Position Paper

Brussels, 8 March 2013

Ensuring a truly complementary, coherent and consistent implementation of REACH and RoHS2

EXECUTIVE SUMMARY

Electrical and Electronic Equipment falls in the scope of both, Directive 2011/65/EU (Recast RoHS Directive, or "RoHS2") and Regulation (EC) No 1907/2006 (REACH).

Manufacturers of such equipment therefore have to implement the requirements stemming from both pieces of legislation. To be in a position to ensure full and timely compliance with all requirements applying on their products and processes due to either regulation, industry needs legal certainty, consistent requirements and no redundant overlaps in requirements.

Legislative overlaps and inconsistencies are however ever more imminent as REACH and RoHS2 implementations progress, especially in two areas:

- Existing and potential new restrictions on the use of certain substances in EEE and the related preparatory substance evaluation processes in RoHS2 and in REACH.
- The obligation on EEE manufacturers to seek REACH authorisations in addition to RoHS exemptions for same substances in same products and processes.

We welcome that the Commission has acknowledges these cases in its REACH Review Communication and is committed to minimise and avoid overlaps.

This paper therefore aims at:

- Providing more information on these overlaps and inconsistencies.
- Providing concrete suggestions for establishing the urgently needed common understanding for a truly complementary, coherent and consistent implementation of RoHS2 and REACH.

In this context, our industry calls regulators to support the following principles:

- A **better interaction between REACH and RoHS to ensure consistent judgements and decisions** that ease the implementation of both regulations in companies in respect of their pursued environmental objectives.
- A **better coordination and structured, continuous communication between the different actors** involved in the implementation of both pieces of legislation, including authorities as well as affected stakeholders.
- **Full transparency** throughout the implementation process of both pieces of legislation.
- **Increased legal certainty** for companies on what procedure, process, rules and criteria will apply in which case.
- Keeping **administrative burden, costs and workload** in companies as well as authorities to the minimum level possible. A **mutually reinforcing and truly consistent implementation** of both pieces of legislation in line with the **EU's wider Industrial Policy**, which requires policy makers to act in a coherent fashion and seeks to reduce administrative burdens.

Orgalime, the European Engineering Industries Association, speaks for 39 trade federations representing some 130,000 companies in the mechanical, electrical, electronic, metalworking & metal articles industries of 23 European countries. The industry employs some 10.2 million people in the EU and in 2011 accounted for some €1,666 billion of annual output. The industry not only represents some 28% of the output of manufactured products but also a third of the manufactured exports of the European Union.

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Our industry seeks regulators' support for the following concrete recommendations for the way forward:

- Regulators should take a **clear decision clarifying which procedure** (REACH restriction, RoHS restriction, REACH authorisation, RoHS exemption, measures under other EU environment and waste acquis, such as the Waste incineration, Industrial Emissions or WEEE Directives) **will be considered appropriate in which case and consequently, a consistent application of this decision** by all regulators involved throughout REACH and RoHS implementation processes. A common guidance document of all affected Commission services would be helpful.
- **Affected stakeholders should be involved and consulted** in a coordinated, well-structured and continuous manner for the establishment of this guidance document and throughout RoHS and REACH implementation: ideally, a Roundtable should be created.
- Substance evaluations need to be built on reliable scientific and technical evidence. Industry asks for **one commonly accepted scientific and technical evaluation per substance that is valid for both, REACH and RoHS implementation**.
- Including **Risk Management Options (RMOs) on a standard basis in Member States´ preparations and submissions of REACH annex XV dossiers as well as any Member State's proposal for RoHS substance restrictions following article 6 RoHS** could in our view be a possible solution for identifying the appropriate procedure in a given case.
  We suggest that a RoHS restriction proposal should equal a REACH annex XV dossier.
- New restrictions under either regulation have to follow a **risk based approach** (risk = hazard x exposure).
- New restrictions under either regulation have to follow **a life cycle approach**, including the **life cycle relevance** of substance effects arising at the waste phase (see article 6 RoHS2).
- Where a substance is already restricted under the sector specific **RoHS2 Directive as lex specialis**, REACH should not establish a restriction for the same substance use in EEE.
- In its **REACH Review Communication**, which we widely welcome, the Commission announced it would minimise or avoid overlaps or potential overlaps through (a) inviting ECHA to change guidance, if appropriate; and (b) implementing legislation under REACH or other EU sector-specific legislation in particular when considering future restrictions and substances subject to authorisation. This **should be fully supported and implemented**.
- In the light of this, the **existing ECHA Guidance on information requirements and chemical safety assessment, chapter** *"R.18: Exposure scenario building and environmental release estimation for the waste life stage",* version 2.1 of October 2012, **needs to be fully implemented** during the REACH implementation process, and taken into account in the implementation process of RoHS2. Where data and information gaps exist, REACH should be the primary vehicle to fill them. The RoHS methodology should determine what kind of information should be generated and made available via a better REACH implementation, that is during registration and evaluation, to allow for a proper RoHS implementation.
- In case Chemical Safety Reports (CSRs) of the REACH substance registration dossier do not include sufficient information regarding risks arising from emissions at the waste stage, the **missing information should be requested** from the respective registrant (Consortium/Substance Information Exchange Forum) **during REACH evaluation**, as foreseen in the REACH Regulation, and subsequently be taken into account in RoHS2 implementation.
- Both, RoHS and REACH, require **a scientifically based, structured preparatory evaluation process before setting any new substance restriction – these processes should be as closely linked with each other as possible:** article 6 RoHS2 opens the door as it explicitly requires that the RoHS evaluation methodology "*shall be coherent with*" REACH and "*maximise synergies*" between both regulations. This should in particular mean:
  - Taking into account/seeking the opinions of the REACH Risk Assessment and Socioeconomic Analysis Committees in the preparatory process of potential new RoHS2 restrictions, next to findings from implementation of the ECHA Guidance on

