



Brussels, 22 May 2007

By e-mail

**To : European Commission  
DG Environment  
ENV-ROHS-DIRECTIVE-REVIEW@ec.europa.eu**

Re : NGO Response to Invitation for Comments on Topics and for Information Supply regarding the Review of Directive 2002/95/EC of the European Parliament and of the Council (RoHS)

The RoHS Directive has been instrumental in changing the electronics sector towards safer materials and products by restricting the use of some of the most hazardous chemicals. Newer safer products have been developed, driving industry towards green chemistry and innovative products.

However, widespread contamination with hazardous substances and materials widely used in electronics is still a matter of high concern due to the very limited scope of the legislation. Many undesirable substances and materials are still used in the production of electronic goods, and they eventually find their way in the environment and human bodies.

Environment and health NGOs call on the Commission to strengthen RoHS during its review process to make sure manufacturers of electronic goods take responsibility for their products from production through to the end of their lives. As a major contribution towards addressing health and environmental problems, manufacturers must develop and design clean products that avoid the use of hazardous chemical components at source.

Below you will find the NGOs' contribution to 3 specific topics solicited by the Commission at this stage, namely on 1) product groups to be included; 2) substances covered; and 3) facilitating implementation.

## **1) PRODUCT GROUPS TO BE INCLUDED**

Expansion of scope of the Directive to equipment which falls under categories 8 and 9 in Annex IA of Directive 2002/96/EC WEEE (medical devices; and monitoring & control instruments).

In these two product groups, at some point or several points during the lifecycle of the medical devices and the monitoring and control instruments, the use of substances currently restricted under RoHS and other hazardous substances not yet restricted under RoHS, are leading to people's exposure, be it workers in the manufacturing sector, users, or the public, including through eventual release into the environment. Given the emerging scientific and medical knowledge about effects and potential effects arising from low doses of exposure, and from mixtures of chemicals in the body, this exposure is undesirable. It is therefore important to include these categories under the legislation.

Numerous medical device manufacturers and suppliers, including in the USA, are already claiming compliance with RoHS. This indicates that the medical devices sector is anticipating being subject to the directive and should be included in RoHS.

One of our information sources, a medical equipment supplier, who requested anonymity, informed us "X Company currently has an initiative underway requesting Certificates of Compliance from each of our suppliers, insuring that mercury, cadmium, lead, PBBs/PBDEs (PBTs) and hexavalent chromium are not present in quantities greater than 0.1 % by mass (0.01 % for Cadmium)."

"X Company electronic products contain lead in the circuit boards, and the percentage by mass is greater than 0.1%. A solder for use in medical devices is currently being developed by the Printed Wiring Board industry which will have a lead content of 0% - 0.1%. 2011 is the projected time it will take to develop and test the new lead free design... "

"A project exists for determining the presence of several toxic materials in our products, lead and cadmium being two of them, but this determination will not culminate until approximately 2008/2009, due to the long process of getting replies from vendors."

A second anonymous respondent has indicated that they are producing electrodes that are free of lead, mercury, cadmium or hexavalent chromium with the possible exception of the brass components. These are a substitute for the disposable electrocardiogram (ECG) electrodes which are made of PVC that would otherwise be dumped or burned (and potentially release dioxins).

It is also worth noting that according to the European Lead Free Soldering Network (ELFNET) Third Yearly Report<sup>1</sup>, 67% of medical equipment manufacturers are using lead free solders.

Therefore, medical devices and monitoring and control instruments should become subject to RoHS, and in order to ensure the proper incentive structure for developing alternatives, no *permanent* exemptions should be given for any application in this group of products.

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<sup>1</sup> Lead-free soldering status survey 2006, TUB Germany, 23 March 2007; p. 31-32.  
<http://www.europeanleadfree.net/POOLED/DOCUMENTS/a285702/ELFNET%20Implementation%20Status%20Report%202006.pdf>

In addition we would also like to invite you to look back at the NGOs' comments mainly concerning mercury but also lead, submitted to the European Commission and the consultant (ERA) who prepared the study on 'Review of Directive 2002/95/EC (RoHS) Categories 8 and 9':

- Environmental and Health NGOs comments on the interim report on the review of directive 2002/95/EC (ROHS) Categories 8 and 9, mainly on mercury<sup>2</sup>, submitted 26/4/2007
- Environmental and Health NGOs position on inclusion of non-industrial thermostats within the RoHS directive. Annex I, Annex II, Annex III [January 13th, 2006]

## **2) SUBSTANCES COVERED**

### **Impacts at products end of life stage for chemicals not currently regulated under RoHS**

Expansion of the global market for electrical and electronic products continues to accelerate, while the lifespan of the products is getting shorter, resulting in a corresponding explosion of the amounts of electronic scrap, commonly called "e-waste".

