

Test & Measurement Coalition

Comments related to current evaluation of RoHS Annex III exemptions

27 May 2021

The T&M Coalition represents an ad-hoc group of companies active in producing test & measurement industrial type products (category 9 industrial under RoHS). The Coalition members are leading companies in the sector including Agilent Technologies, Fluke Corporation, Keithley Instruments, Keysight Technologies, National Instruments, Tektronix and Thermo Fisher Scientific. We estimate the coalition membership represents over 60% of the global production of industrial T&M products and other industrial equipment including chemical analysers.

Our products include a wide range of sophisticated electronic instruments such as signal generators, logic analyzers, oscilloscopes, spectrum analyzers, digital multimeters, chemical and biological analyzers etc. The instruments are used by laboratories (for research and compliance evaluation), universities (for technical training and education), manufacturers (for product development and manufacturing of their products), and governmental agencies (for conformance verification). They are essential to the good functioning of electronic communications networks, heavy industrial processes such as steel manufacturing, the testing of vehicles for compliance with emissions standards, and the monitoring of complex systems of all types.

Industrial Test & Measurement equipment is exclusively used in professional and industrial use, and end-of-life instruments are collected through B2B waste schemes. The whole of the monitoring and control category of equipment represents by weight 1.8% of the total Electrical and Electronic Equipment (EEE) put on the EU market and 0.7% of the total Waste EEE (WEEE) collected in the EU. Industrial Test & Measurement instruments, a subset of monitoring and control category, only represents in weight 0.2% of total EEE put on the market in 2017 in the EU.¹

Bio Innovation Service, UNITAR and Fraunhofer IZM (Institute for Reliability and Microintegration) are currently evaluating several RoHS Annex III Exemptions (4(f), 8(b), 8(b)-I, 9(a)-II, 13(a), 13(b), 13(b)-I, 13(b)-II, 13(b)-III, 15 and 15(a)), which will expire on 21 July 2021 for Categories 1-7 and 10.

We understand that certain exemption applications include uses relevant to category 9 industrial monitoring and control equipment. We would like to stress that industrial monitoring and control producers have extended validity periods of their exemptions until 21 July 2024 due to the complexity of our products; the scale of our portfolios; and the length and breadth of our supply chain.

We would like reiterate the critical importance of Annex III exemptions for category 9 industrial and to stress the need to retain each exemption as originally published in both definition and expiry date for our sector.

The Test & Measurement Coalition members intend to submit their application for renewal of certain exemptions within the legally foreseen deadlines of 18 months before the expiry date of 21 July 2024;

¹ EU official figures, [Eurostat](#) 2017 and T&M data analysis

reflecting the status of the scientific and technical progress and the socio-economic considerations at that point of time. We appreciate the importance of providing solid data and sound justification supporting the request for renewal of the exemptions for our category and we are committed to prepare the required information and analysis in due time.

The legally established expiry dates for Category 9 industrial monitoring and control equipment shall be respected in order to guarantee legal certainty and predictability and avoid undesirable socioeconomic impacts. Article 5.2 of the RoHS Directive defines different validity periods for exemptions depending on EEE category, thus mitigating the risk of the potential socio-economic impacts anticipated by the Commission Impact assessment². Any premature shortening of exemption validity periods will be extremely detrimental to our sector and will result in negative socio-economic impact. Unforeseen workload will divert workforce from product development and slow down innovation.

We request the European Commission to provide clarification on this point and schedule the evaluation of the Annex III exemptions relevant to category 9 industrial applications in due time, i.e., 18 months prior to 21 July 2024.

Should the Commission deem necessary, the Test & Measurement Coalition is ready to engage in the process provide further information on the specificity of category 9 industrial applications of the above-mentioned exemptions, the technical performance and reliability challenges and the socioeconomic considerations.

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Critical importance of legal certainty and predictability related to the availability of Annex III RoHS exemptions to category 9 industrial monitoring and control equipment

The availability of Annex III exemption to category 9 industrial monitoring and control equipment was a key regulatory condition for inclusion of this category in the scope of RoHS. The need to maintain the exemptions initially listed in Annex III of the RoHS Directive for category 9 industrial was confirmed already in 2008 by the ERA report³, then confirmed by the Commission impact assessment⁴ and ultimately by the text of the Directive itself.

The impact assessment highlights in particular: *...”taking into account the specificities of some of Category 8 and 9 products (safety critical, long lifecycles, long product development not least because of diverse and technically demanding functional characteristics) as well as scientific and technical development with regard to substitution of the substances in certain applications, it is considered necessary that some exemptions are granted and that the enforcement dates are staged in such a way for some product categories so that negative social impacts (reduced availability of products due to forced withdrawal of products impossible to be made compliant, limitation of access to high quality health care due to disproportionate increase of medical devices' price) are avoided”.*⁵

The RoHS substance restrictions applied to category 9 industrial monitoring and control instruments since 22 July 2017. Article 5.2 of the RoHS Directive defines different validity periods for exemptions depending

² Impact assessment [EN \(europa.eu\)](https://ec.europa.eu/eia/)

³ ERA Final Report [\(europa.eu\)](https://ec.europa.eu/eia/)

⁴ Impact assessment [EN \(europa.eu\)](https://ec.europa.eu/eia/)

⁵ Impact assessment, p 55

on EEE category, thus mitigating the risk of the potential socio-economic impacts anticipated by the Impact assessment. The exemptions listed in both Annex III and Annex IV for which no expiry date was specified on 21 July 2011, apply to category 9 industrial equipment with validity period of 7 years, starting as of 22 July 2017. This is also explained in the RoHS FAQ, p. 26

http://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf.