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information requirements and chemical safety assessment, chapter "R.18, and additional information obtained during the REACH evaluation process.
    - Taking into account the publicly available knowledge obtained from REACH in RoHS2 implementation, notably the information available at the website of the European Chemical Agency ECHA (http://www.echa.europa.eu).
    - An implementation of article 6.2 RoHS2 (information requirements for proposals for reviewing/amending the list of restricted RoHS2 substances) that is equally coherent with REACH.
    - Where the sector specific RoHS2 Directive, as lex specialis, grants an exemption of a certain application specific use to the RoHS restriction, REACH should in **application of article 58.2 REACH** not require REACH authorisation for the granted duration of the RoHS exemption.
- Where a new substance restriction is established under either regulation, **sufficient timelines need to be given to industry to prepare for compliance.**

Orgalime substantiates its position hereafter:

I. THE CURRENT SITUATION: WHY AN ISSUE?

Electrical and Electronic Equipment (EEE) falls in the scope of both Directive 2011/65/EU (Recast RoHS Directive, or "RoHS2") and Regulation (EC) No 1907/2006 (REACH).

Manufacturers of such equipment therefore have to implement the requirements stemming from both pieces of legislation.

It is the **objective and commitment of our industry to ensure full and timely compliance with all requirements applying on their products and processes** due to either regulation.

However, **legal certainty, consistent requirements and no redundant overlaps in requirements are essential prerequisites** for manufacturers to carry out this task, as well as for realising the environmental and human health objectives pursued by these legislations.

With the final adoption of the Recast RoHS Directive ("RoHS2") and the increasing speed of REACH implementation, manufacturers are increasingly faced with **legislative overlaps and inconsistencies between these two pieces of legislation, double requirements** for the same substance used in the same equipment and the same process. As a consequence, **additional administrative burden and costs occur for companies** with, in most cases, limited or no environmental benefit. Moreover one of the consequences of this (in relation with REACH authorisation which affects manufacturing processes whereas RoHS affects products placed on the market) means that manufacturing in Europe can give rise to a competitive disadvantage.

Overlaps and inconsistencies become particularly evident in the following two areas:

1. **Setting (new) restrictions on the use of certain substances in EEE (Article 6 and recital 10 RoHS2 with REACH title VIII, articles 68-73, annex XVII)**

    - *Annex XVII REACH already today includes certain restrictions that also affect EEE manufacturers in addition to RoHS2 restrictions, e.g.:*
      Commission Regulation 847/2012 restricts the placing on the market of measuring devices intended for industrial and professional (including healthcare) uses containing **mercury** such as in barometers, hygrometers, manometers, sphygmomanometers, strain gauges to be used with plethysmographs, tensiometers, thermometers and other non-electrical thermometric applications, mercury pycnometers and mercury metering devices for determination of softening point.

