



COCIR CONTRIBUTION

On the Substance Review Methodology and the revision of the RoHS Substance Inventory

COCIR, the European Association of the Radiological, Radiotherapy and Healthcare IT Industry is happy to provide a contribution to the public consultation on the RoHS methodology.

COCIR companies support the objective of the RoHS Directive and have been committed to reduce the use of hazardous substances whenever possible and reasonable. Nonetheless experience shows that RoHS restrictions have a significant impact on companies, in particular the ones in the medical imaging device sector, where products have long design cycles (7-10 years), very long service life (10-15 years), are extremely complex (weighting up to 10 tons with more than 260.000 components and around 1.000.000 homogeneous materials).

COCIR therefore believes that the methodology that is used to assess substances for future restrictions has to be solid, objective and to be able to look at all the possible aspects to prove that a restriction is really justified, proportionate, effective and efficient.

COCIR provides some general comments regarding the proposed methodology here below, and more specific ones on the wording of the draft methodology in the annex.

General comments

- 1. The RoHS Directive legally applies to the placing on the market of EEE (article 4.1)** by manufacturers and importers. This concept is clearly defined in the EU Blue Guide. "Placing on the market" does not include the manufacturing phase along the supply chain. For this reason, RoHS cannot legally restrict process substances that are not present in the final EEE. Restricting such substances can be done under REACH but not under RoHS.
- 2. EU legislative measures have to be proportionate, effective and efficient.** The principle of proportionality is a basic principle of European legislation and EU measures have to be efficient and effective.
 - ✓ When the methodology assumes that substances that are not used or pose no risk may be restricted, it violates said principles. If there is no risk, there is also no benefit in restricting the use of the substance, therefore the measure cannot be proportionate: it imposes a burden with no corresponding benefit.
 - ✓ When the methodology assumes that a RoHS restriction could be adopted to solve problems created by illegal activities such as the use improper technologies or by illegal shipment to developing countries, it violates the principles of efficiency and effectiveness. For instance, the most efficient and effective way to deal with improper waste treatment activities is to make sure existing legislation is enforced and the best technologies are adopted.
- 3. Is RoHS an effective measure to protect workers or the environment?** COCIR wonders if a risk in the work place or a risk for environment can be properly controlled by a RoHS restriction. Considering that a RoHS restriction would take 10 to 15 years (or more)

to clear the stream of waste (CRT televisions are still discarded today), we doubt a RoHS restriction can be in any way efficient or effective in protecting the health of workers or the environment. If a risk is detected (not estimated) authorities should be called to take immediate action. A restriction that would take 10-15 years before becoming reducing exposure levels, seems really the least efficient and effective action. Enforcement of Occupational Health and Safety legislation or stricter emission limits would provide an immediate benefit to workers or the environment with no impacts on industry.

4. **The methodology relies on “estimation” in its decision process even when data is available:** the draft methodology seems to ignore that WEEE recycling plants have been around for more than 30 years and the Occupation Health and Safety Legislation (OHS) for more than 40.

- ✓ Each recycling plant in EU is required to monitor the air quality and the exposure of workers and to reduce the exposure below safety level. Monitoring data are stored and communicated to competent authorities upon request.
- ✓ Data from hundreds of facilities from all over Europe, covering at least the past 10 years, is available to the EC and Member States authorities. Estimating release during WEEE treatment or exposure of workers makes no sense and is unacceptable. The only acceptable approach is to run a statistical analysis of the data.
- ✓ The releases from facilities during waste management operations are disciplined by the Industrial Emission Directive (IED) and are controlled with the use of emission treatment systems (electrostatic filters, filters, wet filters, ballistic filters, neutralizing agents etc). Emissions have to be in compliance with limits imposed by national legislation
- ✓ The Exposure of neighboring residents is already controlled by law. Legal requirements about monitoring emissions, noise and odors, the position and distance of waste management facilities from resident areas or potable water wells, restoration activities and fields, including considerations on wind direction and strength, training of personnel, collection of rain water and its treatment, storage and protection of waste and resulting recycled materials, emergency plans in case of fire, spill or accident, are detailed in the authorization released by the national competent authority for each facility based on the kind of waste they treat.

5. **Workers and the environment are not currently exposed to un-acceptable levels of pollutants.** This concept is repeated many times in the methodology as if OHS legislation does not exist. If it was the case, we would have to assume that thousands of workers in the WEEE sector are being exposed above safety levels, that their life is at risk, and that hundreds of companies in the recycling sector are actually criminal organizations. In such a case the priority of the EC and MS should be to immediately take action to save the life of those thousand of workers, rather than discussing about banning a substance from EEE. Luckily this is not the case and recycling companies comply with OHS legislation, protecting their workers.

