Test & Measurement Coalition

Input to consultation on "Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)"

Impacts of potential inclusion in the RoHS Directive of Tetrabromobisphenol-A (TBBP-A), Medium Chain Chlorinated Paraffins (MCCPs), and Diantimony trioxide on Category 9 industrial sector

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Executive Summary

The Test & Measurement Coalition and its members

The Test & Measurement Coalition was created in 2005 and represents an ad-hoc group of companies active in **producing test & measurement industrial type products (Category 9).** 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 test and measurement products and other industrial equipment including chemical analysers.

The Test & Measurement Coalition has been actively participating in all consultations on RoHS. We are pleased now to contribute with further input to the current consultation on the study to review of the list of restricted substances with input on the impacts of potential inclusion of three new RoHS substances – MCCPs, TBBP-A and Diantimony trioxide – on Category 9 industrial sector.

Key issues & recommendations

The three proposed new RoHS substances are anticipated to be present in components of all our equipment. Consequently, our whole product portfolios would be impacted by a restriction and therefore require incremental effort comparable to that required to meet entry into scope of RoHS. These resulted in substantial costs and administrative burden for our industry.

These efforts, costs and time investments to bring our sector into compliance with the proposed three additional substances is disproportionate to the benefits considering the very low quantities of RoHS substances in test & measurement industrial equipment and the consequently negligible improvement in protection of human health from the environmentally sound recovery and disposal of related waste EEE.

Should it be decided to apply these additional substance restrictions to Industrial Monitoring and Control equipment, we estimate the need for a further 12 year transition period *as a minimum* to achieve compliance if the restrictions were applied to our category of equipment.

While X-Ray Fluorescence (XRF) analysis can be used as a screening methodology for detecting the antimony in Diantimony trioxide, there is no screening methodology that can specifically identify TBBP-A nor Medium Chain Chlorinated Paraffin presence. Ensuring compliance to restrictions on these substances will necessitate a detailed supply chain investigation to gather information on substance presence, quantity and planned transition timeframes. From our experience of both the efforts and engagements necessary to bring our portfolios into RoHS compliance, this will take years. This contrasts with the relatively limited efforts required by the addition of the phthalate substance restrictions, which allowed for a five-year transition time for our category of equipment – a period which is proving difficult to meet across all products without unnecessary cost and material scrap.

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, a figure which includes the consumer equipment sector. Considering the longevity of our low-volume industrial equipment, with an active life of up to 40 years, it therefore appears that it will take many decades before there is a complete reduction in risk associated with waste processing hazards.

Additionally, monitoring and control equipment accounted for only 0.7% of the total Waste EEE (WEEE) collected in the EU[1]. Our Industrial Test & Measurement equipment only represent a fraction of this value: an insignificant contribution to the waste stream as compared to other EEE categories. Our equipment is extensively reused (both in whole and as replacement parts) then collected and recycled via business-to-business (B2B) schemes and does not typically end up in the household municipal waste.

It is difficult to give specific quantities at this stage for the three new substances, as this information is currently limited to the component producers. Our investigations have only been able to identify that Diantimony trioxide may typically be present in board mounted component encapsulation in a range of 1 to 3% of homogeneous material. A survey of historical XRF data suggests that upwards of 17% of plastics surveyed contained some amount of antimony and over 16% contained antimony in conjunction with bromine. With many of these materials being used in subcomponents of larger assemblies, it will take significant redesign efforts to remove the affected items.

To ensure effectiveness, efficiency and relevance of the RoHS Directive, the sector calls on the Commission and OEKO to evaluate the cost-effectiveness of proposed measures for Category 9 industrial before restricting additional substances.

[1] EU official figures, Eurostat 2016

Specificities of industrial test & measurement instruments

Overview of specificities

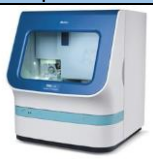
Industrial test & measurement instruments are very different from high-volume consumer products which are frequently re-designed to follow consumer trends. Industrial test & measurement (T&M) instruments (category 9 under the RoHS Directive) are intentionally designed for long useful lifespans with high reliability. These instruments are designed: exclusively for professional and industrial use; to meet high performance requirements in critical applications; and last up to 40 years (10 years typical first life). Redesign is not frequent and happens every 7 years on average (as compared to every 1.5 years or less for consumer products).

The three proposed new RoHS substances are anticipated to be present in components of all equipment. The following aspects that are specific to industrial test and measurement equipment must be considered before determining the applicability and timeline for any of these substances to become applicable to industrial monitoring and control category of equipment.