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- *Both, RoHS and REACH implementations investigate on the same substances in view of possible new restrictions, including of the use in EEE and its manufacturing processes:*
  - *Phthalates* (DEHP, DBP, BBP): Denmark submitted an Annex XV dossier proposing restrictions on four Phthalates (DEHP, DBP, BBP and DIBP). The REACH Risk Assessment Committee and the Socio Economic Analysis Committee have adopted their opinion[1] on these 4 phthalates in articles with a view to whether or not amend the list of restrictions in Annex XVII REACH. Denmark has meanwhile adopted a national restriction on these four phthalates, while under RoHS three of them (DEHP, DBP and BBP), are subject to review and assessment as a priority.
  - *Lead and its compounds* in articles intended for consumer use: Sweden has notified its intention to submit an annex XV restriction dossier to REACH Registry of intentions.

- *Article 6 RoHS establishes a methodology for new restrictions under RoHS, while title XVII REACH provides the relevant EU-wide framework for setting restrictions (EEE not being excluded):*
  - RoHS requires its methodology "*to be coherent*" with REACH. Implementation activities of the responsible Commission services are today, however, happening in isolation from each other without sufficient coordination.
  - Article 6 RoHS particularly emphasises future restrictions to address negative substance effects occurring in the waste phase. Overlaps with REACH are possible, since REACH also addresses issues related to disposal and recovery of waste, and in particular the risks arising from a substance on its own, in a preparation or in an article at the end of life stage.[2]

- *The Commission's REACH Review Communication and preceding study (carried out by consultant Milieu)[3] identify an inconsistency of entry 23(7) of annex XVII REACH and entry 8b RoHS annex III regarding exemption of cadmium from restrictions in electrical contacts*: The REACH Regulation is stated to conflict with RoHS2 as the following REACH term "*on account of the reliability required of the apparatus on which they are installed*" provides a

[1] *Compiled RAC and SEAC opinion*

[2] According to Article 2(2), waste is not a substance, a preparation or an article within the meaning of REACH. However, REACH also addresses issues related to disposal and recovery of waste, and in particular the risks arising from a substance on its own, in a preparation or in an article at the end of life stage. This is e.g. evidenced by :

- The **definition of "exposure scenario"** as provided in **Article 3(37) REACH**
- **Annex I paragraph 5.2.2 REACH**, where the life-cycle is explicitly said to cover the waste stage.
- **Annex I paragraph 5.1.1 of REACH** states that the Risk Management Measures of an Exposure Scenario should cover waste management measures to reduce or avoid exposure during waste disposal and/or recycling.
- **Annex II of REACH** requires this information to be consistently communicated in the supply chain via the safety data sheet.
- **ECHA guidance on information requirements and chemical safety assessments, chapter "R.18: Exposure scenario building and environmental release estimation for the waste life stage**":
  - "R18.2.3.1 Assessment of the relevance of the waste life cycle stage"p.16 reads: "*during the waste stage milling processes (e.g. for electronic articles) may be carried out, potentially leading to respiratory or dermal exposure. In such cases the registrant would be expected to additionally include the conditions at waste stage into his exposure assessment*".
  - "Appendix R18-2 Default release factors for waste treatments processes", which list relevant terminology for waste life cycle stage", p.51 reads: "*In addition, all substances which are included in articles for which specific waste regimes exist, such as vehicles, electric and electronic equipment, batteries and accumulators etc. should be included here. Recycling wastes are normally not hazardous wastes but, especially in the case of complex articles, may contain hazardous components.*
  - Table R.18- 12: Correlation of PCs and other wastes to most likely waste treatment processes.
- **ECHA Guidance for the preparation of Annex XV dossiers for restrictions**, page 57, reads that the information on hazard and exposure and risk characterisation needs to include, amongst other things, "in which life cycle stage(s) the exposure resulting in risk occurs";
- **ECHA Guidance on Substance Evaluation**, p.51 and Appendix 6: Checklist for the CSR, p.111.

[3] *"Final Report on Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps"*[3] carried by the consultant Milieu on behalf of the Commission in the context of the REACH Review.

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stricter rule for the use of cadmium in electrical contacts and thereby create an inconsistency between the two legal instruments. This has been acknowledged in the Commission's recent REACH Review Communication.

