Test & Measurement Coalition

Contribution to Oeko-Institut consultation on RoHS substance methodology and substance inventory

21 December 2018

Introduction to the T&M Coalition

The Test & Measurement Coalition represents an ad-hoc group of companies active in producing Category 9 industrial type products. The Coalition includes leading companies in the sector including Agilent Technologies, Fluke Corporation, Keithley Instruments, Keysight Technologies, National Instruments, and Tektronix. We estimate the coalition membership represents roughly 60% of the global production of industrial test and measurement products and other Category 9 industrial equipment including chemical analysers.

The Test & Measurement Coalition has been actively participating in all consultations on RoHS substances organised by Oeko-Institut, our first engagement dates back to 2008 contributing to the study on the RoHS substances in EEE in the context of the RoHS recast. We are pleased now to contribute with further input to the current consultation conducted by Oeko-Institut on RoHS substance methodology and substance inventory.

Preliminary remarks

We believe the development of RoHS substance methodology is critical for the long term viability of the RoHS Directive as well as the predictability and legal certainty.

A comprehensive methodology should define the criteria for identification and prioritisation of substances, avoiding overlap with other existing legislation.

At the same time, the methodology should outline a clear process focusing on the different steps required for effective identification, prioritisation, and assessment of substances, but also addressing the question of frequency of substance restriction initiatives as well as defining which institution/organisation will be in charge and what the process should be.

Although Oeko-Institut presents its analysis and recommendations related to the methodology, the questionnaire focuses primarily on data gathering and does not

consult on the actual methodology. We believe it is premature to discuss substances and gather data prior to defining the RoHS substance methodology. We have decided therefore to provide comments and recommendations on the draft methodology presented by Oeko-Institut.

Concerns related to the general approach to RoHS substance methodology

Oeko-Institut's approach to RoHS substance methodology is primarily based on the precautionary principle. According to Oeko-Institut "the RoHS Directive interpretation of the precautionary principle may differ from that of the REACH Regulation". We would like to stress that while the RoHS Directive[1] calls for taking into account the precautionary principle, when reviewing Annex II, it should be applied in consistent and coherent way with the other EU legislation.

RoHS Directive's primarily focus is on environmental and health impacts during use and/or waste management. However, Oeko-Institut suggests that RoHS methodology should address also risks arising during manufacturing of the EEE.

We believe this goes beyond the objective of RoHS. Substances representing potential risks during the manufacturing process should be assessed under REACH in view of potential inclusion in Authorisation Annex XIV or Restriction Annex XVII.

In the context of REACH Restriction, the authorities should demonstrate that there is unacceptable level of risk related to the substance. Oeko-Institut suggests that in the context of RoHS, the ***potential risk*** during use or waste phase justifies RoHS restriction. RoHS restriction is justified in their view if the substance is classified with a hazard potentially resulting in risk, regardless of actual occurrence and risk management options. We believe this is disproportionate and results in RoHS introducing stricter conditions for restrictions than those required in the context of REACH.

Substance identification

Oeko-Institut suggests to establish substance inventory with the purpose to prioritise substance for future assessment in view of potential restriction under RoHS. The criteria proposed for the identification of the substances are heavily based on hazard and do refer to other regulatory measures which lead inevitably to overlap and inconsistency.

Oeko-Institut has identified several criteria for substance identification: substances listed in Annex VI CLP or fulfilling the criteria; carcinogenic or mutagenic or reprotoxic, cat 1A, 1B and cat 2; PBT, vPvB, PB; Endocrine disruptors; SVHC; Radioactive substances or substances suspected as any of the above.

We would like to provide the following comments on specific hazard identification criteria which we find problematic:

[1] RoHS Directive Recitals 3, 10, 16 and Art.6 (1)

- *Substance listed in Annex VI CLP or fulfilling the criteria*

Substances undergoing REACH Evaluation or subject to REACH CLP process should not be considered under RoHS before the REACH process is finalised and the classification is confirmed.

We do not support that substances fulfilling the criteria of CLP classification should be identified as potential substances for restriction under RoHS. Oeko-Institut does not specify who will be in charge of determining if a substance is fulfilling the criteria for hazardous classification and what criteria will be used for such assessment.

We would like to stress that CLP is a serious process subject to in depth preparatory work done by a dossier submitter and followed by detailed assessment of ECHA Risk Assessment Committee governed by strict scientific criteria. Moreover, the confirmation of hazardous clarification has a huge impact on its regulatory status and can consequently trigger restrictions under umbrella EU legislation such as REACH as well as under sector specific legislation such as Plant Protection, Biocides, Cosmetics, etc. Therefore the RoHS restriction process should be based only on hazardous classification confirmed by the CLP process.

