substance which is investigated, including all impacts for human health and the environment.

- References to REACH: overall, we urge Austrian UBA to go further in strengthening the coherence between the RoHS2 Directive and REACH regulation. It is crucial to avoid any overlaps and inconsistencies between these two pieces of legislation. The development of the RoHS methodology must not ignore the legal requirements set out in Rec. 10, 16 and Art. 6.1 of the RoHS2 directive. According to these provisions, the review and amendment of the list of restricted substances should be "coherent, maximise synergies with, and reflect the complementary nature of the work carried out under other Union legislation, and in particular under Regulation No 1907/2006". Further, it should "take into account Annexes XIV and XVII to that Regulation". The fact that the REACH regulation and the RoHS2 Directive have different scopes and objectives (as rightly stated on page 8 of the Draft Manual) does not infer that the RoHS Methodology should ignore the work carried out under the REACH Regulation and its assessment procedures.

- Information sources: information gathered under the REACH Regulation should be the main source of data used in the assessment of substances under RoHS, as is acknowledged on page 28 paragraph 5 of the Draft Manual. This includes the results of the ongoing substance evaluation process (CoRAP). Should any other source for information be used in the RoHS substance identification process, a thorough assessment of the quality of its data must be performed beforehand.

- Reassessment of previously assessed substances (such as in the Öko-Institute study of 2008) should only take place when relevant new scientific information is available on potential negative impacts in the relevant life cycle stages, including the waste phase of EEE, due to the presence of these substances. This is an important principle that should also apply for new substances that may be assessed and then rejected, according to the RoHS Methodology.

- Definitions: When referring to categories of substances, the RoHS Methodology should clearly make a reference to the legal provisions where those categories are defined (e.g. "hazardous" according Art. 3 CLP, "PBT" or "vPvB" according to Annex XIII REACH, "SVHC" or "of equivalent concern" according to Art. 57 REACH). Where no agreement exists at EU level on the criteria delimiting a specific category, that category should not be referred to in the Draft Methodology.
    - Endocrine disruptors: no reference should be made to endocrine disrupting properties before the Commission makes its final proposal on the criteria
    - Nanomaterials: the definition used should be in accordance with the Commission's Recommendation of 18 October 2011

  For consistency, wherever the Draft Methodology refers to "hazardous waste", the criteria used should be in accordance to those set out in the Waste Framework Directive and the European List of Waste.

- Responsibility for substance assessment: The undersigned are concerned that no further clarity was brought to this important topic during the 2nd stakeholder meeting. The Draft Manual states (on page 8 second paragraph) that *"There is neither a legal mandate nor an obligation to copy the procedure of substance restriction under REACH and involve ECHA and its scientific committees (RAC, SEAC)",* stating further that the "*The responsible body for the assessment of substances with a view to a potential inclusion in Annex II of RoHS2 is the Commission*". This statement was put in question by the Commission during the stakeholder meeting and we strongly feel that in order to be robust and credible, the RoHS Methodology should establish a unanimously recognised scientific body that will ensure that any restriction is based on a thorough assessment based on scientific evidence, as required by Article 6 of the RoHS2 Directive. Such a quality management process with qualified experts is not foreseen at the moment.

- Illegal management of waste: We believe that the fight against the illegal treatment and shipment of waste is of the utmost importance, but we will nevertheless insist that the scope of RoHS is the **legal European** framework for "the restriction of the use of hazardous substances in EEE to contribute to protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE" (Art. 1 RoHS). Any considerations pertaining to the unlawful export or treatment of waste is inappropriate to RoHS and should therefore be avoided in this text. The Commission is well aware that separate regulatory measures, such as the Waste Shipment Regulation, Basel Convention on the Control of Transboundary Movement of Hazardous Waste and their Disposal have been ratified for this express purpose. If the concern lies with the improper management of waste within the EU, then the Waste Framework Directive and the Waste Shipment Regulation provide an adequate mechanism to deal with this issue. For EEE, the recast Waste Electrical and Electronic Equipment Directive (WEEE) has been explicitly amended with tighter rules regarding the shipment of used EEE to address this issue to the maximum extent possible.