2. The obligations to seek RoHS exemptions and REACH authorisations for the same substances in the same products and processes (article 5 and annexes III, IV RoHS2 and title VII, annexes XIV, XV REACH), which risks competitive disadvantages for manufacturing in Europe besides double administrative burden and costs:

- The substances mentioned in the RoHS Recital 10 as priority substances for new RoHS2 restrictions, have been included in the REACH Candidate list in 2008 and are now also included in the list of substances subject to REACH authorisation (Annex XIV REACH):
  - Hexabromocyclododecane (HBCDD), sunset date: 21/08/2015
  - Bis (2-ethylhexyl)phthalate (DEHP), sunset date: 21/02/2015
  - Benzyl butyl phthalate (BBP), sunset date: 21/02/2015
  - Dibutyl phthalate (DBP), sunset date: 21/02/2015

  In cases where an authorisation for these substances will be refused, but a RoHS exemption to a possible new RoHS restriction will be granted, the substance may not be used in the production process for the very same product for which it can be found in the final product.
  As a result, the product can be marketed in the EU but it cannot be manufactured here. It will therefore inevitably have to be manufactured outside the EU, which is an example of where regulating a process causes distortions in the competitive positions of companies marketing products on the internal market.
  In case a REACH authorisation would be granted but a RoHS exemption would be denied, the product could be manufactured in Europe but not sold here.

- The problem will become ever more relevant in the future, as the REACH candidate list (of to date a total of 138 substances) and its subsequent Annex XIV list of substances subject to REACH authorisation is currently discussed to be extended to further substances that are already restricted under RoHS2, notably:
  - Sweden has submitted annex XV dossiers for the identification of SVHCs for Cadmium and Cadmium oxide. Sweden has also notified to ECHA's Registry of Intentions its plan to submit a further Annex XV dossier for the identification of SVHCs for **Cadmium sulphide**, by 5 August 2013.
  - Eight Annex XV dossiers for the identification of SVHCs for **Lead and Lead Compounds** have been submitted on 3 September 2012 and have been added to the REACH candidate list on December 19th to be subsequently added to annex XIV REACH.
  - On 12 June 2012, l**ead(II) bis(methanesulfonate)** has been added to the ECHA Candidate list as a Substance of Very High Concern (SVHC) and may subsequently become subject to Authorisation, Annex XIV REACH.

- Because of the insufficient coordination between the services managing the application of RoHS2 and REACH, rather than arriving at convergent requirements for manufacturers, industry is seeing a duplication of work (files and test reports for both), overlapping but contradictory requirements, which are particularly negative for manufacturers based in the EU.

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II. PROPOSALS FOR A COMMON UNDERSTANDING FOR A COMPLEMENTARY, COHERENT AND CONSISTENT IMPLEMENTATION OF REACH AND RoHS2

1. General

We welcome that in its REACH Review Report, the Commission acknowledges the case of possible overlaps and inconsistencies between the REACH Regulation and sector specific legislation, such as RoHS. In this context, the Commission announces its wish to minimise or avoid overlaps or potential overlaps through (a) inviting ECHA to change guidance, if appropriate; and (b) implementing legislation under REACH or other EU sector-specific legislation in particular when considering future restrictions and substances subject to authorisation. This should be fully supported and implemented.

RoHS2 requires coherence and maximising synergies between the two legal instruments (see recital 16 and article 6 RoHS2), notably with respect to the application of the new substance restriction methodology and subsequent revision of the list of restricted substances given in Annex II RoHS2. Orgalime fully welcomes this, too.

Proposal for a common understanding:

RoHS2 and REACH, while "*operating mutually independently*", are "*complementary*" to each other (see recital 16 RoHS2). Therefore, their implementations should tie in with each other to the maximum extent possible, instead of developing in complete isolation from and in competition with each other. The REACH Review Communication, REACH Regulation and guidance documents and the legal text of RoHS2 in our view provide a solid basis for a mutually reinforcing, consistent implementation of both regulations.

The **creation of a Round Table bringing together the different responsible Commission services responsible for either RoHS2 or REACH and affected stakeholders**, including our industry, on a regular basis, would in our view be helpful. It would increase and ease an effective flow of information between different regulators and also between regulators and affected stakeholders. It would also provide a platform for building an urgently needed common understanding for ensuring coherence of RoHS2 and REACH and for maximising synergies.

Regulators should take a **clear decision clarifying which procedure** (REACH restriction, RoHS restriction, REACH authorisation, RoHS exemption) **will be considered appropriate in which case and consequently, a consistent application of this decision** by all regulators involved throughout REACH and RoHS implementation processes. It should also be taken into account that certain aspects are covered and may therefore be better addressed via other EU legislation, including the Waste Incineration, Industrial Emissions or WEEE Directives next to further EU waste policy acquis (see article 2.3 RoHS2).