This rapidly growing "e-waste" stream presents additional difficulties because a wide range of hazardous chemicals are, or have in the past been, used in components of electrical and electronic devices, and these subsequently create substantial problems with regard to handling, recycling and disposal of obsolete products. Hazardous chemicals may be released from the "e-wastes" through disposal or recycling processes, with the potential to expose workers as well as allow these chemicals to escape into the environment. Indeed, electrical and electronic waste has been identified as one of the largest sources of heavy metals and organic pollutants in municipal waste<sup>3</sup>, and is identified as the fastest growing waste stream<sup>4</sup>.

Many countries do not have the capacity to deal with the sheer quantity of "e-waste" they generate or with its content of hazardous chemical constituents. For this reason, these countries began exporting the problem to, mainly, Asian countries in which there are no capacities to ensure takeback and safe and environmentally sustainable recycling and disposal practices. There, the products are dismantled, with some materials recovered for reuse and the remainder disposed of to land or water courses.

In many parts of Asia, few controls are in place and dismantling and recycling of electronic wastes is frequently carried out in small workshops and industrial units with little or no exposure or emission controls for hazardous constituents of the waste stream.

There are very few studies that have investigated environmental contamination arising from the recycling and/or disposal of old electrical/electronic equipment. However, the few recently published studies have all found widespread workplace

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<sup>2</sup> [http://www.zeromercury.org/EU\\_developments/060426CommentsonERA-ROHS-scope-report-Mercury.pdf](http://www.zeromercury.org/EU_developments/060426CommentsonERA-ROHS-scope-report-Mercury.pdf)

<sup>3</sup> Boghe 2001 in Brigden, K., Labunska, I., Santillo, D. & Allsopp, M. (2005) Recycling of electronic wastes in China and India: Workplace and environmental contamination.

<sup>4</sup> Betram et al. 2002 in Brigden, K., Labunska, I., Santillo, D. & Allsopp, M. (2005) Recycling of electronic wastes in China and India: Workplace and environmental contamination.

and environmental contamination with either hazardous chemicals that are used in electrical/electronic equipment, or with hazardous chemicals known to be produced under some disposal and/or recycling operations by certain materials used in electrical/electronic equipment. Some of the hazardous chemicals, or materials that can give rise to hazardous chemicals, are not currently regulated by the RoHS Directive.

A study<sup>5</sup> in 2005 investigated industrial units and dump sites associated with the electronic waste-recycling sector in China and India. The analysis of various samples demonstrated widespread contamination with a range of organic chemicals and heavy metals, many with known uses in electrical and electronic products. Two classes of chemicals found at many of the recycling and disposal sites were **phthalate esters (phthalates)** and **brominated flame retardants (BFRs)**.

**Phthalates** were identified in samples from many locations, in sediments from wastewater channels from shredding activities, in wastes derived from acid processing of materials, and in river sediments adjacent to acid working facilities. Additional information on phthalates is given below.

**Brominated flame retardants (BFRs)**. In addition to the brominated flame retardants currently regulated under the RoHS Directive (e.g. PBDEs), other brominated chemicals were identified in samples from a number of sites; in wastewater channels from shredding activities, in wastes derived from acid processing of materials, and at sites of open burning. Amongst these were brominated chemicals known to be used as flame retardants, and brominated chemicals used in the manufacture of flame retardant materials. Additional information on BFRs is given below.

Studies investigating contamination resulting from the processes or disposal of electronic wastes have generally not included data on the presence of the plastic **polyvinyl chloride (PVC)** nor for all possible **brominated flame retardants (BFRs)**. However, a small number of studies have demonstrated contamination with toxic chemicals that can be produced during the processing of materials containing organic-bound chlorine (which includes PVC), or organic-bound bromine (which include all BFRs).