Sectors addressed

Our professional test and measurement products provide the tools for engineers to develop new solutions and businesses to bring them to market. These instruments are used in **Research, Quality Control and Testing laboratories** (including field testing) in Universities, Manufacturing and clinical facilities and by Governmental Agencies for conformance verification and environmental testing. 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 and critical systems of all types**. The example market sectors highlighted below illustrate the criticality of our solutions in the continued function of our modern society:

Sector	Criticality	Sample Products
Aerospace & Defence	Our complex solutions push the boundaries of technical limitations to fuel leading-edge technology innovations. Example applications include spectrum monitoring, signal identification and geolocation; satellite communication simulation and emulation; electronic warfare testing, simulation, and countermeasures; Radar, communications and avionics development and test.	 Spectrum Analyzers
Automotive	The technology revolution in automotive to incorporate e-mobility, autonomous driving, advanced driver assistance systems, connected cars and automotive electronics are all being developed, validated and tested using equipment from our members' portfolios.	 Signal Generators

Sector	Criticality	Sample Products
Clinical & Diagnostics	Our instruments play a critical role in the diagnosis of disease and identification of therapeutic strategies. With our comprehensive portfolio of industry-leading detection platforms and sample preparation automation, we help our customers to take advantage of the growing world of analysis in clinical research. These instruments are essential to maximize laboratory efficiency and are designed to minimize downtown to better enable hospitals and clinics.	 DNA Sequencer  IHC and ISH staining
Communications	The capability of our equipment defines the parameters of international standards for communications. We provide equipment to develop and validate the performance across all elements of the communications networks; be they wired, wireless or optical. We additionally help network operators assure compliance for their network security and efficiency through application and integration of our solutions.	 Wireless Network Emulation
Education	Our equipment and solutions help prepare future engineers for careers in industry or government; through learning how to use our test and measurement instruments correctly and appropriately.	
Energy	From charging technology through cell development and evaluation of solar energy installations, our solutions are necessary to assure the safety, efficiency and effectiveness of modern energy technologies.	 Automotive Energy emulation and test
Governmental Agencies	Our solutions meet the exacting demands of government compliance to allow federal agencies to design, test and operate with confidence. In addition to all the other sectors listed here, we provide equipment is used to assure the integrity of National measurement systems (NMS) and their recognition by the international community.	 Enterprise Network test, emulation and security
Life Sciences	Sophisticated solutions are needed to study life and we provide equipment which is able to do analyses at the cellular as well as biochemical (e.g. protein and nucleic acid) levels.	 Visual & Fluorescent Microcopes  Real-Time Cell Analyzers

Sector	Criticality	Sample Products
Other Lab/Analytical	Accurate and timely results are vital for forensics laboratories and field investigations. Whether testing for poisons in a forensics investigation, screening athletes for performance enhancing drugs, analysing samples for recreational drugs, or checking a crime scene for explosive residue - lives and professions may be dependent on the accuracy and reliability of the equipment.	 XRF Analyzers  Raman Spectrometer
Chemical Analysis	Analytical challenges have never been greater, whether analysing contaminants in wastewater or purity of drinking water or food, measuring indoor air quality, responding to natural or man-made disasters, or identifying emerging contaminants. Environmental analysis must be done more reliably, efficiently and with greater degrees of sensitivity and higher quality results than ever before. With the globalization of the food chain, protecting both the consumer and brands becomes more demanding. Today, the food and agriculture industry face ever-increasing demands for more analytical solutions to specifically meet these needs.	 Mass Spectrometers  Liquid Chromatograph

Market Expectations

Our customers require that our products have greater bandwidth, accuracy, and precision than the products they themselves are producing. Reliability and accuracy of test & measurement equipment are important in applications where quality and integrity of data is essential for correct trustworthy decisions; for example, in standards laboratories for electrical calibration, and for chemical tests in environmental or drug analysis.

Our customers are intolerant of system failures that interrupt their research and manufacturing processes. Test & measurement products must meet their requirements to ensure their operational and uptime expectations. Customers expect more than 10 years of product life, and many products purchased 30 years ago are still in use. One of the biggest differences between test & measurement equipment and other electronic products is the expected useful life of our products. Unexpected interruptions to manufacturing can lead to both loss of productivity and waste of production materials.

Reliability constraints may be imposed or negotiated in customer contracts:

- Some aerospace customers impose conditions (solder composition, component termination finishes) to minimise tin whisker growth because lead-free solder combined with poor material finishes are known to cause premature failure.
- Some customers with critical applications impose financial warranty replacement conditions to enforce overall reliability including clauses such as:

- Warranting against design defects in addition to normal warranty for material and workmanship
- Turnaround repair-time limits to get units working after call-out – e.g., over 95% of call-outs shall be fixed within two working days
- Epidemic failure clauses – Epidemic failure occurs when a specified percentage of products purchased contain the same defect or originating cause of defect in a consecutive period, typically of 24 months. If so, the producer is required to provide a remedy plan within a few working days to correct the units. Furthermore and to the extent that such epidemic failures affect customer production or service launch dates, liquidated damages may apply.

The reliability requirement is one of the most fundamental drivers of our design and service activities. The market, in effect, requires much more in-depth testing of our technology in order to ensure reliability.

Scale of Portfolio, Product Complexity & Supply Chain

In order to address each of the market sectors and their specific test and measurement needs, the portfolio of products offered have a massive scale. Members each make available typically 2,000 - 3,000 products on the market; all having many options and accessories. One member has estimated they currently offer over 30,000 product and option combinations for their hardware offerings.