Affected stakeholders should be involved prior to taking this decision via the proposed Roundtable.

One common Commission guidance document of all services involved would be helpful. Including **Risk Management Options (RMOs) on a standard basis in Member States´ preparations and submissions of REACH annex XV dossiers as well as any Member State's proposal for RoHS substance restrictions following article 6 RoHS** (see next entry) could in our view be a subsequent possible solution for identifying the appropriate procedure in a given case. We suggest that Member States' RoHS proposals should equal an annex XV dossier of REACH.

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2. Ensuring consistency for substance restrictions via title VIII REACH and via Article 6 RoHS2

<u>Proposal for a common understanding</u>:

- Orgalime would support the general approach of establishing restrictions in consumer products under REACH, if RoHS were merged into REACH. As this is not the case today, we believe that any substance and application covered, and therefore restricted already by RoHS2 (e.g.: lead) should be exempted from respective REACH annex XVII amendments (= REACH restrictions).

- The following recommendations suggested by the consultant Milieu in the "*Final Report on Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps", and included in the Commission's REACH Review Communication* should in our view be implemented:
  - *To set up an inventory data base of all restrictions in place for particular substances and amend existing legislation (REACH Annex XVII and /or RoHS exemption) to solve inconsistencies.*
  - *To strongly coordinate REACH and sector specific legislation, i.e.: case by case analysis of uses of a substance restricted in other legislation and included in Annex XIV REACH.*

- **The existing ECHA Guidance on information requirements and chemical safety assessment, chapter "R.18: Exposure scenario building and environmental release estimation for the waste life stage" version 2.1 of October 2012, needs to be fully implemented during the REACH implementation process**. This means that one must ensure that during REACH registration and evaluation the necessary or missing information regarding substance effects occurring at the waste phase, notably from shredding (milling/mixing) or incineration, is gathered and evaluated. This includes that chemical safety reports, exposure scenarios, and subsequent Safety Data Sheets to be provided to downstream users indeed properly include such information.
  Where data and information gaps exist, REACH should be the primary vehicle to fill them. The RoHS methodology should determine what kind of information should be generated and made available via a better REACH implementation, i.e.: during registration and evaluation, to allow for a proper RoHS2 implementation.

- In case Chemical Safety Reports (CSRs) of the REACH substance registration dossier do not include sufficient information regarding risks arising from emissions at the waste stage, the missing information should be requested from the respective registrant (Consortium/Substance Information Exchange Forum) during REACH evaluation, as foreseen in the REACH Regulation.

Both, RoHS and REACH, require **a scientifically based, structured preparatory evaluation process before setting any new substance restriction – these processes should be as closely linked with each other as possible and lead to one commonly accepted evaluation per substance:**

In particular, Article 6.1 RoHS2 requires that "*the review and amendment of the list of restricted substances in Annex II <u>shall be coherent with other legislation related to chemicals, in particular Regulation (EC) No 1907/2006</u>, and shall take into account, inter alia, Annexes XIV and XVII to that Regulation. The review shall use <u>publicly available knowledge</u> obtained from the application of such legislation.*"

Article 6.1 RoHS2 furthermore states that an amendment of the RoHS2 list of restricted substances shall be considered by the Commission on its own initiative or following submission of a Member States' proposal.

Article 6.2 RoHS2 specifies the minimum information requirements to be included in the Commission's or Member State's proposal.

Proposal for a common understanding for implementing Article 6 RoHS2:

- The **implementation of the notion** *"shall be coherent with other legislation related to chemicals, in particular Regulation EC 1907/2006, and shall take into account, inter alia, annexes XIV and XVII to that Regulation*" in article 6.1 RoHS2 should mean at least:
  - taking into account, or, where not yet existing, seeking the opinions of the REACH Risk Assessment and Socioeconomic Analysis Committees (RAC and SEAC) in the preparatory process of any potential new RoHS2 restrictions.
  - taking into account the findings from implementation of ECHA Guidance on information requirements and chemical safety assessment, chapter "R.18: Exposure scenario building and environmental release estimation for the waste life stage" version 2.1 of October 2012.
  - taking into account any additional information provided by the respective registration (Consortium/SIEF) following authorities' request during REACH evaluation (in the case that the initial Chemical Safety Reports of the REACH substance registration dossier did not include sufficient information regarding risks arising from emissions at the waste stage).
  - that the minimum information requirements for RoHS2 restriction proposals following article 6.2 RoHS2 have to be coherent with REACH, too. In particular article 6.2.d confirms the risk based approach of RoHS2 restrictions. Risk Management Options (RMOs) should be included in any such proposals (as well as in Member States´ REACH annex XV dossiers on a standard basis). Member State's RoHS2 proposals should equal a REACH annex XV dossier.
  - Examples of further "*other legislation related to chemicals*" includes the End of Life Vehicles, Packaging, Batteries and Accumulators Directive.
  - Other EU legislation where it affects the purpose of RoHS2 should be taken into account, too, such as the Waste Incineration, Industrial Emissions and WEEE Directives or other EU waste policy measures (see article 2.3 RoHS2).

- The information available at the website of the European Chemical Agency ECHA (http://www.echa.europa.eu) represents "*publicly available knowledge*" in the meaning of article 6 RoHS2.

- Setting restrictions under either regulations follows a **risk based approach** (risk = hazard x exposure), where risk management measures become relevant where actual exposure is above the no effect level (=DNEL/PNEC). According to REACH, restriction represents the last resort of risk management measure (so-called "safety net"), which is equally valid for RoHS2.

- Setting restrictions under either regulation requires **a life cycle approach**, including the **life cycle relevance** of substance effects arising at the waste phase as spelled out in article 6 RoHS. Article 6 refers back to Article 1 RoHS2, which clarifies the subject matter of RoHS2 as being the rules for restricting certain substances "*with a view to contributing to the protection of human health and the environment, including the environmentally sound recovery and disposal of waste EEE*" (however, not the environmentally sound recovery and disposal of waste EEE alone).

This is essential, since substance restrictions can immediately influence the environmental performance of a product at other life cycle stages than the waste phase, and in particular the energy efficiency performance of a product during its use phase.

- Assessing RoHS2 exemption requires equally following a life cycle approach.
- **Stakeholders need to be consulted during the review of annex II** according to article 6.1, last paragraph. This should be a transparent and inclusive process.
- In case of new substance restrictions, **sufficient timelines** need to be given to industry to ensure compliance.
- The notion "*current operational conditions*" of article 6.1.b should be understood in the meaning of treatment standards following article 8 of the Recast WEEE Directive, as currently under development by the European standardisation organisations.

3. Application requests for RoHS2 exemptions and seeking REACH authorisations

Having to seek RoHS exemptions (article 5 and annexes III, IV RoHS2) *and* REACH authorisations (title VII, annexes XIV, XV REACH) for the same substances in the same products and processes, as specified, creates the risk of contradictory decisions for the same substance use in EEE and a doubled burden on the manufacturer, with the subsequent **risks on the competitiveness for manufacturers in Europe besides doubled administrative burden and costs**

Uses covered by RoHS2 are unfortunately not listed in article 56.4 REACH and consequently not as such exempted from REACH authorisation.

Article 58(2) REACH however specifies that exemptions from REACH authorisations can be granted for uses or categories of uses *"provided that on the basis of the **existing specific Community legislation** imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled*". Thereby, Article 58(2) REACH provides for the basis for preventing overlaps between the REACH Regulation and sectoral legislative acts, such as RoHS2. The RoHS2 Directive in our view represents such existing specific Community legislation.

Proposal for a common understanding:

- If a substance is supposed to be added to Annex XIV REACH (list of substances to be authorised), the use category of "electrical and electronic equipment in scope of Directive 2011/65/EU and subject to an exemption under this Directive" shall be exempted from REACH authorisation on the basis of **Article 58(2) REACH for the duration of the granted RoHS exemption**. This is supported by study carried out by the contractor Milieu for the REACH review.
- As indicated previously, Risk Management Options (RMOs) should be included on a standard basis in Member States´ REACH annex XV dossiers/ RoHS2 proposal for substance restrictions.

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III. CONCLUSIONS

RoHS and REACH address the same substances used in the same electric and electronic equipment (EEE) and the same production processes. As a consequence, industry faces overlapping and inconsistent requirements, parallel procedures with additional administrative burden and costs, and partly (in relation with REACH authorisation) risks on the competitiveness for manufacturers in Europe.

We call upon regulators to urgently develop a common understanding for the implementation of REACH and RoHS2 and a consistent application under both legislative instruments.