Some source for information on OHS legislation that applies to all working environment, including WEEE recycling facilities:

- ✓ Extract from the website of the “European Agency for safety and health at work” on the CMD Directive (2004/37/EC and following amendments) are reported in Annex II: <https://osha.europa.eu/en/legislation/directives/directive-2004-37-ec-carcinogens-or-mutagens-at-work>
 - ✓ Practical guidelines of a non-binding nature on the protection of the health and safety of workers from the risks related to chemical agents at work: [link](#)
Directive 98/24/EC sets out minimum standards on health and safety for those working with chemical agents. Aiming to facilitate compliance in the EU Member States, this book outlines practical guidelines on how to implement the rules. The 250 pages guideline provides practical tools on:
 - *how to measure and evaluate air concentrations;*
 - *risk assessment;*
 - *general principles of protection and prevention;*
 - *surveillance of the health of workers exposed to lead.**The documents contain information on labelling and safety data sheets of chemical products, occupational limit values and biological limit values and information on the hierarchy of prevention measures. The Annexes are on R(isk) and S(afety) phrases, simplified risk assessment methodologies, industrial examples and quantitative evaluation. A total of 150 pages deal with the measurement methods for chemical agents listed in Directive 2000/39/EC. Annex 6 is on the analytical methods for lead in air and blood.*
 - ✓ The European Union Risk Assessment Report on DEHP lists measured data on workplace between the sources of information:
Data which can be used for occupational exposure assessments are:
 - *physico-chemical data of DEHP, physical appearance, vapour pressure at different temperatures;*
 - *data regarding methods and use pattern of the product;*
 - *temperature at which production processes take place; amount of DEHP used in the different products (see Section 2).;*
 - *exposure data from HEDSET;*
 - ***measured work place data from use of DEHP or other similar phthalates;***
 - *results from exposure models (EASE).*
6. **New substances versus long-use substances:** as detailed in the previous points, data is available for substances that have been used for a long time in EEE thanks to several EU legislation (OHS, Waste, IED etc). The methodology should clearly make a distinction between how to deal with substances that have been in use for a while (statistical analysis of data) versus substances newly used for which data is not available yet, or partially, where estimation of releases and exposures can be used.
7. **The use of the term “potential” appears everywhere in the draft methodology:** while COCIR agrees that the precautionary principle should play a guiding role, when too many elements are just “potential” and not “established”, the risk can be so low (propagation of probability) that a RoHS restriction could hardly be justified as proportionate.



8. **Determining the time for substitution:** the methodology only hints at determining specific timelines for different categories but do not go further into the details. The time left to companies to comply with a restriction is extremely important as:
- ✓ The impact of a restriction depends on the timeline. Substituting as critical application in 10 years may have limited impact, while doing it in 3 may cause the company to abandon an entire product line.
 - ✓ The more complex a product is, the more important are factors such as reliability. New alternatives must first be tested on less critical equipment (e.g. RoHS 1) before being introduced in 10 tons industrial equipment or medical devices (e.g. RoHS 2).

The methodology should provide a way to determine the time needed for substitution in a such a way that claims from industry can be verified, compared and used as a basis for a proper decision. Average life of the equipment, design cycles, regulatory approval, complexity etc should be duly considered. COCIR developed a methodology that was used in 2015 to assess the time to substitute phthalates and presented it to the European Commission. The methodology can be provided upon request to be used as a basis for further development.

9. **Methodology should be rigorous and detailed:** The draft methodology looks like a guidance, rather than a methodology. A methodology should allow two different consultants to reach the same conclusion based on the same data. This methodology, considering its importance and impacts of RoHS, should at least be comparable with other methodologies, in terms of rigor, already published by the EC and ECHA.



ANNEX I

Detailed comments

Page 15 – Coherence with other legislation

Furthermore, the RoHS Directive interpretation of the precautionary principle may differ from that of the REACH Regulation. From REACH (Article 7(5)(b)) it can be understood that release of a substance classified as hazardous, for example from an article, is a precondition for the assessment of the risk⁹. The REACH Restriction process is further based on the criteria that a risk to human health or the environment exists, which is not adequately controlled and which needs to be addressed (Art. 69). However, looking at the RoHS Article 6(1) criteria suggests that it suffices for a substance

⁹ Under REACH, it can be understood that the Agency (ECHA) may require a substance to be registered when it has grounds to suspect that the substance is released from articles and where the release may present a risk to human health or the environment.(Article 7(5)(b)). It is thus understood that though hazards may be associated with a substance, this does not necessarily mean that a risk is present.

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to have a potential for risk (“could have...”) during use and/or during waste management in order to justify its restriction under RoHS. In this sense, if a substance is classified with a hazard potentially resulting in risk in these phases, a restriction would be justified regardless of actual occurrence and risk management options. . It is thus interpreted that a stricter approach can be taken by RoHS, provided that scientific and technical information show that there is a probability that at least one of the Article 6(1) criteria is fulfilled.

It seems that the methodology suggests that a substance could be restricted even when it is proven that no risk is present. COCIR believes such a measure cannot satisfy the principle of proportionality. How can a restriction of a substance that poses no risk be “proportionate” considering the no-benefits and the impact on industry, innovation and competitiveness?