The nature of the tests and measurements made by our Industrial equipment necessitates that the equipment itself is highly complex; with upwards of 40,000 components necessary to produce a single instrument. Even a relatively simple hand-held instrument incorporates significantly more components that a typical consumer product. See Figure 1: Product Complexity examples.

Handheld oscilloscope: 1,900 parts

Pulse function arbitrary noise generator; 16,000 parts

Performance Network Analyzer; 30,00 parts

Mass Spectrometry; 40,000 parts

Figure 1: Product Complexity examples

Both the scale of portfolios and product complexity dimensions lead to Industrial test and measurement producers managing supply chains of over 100,000 suppliers, covering hundreds of thousands of individual parts.

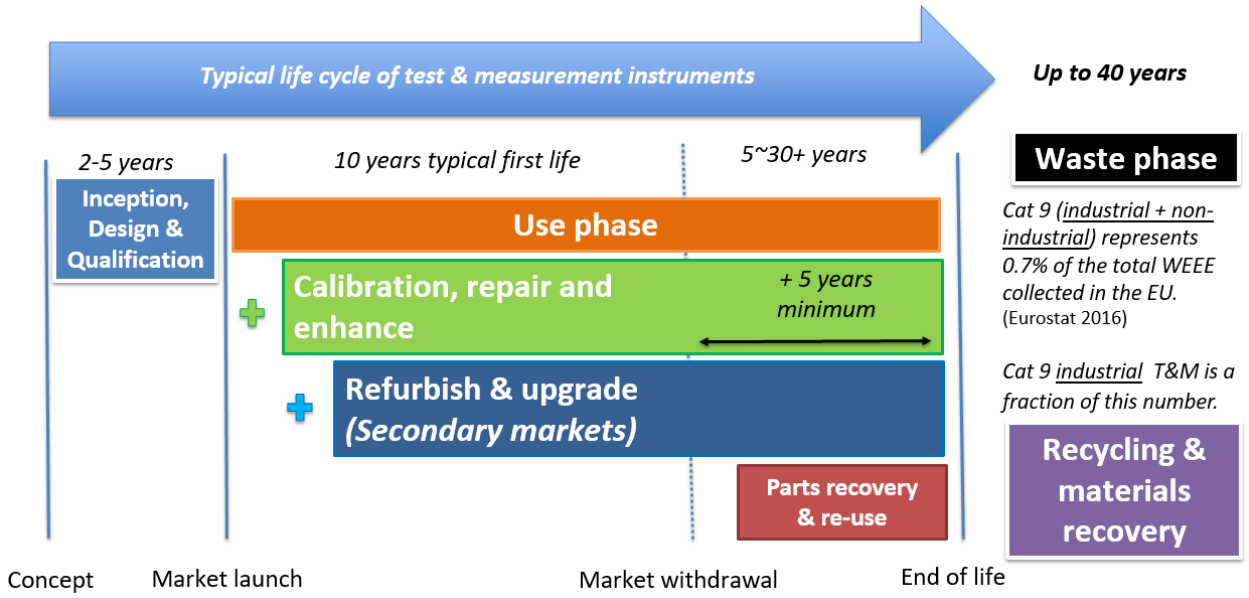
Product Values and Volumes

Unlike consumer product purchases that are easily expensed, the vast majority of Industrial test and measurement equipment become capital assets for our customers. Individual instrument prices can exceed € 1 M Euro, with the cost of solutions for specific customer needs being many million Euro. Helping our customer's minimize depreciation of their equipment assets is supported by the Maintaining, Repairing, and Refurbishing services offer by members. The whole product portfolio was recently redesigned to comply with the initial RoHS substances, which took 12 years. Restricting additional

substances would lead to early obsolescence of specific products, scrap of related components, and go in the opposite direction of the circular economy which aims at encouraging longer use and reuse phases.

End-to-End Lifecycle

The market sectors addressed by Industrial test and measurement equipment can in some cases require that our instruments can be maintained in use for decades. The end-to-end lifecycle model below helps to illustrate how our members contribute to the circular economy by assuring the materials we consume to produce our equipment are kept in use for as long as possible.



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 (EU official figures, Eurostat 2016.) Industrial Test & Measurement instruments, a subset of monitoring and control category, therefore only represent a fraction of these values: an insignificant contribution to the waste stream as compared to other EEE categories.

Cost of RoHS transition

Test & measurement instruments (classified as Category 9 equipment) were initially excluded from the scope of RoHS 1. Member companies of the Test & Measurement Coalition started to prepare for RoHS conversion of their portfolios as early as 2005, or 6 years before the adoption and the publication of RoHS 2. It took substantial effort and expense to bring our portfolio of equipment into compliance with the six initial RoHS substances.

Incorporating RoHS into every aspect and activities of our member companies was truly a transformation at a global scale, on how companies designed, produced and maintained their equipment on the market. **With the whole product portfolio just redesigned for RoHS compliance, restricting three new RoHS substance would mean starting the whole process over from scratch.**

This transformation has driven major costs, the three most important being:

1. **Redesigning products,**
2. **Testing and validation,**
3. **Regulatory compliance.**

The compliance with three new RoHS substances restrictions would result in substantial costs and administrative burden for our industry, which are disproportionate to the benefits. Even after establishing RoHS design and supply chain specifications to control product development processes during the extended transition period, during the 1st RoHS transition **60% of the products in the pre-existing portfolio still had to be redesigned** to meet the requirements of the RoHS Directive. Many test & measurement products had to be retired early from the EU market due to RoHS, and were not replaced. This had a negative impact not only for our sector but also on broad range of EU industry which could not have access to these products used in critical applications and for new product development.