A study<sup>6</sup> of an area in China where electronic wastes are processed found extensive contamination with certain BFRs as well as polychlorinated dibenzo-dioxins and -furans (PCDD/F's), commonly referred to as 'dioxins and furans'. When burned, the chlorinated plastic **PVC** can produce PCDD/Fs<sup>7</sup>. PCDD/F's are recognized persistent bioaccumulative toxic substances, and are included under the Stockholm Convention on persistent organic pollutants (POPs). Additional information on PVC is given below.

Similarly, the burning of materials containing brominated materials, which includes **all brominated flame retardants (BFRs)** can produce brominated dioxin/furans (polybrominated dibenzodioxins and furans, PBDD/Fs) and mixed dioxin/furans

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<sup>5</sup> Brigden, K., Labunska, I., Santillo, D. & Allsopp, M. (2005) Recycling of electronic wastes in China and India: Workplace and environmental contamination. [www.greenpeace.org/international/press/reports/recycling-of-electronic-waste](http://www.greenpeace.org/international/press/reports/recycling-of-electronic-waste)

<sup>6</sup> Leung, A.O.W., Luksemburg, W.J., Wong, A.S., Wong, M. (2007) Spatial distribution of polybrominated diphenyl ethers and polychlorinated dibenzo-p-dioxins and dibenzofurans in soil and combusted residue at Guiyu, an electronic waste recycling site in southeast China. *Environmental Science and Technology* 41(8): 2730-2737

<sup>7</sup> Takasuga, T., Makino, T., Umetsu, N., Senthilkumar, K. (2003) Quantitative analysis of toxic compounds formed from combustion of some plastic materials and newspaper. *Organohalogen Compounds* 63: 86-89

(polybromochlorodibenzodioxins and polybromochlorodibenzofurans, PBCDD/Fs). There is currently no precise data on the toxicity of these compounds, however studies have shown similar toxicity to the related and the more well known chlorinated dioxin/furans (PCDD/Fs) mentioned above<sup>8</sup>.

A study<sup>9</sup> of waste dumping sites in India, Cambodia and Vietnam, where electronic materials containing brominated flame retardants are dumped and at times burned, has demonstrated environmental contamination with brominated dioxins/furans (PBDD/Fs) and mixed (PBCDD/Fs) dioxins/furans.

The RoHS Directive currently regulates the use of four metals; cadmium, mercury, lead and hexavalent chromium. **Beryllium** is another hazardous metal used in electrical and electronic equipment, primarily as copper-beryllium alloys. The recycling of electrical/electronic equipment containing copper-beryllium alloys can generate beryllium dusts, during high temperature processes such as those used at metal refineries and during the shredding and grinding of materials<sup>10</sup>. Recent studies have shown that people working with such alloys can have a significant risk of exposure to beryllium dusts, and suffer health impacts including developing a debilitating condition known as chronic beryllium disease (CBD)<sup>11</sup>. Some studies indicate that some workers can develop CBD at exposure levels significantly below current workplace exposure limits<sup>12</sup>. As a result of these properties, some metal smelters that processes electronic wastes are believed to place maximum limits on the beryllium content of materials they are able to accept.

The “e-waste” problem highlights the urgent need for widening the scope of the legislation so that manufacturers of electronic goods will take responsibility for their products from production through to the end of their lives. As a major contribution towards addressing this problem, additions to the substances covered by RoHS will give a strong legal incentive to manufacturers to develop and design clean products with longer life-spans, that are safe and easy to repair, upgrade and recycle and will not expose workers and the environment to hazardous chemicals.

### **Impacts at the *manufacturing* stage for chemicals not currently regulated under RoHS**

In addition to impacts at end of life, contamination with some hazardous chemicals incorporated into electrical/electronic products has also been seen at some sites where electrical/electronic products are manufactured.