Page 29 - Step P I-3b) Select substances used in EEE which are of concern during use or during WEEE management (Article 6 (1) a, b, c, d)

Examples of effects of substances used in EEE potentially causing risks for human health and the environment and which may require special emission control and treatment measures during WEEE management are (not exhaustive):

- Leaching of substances when the WEEE-components end up in landfills (e.g. metals and BFRs), leading to contamination of soil, surface water and ground water;
- Emissions of particle bound substances (e.g. Ba oxide; phosphor coatings; BFRs as TBBPA, HBCDD; metals such as Be, As or Ni) via fine dust during collection, transport, dismantling, shredding and mechanical treatment;
- Effects on humans caused by inhalation of dust or contaminated air during shredding and dismantling processes;
- Effects on humans caused by skin contact and/or inhalation of workers during manual dismantling of WEEE;
- Emissions of substances not being destroyed or immobilised during thermal processes (heavy metals, phthalates);
- Negative impacts may arise due to derivatives of a substance that are generated during waste treatment. For example, halogenated substances (e.g. PVC-plastics and BFRs) are dioxin precursors in thermal processes (considering that other substances such as Cu and Sb are very potent catalysts in the transformation reactions). These lead to risks for human health and the environment when WEEE materials are incinerated without using best available techniques, which is the case also in several countries within the EU; and
- Emissions of volatile substances (e.g. Hg) from broken components during collection, transport, dismantling, shredding and mechanical treatment.

COCIR would like to point out a few shortcomings of the provided examples:

Bullet point 1: leaking in landfills - WEEE cannot be landfilled as such, as this would be in violation of the landfill Directive. The landfill Directive clearly specifies that:

- ✓ waste must be treated before being landfilled;
- ✓ hazardous waste within the meaning of the Directive must be assigned to a hazardous waste landfill;
- ✓ landfills for non-hazardous waste must be used for municipal waste and for other non-hazardous waste;
- ✓ landfill sites for inert waste must be used only for inert waste;
- ✓ criteria for the acceptance of waste at each landfill class must be adopted by the Commission in accordance with the general principles of Annex II.

If there is any evidence of leaking of hazardous substances into underground water, soil or surface water at a specific landfill site, it is very likely that the landfill is not compliant with the requirements set in national legislation, as **this is not allowed to happen**. Leakage and percolate are supposed to be collected under the landfill and treated/decontaminated.

If an environmental contamination is detected through data analysis across Europe, then it means that the landfill directive failed to ensure health and environmental protection. The revision of the 2 Directives, waste and landfill, or stronger enforcement is the only route ensuring efficacy and efficiency.



Only if it is proven that a substance present in the output of WEEE recycling, destined to landfill, creates an unavoidable exposure that cannot be easily or economically contained in landfill through other means, then a RoHS restriction could be a reasonable and proportionate solution.

Bullet point 3: human exposure via inhalation - The occupational health and safety legislation already forces recycling plants to control air quality and monitoring contaminants. The same legislation does not allow for any safety level to be exceeded, therefore it is not clear at all what role RoHS can play.

If an exposure beyond safety level is identified through the statistical analysis of field measurements (data available to MSs authorities) it would mean the utter failure of enforcement of OHS legislation in MSs. The only solution would be to strengthen enforcement activities.

If it is proven, through an economic and technical analysis of the recycling technology, that the presence of a certain substance requires costly and complicated measures to reduce the exposure below safety levels, then banning the substance under RoHS could reduce the cost of recycling or increase its efficiency. In this case, and this case only, a RoHS restriction would be a reasonable solution.

Bullet point 4: human exposure via manual dismantling - The occupational health and safety legislation already forces recycling plants to control exposure of workers during any operation of the facility, including manual dismantling. The same legislation does not allow for any safety level to be exceeded, therefore it is not clear at all what role RoHS can play.

If an exposure beyond safety level is identified through the statistical analysis of field measurements (data available to MSs authorities) it would mean the utter failure of enforcement of OHS legislation in MSs. The only solution would be to strengthen enforcement activities.

Bullet point 5: Substances not destroyed by thermal processes – The simple fact that a substance is not destroyed during incineration process does not mean the substance is released in the environment. Incineration plants are disciplined by the waste directive, the waste incineration directive and possibly the IED. Emissions are controlled, monitored and reported and the release in the surrounding environment controlled and kept below safety levels. Filters of different kinds, neutralizing agents and catalytic technologies are used to remove pollutants from the emission of incineration plants.

Only if it is proven that Best Available Technologies for incineration and purification are not able to block hazardous substances from WEEE or only at a great price in terms of costs and efficiency, then a RoHS restriction would made sense and could be justifiable and proportionate. Of course, it must be proven the EEE are the main cause of the emission, otherwise the restriction would sort no effects at all.

Otherwise enforcing BAT and emission limits on incineration plant would be the only reasonable solution.

Bullet point 6: derivative substances – European legislation, as already mentioned above several times, provides a framework to ensure proper control of emissions. If est-European Member States do not use proper technologies for incineration, the solution is to require such MSs to comply with EU legislation and to adopt BAT. RoHS has no role to play in addressing non-compliance of facilities with EU and National legislation.