- The procedure to assess and adopt proposals for future modifications to Annex II of the RoHS2 Directive and its methodology need to take into consideration:
    - Proposals by Member States for additional restrictions and the periodical reviews by the European Commission should follow all the steps of the Methodology
    - Stakeholder consultations should be foreseen throughout the assessment and the adoption of any additional restrictions
    - Care will be taken to avoid any "black-listing" or premature de-selection of substances due to the publication of intermediate lists from the various stages of the assessment

3 – Comments on the methodology presented in the second Draft Manual of May 2013

- Figure 1 - overview of the RoHS Methodology: This decision tree establishes a "fast track" possibility for Member States to skip a crucial part of the process and proceed directly to Part 2 of the assessment, which does not appear to be justified. We believe this would be inefficient as it may create duplication and overlaps. For example, any hazardous properties determined in Part 1 should not be subject to reassessment in Part 2.

  In view of these considerations, we propose to replace the original decision tree by the one detailed here below, in order to simplify the process and make it more transparent, whilst avoiding any duplication of work. The table we propose here, on page 4, combines the decision trees presented in pages 12 and 20 of the Draft Manual:

    - Part 1: Identification. For a substance to be identified for pre-assessment, it should be:
        - Present in EEE and
        - Hazardous according to the CLP Regulation (includes Annex VI with mandatory harmonised classifications), REACH Annexes XIII, XIV or REACH Art. 57f

      If the substance does not comply with the above criteria, the substance will exit the system and should only be re-assessed if new scientific evidence comes to light.

      Remarks:

        - If legally binding measures exist or are under consideration for restricting the substance in EEE (e.g. under REACH, POPs convention), it should be discarded for further assessment under the RoHS2 Directive. This assessment is of key importance to avoid overlaps in restrictions with other pieces of EU legislation, as has been acknowledged by the Commission in the REACH Scope Review (SWD/2013/025). Therefore, it is crucial that this assessment be carried out in a systematic and exhaustive manner

          In the case of REACH, it has been established as part of the RMO analysis that sector- or use-specific legislation such as the RoHS2 Directive can be used to address the identified risk for human health or the environment. This should therefore be assessed as early as possible in the process, in order to avoid any unnecessary duplication of work.

        - Nanomaterials are to be dealt with according to the Commission Recommendation of 18 October 2011. A report published in 2009 by the EU Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) states that: "… nanomaterials are similar to normal chemicals/substances in that some may be toxic and some may not. As there is not yet a generally applicable paradigm for nanomaterial hazard identification, a case-by-case approach for the risk assessment of nanomaterials is still recommended."

- Part 2: Pre-assessment – prioritisation for full assessment – The criteria to be considered during this phase should be:
    - 1° Relevant volume specifically used in EEE applications
    - 2° Potential concern for release, including during waste phase
    - In the case that a high score is obtained for both the first and second steps, only then should the scoring for human health and/or environmental hazards should be carried out.
    - There should be no specific scoring of nanomaterials, as singling them out as a group goes against the conclusions of the 2nd regulatory review on nanomaterials, which establish that nanomaterials are not to be considered as more or less hazardous than their "macro" equivalents. By including all nanomaterials in Part 1, their assessment in Part 2 becomes redundant
    - Here again, if the substance does not comply with the above criteria, the substance will exit the system and should only be re-assessed if new scientific evidence comes to light
- Part 3: Full assessment
    - Assessment of the risk for human health and the environment and proof of uncontrolled risk, including during the waste phase of the EEE
    - Additional risk reduction beyond what is already provided for under existing EU legislation (e.g.: workers' protection, Industrial Emissions Directive, Water Framework Directive, EU waste legislation, REACH or other EU chemicals legislation) is to be taken into account for the full assessment.
    - Socio-economic assessment, including considerations on how critical the substance is for EEE
    - Existence of fully assessed substitutes that are suitable for the entire range of applications. All factors, e.g. HSE profile, risk during all relevant life cycle stages, technical performance, cost, availability and reliability should be taken into consideration. If this criterion is not satisfied, the substance should exit the system and be reassessed again only if/when suitable substitutes are identified.