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<sup>8</sup> Birnbaum, L. S., Staskal, D. F., Diliberto, J. J. (2003) Health effects of polybrominated dibenzo-*p*-dioxins (PBDDs) and dibenzofurans (PBDFs). *Environment International*. 29, 855-860

<sup>9</sup> Takahashi, S., Kunisue, T., Isobe, T., Noda, S., Subramanian, A., Kajiwara, N., Tana, T.S., Viet, P.H., Miyazaki, T., Sakai, S., Tanabe, S. (2006) Polybrominated diphenyl ethers and dioxin-related compounds detected in soil samples from waste dumping sites in Asian developing countries. *Organohalogen Compounds* 68; 1847-1850

<sup>10</sup> Basel (2004) Technical guidelines on the environmentally sound recycling/reclamation of metals and metal compounds (R4). Conference of the Parties to the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, UNEP/CHW.7/8/Add.3. Available [www.basel.int/meetings/cop/cop7/docs/08a3e.pdf](http://www.basel.int/meetings/cop/cop7/docs/08a3e.pdf). OECD (2003) Technical guidance for the environmentally sound management of specific waste streams: used and scrap personal computers. Organisation for Economic Co-operation and Development (OECD) Working Group on Waste Prevention and Recycling. ENV/EPOC/WGWPR(2001)3/FINAL.

<sup>11</sup> Balkissoon, R. C. & Newman, L. S. (1999) Beryllium copper alloy (2%) causes chronic beryllium disease. *Journal of Occupational & Environmental Medicine* 41(4): 304-308. Schuler, C.R., Kent, M.S., Deubner, D.C., Berakis, M.T., McCawley, M., Henneberger, P.K., Rossman, M.D. & Kreiss, K. (2005) Process-related risk of beryllium sensitization and disease in a copper-beryllium alloy facility. *American Journal of Industrial Medicine* 47(3): 195-205

<sup>12</sup> Kolaniz, M.E. (2001) Introduction to Beryllium: Uses, Regulatory History, and Disease. *Applied Occupational and Environmental Hygiene* 16(5): 559-567

Substantial concerns exist for many chemicals used in the manufacture of electronic products, both for potential exposure in the workplace and the possible environmental consequences of their release in waste streams.

A recent study<sup>13</sup> demonstrated the nature of environmental contamination due to the manufacture of some components used in electrical/electronic equipment at multiple sites in many countries.

Evidence of environmental contamination by a diverse range of chemicals, many with known uses in this industry, was found for each of the three sectors investigated. This included both chemicals incorporated into the products as well as chemicals used in manufacturing processes, many with known toxicity to humans and other potential environmental impacts. Some chemicals were found in wastestreams from more than one sector. These included some toxic and environmentally persistent groups of chemicals: brominated flame retardants and phthalates.

The ineffective treatment of wastewaters by the waste water treatment plants (WWTPs) to which they are discharged has been demonstrated at some industrial estates in Thailand where PWBs are manufactured. As is the case for many industrial estates where common WWTPs receive mixed wastes from many facilities, treatment processes that may be able to degrade certain chemicals are not effective at dealing with persistent organic chemicals and heavy metals in wastewaters. As this study has found, this can mean that such chemicals are still present in treated wastewaters discharged to the environment. Furthermore, their accumulation in WWTP sludges creates an additional wastestream contaminated with heavy metals and persistent organic chemicals.

### **PWB manufacturing**

**Phthalates and TBBPA** were found in wastewaters from facilities in China. Overall, the results from the above study<sup>14</sup> clearly demonstrate that the current use of hazardous chemicals and practices in the manufacture of electronic equipment is resulting in contamination of the environment with many hazardous chemicals not yet included under RoHS, some of which are persistent. Commonly used wastewater treatment processes are unable to deal with many of the chemicals used.

PWBs are essentially complex copper circuitry embedded within an electrically insulating baseboard. Baseboards are generally made from glass fibre-epoxy resin based composites to which flame retardant chemicals are commonly added. Tetrabromobisphenol-A (TBBPA), a brominated flame retardant (BFR), is widely used in epoxy resin boards. This compound becomes largely chemically bound into the polymer, though traces of unreacted TBBPA do remain unbound in the finished board (Sellstrom & Jansson 1995) and the harsh chemical environments used during PWB production may be expected to cause some leaching of unreacted monomer.