Page 34 – Radioactive substances

The use of radioactive substances is disciplined by the Euratom Directive 2013/59 (Basic Safety Standards). The use of radioactive substances is subject to notification, licensing or authorization, or exemption depending on many factors such as the activity, the activity/concentration, the amounts, etc. The use of radioactive substances is not and should not be a concern for RoHS.

Page 35 – Criterion A)

Criterion a) is fulfilled if one of the following facts is true:

- Evidence exists that the substance hinders recycling or recovery as it has adverse effects on recycling / recovery processes (examples are Pb in glass fractions, or halogenated polymers in fractions to be used for energy recovery)
- Evidence exists that large proportions of the substance⁶² remain in the recycling loop and is/are not discharged during the treatment processes and collected for subsequent safe disposal. As a consequence:
 - Use of respective recycled content (secondary materials) is limited to certain application areas or completely prohibited; or
 - The hazardous substance / substance group may be distributed across various types of recycled materials such as metals, plastics, glass or building material and finally in the environment.

Bullet point 1: Evidence should exist that the presence of the substance has adverse effect on the Best Available recycling/recovery processes. The assessment should not be performed on sub-par processes.

Bullet point 2: it is also important to assess the reusability of the recycled material. If the material has no market or use and would be destined anyway to landfill or incineration, then it cannot be claimed that the presence of the substance has an adverse effect on recycling/recovery.

Page 36 – Criterion b)

Criterion b) is fulfilled if one of the following applies:

- The substance/substance group is comparably easily releasable during use or during waste management due to following reasons:
 - The substance is used in or as a liquid (under ambient conditions) in EEE
 - The substance is in particulate form in EEE
 - The substance is highly volatile (under ambient conditions) when used in EEE

As for criterion a) it is important that **evidence exists**. This important concept is **missing** here. The dispersal or release of a substance cannot be inferred by its chemical/physical properties, but it depends on the recycling technology used, and the analysis must be performed for the best available technologies used.

Moreover, as already stated, the OHS and waste legislation ensures that operations are performed to control any dispersion, even accidental (emergency procedure must be defined) and that safety levels are ensured for workers and the environment.

If release arises for sub-par technologies or operations, then the enforcement of better technologies should be the priority, and the only way to control the release in the environment. RoHS does not play a role.

- Evidence that the substance/substance group was measured at significantly elevated levels in the environment (air, water, soil, biota) in urban areas and/or near WEEE treatment installations / locations. For example, there is evidence related to elevated levels of certain POPs in urban areas (Bogdal et al. 2014), some of which are or have been used in the past in EEE.

COCIR deems this point un-acceptable. The mere presence of a substance in urban areas or near WEEE recycling plant means nothing. **A causal link must be proven to exist, to link the presence in the environment with release from EEE or WEEE management.**

The elevated levels of environmental contamination could be due to a pre-existing industrial activity that polluted the area around the WEEE treatment plant (normally such plants are built in industrial areas that inherit serious issues of soil contamination from previous activities). The elevated levels in urban areas can be due also to multiple sources such as upwind industrial plants, widespread use of the substance, vehicular traffic, etc.

Moreover the causal link must be proven through a statistical analysis of field data (available at MS competent authorities). A few cases cannot be used to infer a general non-compliance with EU environmental legislation of an entire industrial sector.

Any RoHS measure must be proportionate according to basic principles of the European Legislation, therefore there must be evidence that:

- links the EEE use or WEEE management to an exposure
- a RoHS restriction is the most adequate measure.

- Evidence exists that hazardous⁶³ degradation/transformation products are formed during WEEE management (including thermal processes (combustion, milling), mechanical, chemical and biological processes (mechanical biological treatment, landfilling))

The transformation of hazardous substances into another is not by itself a concern. According to the OHS legislation exposure to any substance in working environment is already controlled in such a way to be below safety levels. If an exposure beyond safety level is identified through the statistical analysis of field measurements (data available to MSs authorities) it would mean a failure of enforcement of OHS legislation in MSs. The only solution would be to strengthen enforcement activities.

If it is proven, through an economic and technical analysis of the recycling technology, that the presence of a certain substance arising from transformation/degradation, requires costly and complicated measures to reduce the exposure below safety levels, then banning the substance under RoHS could reduce the cost of recycling or increase its efficiency. In such a case a RoHS restriction could be a proportionate measure if proven by a cost/benefit analysis.

Page 37 – Criterion c)

Criterion c) is fulfilled if one of the following facts is true:

- Evidence exists that negative health impacts during WEEE management occur
- The substance was found at significantly elevated levels in humans in proximity of WEEE treatment plants /locations

Bullet point 1: As already stated, it's the role of OHS legislation to ensure that workers ARE NOT EXPOSED to any hazardous substance beyond safety levels.