- *Endocrine disruptors*

The Commission issued in November 2018 its communication on Endocrine disruptors. Any initiatives aiming at identifying substances for restriction under RoHS for endocrine disruptor concerns, should be consistent with the approach envisaged by the Commission and coherent with the developments related to endocrine disruptors under REACH.

- *SVHC*

The selection of substances under RoHS should avoid overlaps with REACH. We therefore strongly recommend that RoHS substances should not be picked up from REACH SVHC, Annex XIV, and Annex XVII as the concerns related to these substances have been already addressed by the respective REACH regulatory tools. Moreover, substances are identified as SVHC candidates solely on the basis of their classification which should not be the only criteria for identifying substances for RoHS restriction purposes, e.g. without assessing the risk in EEE. SVHC are consequently included in REACH Authorisation Annex, which bans the use of the substance in the EU, unless authorisation is granted.

- *Radioactive substances*

Identifying radioactive substances as a priority for restriction under RoHS lacks coherence with existing legislation: EURATOM has not been referenced by the methodology, despite preceding WEEE and RoHS Directives by more than a decade. There should be no need to add radioactivity into the RoHS criteria as this is fully covered by EURATOM. Ionizing Radiation sources within the scope of the EURATOM

regulations are removed from EEE and separately managed for nuclear reprocessing. Strict controls extend to use, transportation and end of life management.

- *Substances suspected of hazardous properties mentioned above*

RoHS restriction process leads to substantial impacts on product design and market access of EEE. These are serious consequences and cannot be triggered by the simple suspicion of hazardous properties of the substance. We would like to stress that in the context of REACH SVHC identification, there is a criteria related to existence of equivalent concern. This equivalence of concern is however justified by the Annex XV submitter and is a subject of detailed assessment and decision of the Member State Committee of ECHA and in absence of unanimity, the dossier is transferred to the European Commission. In some cases, substances have not been confirmed as SVHC, as the authorities concluded that criteria of equivalence have not been met.

In the context of RoHS, Oeko-Institut does not specify who is going to decide on the presence of suspected hazard and what would be the criteria and the process used. This is not acceptable as it leads to legal uncertainty and lack of surety that the process will be science-based and transparent.

- *Substances not present in EEE*

Oeko-Institut suggests that substance which are not present in EEE could be included in the inventory for two reasons:
1. To avoid regrettable substitution, in case the substance is not yet used in EEE but the producers could consider using the substance in the future;
2. Process chemicals may react during the manufacturing process and as a result may form derivatives of hazardous nature which may occur in the final product.

We disagree with this approach.
In the first case, substances cannot be listed as hypothetical substitute in the future without any serious grounds. The inventory will be in this case populated by endless number of substances not yet used in EEE. This should not be regarded as serious criteria for substance identification.
We believe it is inappropriate to consider restriction under RoHS of substances not present in EEE. REACH is a better regulatory tool to address concerns resulting from process chemicals. In fact, many of the substances added in the Annex XIV are industrial process chemicals which are not present in EEE.

In the second case, if this criteria would apply it would mean that RoHS should regulate process chemicals and derivatives. Would then the intermediate be subject to restriction under RoHS or the derivatives? How should this assessment be done and by who? What would be the concentration level of the derivate which would trigger hazardous concern?
It is also very important to consider how the enforcement will be done in practice, in case the restriction does apply to substance not present in the EEE or present in insignificant quanatity, as a derivative.

- *Nanomaterials*

According to Oeko Institute, due to the lack of knowledge on the fate and behaviour of nanoparticles in the environment and the human body, the precautionary principle should be applied. We would like to stress that nanomaterials are not a hazard category. The questions of hazard and risk related to nanomaterials should be addressed under REACH, using substance-by-substance risk management approach. The reference to national nano registers as source of information is not appropriate as none of the existing registries use hazard or risk based criteria for registering these substances. Therefore the fact that a nano is registered does not imply risk associated to its use.

- *The Substances Inventory*

The concept of a comprehensive database of **all** possible substances in EEE is unworkable for many reasons:

Most producers of EEE limit data collection to regulated and restricted substances and those of very high concern which may need authorisation or be restricted in the future.

Elemental substances such as copper are essential to conduction of electricity but have no regulatory concern. Consequently beyond noting the obvious main function of conduction there appears to be no value in this type of data which will never be exhaustive.

