Oeko Institut
Germany

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Subject: Consultation Questionnaire on the revised manual (draft) methodology to identify and assess substances for possible restriction under the RoHS Directive

1 RINA CONSULTING

RINA is pleased to provide the following submission to the RoHS additional substance restrictions methodology. RINA has incorporated ERA Technology Ltd and EdifERA.

2 ANSWERS TO QUESTIONS

Q1. *Please specify additional lists of relevance for specifying substances identified or suspected of having hazardous properties. (Section 1.1., pg. 24)*
Answer: We do not believe that there is any need to consider substances that are not: a) classified as hazardous by CLP Regulation (which includes CMRs), b) are PBTs, c) vPvB and / or d) endocrine disruptors. This because all of the substances that are used in EEE which have at least one of these classifications (a to d) would include all of the substances that could potentially harm humans or the environment. There is no evidence that substances that do not have at least one of these classifications is harmful.

Q2. *Please specify additional lists of relevance for specifying substances used or suspected of being used in EEE. (Section 1.2., pg. 27)*
Answer: We are not aware of any published lists of substances that are used in EEE. There are lists of substances used in vehicles by the automotive industry (GADSL) but this list includes many process chemicals and substances that are not used in EEE and so would not be useful for RoHS.

Q3. *Please submit reference to legislation and/or to standards where thresholds are defined for the criteria mentioned, e.g. under what circumstances and measurement conditions would the volatility of a substance potentially lead to emissions from an article in which it is contained (including non-intended use such as in case of breakage)? (Section 2.2., pg. 35)*
Answer: Most substances used in EEE are not volatile since, if a volatile substance were to be used, it would be lost from the product over time and cease to provide a function. The main material types used in EEE are metals and ceramics where volatile substances are never used and plastics where volatile substances are very unusual. Some types of plastics contain plasticisers and lubricants used are liquids – but these usually have very low vapour pressure so that the level of exposure to humans and the environment in the use phase should be much lower than safe limits. These substances would usually decompose to CO2 and water during thermal recycling (incineration). The very few examples of fluids being used with a few types of EEE, such as fuels, lubricating oils and hydraulic fluids, these are often supplied separately to the EEE which do not contain these fluids when they are placed on the market.

Q4. *Please indicate criteria for specifying when a potential for release is to be considered significant. (Section 2.2., pg. 35)*
Answer: The potential for release can be considered significant if the level of exposure, from these emissions, by workers, consumers or the environment exceeds known published safe levels. Release can occur during end of life recycling as emitted vapours, gases or dusts, especially from grinding or incineration processes and especially if this is not carried out with adequate hygiene equipment to trap emissions. Emissions during the use phase are very unusual and no emissions usually occur. Dermal exposure may occur from some external surfaces of EEE as well as from non-electrical products, but it is very unlikely that dermal exposure levels will reach harmful quantities except with a few types of hazardous substances that are already restricted by REACH Annex XVII and the EU POPs Regulation which already

restrict substances where it is known that dermal exposure can be harmful as well as restricting dangerous process chemicals.

Knowledge of the levels of exposure to emissions is important to determine if these exceed the end-point limits such as NOAEL, LOAEL and PNEC values. This data can usually only be obtained by measurement and so searches of published scientific literature will be needed to identify this sort of data. Operators of factories and recycling sites may have data on emissions if they are regulated by the Industrial Emissions Directive as they need to monitor emissions to ensure that they comply with their permitting conditions. Some manufacturers and recyclers may also carry out health monitoring of workers or air monitoring to ensure that they comply with workplace exposure limits. There may be useful data included in EU risk assessments of substances carried out for the REACH Regulation. For example, at https://echa.europa.eu/documents/10162/e614617d-58e7-42d9-b7fb-d7bab8f26feb These types of assessment are very comprehensive and also determine if control measures such as restrictions are needed. However, they are available for only a limited number of substances. Note that there are also some impact assessments published by EU Member State governments for potential REACH restrictions as well as by non-EU organisations such as the US EPA.