Measurements performed by hundreds of recycling plants in EU every year are available and in the hands of Member States Authorities. If there was an exposure beyond safe levels, this would have been already detected and addressed as a legal non-compliance. If this would not be the case, it would mean the failure of OHS legislation or its enforcement by employers and MS authorities.

Bullet point 2: As already stated, the point cannot be used as evidence that the criterion is fulfilled, unless it is amended to include the evidence of a clear causal link between the WEEE management activity and the measured level in environment.

Any RoHS measure must be proportionate, therefore there must be evidence that links the EEE use or WEEE management to an exposure and a clear indication that a RoHS restriction is the most adequate measure.

The methodology should be amended so that the 2 points reflect the specific case of newly used substances.

Page 40 - 6) Targeted approach for refined prioritisation of high priority substances

3. The tabulation shall be supplemented with questions for stakeholders (see template provided in the Appendix, Section A.3). A stakeholder consultation shall be held to collect additional information on the substances. Stakeholders shall be asked to use the excel format to provide information for all substances subject to the refined prioritization, though provision of additional data and information shall also be possible.

COCIR sees a problem with the proposed activities to refine prioritization of substances. Manufacturers with thousands of suppliers, supply chains with up to 7 levels, partially located outside of Europe cannot collect any meaningful information on the use of substances or possible alternatives in the short time span of a consultation.

Considering that substances proposed for prioritization are not yet regulated, the use of such substances is probably unknown to the user of components (due to intellectual property reasons) in many applications, some of which possibly critical, with limited amounts involved (e.g. application in advanced electronics).

The methodology should recognize that information collected at this stage can be misleading, incomplete or grossly estimated. A real risk is present that most of then critical applications are not detected at this stage.

Page 41 – Detailed assessment

The decision on which substances are to undergo a detailed assessment is to be taken by the Commission. Prioritization of substances, performed according to Part II, shall feed into such decisions. Nonetheless, the Commission may decide to prioritize substances for assessment that were not specified with the highest priority or with any priority for that matter. This may be the case for example:

- when a RoHS assessment is initiated in the context of the various assessments performed under REACH, for example under the risk management option analysis (RMOA) or under the restriction procedure; or
- when a Member State submits a proposal for a RoHS restriction.

Bullet point 2: COCIR wonders about the logic of the proposed mechanism. If it is enough for a MSs to submit a proposal to start a detailed assessment, then the prioritization of substances seems a useless exercise that can be abandoned, saving a lot of time and resources.

COCIR believes that the only reasonable solution is to allow a MS's proposal to:

- ✓ Change the priority of a substance, as new evidence is available
- ✓ Add a substance to the list, that was not considered appropriate because new evidence is available

We also believe that the statement should not be in a methodology. The methodology should deal with how to perform a detailed assessment on any substance propose to be added to Annex II of RoHS, not to provide information on how a political decision is taken.

Page 43 – Question for stakeholders

Question for Stakeholders participating in the stakeholder consultation:

For the purpose of specifying an exhaustive list of socio-economic impacts to be considered, please specify categories that should be taken into consideration.

Company's resources are limited therefore resources spent on RoHS compliance are normally diverted from R&D, at least in some sectors, such as the medical devices one.

The impact on innovation must be considered.

For instance, substituting 200 grams of lead, globally used in bearings of x-ray tubes every year, is going to cost tens of millions to each company and would involve engineers, test labs, suppliers, which could be employed in developing new life saving medical technologies. Considering the almost irrelevant amount of lead involved every year (200 grams) and the fact that it can be easily separated and recycled, it is easy to see how it is very hard to justify the impact on innovation with the benefits for environment.

Page 44 – Socio-economic assessment

- possible exposures during use and during waste management (Figure 3-1, step 3).

COCIR has some concerns regarding the choice of words. The exposure during use and waste management should not be "possible" but "established". Empirical evidence, coming from statistical analysis of measured exposures should be present and included in the dossiers. The approach of considering "possible" exposures, could be valid only for newly used substances. The methodology should reflect the different approach for the 2 cases.

- The analysis undertaken and findings related to impacts related to the use of the substance in EEE is to be documented in the dossier in relation to:
 - Impacts expected during use and/or during waste management (Figure 3-1, step 4a). To estimate whether impacts are to be expected during the use phase and/or during the waste phase, the potential for exposure under certain conditions needs to be estimated as part of the evaluation. For this purpose, specific exposure scenarios for assessing substances during WEEE management have been developed for this manual;

COCIR deems this point un-acceptable.

Impacts during use and waste management are not "expected" but they should be documented. Data coming from environmental monitoring and OHS legislation are available and must be used as already explained in the general comments and in the previous part of this annex.

The “potential for exposure under certain condition” **does not need to be estimated but measured**, or the data already available must be collected and analysed.

Moreover it is appropriate to remember that exposure of workers or environment is already strictly controlled by existing legislation and is ALWAYS below safety levels.

“Estimations of expected exposures” can be only used, with care, for newly used substances, for which no data is available.