### **Additional information on phthalates and PVC<sup>15</sup>**

#### **Phthalates**

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<sup>13</sup> Brigden, K., Labunska, I., Santillo, D. & Waters, A. (2007) Cutting Edge Contamination: A Study of Environmental Pollution during the Manufacture of Electronic Products  
<http://www.greenpeace.org/raw/content/international/press/reports/cutting-edge-contamination-a.pdf>

<sup>14</sup> Brigden, K., Labunska, I., Santillo, D. & Waters, A. (2007) Cutting Edge Contamination: A Study of Environmental Pollution during the Manufacture of Electronic Products

<sup>15</sup> For more information, please check the Greenpeace Briefing called Toxic Tech: The dangerous chemicals in electronic products. [www](http://www.greenpeace.org)

**Toxicity.** Phthalates are a group of related chemicals, many of which are widely used as plasticizers (softeners) in plastics, especially PVC. Many phthalates are toxic to wildlife and humans, often through their metabolites (chemicals to which they breakdown in the body). Some widely used phthalates are known to be toxic to reproduction, capable of causing changes to both male and female reproductive systems in mammals<sup>16</sup>. Some phthalates (e.g. **DEHP** and **DBP**) are classified as “toxic to reproduction” within the EU<sup>17</sup>. Certain other phthalates (DINP and DIDP) can affect the liver and kidneys.

**Migration from products.** Phthalates that are incorporated into plastic materials are not chemically bound to the plastic, but are able to migrate out of the material over time. This can result in substantial losses to the environment during the lifetime of products, and again following disposal (amounting to thousands of tonnes per year across the EU<sup>18</sup>). Phthalates are known to be used in some external components of electrical products (e.g. the plastic coating of power cables for laptop computers<sup>19</sup>).

**Regulated in other products.** Phthalates are not currently included amongst the chemicals regulated under the RoHS Directive. However, due to concerns over human exposure to toxic and potentially toxic chemicals, the use of certain phthalates is restricted in some products within the EU (toys and childcare articles)<sup>20</sup>. This Directive prohibits the sale of toys and childcare articles that include plastic containing more than 0.1 % by weight of phthalates including DiNP and DiDP (for products that can be placed in the mouth by children), as well as those with more than 0.1 % of DEHP or DBP (for all such products). The recently revised Medical Devices Directive also, while not banning phthalates, has imposed tighter conditions on the usage of all phthalates which have been categorised as Carcinogens, Mutagens, or Toxins to Reproduction Categories 1&2 in medical devices for certain vulnerable groups.

## **PVC**

Although PVC does not have direct toxicity, this plastic does presents its own manufacturing and waste management problems by acting as a source of organic-bound chlorine to the waste stream (e.g. dioxin/furan formation), as well as raising additional concerns at other points in its lifecycle. Furthermore, the use of PVC in certain applications requires the use of additive chemicals, such as phthalate esters (phthalates) used as plasticisers (softeners).

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<sup>16</sup> Park, J.D., Habeebu, S.S.M. & Klaassen, C.D. (2002) Testicular toxicity of di-(2-ethylhexyl)phthalate in young Sprague-Dawley rats. *Toxicology* 171: 105-115. Gray, L.E., Ostby, J., Furr, J., Price, M., Veeramachaneni, D.N.R. & Parks, L. (2000) Perinatal exposure to the phthalates DEHP, BBP and DINP, but not DEP, DMP or DOTP, alters sexual differentiation of the male rat. *Toxicological Sciences* 58(2): 350-365

<sup>17</sup> EC (2001) Directive 2001/59/EC of the European Parliament and of the Council of 6 August 2001 adapting to technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labeling of dangerous substances. Official Journal of the European Communities L225, 21.8.2001: 1-333 [http://ecb.jrc.it/documents/Classification-Labeling/ATPS\\_OF\\_DIRECTIVE\\_67-548-EEC/28th\\_ATP.pdf](http://ecb.jrc.it/documents/Classification-Labeling/ATPS_OF_DIRECTIVE_67-548-EEC/28th_ATP.pdf)

<sup>18</sup> CSTE (2001a) EC Scientific Committee on Toxicity, Ecotoxicity and the Environment, Opinion on the results of the Risk Assessment of: 1,2-Benzenedicarboxylic acid, di-C8-10-branched alkyl esters, C9-rich and di-“isononyl” phthalate - Report version (Human Health Effects): Final report, May 2001. Opinion expressed at the 27th CSTE plenary meeting, Brussels, 30 October 2001: 7 pp. [http://europa.eu.int/comm/food/fs/sc/sct/out120\\_en.pdf](http://europa.eu.int/comm/food/fs/sc/sct/out120_en.pdf)

