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Response to stakeholder consultation held as part of a "Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)"

MedTech Europe comments on the Substance Review Methodology and the revision of the RoHS Substance Inventory

MedTech Europe and RoHS

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members research, develop, manufacture, distribute and supply medical devices and in vitro diagnostics.

RoHS category 8 'Medical Devices' includes EEE *in vitro* diagnostic medical devices (IVDs) and medical devices as defined by their sectoral legislation. It does not include active implantable medical devices (AIMD). All CE-marked IVDs and medical devices (excluding AIMD) are therefore category 8.

The medical technology sector includes a very wide range of products mainly aimed at healthcare facilities but also used by general practitioners and in some cases consumers themselves. Some are relatively simple products while others are some of the most complex electronic products available, including heart-lung machines, anaesthesia machines and CT scanners, PET and MRI. Medical devices often have extremely complex designs because of the number of parts which must withstand extreme operating conditions.

MedTech Europe's members are committed to ensuring full and timely compliance with all regulatory requirements of RoHS. However, long term legal certainty and legislative consistency are essential for manufacturers to carry out these requirements and at the same time support the objectives of the legislation.

MedTech Europe
from diagnosis to cure

Contribution related to Task 1 (Substance methodology manual draft)

Questions 1-5 – Substance methodology

The focus of the RoHS Directive is exclusively on the waste phase, seeking to address risks from the improper disposal of EEE as well as environmental and health impacts which could arise during waste management/WEEE recycling. Risks associated with the manufacturing stage or the use of an EEE are beyond the scope of RoHS and should not be included in any of the 3 prioritisation steps. As outlined in Article 6(1) of the directive, **RoHS does not consider the use phase or manufacturing risks**. Substances representing risks during the manufacturing process should be assessed under REACH in view of potential inclusion in Annex XIV (Authorisation) or Annex XVII (Restriction).

As it stands, the text suggests that **a substance would only have to be "suspected" of posing a risk, as opposed to requiring evidence (hazard * exposure = risk)** as required under REACH and other regulations. The draft methodology seems to imply that in the context of RoHS, the potential risk during the use or waste phase would justify RoHS restriction, regardless of actual occurrence and risk management options. This is disproportionate and results in RoHS introducing stricter conditions for restrictions than those required in the context of REACH where the authorities must demonstrate that there is an unacceptable level of risk related to the substance.

Furthermore, we recommend to **further define and clarify the "suspected as any of the above" category** (p. 22). In practice, this category would be redundant or would offer an almost limitless latitude of "suspect" chemicals, possibly without evidence. Any list of hazardous substances should be clearly targeted as this directly affects the efficiency of the RoHS framework, including the manageability of the exemption process (for all stakeholders).

In addition to these general considerations, we would like to highlight the following specific comments on the proposed methodology:

- The prioritisation process should start with step P I-3B, where for the first time we find substances in EEE, of concern, and the waste treatment risks identified in the RoHS Directive (Art. 6.1. a, b, c, d). **Any substance which does not meet all three criteria should be, by definition, out of the scope of this methodology**.
- The strength of RoHS has been its focus on substances which are present, and critical, in EEE. **RoHS-related substance studies should therefore focus on priority substances which are found in the final product**, and be limited to those that have a measurable risk of exposure that are identified in a product life cycle

assessment. This would help planning processes in companies by receiving clear and effective substitution directions.

- P. 11: It seems that the **methodology only partially addresses the requirements of the precautionary principle** outlined in the Commission's Communication of 2000. The draft methodology fails to consider the impact of risk management and communication – instead relying on 'suspected' risks.
- P. 12: The intent of the Common Understanding Paper on REACH and RoHS appears to be taken out of context. In our view, the Common Understanding Paper focuses on coherence (specifically recognising REACH and CLP) and **does not specifically call for establishing a separate methodology for evaluating manufacturing uses** in the specific scope of RoHS.
- **Grouping of substances** (p. 17): Whether using a grouping approach or not requires an in-depth analysis on chemical properties within the group. Grouping might bring efficiency during the regulatory phase, but this in no way helps the efficiency of enforcement. P. 48: Beware of read across: substances in the same chemicals group do not necessarily all have the same properties.
- P. 21: We suggest removing the reference to studies raising concern about substances in EEE during the use phase.
- We recommend clarifying the terminology used on p. 30: **Prioritisation through RoHS is not a classification process.** Classification is conducted through CLP; a substance which fulfils the RoHS Art. 6(1) criteria (especially regarding Analysis of Alternatives in 6(1)(d) is not necessarily classified as hazardous.
- Several references (e.g. p. 35, 59, etc.) are made regarding evidence that RoHS substances of concern hinder recycling or recovery. We strongly recommend providing reference to this evidence.
- We suggest **aligning the RoHS assessment with the official EU classification of persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB) substances**, and not to consider PB as a separate category. PBT substances are recognised as being of very high concern, focusing on P and B only in our opinion is not the right ground for prioritisation.
- Prioritising nanomaterials is contradictory with the Commission view laid out in the Second Regulatory Review on Nanomaterials, which concluded that nanomaterials should be addressed under REACH, using the regulation's tried and tested substance-by-substance risk management approach. **Nano is not a hazard category and should only be considered for RoHS assessment if the nano form of a substance poses a risk at end of life**. The reference to nano registers (national or from other institutions) as a source of information (Appendix 1, section A.1.1) is not appropriate. The main purpose of nano-registries is to identify where nano materials

are used and are not based on hazard or risk based criteria for registering these substances.