Page 45 – workflow of the detailed assessment

<p>Step 4b Evaluation of the risk for the environment during use and/or during WEEE management Q: Is the exposure of the environment above no effect levels (PNECs) or do other reasons for concern exist?</p>	<p>Step 4c Evaluation of the risk for workers during WEEE management Q: Is the exposure of workers/neighbours > acceptable exposure levels or do other reasons for concern exist?</p>
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Step 4b: if there is a statistically solid evidence that recycling plants are the cause of environmental exposure to hazardous substances, the questions that spontaneously arise are:

- ✓ Is the exposure known to MS authorities?
- ✓ If yes, as it should be, what MSs’ authorities have done so far?
- ✓ What is the cause of the measured exposure? A lack of enforcement, the use of sub-par technologies?

Step 4c: according to OHS legislation there cannot be an exposure that is not acceptable. If such an exposure is **measured**, not estimated, it would mean a failure of OHS legislation. the questions that spontaneously arise are:

- ✓ Is the exposure known to MS authorities?
- ✓ If yes, as it should be, what MSs’ authorities have done so far to protect workers?

Moreover, considering that old EEE continue to be treated for 5-10 years (or more) after a RoHS restriction becomes effective, COCIR would expect a RoHS restriction to be the last action taken by authorities to ensure health of workers and protection of the environment.

Page 52 – Determine which treatment the substance undergo

COCIR considers that guessing treatment options, not based on any solid data, is not the right way to start and apply a methodology.

A significant share of WEEE is not collected by the foreseen systems so that average collection rates have been below 40% in the majority of EU member states in 2015¹¹³. Therefore, also processes applied in the treatment of waste streams, where the non-appropriately collected WEEE typically end up, i.e. mainly land-filling, incineration and mechanical treatment and sorting, have to be considered.



40% of collection applies to all WEEE, not to single individual categories. Such an estimation is therefore irrelevant when assessing the treatment of EEE containing the substance in question, which may belong to a specific category only.

The statement that non-appropriately collected WEEE ends up in landfill seems in conflict with the actual legislation on landfills, that makes it impossible for non-treated waste to be landfilled. The same way we seriously doubt that WEEE are incinerated, as it would be in violation of the Incineration of Waste Directive. Moreover, incineration plants are quite careful regarding what kind of waste they feed to the plant as they have to:

- Ensure enough calorific input to maintain the combustion
- pay for the disposal of the resulting ashes as very hazardous waste.

Feeding non-incinerable WEEE into a furnace would make no sense whatsoever.

COCIR believes it is of fundamental importance that any consideration on non-appropriately collected waste is based on evidence and real data, not on some old and outdated generic study and assumptions. Proper enforcement of recycling standards and technology is the only solution to reduce health and environmental risks of such operations.

PAGE 55/56 – Information required for assessing exposure

Information required

A quantitative release estimation related to waste management operations shall be performed based on available information regarding the substance content in the typical waste processes and the amounts treated per annum. Depending on data availability and the waste management routes of typical EEE of relevance to the substance under assessment, the estimation shall take into account possible emissions from both dedicated and non-dedicated WEEE installations. Where data is not available to allow estimation, assumptions shall be made as to the amount of relevant WEEE treated per annum, respective volumes of the substance therein and respective shares of the substance to be emitted to the environment (air, water, soil as supported by availa-

COCIR believes this approach is not acceptable

WEEE management facilities have been around for almost 30 years. Information about release of contaminants, air quality in working environment, exposure of workers is available and easy to get from Member States Competent Authorities. There is no need to estimate anything. Estimation can be used when data is unknown and impossible or too hard to measure. In this case none of the conditions is satisfied.

Data is available and must be used. A significant statistical sample of facilities implementing BAT must be chosen and a statistical analysis of the exposure must be performed. Sub-par treatment facilities could be included as well, with the clear understanding that if exposure is present, something failed in the OHS legislation, and there it should be addressed.

Estimation of releases is always a bad approach and should be used only in extreme cases, for instance in the case of newly used substances.

Based on the collection rates for a particular WEEE category, the material composition of the relevant WEEE category and the distribution of such WEEE between specific application treatment operations, the overall amount of the substance treated in a particular process on EU level can be estimated.

COCIR strongly disagree with this statement. The resulting estimation is at best a rough guess, ignoring all the physical phenomena of the real world at play during waste management operations. While it may be acceptable for newly used substances, it is un-acceptable for other substances for which Europe-wide historic series of data are available.

Appendix A.5 (to be added) will provide values for separate collections of individual WEEE categories; average material composition of WEEE; the share of applied treatment processes; values for the number of installations and the operational hours of individual treatment processes; and examples of release factors for WEEE treatment processes. This data is provided to support assumptions for estimating the amount of substance treated and respective emissions.

The qualitative assessment of substance release from WEEE treatment processes should be based on:

- the amount of substance entering treatment;
- physico-chemical properties of the substance (volatility, water solubility, degradability and adsorption behaviour, etc.);
- formation of hazardous degradation/transformation products;
- conditions under which the treatment is performed.