Our ex post analysis shows that despite the long transitional period and numerous exemptions, **7.5% of our products had to be withdrawn from the EU market due to the 1st RoHS transition, affecting 7% of companies' turnover**. Both the product withdrawals and the reduced pace of R&D / new product innovation necessitated by diverting resources to redesign activities have had a negative impact on EU customers and their related industries. The cost for RoHS-compliance for the initial substances is estimated at **10% of product turnover. Restricting three new RoHS substances and starting the process over from scratch would create costs on the same magnitude for the sector.**

Cost-effectiveness of additional substance restriction

The cost effectiveness analysis shows the disproportionate character of the costs of compliance with three new RoHS substances restrictions, compared to the extremely low benefits involved (minimal quantities and specificities of the sector). Given the specificity and complexity of our products, it is extremely challenging for our sector to adapt to frequent changes of the RoHS substance restriction scope. The Test & Measurement Coalition members' ability to transition to RoHS compliance products by 2017 was strictly linked to the assumption that no new substances would be added in addition to granting of Category 9 industrial specific exemptions and continued availability of RoHS 1 exemptions.

In this context, potential restriction of additional proposed RoHS substances will essentially require our sector to restart our RoHS programs from the very beginning, undermining all the achievements of transforming our portfolios to be RoHS-compliant if these substance restrictions were to apply to Category 9 industrial.

Regarding the costs entailed by potentially restricting up to three additional substances – MCCPs, TBBP-A and Diantimony trioxide – they would focus **on refreshing the supply chain data through in-depth investigation, assessment of suitability of substitutions with additional testing and new application to third party certification for specific components**. Taking into account the specificities of the sector (product complexity and portfolio, number of components and suppliers), this translate into significant costs. It should however be noted that the costs should not be considered as completely separate individual costs, as there would be some overlaps and combinations of efforts should the restrictions happen simultaneously. Costs for one substance therefore cannot simply be multiplied by two or three should two or three substances be restricted. But on the other hand the cost of compliance will still be incremental for companies with the number of new substances restricted as they imply different suppliers, products and timelines.

Sector-specific consideration on the relevance of additional substance restriction

It should be noted that following the opening of the scope to cover all EEE types, the differences between product categories increased even further, as the wide variety of 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. **RoHS should focus on restriction of substances which are relevant to the type of EEE and raise concerns in the end-of-life phase.** It is essential to introduce even **more substantial differentiation in treatment** of the different categories. A detailed cost benefit analysis of future restriction should be performed, taking into account the amount of substance present in the category 9 industrial EEE, the potential for release to the environment, potential risk in the end of life phase; the cost for not using the substance (redesign, compliance costs, market delays or inaccessibility, etc.)

In this respect, our recommendation is that the three new substance restrictions should not apply to Category 9 industrial as there is no cost-benefit justification for this sector. Should Category 9 industrial be in the scope of the new substance restriction, a differentiated timeline is necessary and additional time granted (12 years minimum.) The current recommendation from OEKO to simply add these substances to the Directive is NOT *suitable or cost-effective solution and therefore is not in line with the Better Regulation principles.* OEKO must assure sufficient time is made available to understand the need for necessary exemptions plus an adequate timeframe for application submissions, their review and approval.

Substance screening and identification methodologies

In addition, it is very important to consider **the feasibility of testing methods in practice and the availability of analytical methods for screening and quantitative analysis** of new potential restricted substances. Indeed, without easily available testing methods, it is not possible for producers to quickly check the presence of substances and a whole supply chain investigation becomes necessary.

Regarding the three substances currently being considered for restriction, there are challenges regarding their screening and analytical methods which may create very concrete feasibility challenges to producers but also to enforcement authorities should they be restricted:

- For **Diantimony trioxide** limited screening for antimony can be done with a X-ray fluorescence, but quantitative analyses require using expensive, specialized Inductively coupled plasma mass spectrometry.
- For **TBBP-A**, the analytical methods are a bit more uncertain as it is not substance-specific (screening might be done with Energy Dispersive X-Ray Spectroscopy while quantitative analyses can be either Gas chromatography–mass spectrometry or Liquid chromatography–mass spectrometry.) These methods are not suitable for manufacturer screening activities.
- **MCCP** is by far the most difficult to analyze, as MCCPs are complex mixtures of compounds and isomers. No screening methods seems to be available, quantitative methods are demanding, complex, and destructive (e.g. quadrupole time-of-flight high-resolution mass spectrometry (GC-NCI-qTOF-HRMS)); additionally, good standards are still not available.