Question 6 – Socio-economic impact

The introduction of new restricted substances under short timelines could lead to premature obsolescence and forced withdrawal of products from the EU market. This is particularly true for product categories with long life times, such as IVDs and medical devices.

If new substances are considered to be added to the list of restricted substances (Annex II), the **impact on IVDs and medical devices (category 8) must be assessed separately avoiding any unjustified risk to the availability of these devices to patients.** This relates to development of new products (delaying market introduction) and re-development of existing products. Separate assessment would reflect the particularly long development cycles and the need for additional exemptions to ensure reliability and safety of medical devices (which RoHS already recognised with the later entry into scope of this product category).

In this context, we have the following specific comments/requests:

- Establish a **predictable and periodic time frame for the review cycle, study periods, and default transition periods** (e.g. aligned with the 4-year periodic review of RoHS) in order to provide planning certainty for equipment manufacturers.
- Restriction under RoHS **should not apply to substances not present in EEE**. REACH is a better regulatory tool to address concerns resulting from process chemicals. In fact, many of the substances included in REACH Annex XIV are industrial process chemicals.
- **A distinction should be made between different categories of products**. Separate assessments of the different product categories (1 to 11) regulated under RoHS will allow consideration of the specific impact of substances relevant for these uses and will lead to better estimation of the timelines necessary for implementation.
- Given the complexity of the analysis and the important consequences of substance restrictions, we recommend that **a scientific body assists the Commission in the assessment of candidate substances**. Stakeholder involvement could also be critical at that stage to ensure that appropriate data are available (e.g. information on alternatives or socio-economic data) in due time. The methodology should integrate this as a key step in the process.

It needs to be highlighted that **any changes to RoHS, including and not the least changes to restricted substances, should consider the impact outside of the EU where RoHS-like**

regulations have been adopted. RoHS-type laws have been introduced or are currently being introduced in more than 40 jurisdictions outside the European Economic Area (EEA). These include China, India, the Eurasian Customs Union and the Gulf States. Each time the EU updates the legislation, for example by withdrawing, renewing or granting an exemption, or adding a substance, it has a domino effect on the rest of the world. This has a very real and direct impact on companies that operate in more than just one region of the world – as is the case for many of MedTech Europe's members.

Question 7 – REACH/RoHS interface

The Common Understanding Paper on REACH and RoHS was a step in the right direction, and has provided some good guidance to avoid overlaps between legislations. **It is inappropriate for the draft methodology to include any considerations on the REACH/RoHS interface which go beyond the Common Understanding Paper.**

In order to avoid any subjective interpretation, we recommend including a simple reference to the Common Understanding Paper and **leave any further interpretation questions to the European Commission and ECHA**.

In the context of this methodology, we would like to underline that **substances undergoing REACH evaluation or subject to the REACH CLP process should not be considered under RoHS before the REACH process is finalised and the classification is confirmed**. A key point to consider under the RoHS framework is that managing a rolling system of substances being assessed under both REACH and RoHS in parallel would be a significant challenge.

Specifically, we do not agree with the following statements in the proposed methodology:

- §1, p. 16: "RoHS restrictions can go beyond REACH restrictions". We believe that REACH is better placed to manage certain risks, in line with the REACH RMOA approach and the EU Common Understanding Paper.
- §6, p. 16: "If REACH restricts a substance, RoHS should not grant exemptions." **The REACH restriction process is not designed to look into the specificities of product design and application** in the way the RoHS exemption process is.
- P. 31: "Only substances covered by Montreal and Stockholm convention annexes can be excluded from RoHS assessment." This is not our understanding. **Also substances covered by a REACH restriction should be eligible to be excluded from RoHS assessment.**

Contribution related to Task 3 (Substance inventory)

It is crucial that the RoHS substance methodology is finalised before assessing substances and their potential for restriction under RoHS. Future lists (if any) should be based on an agreed methodology, just like the assessment of the 7 new substances can only be concluded once the methodology for substance restrictions is finalised.

We suggest that **the list be limited to the substances that are explicitly under consideration for identification and assessment**. It will be critical to explain the meaning of any 'priority' list to avoid a 'black listing effect' with direct repercussions on supply chains, and bringing unpredictability to business planning activities.

We recommend **excluding 'suspected' substances from the inventory**. Any list of hazardous substances should be clearly targeted as this directly affects the efficiency of the RoHS framework, including the manageability of the exemption process (for all stakeholders).

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About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

For more information, visit www.medtecheurope.org.