POSITION PAPER

DATE: 02/04/2024

JBCE'S POSITION ON AMENDING ROHS DIRECTIVE 2011/65/EU AS REGARDS THE RE-ATTRIBUTION OF SCIENTIFIC AND TECHNICAL TASKS TO THE EUROPEAN CHEMICAL AGENCY

Being a cross-sector association with member companies operating in different industries and stages in the supply chain (electronics, chemicals, polymers, automotive, HVACR, machinery, semiconductors, wholesale trade, precision instruments, pharmaceuticals, steel, non-ferrous metals, textiles, ceramics and glass products), JBCE welcomes the opportunity to contribute to the discussion regarding the amendment of RoHS Directive 2011/65/EU as regards the re-attribution of scientific and technical tasks to the European Chemical Agency.

From the proposal stage of RoHS Directive, JBCE has been striving to contribute to the discussions to render the Directive more effective. Based on our extensive experience, we believe it is essential to provide for feedback opportunities at early, advanced, and final stages of the decision-making to incorporate the industry's expertise effectively. JBCE also aims to provide its comments on the re-attribution of tasks to the European Chemicals Agency (ECHA).

KEY MESSAGES

1. The proposal focuses on shifting scientific tasks to ECHA but excludes other aspects like **proportionality** and **exemption periods**. If Articles 5 and 6 are amended, **the final report's points should be considered**, and stakeholders should be allowed to comment on the proposed changes.
2. During the exemption evaluation, the **regular communication** between applicants and consultants plays a very important role in terms of clarifying arguments and technical information, answering questions etc. Therefore, it should not be limited only to written communications. **JBCE aims to contribute to the process of the re-attribution of scientific and technical tasks** to the ECHA based on its experience. In fact, with a diverse industry membership, we have addressed supply chain difficulties and challenges and provided substitution proposals.
3. While we appreciate ECHA's role in chemical assessment, an assessment of **alternative substances solely based on chemical characteristics may not always suffice at product level**. Safety must be ensured not only for chemicals but also for products. Electrical and Electronic Equipment (EEE) must comply with legal requirements contained in a series of

i.e. EU legislation Therefore, we urge ECHA to conduct evaluations **with a comprehensive understanding of EEE** as a product and chemicals.

4. Medical equipment in Category 8 and monitoring and measuring equipment in Category 9 are essential to society. Category 8 and 9 products represent only less than 3.6% of all EEE placed on the EU market, however, these category products still require a significant number of exemptions (i.e. they represent 41% of all RoHS exemptions). **JBCE therefore strongly supports maintaining the possibility to apply for and use granted specialised applications.**
5. **Substitutes** should not be recognized if they are only accessible to a limited number of manufacturers. **They should be recognized only if widely used across the supply chain and accessible to all manufacturers.**
6. **The proposal to introduce fees for exemption applications,** as mentioned in the report, **warrants careful consideration.** Small companies, including SMEs, apply for special exemptions under Annex IV and introducing fees could burden them heavily. In case essential products would, as a consequence, disappear from the market **it would negatively impact EU citizens' lives, the environment and innovation in the EU**.
7. JBCE strongly supports the product re-use (**spare parts**), refurbishment and extension of lifetime. This idea is also in line with the "**Right to Repair**" concept currently promoted by the EU. The "**repair as produced**" principle, which is currently in force, is very important to extend the lifetime of EEE.
8. **The transition period should be set adequately**. When the exemption is used for a critical part of a product, not only design changes but also safety and durability tests would be necessary.

DETAILS

【General proposal】

- **Additional Amendment to Article 5 and 6 other than the re-attribution to ECHA:**
  This proposal to amend Articles 5 and 6 covers solely the re-attribution of scientific and technical tasks to ECHA. The final report mentions additional aspects related to Articles 5 and 6, such as proportionality and the exemption period; however, these fall outside the scope of this proposal. If amendments to Articles 5 and 6 are pursued, the points discussed in the final report should also be addressed, and we propose providing stakeholders with the opportunity to comment on the proposed amendments.

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- **Communication with stakeholders:**

  JBCE aims to contribute to the process of re-attribution of scientific and technical tasks to the ECHA based on its experience. JBCE has been contributing to RoHS Directive as an expert stakeholder until now. Being a cross-sector association with member companies in different industries and stages in the supply chain, JBCE has also been discussing the difficulties and challenges in each stage of the supply chain. With this background and extensive experience JBCE believes that it can contribute the re-attribution process.

  JBCE was also involved in exemption renewal processes as one of exemption's applicants and has been providing constructive proposals to the substitution through regular communication with the consultants. During the exemption evaluation, the regular communication between applicants and consultants plays a very important role and it should not be limited only to written communications. Especially when conflicting information is available, an occasion such as an online meeting is very effective for clarification purposes. JBCE believes that such communication during the exemption evaluation is important also after the re-attribution of the task to ECHA.