Input on Medium Chain Chlorinated paraffins (MCCPs)

The ability of the Test & Measurement Coalition to give input to the consultation is limited by the availability of data from suppliers on the full material composition of components. As explained above regarding the complexity of test & measurement instruments and the product portfolio, Test & Measurement Coalition members are dealing with hundreds of thousands of parts and suppliers with different levels of knowledge and experience with RoHS. Significant time would be necessary to investigate further and refine the analysis on the feasibility, complexity and cost of substitution.

Number of products and quantity of substance in T&M equipment

At this stage, it is difficult to evaluate the exact number of products impacted as well as the precise content of the substance in our products. This information is not readily available due to the lack of full materials composition information in the vast majority of part-level RoHS conformity declarations.

Each producer will need to run in-depth supply chain surveys to get confirmation and to quantify impacted parts using MCCPs across our portfolios.

In the absence of this information and the potential broad use of this substance, T&M Coalition members anticipate that the entire portfolio of products will be impacted. To our current knowledge, the substance if present would typically represent a very insignificant part of the total product weight.

Function

MCCPs are known to be used both as a plasticiser and a flame retardant. Currently, over a very large number of formulations are in use for a wide range of industrial applications, as described in the Öko-Institut Consultation notes.

Possible Alternatives

To date, no known suitable alternative exists which can perform all functions of MCCPs.

It is anticipated that no direct substitution that can be consistently applied, different solutions will need to be specifically tailored in each applicable use. This will extend the time needed to determine if the reliability of substitutes is assured for our sector's applications.

In addition, for each potential alternative to flame retardant applications, updates to the product safety third-party certifications will be needed. The assurance of component certification continuity by the supply chain critical to our maintenance of product safety.

Cost implications resulting from potential restriction

Further insight into performance of alternatives and reliability of substitution in the supply chain is required to be able to assess the total impact of potential restriction. While it is anticipated that raw component costs will directly increase, the substantial costs are all related to the effort and actions

required to establish the reliability of component substitutions in our equipment while retaining performance and product conformity.

In absence of suitable alternatives, producers will be forced to redesign, test and requalify the entire portfolio. This will have severe negative impact on the product availability and innovation not only on Category 9 industrial producers but also on our customers.

The feedback provided by the T&M Coalition is specific to the impacts of our sector, a subset of the Industrial monitoring and control category. While substitution may be happening for some consumer goods, there are other challenges for industrial products which is why the scope of substance restrictions should be differentiated by sector. The specificity of this sector and its unique requirements have been well established though more than 15 years of engagement with the EU Commission and its consultants. Consequently, it does not follow that the ability of producers in different sectors to transition from substance use can equally apply to producers of Industrial test and measurement equipment. Sector-specific considerations on the relevance of additional substance restriction recommendations are needed.

As previously stated, the Commission estimates that *"the cost of RoHS compliance for some complex products could be as high as 7-10% of turnover"*[2]. These costs cover the **complete refresh of the supply chain data**, which represents more than 8 years' effort to cover over 100,000 suppliers and over 200,000 component part numbers, but **also assessment of suitability of substitutions** taking into account the product complexity and portfolio scale of 2,000 to 3,000 products (average of members) with tens of thousands of product plus option combinations. The costs also entail for some components requalification, re-application and recertification with third-party certification.

This estimation is justified by the historical costs of RoHS conformity and RoHS compliance maintenance.

Time needed

Substantial research and testing of the performance of alternatives and reliability of substitution in the supply chain is required to be in a position to estimate the timing for compliance with potential restriction. This effort is similar to the experience we had with RoHS I, and we anticipate than 12 years will be needed for category 9 industrial products to comply with the restriction.

Need for exemptions

Substantial research and testing of the performance of alternatives and reliability of substitution in the supply chain is required to be in a position to estimate the timing for compliance with potential restriction. This effort is similar to the experience we had with RoHS I, and we anticipate that 12 years will be needed for category 9 industrial products to comply with the restriction. A review period of 12 years has become the standard in the context of REACH authorisation decisions for industrial uses[3].

[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2930:FIN:EN:PDF

[3] https://echa.europa.eu/applications-for-authorisation-explained;
https://echa.europa.eu/documents/10162/13637/tecch_report_socioeconomic_impact_reach_authorisations_en.pdf

Compliance and enforcement challenges

Out of the three substances considered for restriction, MCCP is by far the most difficult to analyse, as they are complex mixtures of compounds and isomers. No screening method seems to be available, quantitative methods are demanding and complex (e.g. GC-NCI-qTOF-HRMS) and good standards are still not readily available. The proposed restriction entails significant feasibility challenges for companies assessing the presence of the substance in their portfolio, as well as for enforcement authorities.

In terms of quantitative methods, the analysis of the entire class of chlorinated paraffins (CPs) is challenging, as they are complex mixtures of compounds and isomers. Analytical method for the analysis of short-chain CPs (SCCPs) and medium-chain CPs (MCCPs) use complex methodologies, e.g. quadrupole time-of-flight high-resolution mass spectrometry (GC-NCI-qTOF-HRMS). This method employs gas chromatography with a chemical ionization source working in negative mode.