Certain Annex III RoHS exemptions have been already subject to review and their validity period or their expiry date for category 9 industrial have not been questioned. In its evaluation report published in 2016, Oeko institut referred to the contribution of the Test & Measurement Coalition *“raising legal question as to the availability of the current exemption to category 8 and 9 equipment. TMC and JBCE claim the availability of Annex III exemptions to category 8 and 9 for seven years starting in 22.7.2017.”* In its report, Oeko Institut recommended the expiry dates for the different categories to be specified and confirmed the expiry date of 21 July 2024 for category 9 industrial.⁶ This approach has been validated by the Delegated act which listed specific expiry dates for the different categories.

The exemptions 4(f), 8(b), 8(b)-I, 9(a)-II, 13(a), 13(b), 13(b)-I, 13(b)-II, 13(b)-III, 15 and 15(a) are currently subject to evaluation as they will expire on 21 July 2021 for categories 1-7 and 10. However, these exemptions continue to apply to category 9 industrial till 2024. The assessment of their renewal relevant to category 9 industrial monitoring and control equipment should be envisaged 18 months prior to the expiry date.

Questioning of the initial validity period of RoHS exemptions could be envisaged only in case of proven scientific progress which makes earlier successful substitution possible for the specific product category. However, the applications submitted to the Commission, subject to this consultation, do not provide such evidence for category 9 industrial, on the contrary, they confirm the need for continuation of the specific exemptions for all RoHS categories.

It is therefore critical to guarantee the legal certainty and predictability of the applicability of these exemptions to category 9 industrial monitoring and control equipment until their expiry date of 21 July 2024.

Lack of regulatory efficiency of early evaluation of exemptions relevant for category 9 industrial monitoring and control equipment

The regulatory approach for category 9 industrial products is very different from the one related to consumer products. The exemption validity period of 7 years for category 9 industrial is foreseen by the RoHS Directive for a number of reasons, which are linked to the long product lifetime (average of 10 years), infrequent product redesign etc. The test and validation of potential alternatives, is substantially long – up to 2 years, to guarantee high performance and reliability during the product use phase, which can be up to 40 years. Experience with RoHS compliance showed that shorting of the testing period leads to false negative result for potential candidate for substitution. It is therefore important to respect the foreseen period of 7 years before evaluating the need for continuation of exemption for category 9 industrial products. Early examination of status of scientific and technical progress could lead to indication of need of potentially more exemptions than if this done at the end of the seven-year period, as foreseen by the Directive itself.

⁶ Oeko report, exemption 6a, p.313 ; exemption 6b, p.335 ; exemption 7a, p.419 ; exemption 7 (c) I, p.497 ; exemption 7 (c) II, p.516.

This has been acknowledged by the Impact assessment which warns that in case of early inclusion of category 9 “more exemptions (probably more than 10) will be needed for 2012 in comparison to a later entry into force.”⁷

Early evaluation will result in additional administrative cost and workload for both industry, the European Commission and its consultants, Member States and European Parliament

The work related to RoHS exemptions is planned according to the established regulatory deadlines. We would like to remind that it took 12 years for our members to redesign of their products for RoHS compliance and the work is ongoing to meet the deadline for compliance with the restriction of the phthalates. Meeting of the initial 2017 deadline was only possible because our members started the research process in 2005, well before the Directive formally introduce this category into the scope of RoHS. The initial efforts for coming into the scope of RoHS resulted in costs as high as 10% of member companies’ turnover. Our members invest over 4 million EURO per year to maintain RoHS compliance. It important to stress that 7.5% of our products were withdrawn prematurely from the EU market following the RoHS enforcement date, limiting the access of EU industry to category 9 industrial equipment, critical for the R&D, innovation and competitiveness. Any additional and unforeseen disruption, such as premature shortening of exemption validity periods will be extremely detrimental to our sector and will result in negative socio-economic impact. Unforeseen workload will divert workforce from product development and slow down innovation. RoHS exemption process has been systematically criticized for its length (in some cases, more than 5 years were needed!), which resulted in real negative business impacts. Adding early assessments for category 9 industrial equipment to the initially foreseen workplan of the Commission will create substantial delays in the process and cause further unpredictability. This situation must be avoided, especially in the case of category 9 industrial where the existing legal deadlines foresee sufficient time for the submission of renewal applications. The cost associated with the exemption procedure as such should not be underestimated, both for industry and for public authorities.

