AmCham EU
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

Our position

New categories entering into the scope of RoHS: Learning from the experience of Cat.8 and 9 goods

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American Chamber of Commerce to the European Union
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Background: Entry into scope of Cat.8 & 9

The first RoHS Directive (2002/95/EC) was limited in scope. Its purpose was to restrict the presence of six harmful chemical substances (including heavy metals and their compounds) in electric and electronic equipment (EEE). Following the RoHS recast proposed in December 2008, more categories of EEE were included in the Directive's scope, including business to business (B2B) categories related to medical devices (**Category 8**) and industrial monitoring and control equipment (**Category 9 industrial**). Both categories 8 and 9 were excluded from the scope of RoHS 1 because of the products' complexity and how critical their applications were.

Specificities of Cat.8 & 9

Most of the EEE covered by the RoHS scope are products designed for high-volume consumer applications, and which are regularly re-designed to follow consumer trends (every 1.5 year on average). **This is not the case for Cat.8 and Cat.9** products. Few companies produce **Cat.8 and Cat.9** products, and they are each responsible for a large portfolio of products which are **intentionally designed to be used for decades, and meet the highest reliability standards**. Their portfolio can reach 2000 to 3000 products available to be sold on the EU single market. They are **designed for professional and/or industrial use**; to meet high performance requirements in critical applications; and last up to 40 years (10 years are a typical first life, but these products are then recalibrated regularly for the secondary market until they reach their end of life, when they will be harvested for parts).

Redesign is not frequent and happens on average every 7 years, after which these goods typically enter a long-term 'customer support period[1]'. A typical product from these categories can have between 2,000 and 40,000 parts; requiring a vast supply chain involving tens of thousands of suppliers and hundreds of thousands of items, including many custom-designed components. Both the size of the product portfolio, and the products' own complexity, means producers of goods in these Categories manage **supply chains of > 100,000 suppliers,** covering hundreds of thousands of individual parts.

The burden of complying with RoHS is therefore enormous for goods which represent only a fraction of EEE on the EU market. Eurostat's WEEE data[2] shows for example that Cat 9 was only 0.7% of all EU electronic equipment placed on the market by weight.

Challenges of entering into scope

The initial caution about including these categories in the scope of RoHS 1, was amply justified by the **subsequent efforts** required to identify and validate acceptable alternative materials suitable for long-lived, high reliability, equipment and to transition large numbers of custom-made parts frequently sourced from SME suppliers. This task is still in progress today, 9 years after RoHS 2 was adopted.

The main challenges associated with the entry into scope were the following:

- Unique applications specific to Category 8 and 9 equipment required additional exemptions specific to these sectors. These were published as Annex IV of the RoHS 2 Directive. Maintaining these exemptions

[1] "Support life" for these goods, means the period covered of minimum 5 years where the customer pays the producer for an aftersales contract, to provide calibration/repair/enhancement services.

[2] Eurostat: WEEE Data 2016 – *no distinction between industrial and non-industrial equipment*

required substantial effort. The process was further complicated by the parallel scientific and technical review of exemptions for Categories 1~7 & 10. It took over three years from the Recast publication in April 2011 to reinstate exemptions for Categories 8 & 9 that had been modified for the other categories. The legal uncertainty was damaging and may have impacted the number of products from these categories which had to be removed from the EU market.

- EU customers were penalised by category 8 & 9's inclusion into RoHS first and foremost because products which could not be RoHS compliant for technical reasons were removed from the EU market. Secondly, because efforts and resources which would have gone into product R&D, were instead **diverted to redesign activities. This limited the supply of these categories' products in the EU, and often led to** delays in providing state-of-the art equipment.

- Complying with RoHS radically altered a number of these companies. RoHS became a part of many of their daily activities and often required a transformation on a global scale. This transformation drove up company costs, especially around: **Redesigning products, Testing and validation, and Regulatory compliance.**

    - **Cost associated with initial investment in RoHS compliance**: Substantial R&D investment was initially required to prove the viability of new materials and processes that could meet the Categories' reliability needs. Additional costs were also associated with new internal procedures to coordinate across departments, and ensure the product portfolio could be made RoHS compliant, and therefore access the EU market. Finally, getting ready for RoHS compliance required investments in new materials & supply chain data management practices and holistic enterprise-wide process design and deployment.
    - **Annual cost for compliance with RoHS**: In addition to these upfront investments, additional costs associated with IT tools and yearly licenses was substantial. Annual licensing, management and maintenance of enterprise resource planning IT tools, and costs associated with other solutions needed to process RoHS data. Implementation of massive operational and process changes to maintain compliance, including: **due diligence processes** and procedures to ensure a streamlined output that continues to comply over time. Design for compliance necessitates the management and maintenance of many **internal standards** to support R&D. **Experiments** continue to be required to maintain the reliability of these state-of-the art equipment as new technologies or potential substitutes emerge.

- Due to the sectors' specificities, chemical substitution is very challenging as Cat. 8 and 9 equipment must guarantee very high and long-term reliability over an extended lifetime. **Material or component substitutions must be validated through a number of tests under extreme conditions**. Testing programmes can last one or two years. It is imperative to our customers that we verify any product changes do not reduce product reliability or performance against published specifications. The substitution of substances is driven by the progress of R&D and the availability of suitable alternatives which can meet the high reliability requirements for these sectors. Given the current status of research, **a very large number of the current for Cat. 8 and 9 RoHS exemptions will need to be extended and renewed for the foreseeable future**.

- A simple cost benefit analysis of cat. 8 and 9's inclusion into RoHS demonstrates the disproportionate nature of RoHS compliance costs, with the extremely low environmental and health protection benefits gained, given the low volumes of chemicals used, small number of products sold, and the extended lifetimes of these categories of equipment.

The example of Cat.9 industrial (Industrial Test & Measurement Equipment):

- Companies producing Category 9 industrial goods started to prepare their portfolio of products for RoHS compliance **as early as 2005**, or 6 years before the adoption and the publication of RoHS 2. It took 12 years to redesign products for conformity. This process is still ongoing for the substitution of DEHP and the other phthalate restrictions that will come into force in 2021.
- Bringing the portfolio of products to compliance, and phasing out the six initial RoHS substances came at substantial effort and expense. Even after establishing RoHS design and supply chain specifications to control product development processes during the extended transition period, **60% of released products in production across the sector had to be redesigned** and **7.5% of these products** had to be prematurely withdrawn from the EU market.
- Due to the extended use-phase of Industrial test and measurement equipment of up to 40 years, **it will take until the late 2050's before any health or environmental benefit from phasing out the original six RoHS substances can be seen, if at all**. Waste streams for Industrial test and measurement equipment will continue to have address the risks associated with non-RoHS compliant equipment for the foreseeable future.
- Direct costs associated with the continuous investment in maintaining RoHS compliance are reported to be of 4,185,000 EUR annually, and that is assuming that the RoHS substance restrictions and exemptions remain unchanged. The cost of RoHS-compliance is therefore estimated at **10% of product turnover sector-wide.**
- **Any additional substance restrictions are likely to require a full assessment of portfolios for RoHS compliance.** We assume the costs associated with new substances into RoHS will require the same upfront investment as when the category was brought into scope in 2011, at least 12 years to achieve and no demonstrable health or environmental benefit during EEE Waste processing for 40 years.