<sup>19</sup> Brigden, K. and Santillo, D. (2007) Analysis of hazardous substances in a HCL laptop computer. Greenpeace Research Laboratories Technical Note 02/2007, March 2007: 15pp. [http://www.greenpeace.to/publications/HCL\\_Report\\_2007.pdf](http://www.greenpeace.to/publications/HCL_Report_2007.pdf)

<sup>20</sup> EC (2005) Directive 2005/84/EC of the European Parliament and of the Council of 14 December 2005 amending for the 22nd time Council Directive 76/769/EEC on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations (phthalates in toys and childcare articles). Official Journal of the European Communities L344, 27.12.2005: 40-43 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:344:0040:0043:EN:PDF>

### **Additional information on flame retardants<sup>21</sup>**

Flame-retardants are chemicals added to a wide variety of materials, including casings and components of many electronic goods, to prevent the spread of fire.

#### **TBBPA (Tetrabromobisphenol-A)**

Tetrabromobisphenol A (TBBPA) is used widely in various industrial and consumer products including electrical and electronic appliances (Lassen et al. 1999). This chemical is most frequently used in polymeric form, i.e. bound to the polymers in which it is incorporated, though a small percentage of total use is in additive uses (i.e. in a similar manner to the common additive flame retardants PBDEs and HBCD). Despite its primary use in reactive, polymeric forms, TBBPA has been found in the indoor environment, including in office dust samples (Leonards et al. 2001).

It has been reported that TBBPA may interfere with the binding of thyroid hormones (Meerts et al. 1998, 2001), raising the potential for diverse effects on growth and development. Concerns have also been raised that TBBPA can induce oestrogen-like properties (Meerts et al. 2001, Samuelsen et al. 2001, Olsen et al. 2003), neurotoxicity (Mariussen & Fonnum 2003), immunotoxicity (Pullen et al. 2003), nephrotoxicity (Fukuda et al. 2004) or hepatotoxicity (Ronisz et al. 2004, Tada et al. 2006). However, most of the studies are in vitro studies and these are not used for the purpose of risk assessment.

A risk assessment report published by European Commission in 2006 (EC 2006) has concluded that “No health effects of concern have been identified for TBBP-A”. The United Kingdom prepared this study on behalf of the European Union and it was based on the scientific publications up to 2004. But very recently the UK revised the environmental risk assessment to take into account new test data and exposure information provided by Industry (DEFRA 2006). “The exposure section was updated with site-specific monitoring data. Initial results of studies of degradation in anaerobic sewage sludge and anaerobic sediment were added. These show de-bromination of TBBPA to form bisphenol A, another substance being assessed under the Existing Substances Regulation. Other recent studies in the published literature also found evidence for debromination of TBBPA in the environment. The Technical Committee of the New and Existing Substances (TC NES) agreed that this source of Bisphenol A to the environment should be considered further in an update to the Bisphenol A risk assessment”. Finalisation of this revised environmental risk assessment, expected to identify some significant risks to the environment, is expected shortly.

***The above mentioned chemicals and materials of concerned is not intended to be an exhaustive list of likely candidates to add under RoHS. However, they are clear examples of the need for expanding the list of restricted chemicals.***

### **3) FACILITATING IMPLEMENTATION – MECHANISM FOR EXEMPTIONS**

Exemptions from the general substitution requirement of the ROHS directive are permitted currently 1) if substitution is not possible from the scientific and technical point of view; 2) if the negative environmental or health impacts caused by substitution are likely to outweigh the human and environmental benefits of the substitution, or 3) if it is not compatible with the health and safety of users of electrical and electronic equipment.

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<sup>21</sup> For more information, please check the Greenpeace Briefing called Toxic Tech: The dangerous chemicals in electronic products. [www](http://www.greenpeace.org/usa/toxic-tech)

The Environment and Health NGOs believe that whenever exemptions are given, these should only be for a time limited period to drive innovation and substitution, and should be based on the existing criteria.

Although the process might be considered long for the operators, the practice proves that strict controls and verifications are needed when an application for exemption is made by industry.