Detection and quantification of CPs poses further analytical challenges: CPs are present in the environment at low levels. They are very complex isomeric mixtures and thus difficult to separate chromatographically. Although there is no consensus so far for the use of a validated analytical procedure for the routine monitoring of CPs in environmental samples, biota as well as food and feed, there are several analytical methods that are used to detect and quantify CPs. However, sample sizes used for current detection methods are very large in comparison with typical material amounts used in electronics, and currently available analytical standards are inadequate for the demanding task of quantifying MCCPs and LCCPs[4]. Improved analytical standards are therefore required.

[4] Environ. Sci. Technol. Lett. 2018, 5, 12, 708-717
This review provides an overview of the available analytical CP materials, discusses their advantages and disadvantages for accurate CP analysis, and gives a recommendation for improvements. Recommendations for improved analytical standards include (A) complex CP mixtures that better resemble technical CP mixtures, (B) single-chain CP mixtures of different carbon chain lengths (C10–C30) and varying degrees of chlorination (40–70 wt%Cl), (C) constitutionally defined CPs with representative chlorination patterns, and (D) isotopically labeled CP isomers that represent a broad range of CPs.

Input on Tetrabromobisphenol A (TBBP-A)

The ability of the Test & Measurement Coalition to give input to the consultation is limited by the availability of data from suppliers on the full material composition of components. As explained above regarding the complexity of test & measurement instruments and the product portfolio, Test & Measurement Coalition members are dealing with hundreds of thousands of parts and suppliers with different levels of knowledge and experience with RoHS. Significant time would be necessary to investigate further and refine the analysis on the feasibility, complexity and cost of substitution.

Number of products and quantity of substance in T&M equipment

TBBP-A is used in large number of products, we anticipate that our entire portfolio of products will be impacted. As with diantimony trioxide, each producer will need to run in-depth supply chain surveys to get confirmation of the presence or absence of the substance and to quantify the extent of impacted parts across our portfolios.

On the presumption that the application of TBBP-A as an intermediate in the production of fire-retardant PCB laminates is not applicable for RoHS, T&M Coalition members still anticipate that the entire portfolio of products will be impacted and a focused data collection on parts with the potential to contain polycarbonates will be required to establish impacted commodities. To our current knowledge, the substance would typically represent a very insignificant part of the total product weight.

Function

TBBP-A is known to be used as plasticiser and flame retardant. The presence of the substance in the electronics supply chain is most broadly known to be used in two very different applications – as a reactive component used to formulate printed circuit board laminates and as a component in certain polymers.

- **Use of TBBP-A as flame retardant in PCB laminate materials**

TBBP-A is the most widely-used flame retardant in PCB laminate materials. In use, it is reacted into the epoxy polymer where it is not separable back into TBBP-A and is not biologically available.

During this process it becomes an integral element that defines the electrical performance properties of the printed circuit board material which are a critical design element for the specifications of industrial monitoring and control equipment. ***"TBBP-A is employed as a starting material that fully reacts to form the epoxy resins of laminates for printed circuit boards. This full integration into the epoxy resin ensures that the final product, flame retarded printed circuit boards, no longer contains TBBP-A, leaving the user free from any possible exposure."*** [5]

[5] http://www.isola-group.com/wp-content/uploads/Fire-Retardancy-What-Why-and-How.pdf

Consequently, TBBP-A is not detectable in finished printed circuit boards and so this application is not applicable for RoHS. In order to avoid costly and unnecessary testing this inapplicability should be clearly indicated should any restriction on the use of the material in finished EEE be established.

- **Use of TBBPA-A as a component in certain polymers**

The other main known use of TBBP-A in the electronics supply chain is as a component of polymers, meaning that it is incorporated into the polymer backbone. It is specifically used as a substitute for Bisphenol A to produce fire-resistant polycarbonates, including ABS.

In category 9 industrial products, our use of TBBP-A in polycarbonate materials will require further investigation to establish the full breadth of supply chain use.

Possible Alternatives

No drop-in replacements are available for all applications. Previous studies[6] failed to identify adequate substitutes that did not have potentially similar or greater risks for environment and health.

Substitution of TBBP-A would require revision of nearly every product in our member companies' portfolio for both of the applications discussed above. It is anticipated that it will be extremely difficult to find alternatives that meet all performance and safety requirements, especially for PCB laminate materials.

Monitoring and control instrumentation relies on parameters inherent to the printed circuit board materials and trace layout to enable products to meet performance demands exceeding those of the products under test. Change to the board material would require a minimum board re-layout and product requalification (EMC, safety, reliability, environmental) presuming performance could be duplicated with a new material. Forced substitution would require premature design cycling of the entire portfolio and would risk market withdrawal of products which could not meet specifications with new materials.

While Halogen-free PCB laminate materials are available today, they do not exist for all applications, especially in high-frequency circuitry. Those that do exist do not have all necessary safety approvals.

Cost implications resulting from potential restriction

A full supply chain survey will be needed to be able to confirm and quantify impacted parts in finished EEE products. At this stage, our assessment is that potential restriction would impact the entire product portfolio.

In addition, substantial costs will result from the update and validation of product safety third-party certifications required for any changes to safety critical parts.