- **Alternative substances do not always function in EEE:**

  With regard to the transition of scientific and technical tasks from consultants to ECHA, we understand the benefice of the One Substance One Assessment (OSOA)'s main objective and resource allocation. We appreciate ECHA's role in assessing chemical substances. However, the assessment of alternative substances based solely on chemical characteristics may not always suffice at product level. Safety must be ensured not only for chemicals but also the products themselves. EEE must comply with various EU legislation such as EMC Directive, Machinery Regulation, Low Voltage Directive, Medical Device Regulation, In-Vitro Diagnostic Regulation besides the specific Chemical legislation. Therefore, we urge ECHA to conduct evaluations based on a comprehensive understanding of EEE as a product as well as chemicals.

- **Avoid double Regulation:**

  RoHS Directive is a successful piece of environmental legislation. The final report mentions that more than 50% of restricted substances are substituted thanks to RoHS Directive. Any double regulation with REACH Regulation, battery Regulation and Eco-design Regulation should be avoided so that the RoHS Directive continues to help improving the environment also in the future.

- **Amendment of the list of restricted substances in Annex II:**

According to the proposed amendments, ECHA and Member States can suggest new restrictions.

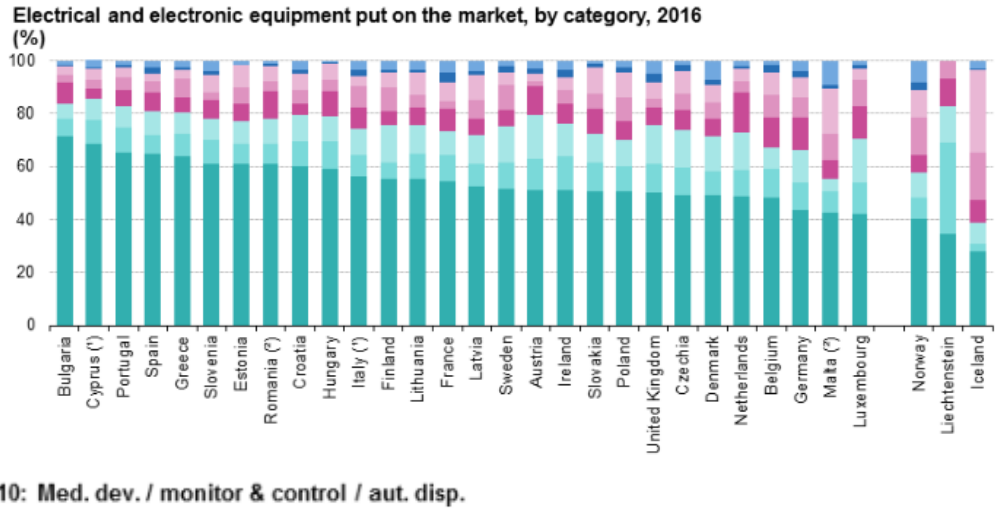
If new restricted substances are introduced frequently, it is difficult to comply with the decisions especially for the EEE whose production lifetime is long and model change is not frequently done (professional use product such as category 8 and 9 products).

- **Annex IV includes special applications**:

  Categories 8 and 9 products need many exemptions. On the one hand, the number of category 8 and 9 products placed on the EU market annually is only 3.6 % of the total EEEs[1]. However, the number of exemptions for Categories 8 and 9 products (Annex IV) is 41% of all exemptions. This is because these products have a wide range of special applications.

  Many of Categories 8 and 9 products are essential for the society. For example, medical equipment in Category 8 is essential for people's health, while equipment in Category 9 make a significant contribution to environmental sustainability, for example, in the development of sustainable renewable energy technologies, as described in recital (17). Category 9 monitoring and measuring equipment is also essential for the safety of society, for example, fire alarms and analytical measurement of chemicals.

  JBCE welcomes the strategy to keep a wide range of specialist applications available in EU and at the same time to reduce hazardous chemicals.



Source: Eurostat

[1] https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Waste_statistics_-_electrical_and_electronic_equipment#EEE_put_on_the_market_and_WEEE_collected_in_the_EU (last accessed on 17 January 2020)

- **Criteria for the justification of the exemptions**:

  Article 5(1) shows the justification for the exclusion. In addition, the following points should be considered:

  - Substitutes should not be considered to exist when they are only available to some limited number of manufactures. Substitutes should only be considered to exist when they are widely used in the supply chain and when substitutes are available to all manufacturers.