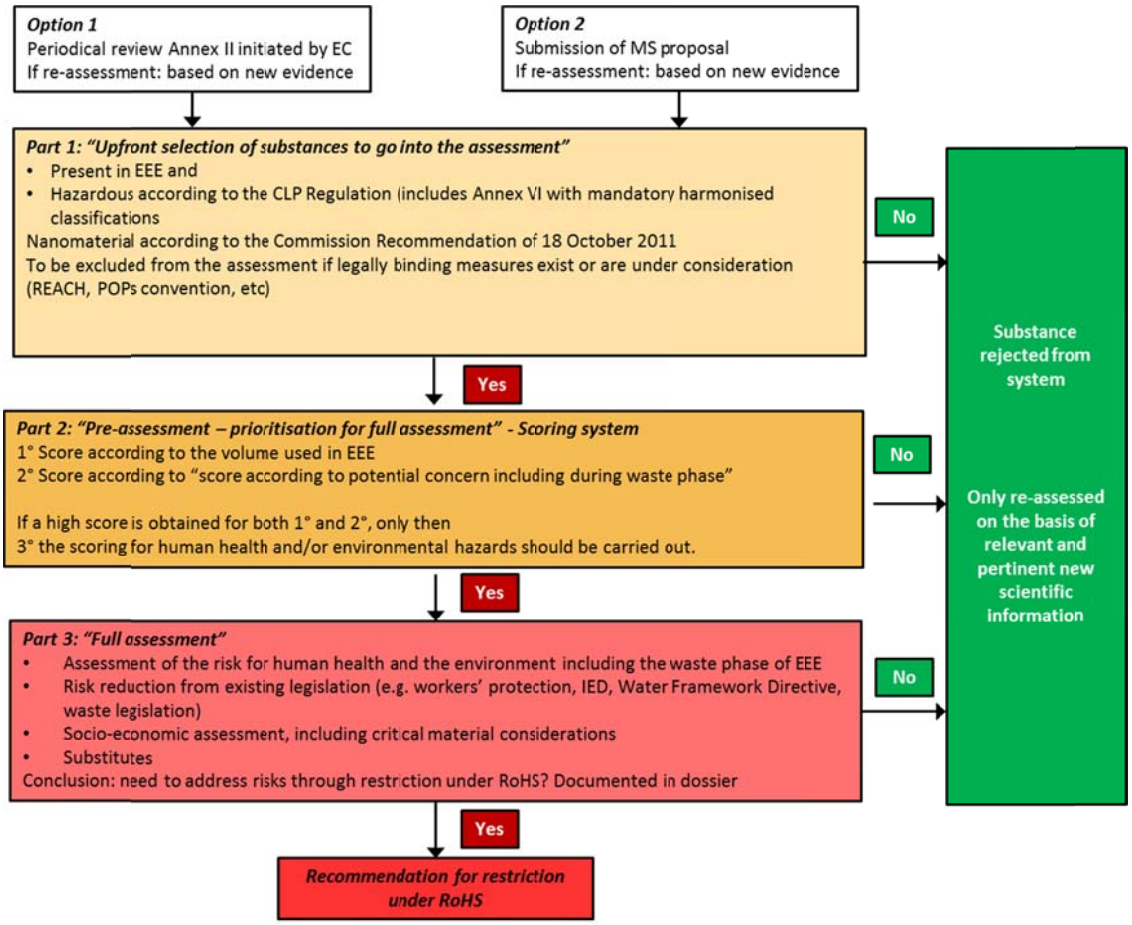

Fig. 1 – overview of the methodology

- Working list: Substances going through the identification and assessment process described above will constitute the "working list". During the 2nd stakeholder meeting, it was clearly stated by both the Austrian UBA and the Commission representatives that this working list will not be made public. The undersigned salute this decision as disclosing the list would lead to premature and pre-emptive de-selection.

4 – Pre-assessment and prioritisation – Scoring system

- As a general remark, we would like to point out that the scoring categories suggested in pages 23, 24 and 26 of the Draft Manual either duplicate existing hazard classes, as pointed out in our preliminary remarks page 1 and in our decision tree page 4, or take into consideration aspects that should not be relevant to prioritisation.
- Endocrine disruptors (EDs): the methodology mentions three categories although the Commission work on defining criteria for endocrine disruptors is still ongoing. As discussed during the stakeholder meeting, we therefore suggest deleting any mention of EDs until the Commission finalises its work on their characterisation.
- Production volumes: table 3 on page 26 of the Draft Manual uses the three categories of the ECHA registration database. It must be stressed that these registration volumes are relevant to the total produced volume of a given substance, without any information regarding their presence or use in EEE. The decision tree we suggest on page 4 simplifies this by using two categories according to their use in EEE specifically. These two categories should be defined with the input of all affected stakeholders. We therefore suggest deleting table 3 on page 26.

- The Draft Manual does not foresee in steps 5 and 6 to assess whether or not other risk management options exist - other than a ban of the substance - that could solve the problem, e.g.: improving collection, dismantling and sorting of waste. Furthermore, the evidence that some treatment methods require "higher sophistication" should not be listed as "negative impacts on waste management" (cf. pages 41-42 of the Draft Manual) but should rather be viewed as risk management options.