Q5. *Evidence of elevated levels measured in the environment shall be considered significant when end-point related limit values are exceeded (i.e. DMELs, PNEC, etc.). Do you support this specification - please explain your views and provide supporting data to explain them if relevant. (Section 2.2., pg. 35)*

Answer: Yes, we support this approach. This approach is sensible because these limit values are determined by research to determine the levels above which harm has been shown to occur. This approach is used for REACH restrictions. NOAEL, DMEL, PNECs values are usually published for the more commonly used hazardous substances and at least for the more severe hazard classifications. Often a margin for error is used as the level of emissions and the NOAEL, etc. values are not known with high precision. Therefore it is common practice to allow a margin of error of 10, 100 or even 1000 times, based on the accuracy of available data. As an example, California Proposition 65 legislation allows suppliers to avoid providing warnings if it can be shown that emissions of carcinogens or reproductive toxins are more than 1000 times lower than published No Observable Effect Levels. Clearly, if emissions data and NOAEL / PNEC data is fairly accurate, much smaller margins should be used.

There are several complicating factors that should also be taken into account. For example:

- For substances that are aquatic toxins, biodegradation rates are important because the substance will build up to higher concentrations if this rate is very low, whereas equilibrium concentrations may be very low if biodegradation rates are high.
- Take up within the body is often not 100% so that although a person may be exposed to a certain quantity of a substance, the amount absorbed may be only a small proportion of this amount. Take up rates depend on exposure route (usually higher via inhalation than dermal) and are higher for children than adults.
- Repeated exposure dose toxicity should be used, not single acute dose toxicity because repeated dose levels that cause harm are much lower that single dose toxicity levels and exposure will usually be for daily exposure for extended periods.

It is an unfortunate fact that very many substances are hazardous. If all were to be banned it would not be possible to make almost any EEE. However the requirement of RoHS Article 1 is to prevent harm and so being hazardous is not enough, there must also be evidence that harm may be caused and that this cannot be prevented by effective control measures. The approach suggested should determine if harm may occur or not and so whether a restriction should be considered if control measures (such as workplace exposure limits, which are applicable at recycling sites) are not effective at preventing harm to humans or to the environment.

Q6. *For the purpose of specifying an exhaustive list of socio-economic impacts to be considered, please specify categories that should be taken into consideration. (Section 3., pg. 43)*

Answer: There is very useful guidance on how to carry out Socio-Economic Assessments at https://echa.europa.eu/documents/10162/23036412/sea_restrictions_en.pdf/2d7c8e06-b5dd-40fc-b646-

3467b5082a9d This is relevant to substance restrictions and so would be applicable to RoHS. It includes all applicable impacts that should be considered.

Q7. *If you have any further comments, where relevant, please note the section/page to which they refer or quote the text of relevance from the manual to support understanding*

Answer:
Pages 33 and 34: Human hazards group I includes "Acute toxic category 1", but the Environmental hazards group includes "Hazardous to the aquatic environment (Chronic Category 1, 2)" and "Hazardous to the aquatic environment (Acute Category 1)" in Group II. This seems inconsistent. Why are the most harmful environmental toxicity classifications "aquatic acute and chronic category 1" not in the same group as human "acute toxicity category 1"? Perhaps aquatic acute and chronic category 1 should both be in group I or both in II?

Page 34, Radioactive substances. These are not regulated by REACH or CLP because they are already covered by other EU legislation; the EU 2013/59/EURATOM Regulations. This already regulates the import, manufacture and use and disposal of radioactive substances.

Page 35, section 2 1st bullet. Two examples are given that incorrectly suggest that hazardous substances have an adverse effect on recycling. Lead in glass – lead is permitted only in optical glass which is used in electronic components and equipment. These glass components are never collected and recycled with other types of glass such as bottles or window glass. Leaded glass in electrical equipment does not hinder recycling as all EEE recyclers have to be able to recover lead that is present in old pre-RoHS equipment, equipment that is out of scope of RoHS and from exempt forms of lead including optical glass. WEEE recyclers often also recycle other types of waste that contain lead. Therefore their processes are designed to safely recover lead and it does not hinder the process.

Similarly, halogenated polymers do not hinder recycling. The main barrier to recycling plastics is that so many different types of polymer with many different additives, colours, etc., are collected together and cannot be physically separated. Even if separation is possible, EEE manufacturers are reluctant to use recycled plastics because they may contain restricted substances with no applicable exemptions. Therefore incineration for energy recovery is often used and this is regulated by the Industrial Emissions Directive in the EU. Modern incinerators are capable of treating halogenated plastics in their feedstock without emitting hazardous substances in quantities above the very low limits permitted in the EU and also in many other countries. It is correct that these rules are not always followed, especially outside of the EU, but it is not correct to say that halogenated substances (or most other hazardous substances) inhibit recycling processes. There will be examples of substances that may inhibit recycling, but these will include possible substitutes, for example bismuth which can be used as a substitute for lead in solders, but when used as an additive can inhibit metals recycling.