Given the critical applications of our products and the very long lifetime, the component certifications are critical to ensure product safety.

Restricting TBBP-A will lead to:

[6] https://echa.europa.eu/documents/10162/17c7379e-f47b-4a76-aa43-060da5830c07

- Forced redesign and requalification testing of entire portfolio;
- Lost opportunity for introduction of new, cutting edge products;
- Withdrawal of products from EU market.

Impacts on innovation of users unable to access withdrawn products.

The feedback provided by the T&M Coalition is specific to the impacts of our sector, a subset of the Industrial monitoring and control category. While substitution may be happening for some consumer goods, there are other challenges for industrial products which is why the scope of substance restrictions should be differentiated by sector. The specificity of this sector and its unique requirements have been well established though more than 15 years of engagement with the EU Commission and its consultants. Consequently, it does not follow that the ability of producers in different sectors to transition from substance use can equally apply to producers of Industrial test and measurement equipment. Sector-specific considerations on the relevance of additional substance restriction recommendations are needed.

As previously stated, the Commission estimates that *"the cost of RoHS compliance for some complex products could be as high as 7-10% of turnover"*[7]. These costs cover the **complete refresh of the supply chain data**, which represents more than 8 years' effort to cover over 100,000 suppliers and over 200,000 component part numbers, but **also assessment of suitability of substitutions** taking into account the product complexity and portfolio scale of 2,000 to 3,000 products (average of members) with tens of thousands of product plus option combinations. The costs also entail for some components requalification, re-application and recertification with third-party certification.

This estimation is justified by the historical costs of RoHS conformity and RoHS compliance maintenance.

Time needed

Substantial research and testing of the performance of alternatives and reliability of substitution in the supply chain is required to be in a position to estimate the timing for compliance with potential restriction. This effort is similar to the experience we had with RoHS I, and we anticipate that at least 12 years will be needed for category 9 industrial products to comply with the restriction in polycarbonates. A review period of 12 years has become the standard in the context of REACH authorisation decisions for industrial uses[8]. A restriction on the reactive use of TBBP-A in the formulation of PCB laminates would be considered catastrophic as it would likely lead to a much higher percentage of product market withdrawal due to cost, effort and extent of required redesign even if suitable substitutes could be identified for some products.

Need for exemptions

If TBBP-A in non-PCB applications is restricted under RoHS, this restriction should not immediately apply to Category 9 industrial producers. Further research by Commission services will be required to define what exemptions will be necessary should this restriction apply to our sector.

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[7] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2930:FIN:EN:PDF

[8] https://echa.europa.eu/applications-for-authorisation-explained;
https://echa.europa.eu/documents/10162/13637/tecch_report_socioeconomic_impact_reach_authorisations_en.pdf

TBBP-A as used in the formulation of PCB laminates should by definition not be considered for restriction under RoHS since it will not be present in homogeneous materials, but if such a restriction is contemplated it must not apply to Category 9 industrial products.

Compliance and enforcement challenges

In terms of screening method, TBBP-A are frequently detected as brominated flame retardant additives by the energy dispersive X-ray (EDX) analysis screening method detection of bromine.

Regarding quantitative methods, Gas chromatography/mass spectrometry-based analysis LC-MS methods are used.

US EPA has not recommended an analytical method for analysis of TBBP-A[9]. Further, the interagency National Environment Methods Index (NEMI) does not list any analytical method for analysis of TBBP-A. However, there are a number of peer reviewed, published methods for determination and quantification of TBBP-A in a variety of environmental media. This includes several optimized for environmental water samples, such as the two mass spectrometry based methods described in Labadie et al. (2010) and Yang et al. (2014), which could be adopted and validated for testing purposes, in lieu of novel method development [10].

[9] https://www.epa.gov/sites/production/files/2017-01/documents/tbbpa_petition_appendix_final.pdf from 2016

[10] Review in TrAC Trends in Analytical Chemistry, Volume 83, Part B, October 2016, Pages 14-24
Review in Journal of Chromatography A, Volume 1216, Issue 3, 16 January 2009, Pages 320-333

Input on Diantimony trioxide

The ability of the Test & Measurement Coalition to give input to the consultation is limited by the availability of data from suppliers on the full material composition of components. As explained above regarding the complexity of test & measurement instruments and the product portfolio, Test & Measurement Coalition members are dealing with hundreds of thousands of parts and suppliers with different levels of knowledge and experience with RoHS. Significant time would be necessary to investigate further and refine the analysis on the feasibility, complexity and cost of substitution.

Number of products and quantity of substance in T&M equipment

At this stage, it is difficult to evaluate the exact number of products impacted as well as the precise content of the substance in our products.

Diantimony trioxide may have limited use in custom components of T&M equipment producers. From our research, it is understood this substance is widely used as flame retardant in component encapsulation by our upstream supply chain. A survey of historical XRF data suggests that upwards of 17% of plastics examined contained some amount of antimony and over 16% contained antimony in conjunction with bromine. With many of these materials being used in subcomponents of larger assemblies, it will take significant redesign efforts to remove the affected items.