5 – Detailed assessment of prioritised/selected substances

- Figure 4 page 29: scheme of the detailed assessment
    - This table contains elements that are at odds with what has been described in pages 1 to 28 of the Draft Manual
    - The table refers to "compilation of information on hazard and risk for human health". We believe the main source of data for the assessment of substances should be the REACH Regulation, as acknowledged on page 28 paragraph 5 of the Draft Manual. A thorough assessment of data quality and relevance of this additional data must be performed before any other data sources are used as a reference.
    - Information sources: the Draft Manual in points 5.1 and 5.2 suggests several data sources. We strongly believe that this will simply add confusion and distract from the true purpose of the methodology: to identify substances that should be prioritised for assessment of their hazard in the context of EEE applications. In order to avoid confusion in the future we recommend that any reference to non- governmental or other individual stakeholder lists be removed from this methodology. As a result, steps 1c and 1d should be deleted. and step 1 should simply read: "Compilation of detailed information on the identification, classification and labelling status of the substance, on its use in EEE (specifying in which component) and on the legal and restriction status"

To avoid confusion, we therefore recommend that steps 1 to 4 should proceed as in the diagram below, with steps 5 and 6 remaining as they are described currently in the Draft Manual:

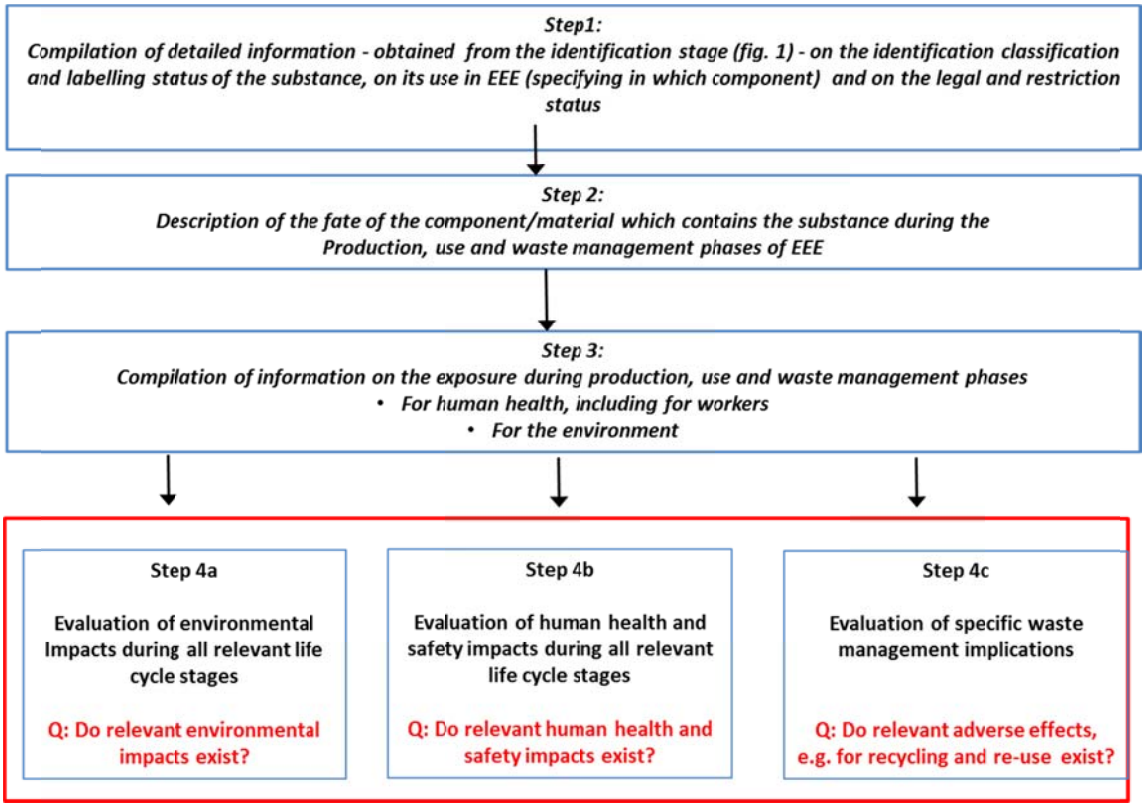

Fig. 2 Scheme of the detailed assessment

For further information, please contact:
Cefic: *Maggie Saykali, Advocacy Director Petrochemistry, msa@cefic.be*
Eurometaux: *Dr. Inneke Claes , EHS Manager waste and chemicals, claes@eurometaux.be*
Orgalime: *Sigrid Linher, Energy and Environment Manager, Sigrid.linher@orgalime.org*
PlasticsEurope: *Patricia Vangheluwe, Director Consumer & Environmental Affairs, patricia.vangheluwe@plasticseurope.org*