Several other issues need to be taken into account:
Will substitutes exist? If a substance is expensive (such as gold), manufacturers will already have made great efforts to identify cheaper, but suitable, alternatives so that all remaining uses are those where substitutes do not exist and will probably never exist. Under these circumstances, a RoHS restriction would be pointless.

Precautionary principle and possible substitutes. Article 6.1 of the RoHS Directive requires that the Commission take into account the Precautionary Principle. This is often interpreted too narrowly by ignoring the possibility of harm from substitutes. If it is determined that a substance is potentially harmful, the potential for harm from possible substitutes should also be considered for two reasons:

a) Substitutes that are similar and so may cause the same level of harm (e.g. diisobutyl phthalate is very similar to dibutyl phthalate) should also be restricted to prevent manufacturers substituting one substance for another that is equally harmful.
b) Possible harm caused by substitution due to a restriction may be due to many reasons. For example, restriction of flame retardants could encourage manufacturers to use more flammable plastics which may increase the number of deaths and injuries in the EU due to electrical fires (which are already very significant with many 100s of deaths per year). In this example, if the precautionary principle were applied to all alternatives to

restricting a flame retardant including use of more flammable plastics, the potential for harm may be increased, not decreased as is required by Article 1 of the RoHS Directive.

Related to the precautionary principle: Substances that are persistent and bioaccumulate are potentially more dangerous that non-persistent substances. This is because they build up in the human body or in the environment and remain for long periods. This is not a concern if it has no toxicity and is not harmful, however, it should be a concern if any toxicity is discovered, such as in animal testing. Often with relatively new substances (that may be considered as substitutes), the true hazard classification is not yet known because insufficient testing has been carried out and the effect on human health or the environment is unclear. This is why REACH is so important as it forces manufacturers to determine whether substances are hazardous and if they have any harmful effects. Therefore, any future substance restriction assessments (and of possible substitutes) should look for and take into account results of animal and environmental testing, especially for persistent and bioaccumulative substances.

Exemptions: Currently it is taking the Commission a very long time to process new exemption requests due to workload and a lack of resources. Also, significant resources are needed when exemptions are due for renewal. Leading up to the July 2021 expiry deadline, another 30+ exemptions will most likely be requested for renewal. Before any additional substances are restricted, it would be advisable to consider the resources available for new exemption requests so that applicants' exemption requests that are justified and recommended for granting are published in the Official Journal well before the restriction takes effect. Also the time taken for processing new requests (from submission to Commission Delegated Act publication) needs to be much shorter than at present.

Other non-EEE uses: Often a substance that is considered for restriction by RoHS is also used in other applications and these can account for the majority of the substance that is used in the EU. If a substance is proven to be harmful but most is not used in EEE, then a RoHS restriction will not be effective in preventing harm from this substance unlike a broader REACH restriction.

Timescales: If it is demonstrated that a substance widely used in EEE is harmful and it is decided that a restriction is necessary to protect health and the environment, a realistic transition period is essential. This timescale will depend on the substance and will need to be much longer for some substances than others and each substance needs to be carefully considered on a case by case basis. Manufacturers often do not know if a substance is used in the parts and materials that they use and so their first task is to find this information. Their suppliers are often unwilling to provide this data until a restriction has been published in the Official Journal, so this tends to be the starting date for substitution. For widely used substances, it can take 1 – 2 years or longer to identify all uses. Often there will be no drop-in replacements available and so research and reliability testing will be needed. This can take an additional 3 – 5 years depending on the number of parts needing to be replaced, the number of end-products and the level of reliability required (e.g. medical device reliability is much more critical than that of consumer products). Some types of product cannot legally be sold until approvals have been granted. A total elapsed time can be as long as 8 – 10 years for complex "high-end" products. However, if no suitable alternatives are identified, the manufacturer will require an exemption. From recent experience, this takes three to six months to write the request and then another 3 to 4 years before publication in the Official Journal and this must occur before the restriction takes effect to avoid the products having to be withdrawn from the EU market. This timescale is 1 – 2 years to determine if the substance is present, 1 – 2 years to search for and test substitutes and another 3 – 4 years for an exemption to be granted and published. Therefore, this also requires a transition period of at least 8 years, unless the Commission can guarantee that it can significantly shorten the time between submission to Commission Delegated Act publication.

We trust that you find the above helpful. If you have any queries please do not hesitate to contact me.

Yours sincerely:

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