The reporting of diantimony trioxide presence is not mandatory. This information is not readily available due to the lack of full materials composition information in the vast majority of part-level RoHS conformity declarations. Each producer will need to run in-depth supply chain surveys to get confirmation and to quantify impacted parts across our portfolios. In the absence of this information and the broad use of this substance, T&M Coalition members anticipate that the entire portfolio of products will be impacted. To our current knowledge, the substance would typically represent a very insignificant part of the total product weight.

Function

Diantimony trioxide is generally known as a flame retardant suitable to being used for polyethylene, polystyrene, polyvinyl chloride, polyester, epoxy resin, polyurethane and other plastics.
In our products, it additionally has a specific known use as flame retardant in packaged integrated circuit chips including semiconductors.
Other uses are yet to be discovered through supply chain survey, but presence of antimony detected in various plastics is suggestive of widespread application.

Encapsulation material using Diantimony trioxide (with 1 to 3% of Diantimony trioxide in the material) is used in integrated circuits and diodes. However, as Diantimony trioxide is opaque, it is not used in LEDs, which are more likely to use brominated flame retardants.

Possible Alternatives

Potential alternatives for the flame retardant function could exist, such as some halogenated flame retardants, excluding PBBs and PBDEs. However, these alternatives may prove to have larger negative environmental impact, especially in the waste phase. Therefore they may not qualify as suitable alternatives.

Cost implications resulting from potential restriction

We anticipate that complete product redesign will be needed wherever no "substance-free" equivalents are available from component manufacturers. The available alternatives have to be validated to meet Category 9 industrial performance and reliability requirements.
Forced redesign of entire portfolios to eliminate antimony based flame retardants would lead to reduction in innovation in new products, withdrawals from EU market, and potentially premature end-of-life for existing products. In addition, substantial costs will result from the update and validation of product safety third-party certifications required for any changes to safety critical parts. Given the critical applications of our products and the very long lifetime, the component certifications are critical to ensure product safety.

Restricting Diantimony trioxide will lead to:

- Forced redesign and requalification testing of entire portfolio;
- Lost opportunity for introduction of new, cutting edge products;
- Withdrawal of products from EU market.
- Impacts on innovation of users unable to access withdrawn products.

The feedback provided by the T&M Coalition is specific to the impacts of our sector, a subset of the Industrial monitoring and control category. While substitution may be happening for some consumer goods, there are other challenges for industrial products which is why the scope of substance restrictions should be differentiated by sector. The specificity of this sector and its unique requirements have been well established though more than 15 years of engagement with the EU Commission and its consultants. Consequently, it does not follow that the ability of producers in different sectors to transition from substance use can equally apply to producers of Industrial test and measurement equipment. Sector-specific considerations on the relevance of additional substance restriction recommendations are needed.

As previously stated, the Commission estimates that *"the cost of RoHS compliance for some complex products could be as high as 7-10% of turnover"*[11]. These costs cover the **complete refresh of the supply chain data**, which represents more than 8 years' effort to cover over 100,000 suppliers and over 200,000 component part numbers, but **also assessment of suitability of substitutions** taking into account the product complexity and portfolio scale of 2,000 to 3,000 products (average of members) with tens of thousands of product plus option combinations. The costs also entail for some components requalification, re-application and recertification with third-party certification.

This estimation is justified by the historical costs of RoHS conformity and RoHS compliance maintenance.

Time needed for compliance with potential RoHS restriction

Substantial research and testing of the performance of alternatives and reliability of substitution in the supply chain is required to be in a position to estimate the timing for compliance with potential restriction. This effort is similar to the experience the member companies had with RoHS I, and we anticipate 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

[11] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SEC:2008:2930:FIN:EN:PDF

impact on customer innovation and critical downstream industries. A review period of 12 years has become the standard in the context of REACH authorisation decisions for industrial uses.

Need for exemptions

If Diantimony trioxide is restricted under RoHS, this restriction should not immediately apply to Category 9 industrial producers. Further research by Commission services will be required to define what exemptions will be necessary should this restriction apply to our sector.

Compliance and enforcement challenges

For solid samples, typical of electronic products, an X-Ray Fluorescence (XRF) analyzer can be used only for screening for the presence of antimony and cannot be used to explicitly identify the presence of Diantimony trioxide.The speciation and physico-chemical state of antimony are important for its behaviour in the environment and availability to biota. For example, antimony incorporated in mineral lattices is inert and unlikely to be bioavailable and therefore XRF screening would lead to many false-positive results when used as a detection method for Diantimony trioxide.

Destructive analysis of the samples is necessary to provide verification of the specific compound Diantimony trioxide and its concentration. For such quantitative testing, analytical verification of Diantimony trioxide is typically done using inductively coupled plasma-mass spectroscopy (ICP-MS). The sample has to be dissolved in an acid, then undergo additional testing e.g. inductively coupled plasma optical emission spectroscopy (ICP-OES), ICP-MS, atomic absorption spectroscopy (flame AAS or GFAAS), or microwave plasma atomic emission spectroscopy (MP-AES). Such methods require costly equipment and expert operators and are not suitable for localized enforcement activities.