  - The feasibility of supplying alternatives should be considered and should not conflict with the Critical Raw Material Regulation currently discussed. For example, tungsten is suggested to be an alternative for X-ray shielding lead (Annex IV-5)[2] is mainly supplied by China.*

* CRMS 2023 - SCRREEN2 „Tungsten“ p.5) (European Critical Raw Materials Act (europa.eu); Critical raw materials: Securing the EU's supply and sovereignty | News | European Parliament (europa.eu)

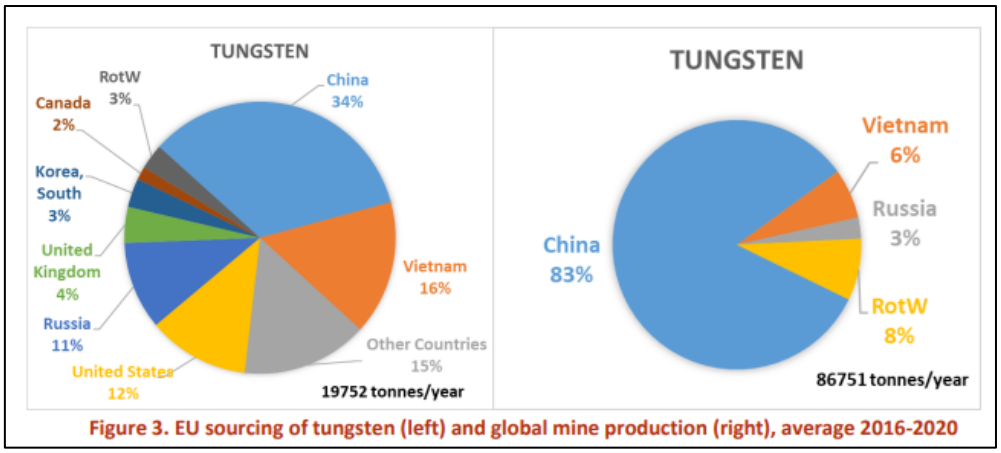


Figure 3. EU sourcing of tungsten (left) and global mine production (right), average 2016-2020

- **Introduction of a fee for exemption applications:**

  The introduction of a fee for exemption applications mentioned in the report[3] should be carefully considered.

  In particular, there are many special applications in Annex IV that are placed on the EU market by a small number of companies including SMEs and only a small number per year. If a fee is introduced for such exemptions, it will be a heavy burden for SMEs, forcing them to give up on production. In that case, these products could disappear from the European market, even if they are essential to society. This has in fact happened with the introduction of the Medical Device Regulation: It has resulted in devices for niche applications, such as

[2] https://www.rohs.biois.eu/Ex_5-IV_COCIR-JBCE-TMC_Renewal-Request.pdf

[3] Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions of the review of the Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment" COM(2023). 760 In final 7.12.2023.

special medical devices for children, disappearing from the European market. It is threatening the lives of patients with rare diseases[4]. If the same phenomenon occurs for RoHS exemptions, it not only has a negative impact on the lives of EU citizens, but also gives a negative impact on environment and hinders innovation in the EU.

- **Re-use, refurbishment and extension of lifetime:**
  JBCE strongly supports the product re-use, refurbishment and extension of lifetime as mentioned in recital (20), including its spare parts. This idea is also in line with the Right to Repair concept promoted currently by EU. The "repair as produced" principle, which is currently in force, is very important to extend the lifetime of EEE. Components are often purchased in batches for the entire production-life of a product to maintain the quality. It is not possible for EEE manufacturers to obtain new components when a new chemical legislation is introduced.

- **Transition period**：

  According to Article 5(6), the exemption shall expire at the earliest 12 months, and at the latest 18 months, after the date of the decision if the application for exemption renewal is rejected. When the exemption is used for a critical part of a product, not only the design change but also safety and durability test would be necessary. For some products a third-party certification would also be required. Therefore, the transition period should be set adequately.

- **Exclusion for the devices for calibration:**
  Under REACH Regulation, substances for calibration are derogated under the “scientific research and development”. Similarly, the devices used for calibration purposes should be excluded under RoHS Directive.

【Detailed comment to Annex】

- Article 1 (1) (a) Rejection of application:
  It states that applications will be rejected if they are not complete:
  “Where the applicant does not complete the application with the missing elements identified by the Agency in compliance with Annex V within the deadline provided in

[4] Current assessment of the German medical device manufacturers on the effects of the EU Medical Device Regulation (MDR) (spectaris.de)

accordance with the first subparagraph, point (c), the Agency may reject such application." It is not clear under which criteria ECHA will regard an application as not complete. JBCE welcomes the introduction of a clear and transparent criteria.

- Article 1 (1) (a): "without undue delay":

It is not clear what "without undue delay" means . JBCE calls s for the introduction of a clear and transparent definition.

- Article 1 (4) „Article 6a. 3: "publish without delay":

  Similarly, it is also not clear what "publish without delay" represents. JBCE therefore also calls for the introduction of clear and transparent definition.

- Review of this amendment:

  JBCE strongly supports the periodic review of the re-attribution of scientific and technical tasks to ECHA.

- Proposal §5 4(e) and 4(f):

  A fundamentally important question is as follows: At which point in time during the SEAC (RAC) work will the summary be published and public consultations launched? JBCE strongly calls the introduction of a clear and transparent process definition *and timeline.*

ABOUT JBCE

Founded in 1999, Japan Business Council in Europe (JBCE) is a leading European organization representing the interests of over 100 multinational companies of Japanese parentage active in Europe. Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, textiles, and glass products.

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