This is again unacceptable. The **quantitative** assessment of substance release from WEEE treatment process must be determined via the statistic analysis of the data of air quality monitoring available at any treatment plant and competent authority. Such data has been collected for the past 30 years, mostly all over Europe, by hundreds of facilities, under the OHS legislation of each EU Member State.

If substances are released during the treatment of WEEE, **that release is already known** to recyclers and competent authorities and **appropriate measures have already been taken** to reduce the exposure below safe levels.

The approach of estimation can be acceptable only for new substances never used before or for substances for which new evidence can suggest different risks are involved.

The outcome of the qualitative assessment has to include:

- a qualitative justification as to why release of the substance from a particular WEEE treatment process is to be expected (or why they are not expected where this is the case).
- a qualitative justification as to why the conditions in the specified treatment will result in release of the substance or in the generation of hazardous degradation products in the process (or why this shall not happen where this is the case).

In case of known substances, which have been used for years in EEE, such as the 7 ones under assessment, the assessment of existing data will provide a clear understanding if any exposure really happens. **It is not about what is expected or estimated.** As already said, if an exposure occurs, this is already well controlled and below safety levels.

The same is true for degradation products. If such degradation products are released in the working environment, they are already monitored to ensure the safety of workers. If such products are released in the external environment, they are already measured and controlled under the Industrial Emission Directive and other legal requirements connected with the industrial activity. Again, there is no need to estimate, as data on emissions are available at ANY facility in EU and at ANY competent authority in ANY MS.

Page 56 – Source of information

Sources of information (Steps P III-2a and 2b)

Information sources that can be used to obtain data on treatment and emissions for estimations:

- Information already collected in previous steps
- Chemical Safety Reports (if available and data appropriate for quantitative release) from ECHA or the registrant;
- Studies and research
- ECHA guidance documents¹¹⁵:
 - Environmental exposure estimation (R16)
 - Estimation of exposure from waste life (R18)

Facts about relevant waste streams and treatment processes as well as the outcome of release estimations will be documented in Chapter 5 of the Dossier.

The most important data source is missing: data on monitoring of working environments according to OHS legislation. Such data is available at ANY recycling facility in EU and at ANY competent authority in ANY EU MS.

Page 57 – Exposure estimation during use and WEEE treatment

Approach: Existing information on human and environmental exposure related to the relevant WEEE treatment processes shall be used to estimate the range of possible exposures. Where data is available, exposure estimations shall be performed using suitable models (e.g. ECETOX-TRA, EUSES).

COCIR cannot see the need to use any model to estimate exposure, as exposure, if any occurs, is already well known and controlled as already pointed out so far. Data on exposure in working environment can be analysed, in case that could provide any useful information.

The draft methodology should be amended to reflect that such estimation can be used only in the case of newly used substances, when it is proven that exposure data is not available.

Information required

Available and relevant data regarding exposure (e.g. monitoring data; population group, exposure time, exposure concentration) have to be collected. Literature on human and environmental exposure to a specific substance as a result of waste management shall be summarised. On the basis of the release estimates calculated in step P III-1b and step P III-2, exposure concentrations for end-users for the environment and for workers shall be calculated.

Literature is a useful source, but it has lower priority than real data.

As already pointed out, the calculations in step III-1b and III-2 are only acceptable for newly used substances. For well known substances that have been used for a long time, data is already available and does not need to be calculated. OHS legislation already ensures that exposure levels are kept under control and below safe level. A statistical analysis of the data can only confirm it. Different results would point to a failure of OHS and according to the principles of effectiveness and efficiency, the problem should be addressed in the OHS legislation and relative enforcement, not in RoHS.

Page 58 - Step P III-4a) Evaluation of risks for end-users of EEE

This section of the methodology has to be amended to reflect the fact that such kind of analysis can only be performed for newly used substances, but not for substances that have been in use for a long time. The exposure of workers is kept below safety level as mandated by OHS legislation. If it was not the case, we would have to assume that thousands of workers in the sector are being exposed above safety level, that their life is at risk, and that hundreds of companies in the recycling sectors are actually criminal organizations.

Page 59 - Step P III-4b) Evaluation of negative impacts on WEEE management as specified by Article 6(1)a

Already commented previously.

Page 59 - 3.10. Step P III-4c) Evaluation of risks for workers and neighboring residents

- If appropriate data are available, it will be examined if there is an unacceptable exposure of workers involved in WEEE operations
- If appropriate data are available, it will be examined if neighbouring residents are at risk (e.g. due to persistent or volatile properties of substances)

Result/Expected Outcome: The risk characterisation for human health will determine if, in the defined exposure scenarios, risks to human health are to be expected for workers and neighbouring residents. If monitoring data of sufficient quality (relevant and reliable) are available, the risk characterisation will be based on measured data. It shall be assessed if there is a margin of safety which is considered to be sufficient. The data source for exposure assessment will be explained in order to identify uncertainties and underlying assumptions.