Our suggestion for such a common understanding for implementation are summarised in attached flowcharts.

Similar situations and issues are likely to arise between REACH and other sector specific regulations, notably the End of Life Vehicles or Batteries Directives.

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Flowchart 1: CONSISTENCY RoHS-REACH from the perspective of RoHS2

Step 1: RoHS review/amendment proposal for a substance restriction (Art. 6.2 RoHS2)

- To contain the minimum information requirements of article 6.2 RoHS2 and missing elements of an annex XV REACH dossier; a Member State's RoHS proposal should equal an annex XV REACH dossier
- Risk Management Options to be included (as of preparation process of the dossier)
- A horizontal Commission guidance document should explain what procedure should apply in which case (REACH restriction, RoHS restriction, REACH authorisation, RoHS exemption, other EU environment/waste policy measures, i.e.: Waste Incineration, Industrial Emissions or WEEE Directives)

Step 2: Preparatory Substance Assessment (Methodolgy art. 6.1 RoHS2)

- Implementation of art.6.1 RoHS2 "*shall be in coherence with REACH*", shall mean at least:
- RAC and SEAC opinions to be taken into account, or where not yet existing, to be sought for any substance restriction under either RoHS2 or REACH
- Proper implementation of ECHA Guidance R.18 , and its results to be taken into account under RoHS2
- (Additional) results REACH evaluation process, notably for substance aspects in waste phase, to be sought and taken into account
- The RoHS2 methodology shall specify the information needed for proper RoHS2 implementation - this information shall be gathered via REACH
- Objective: **one common scientific conclusions per substance**, which will be relevant for RoHS2 and REACH implementation

Step 3: Stakeholder Consultation

- Minimum 8 weeks - announcement and results to be made available publically

Step 4: Commission decision

- On the basis of Commission guidance document (what procedure in what case) whereby:
- In case of an existing RoHS2 restriction - RoHS2 as lex specialis sets relevant restriction (no REACH authorisation for RoHS2 scope in application of article 58.2 REACH)
- In case of setting a new restriction - either in RoHS2 (if case specific) or REACH annex XVII (but not twice for the same equipment); no REACH authorisation process
- Where RoHS2 grants an exemption, no REACH authorisation should become necessary in application of article 58.2 REACH
- Sufficient timelines for industry to ensure compliance with any new restriction

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Flowchart 2: CONSISTENCY RoHS-REACH from the perspective of REACH

Step 1: Registration

- Registration dossiers (Chemical Safety Reports, Exposure Scenarios) to properly implement ECHA Guidance R.18, and its results to be taken into account under RoHS2
- The RoHS article 6 Methodology shall specify, which information would be needed to ensure a proper RoHS implementation; this information should be generated via REACH
- Objective: **One common scientific conclusion per substance**, which will be relevant for REACH and RoHS2 implementation

Step 2: Evaluation

- Where data and information gaps should exist (especially on susbstance aspects in the waste phase, including on the information required by article 6-RoHS methodology), these should be filled by REACH, including during evaluation process
- Objective: **one common scientific conclusions per substance**, which will be relevant for RoHS2 and REACH implementation

Step 3: Authorisation

- Annex XV dossiers (and their preparation) to include Risk Management Options
- Commission guidance document to explain what procedure should apply in which case (REACH restriction, RoHS restriction, REACH authorisation, RoHS exemption, other EU environment/waste policy measures, i.e.: Waste Incineration, Industrial Emissions or WEEE Directives)
- Where RoHS2 grants an exemption, article 58.2 REACH shall be applied
- Prior to setting any authorisation requirement, the opinions of RAC and SEAC need to be sought

Step 4: Restriction

- Annex XV dossiers to include Risk Management Options
- On the basis of Commission guidance document (what procedure in what case) whereby:
- In case of an existing RoHS2 restriction - RoHS2 as lex specialis sets relevant restriction (no REACH authorisation to apply following article 58.2 REACH; no new REACH restriction to be set for Electrical and Electronic Equipment)
- In case of setting a new restriction - either in RoHS2 (if case specific) or in REACH annex XVII (but not twice);
- Where RoHS2 grants an exemption, article 58.2 REACH shall be applied
- Prior to setting any restriction, under RoHS or REACH, the opinions of RAC and SEAC need to be sought
- Sufficient timelines for industry to ensure compliance with any new restriction

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