Until now more than 100 additional (to the initial RoHS directive) requests for exemptions have been submitted by industry. Public consultation and the analysis from the consultants have proven however that not all of these justify adoption. Only 28 have been approved so far, showing that many requests were not justifiable.

The invitation for comments mentions that some stakeholders expressed the view that the current system for granting exemptions has created practical problems. However the practical problems claimed by the operators have rather been caused by their delay in dealing with the directive's requirements, as can be seen by the fact that most of the requests are for applications which existed before publication of the directive. Delays in the process are also caused by late submissions for exemptions, and unclear justifications.

The mechanism for exemptions should not be streamlined on the basis of the mentioned claims. Rather, the review should take into account the following issues:

- Full evaluation is needed for every exemption request to ensure whether safer alternatives are available and follow the criteria set on the directive;
- The burden of proof should lie with industry and not the public authority;
- Cost evaluation is NOT foreseen by the RoHS Directive Article 6, and this should not be changed unless it takes into account ALL costs of allowing exemption, e.g. human health impacts<sup>22</sup>. Exemptions should only be based on scientific facts and not on simplistic cost considerations.
- The evaluation carried out by the consultants should be broader: it should include investigation of the availability of safer alternatives, including the active searching for such information, not relying solely on voluntarily submitted information. Furthermore the cost for such detailed investigations should follow the polluter pays principle and be borne by the requesting industrial entity: e.g. each request for exemption should be accompanied by a fee payment, – the fee would cover part of the cost of an independent consultant hired by the Commission to examine the details of the request including availability of alternatives.
- inclusion of time limits for all exemptions (e.g. as per the 1 year derogation for hexavalent chromium recently introduced);
- mechanisms to ensure that any granted exemptions are specific to the applications that it has been demonstrated they are necessary for;

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<sup>22</sup> As an illustration that the 'hidden costs' can be very high, and therefore any simplistic financial balance should not be allowed to be used to approve exemptions, please check the following studies:

- Pricing hazardous substance emissions by ECON - Centre for Economic Analysis for the Norwegian Research Council – NFR. ECON-report no. 63/97, Project no. 10228. ISSN: 0803-5113, ISBN: 82-7645-216-7. Oslo, Norway.
- Public Health and Economic Consequences of Methyl Mercury Toxicity to the Developing Brain (emissions of mercury from coal power stations, but the implications are there for mercury emissions from all sources (e.g. incineration of mercury containing products). This study estimates the economic costs of methyl mercury toxicity attributable to mercury from these plants, with figures of billions of dollars annually)

- a time-limited exemption should be able to be shortened or terminated when an alternative becomes technically feasible before the end of the existing exemption period.

### **Lessons to learn from the DecaBDE exemption case**

The proposal of the European Commission to exempt the flame retardant decabromodiphenyl ether ('decaBDE') in polymeric applications from a ban of its use in electrical and electronic applications from 1 July 2006 should be seen as a case study of how NOT to carry out future exemptions under the RoHS Directive.

Particular consideration should be given in the RoHS review to questions raised regarding:

- the Commission's lack of competence: Based solely on risk considerations, it is questionable whether the Commission adhered to the criteria of Article 5(1)(b) RoHS Directive concerning its implementing powers.
- the Commission's duty to state reasons: the exemption was motivated with reference to an as yet unfinished risk assessment which is still subject to discussion in the Community institutions as well as the Technical Committee of the New and Existing Substances (TC NES);
- the respect of the principle of proportionality: Because the proposed Council Decision entails a radical shift of policy from substitution to exemption from substitution for most decaBDE applications without justifying that this is necessary to achieve the aim of the decision, it is legitimate to question whether the proposal is in line with the principle of proportionality (i.e. no study was ever carried out of safer alternatives)
- the respect of the precautionary principle: Given the politically agreed level of protection, given the existing technical substitution possibilities for decaBDE in most polymeric applications, and given the continued scientific uncertainty regarding the impact of decaBDE on human health, it is questionable whether a proposal to remove the ban on decaBDE in polymeric applications complies with the precautionary principle as a general principle of the Community law.

We trust that the Commission will also consider the implications of the ongoing court cases on this matter in the ECJ by the European Parliament and Denmark with regard to future review of RoHS.

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