OHS legislation, the Industrial Emission Directive and Waste Directive authorization to waste management plants already ensure that:

- ✓ The exposure of workers is maintained below safety levels
- ✓ The emissions during waste management operations are controlled with the use of emission treatment systems (electrostatic filters, filters, wet filters, ballistic filters, neutralizing agents etc). Emissions have to be in compliance with limits imposed by national legislation
- ✓ The Exposure of neighboring residents is already controlled. Legal requirements about monitoring emissions, noise and odors, the position and distance of waste management facilities from resident areas, potable water wells, restoration activities and fields, including considerations on wind direction and strength, training of personnel, collection of rain water and its treatment, storage and protection of waste and resulting recycled materials, emergency plans in case of fire, spill or accident, are detailed in the authorization released by the national competent authority.

Page 60 – Step P III-4d) Evaluation of the risk for the environment

3.11. Step P III-4d) Evaluation of the risk for the environment

The aim of this step is to assess the environmental risks associated with waste management operations.

Approach/Criteria: Environmental concentrations near EEE processing plants (if available) and Predicted Environmental Concentrations (PECs) as calculated and described in previous steps will be compared with Predicted No Effect Concentrations (PNECs) in order to evaluate a potential risk for the environment. If the PEC values are above PNECS a risk for the environment cannot be excluded. A qualitative assessment will be performed in case there are PBT and vPvB substances for which no PNEC can be derived.

Result/Expected Outcome: The risk characterisation for the environment will determine if any risks for the environment are to be expected in the defined exposure scenarios. The data source for exposure assessment will be explained in order to identify and document uncertainties and underlying assumptions.

As already stated, environmental presence of hazardous substances near treatment facilities is already controlled and the data are already available. Estimating environmental concentration is only legitimate for newly used substances.

Pager 66 - Step P III-7) Decision on inclusion and rationale

- If the presence of the substance or substance group (respectively one of its members) in secondary materials is to be tolerated (in all or in specific EEE applications of such materials), the terms of restriction of the substance or substance groups in secondary materials should be defined through an exemption.. The exemption would first come into scope at the end of the transition period (previously 4 years and above granted) with a duration of 5 years. It is noted that the transition period may differ between Annex I categories and thus category specific validity periods may need to be specified for the exemption. A reevaluation of the further need for the exemption, if applied for, could be performed shortly before the end of the 5 year period, adapting the conditions of exemption if necessary. It should also be noted that should such exemptions become common (in light of circular economy efforts), that a certification system would be needed to document the use of secondary materials contaminated with restricted substances so as to avoid misuse of the exemption.

The restriction dossier could already propose the conditions of the exemption, if these can be clarified. This would give stakeholders certainty and motivate the use of secondary materials. In this case, the following details should be specified: formulation of the specific conditions of exemption, including as relevant detail of tolerated substance thresholds (limit values) and EEE application areas (if relevant).¹²⁷.

It is not very clear why a duration of 5 years for exemptions is mentioned, when it is longer for categories 8 and 9.

COCIR is also concerned about the strange statement on a “certification system”. Such concept deviates significantly from the legal requirements of the Directive, so it is not clear if it intends to be a suggestion for the European Commission, but it should be removed from the methodology.



ANNEX II

Some extracts from the website of the “European Agency for safety and health at work” on the CMD Directive (2004/37/EC and following amendments) are reported in Annex II.

<https://osha.europa.eu/en/legislation/directives/directive-2004-37-ec-carcinogens-or-mutagens-at-work>

The employer shall assess and manage the risk of exposure to carcinogens or mutagens. This process shall be renewed regularly, and data shall be supplied to the authorities upon request. Special attention should be paid to investigate and take account of all possible ways of exposure (including all skin-related possibilities), and to persons at particular risk.

Workers' exposure must be prevented. If replacement is not possible, the employer shall use a closed technological system. The employer shall reduce the use of carcinogens or mutagens by replacing them with a substance that is not dangerous or less dangerous.

Where a closed system is not technically possible, the employer shall reduce exposure to the minimum. Exposure shall not exceed the limit value of a carcinogen, as set out in Annex III.

Wherever a carcinogen or mutagen is used, the employer shall:

- *Keep the number of workers exposed as low as possible;*
- *Design the work processes so as to minimise the substance release;*
- *Evacuate carcinogens or mutagens at source, also respecting the environment;*
- *Use appropriate measurement procedures (especially for early detection of abnormal exposures in the event of unforeseeable events or accidents);*
- *Apply suitable working procedures and methods;*
- *Use individual protection measures if collective protection measures are not enough;*
- *Provide the necessary hygiene measures (regular cleaning);*
- *Keep workers informed about related issues;*
- *Demarcate risk areas and use adequate warning and safety signs (including “No smoking” signs);*
- *Draw up emergency plans;*
- *Use sealed and clearly/visibly labelled containers for storage, handling, transportation and waste disposal.*

Employers shall make certain information available to the competent authority upon request (activities, quantities, exposures, number of exposed workers, preventive measures) and inform workers if abnormal exposure has happened.