

Test & Measurement Coalition

Comments related to current evaluation of RoHS Annex III exemptions

3 March 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.

Oeko Institut is currently evaluating exemptions RoHS Annex III Exemptions 6(a)/6(a)-I, 6(b)/6(b)-I, 6(b)-II, 6(c), 7(a), 7(c)-I, 7(c)-II, 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; reflecting the status of the scientific and technical progress and the socio-economic considerations at that point of 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 socio-economic impacts.

We urge the European Commission to provide formal clarification on this point as soon as possible. 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 socio-economic considerations.

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 report¹, then confirmed by the Commission impact assessment² 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”.*³

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 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.⁴

This approach has been validated by the Delegated act which listed specific expiry dates for the different categories.

The exemptions 6(a)/6(a)-I, 6(b)/6(b)-I, 6(b)-II, 6(c), 7(a), 7(c)-I, 7(c) are currently subject to evaluation as they will expire on 21 July 2021 for categories 1-7 and 10. However, these exemptions

¹ ERA [Final Report \(europa.eu\)](http://ec.europa.eu/era/)

² Impact assessment [EN \(europa.eu\)](http://ec.europa.eu/era/)

³ Impact assessment, p 55

⁴ 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.

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.

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.”*⁵

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.

⁵ Impact assessment, p. 44

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;

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.

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 6(a)/6(a)-I, 6(b)/6(b)-I, 6(b)-II, 6(c), 7(a), 7(c)-I, 7(c)-II 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.