Importance of maintaining the exemption’s references unchanged

Based on the outcome of prior exemption renewal request, the current evaluation of the RoHS exemptions is likely to result in scope modifications of the exemptions. During the latest evaluation process in 2015, changes of the structure, wording, numbering and expiry dates of certain Annex III exemptions have been considered by Oeko Institut. Although this evaluation did not concern our category of products, we had to proactively engage during the process to ensure regulatory coherence is maintained and that the exemptions are maintain in their original format and wording.

Amending the scope of the exemption by changing the application or substance restriction value has a significant administrative burden to Industry, independent of equipment category.

Examples of such an important impact on compliance management include:

- Data management and ERP Solution re-engineering to segregate existing supplier declarations from those of the new Exemption takes IT investment, time and resources and is open to error;
- Separating and managing suppliers’ declarations when schemas are in transition adds huge complexity where the same exemption number exists with a different description;

⁷ Impact assessment, p. 44

The above introduces additional risk to compliance, yet has no perceivable benefit. Industrial Monitoring and Control producers have to manage supplier's declarations for hundreds of thousands of items.

To avoid these additional administrative burdens and risks to RoHS Compliance integrity, it is important to retain each Exemption **as published in its original Annex** until it is no longer relevant to any category of EEE. Amending the scope to remove or limit applicability for specific categories if EEE is acceptable.

A new exemption with a unique number should be created every time an exemption description is modified, such as the application or substance restriction value. These actions will substantially reduce the risks of confusion and mistakes both in data creation and management, thus reducing risk to industry across all product categories in maintaining the compliance of their products.

The Exemption shall remain unchanged, including the description, scope, dates of applicability or the exemption number and Annex, for category 9 Industrial equipment.

Specific comments for exemptions 8(b), 8(b)-I, 15 and 15(a)

Bio Innovation Service, UNITAR and Fraunhofer IZM (Institute for Reliability and Microintegration) are currently evaluating several RoHS Annex III Exemptions, including Exemptions 8(b) and 8(b)-I, 15 & 15(a) in which we would like to focus in this letter. It must be recognized that the extended lifetime of the equipment in our portfolios mean that any change in the following exemption definitions will not result in any change in the protection of health nor the environment for many decades; and that the magnitude of such changes are negligible given that Industrial Category 9 equipment is estimated to be 0.2% of all EEE placed on the EU market. Retention of the exemptions as currently published is critical to the continued availability of Industrial Cat 9 equipment to the EU market.

- **Regarding Exemption 8(b) and 8(b)-I:** this exemption remains valid for Category 9 industrial until July 2024. This timeline must be respected. In this process, the consultants are questioning why exemption 8(b)-I cannot be applied to Cat 8 & 9 (inc. industrial). The reason is that these categories have high reliability expectations to support up to 40 years active life, which requires additional reliability. This argument was already made in the previous consultation on exemption 8(b)-I exemption, which was then tied to the application of components within equipment, which would have to be validated for each and every component's use within each product, therefore significantly adding complexity to exemption management. Considering the scale and complexity of portfolios in cat.9 industrial; up to 30,000 product and option combinations by producer; the impact of this change would be extremely significant and require appropriate timelines to complete such an assessment.
- **Regarding Exemption 13(a) and 13(b):** we would request to retain the existing wording for the continuity of Exemption 13(b). Forcing the segregation into each one of the sub-categories 13(b)I, 13(b)II and 13(b)III will multiply the work and add significant complexity for exemption management. The exemptions 13(a) and 13(b) must be maintained in their original format and wording.
- **Regarding Exemption 15 and 15(a):** this exemption request looks to change the scope of exemption 15(a) to add Category 9 (including industrial), while Category 8 (non-IVD) is requesting continuity for Exemption 15. Such a change would cause significant administrative

burden to validate technology node size of each device currently applying exemption 15. This would be especially problematic for lifetime buy inventory, where this information may not be readily available. Should it not be possible to validate continued conformance of the impacted components, product redesign and potentially product withdrawal from the market would be necessary.

We appreciate your attention to our comments and recommendations and we are pleased to answer any questions you may have in this respect.

Conclusions

The Test & Measurement Coalition representing 60 % of the companies active in the production of industrial monitoring and control equipment, has been actively participating since 2005 in the work of the European Commission and its consultants, on the exemptions needs for category 9 industrial.

We have provided the initial data and socio-economic justification on the basis of which annex III exemptions have been extended to category 9 industrial equipment when coming into the scope of RoHS.

We believe the current evaluation of exemptions 4(f), 8(b), 8(b)-I, 9(a)-II, 13(a), 13(b), 13(b)-I, 13(b)-II, 13(b)-III, 15 and 15(a) with regards to category 9 industrial applications is premature. The current review should focus on categories 1-7 and 10 for which the expiry date is July 2021. With regards to category 9 industrial, these exemptions should be assessed in a later stage, subject to the timely submission of renewal requests 18 months prior to the expiry date of July 2024.

We urge the European Commission to provide clarity in this respect as soon as possible. Should the Commission decide to carry the assessment of the exemptions for category 9 industrial application in the context of the current review, the Test & Measurement Coalition would gather further information, especially on the socio-economic aspects. We appreciate your attention to our comments and recommendations and we are pleased to answer any questions you may have in this respect.

Thank you in advance for your attention.

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