Many downstream suppliers limit substance data availability to align with IEC 62474. This is already screened as relevant to EEE. Data on the other substances identified by Oeko-Institut is rare particularly where parts are sourced from Asia or elsewhere outside the EU. Of these 195 such as toluene-4-sulphonic acid have no main function identified by Oeko-Institut which gives no indication of the types of parts that may use them. This makes targeted outreach impossible to those suppliers that could potentially use a substance in their components or sub-assemblies. This issue of data availability is especially problematic for materials used both in EEE and wider industry, as there would be no matching horizontal requirement for suppliers to provide the data on non-regulated substances.

We recommend that the four radioactive isotope substances be deleted from the list as they are not present in WEEE but separately collected for reprocessing at nuclear facilities. It should be realised that they do not represent those used in medical devices or industrial monitoring and control instruments. Medical devices alone use over 40 different radioactive substances in therapy applications including isotopes such as Carbon-11, Nitrogen-13 and Molybdenum-99.

We strongly recommend stopping further work on a large scale substance inventory and instead align with IEC 62474 list of declarable substances. As this aligns with existing practice in the electronics industry it will maximise coverage of relevant data for further assessment.

Consequently the Test and Measurement Coalition will not provide substance level feedback as requested by Oeko-Institut on the 816 substances listed except to note

that it is impossible for nearly any manufacturer of complex equipment to provide comprehensive information on their use or non-use due to the limitations on available information in the extended supply chain.

Further recommendations related to the RoHS methodology

- *Process related issues: Frequency of the restriction proposal, criteria for determining of restriction timeline*

Oeko-Institut should complete its draft methodology with a proposal for the frequency of introducing substance restriction proposals under RoHS. As the result is restriction of the substance in EEE, with possibility for applying for exemptions, sufficient time should be given for industry to adapt and prepare for compliance. The restriction of the initial 6 substances resulted in massive redesign of products and a large amount of exemption requests, which was underestimated by the authorities. It is therefore of key importance to introduce a logical cycle of at least 5 years for new substance restrictions with additional compliance transition periods for implementation delineated by equipment category.

It should be noted that following the opening of the scope to cover all EEEs, the differences between product categories increased even further, as the products have very different lifetime, reliability requirements, redesign cycles etc. To ensure effective and proportional implementation of any new restrictions, the differences in the product categories must be considered. In this respect, substance restrictions should be introduced with differentiated timeline adapted to each category.

Our experience with RoHS compliance shows that at least 12 years will be needed for category 9 industrial products to comply with the restriction in order to minimize consequent premature withdrawal of portfolio products from the market and the consequent impact on customer innovation and critical downstream industries.

The same should apply for the RoHS exemption process - longer review periods should be considered for industrial and professional EEE. A review period of 12 years has become the standard in the context of REACH authorisation decisions for industrial uses.

- *Coherence with REACH SEA methodology*

Oeko Institut’s request to provide inputs for “the purpose of specifying an exhaustive list of socio-economic impacts” is not a practical outcome as the state of the art will continually evolve. Leverage and reference should instead be made to the substantive

work[2] documented by ECHA with respect to socioeconomic impact assessment. SEA under RoHS should follow the same methodology.

- *Use of ECHA RAC and SEAC expertise*

Although RoHS does not prescribe the involvement of RAC and SEAC in the assessment of potential candidates for RoHS restriction, this option should be thoroughly considered. We therefore recommend that this analysis are included in the RoHS methodology preparation.

- *RoHS substance methodology focus should be on EEE waste phase and on facilitating the recycling of EEE*

It must be considered that EEE, especially in professional or industrial uses, may only enter the waste stream many decades after being placed on the EU market. The hazards present in such equipment still need to be controlled by WEEE processing operations to meet their EHS obligations.

Given the criteria stated in Article 6.1 (a) through (c) are focused on the protection of health and of the environment during the preparation on processing of WEEE, it is imperative that the methodology starts from an assessment of where restrictions are *necessary* based the state of the art in the activities of EU licensed WEEE operatives

[2] https://echa.europa.eu/support/socio-economic-analysis-in-reach
https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf

taking into account the nature of substances present in electronic waste and associated controls available.

This approach will be:

• Proportionate: the scope is limited to the substance-related risks experienced by licenced WEEE operatives by comparison to the scale of attempting an unnecessary inventory of all substances possible in EEE in all sectors;

• Appropriate: an assessment of both the hazards present and the associated controls available are required to determine when additional regulation of EEE is appropriate that would exceed the WEEE operatives' capability;

• Better Regulation: focusing assessment on the licenced WEEE operatives will have both a reduced cost and produce more repeatable accurate results compared to the proposal to assess the whole of the electronics industry.