

Adaptation to scientific and technical progress under Directive 2002/95/EC

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1 Background and Objectives

Article 4 (1) of Directive 2002/95/EC on the restriction of the use of certain hazardous sub-stances in electrical and electronic equipment provides “that from 1 July 2006, new electrical and electronic equipment put on the market does not contain lead, mercury, cadmium, hexavalent chromium, PBB or PBDE.” The annex to the Directive lists a limited number of applications of lead, mercury, cadmium and hexavalent chromium, which are exempted from the requirements of Article 4 (1).

Article 5 (1) (b) of the Directive provides that materials and components can be exempted from the substance restrictions contained in Article 4 (1) if their elimination or substitution via design changes or materials and components which do not require any of the materials or substances referred to therein is technically or scientifically impracticable, or where the negative environmental, health and/or consumer safety impacts caused by substitution outweigh the environmental, health and/or consumer safety benefits thereof.

On the basis of this provision the Commission has received (and is still receiving) additional requests for applications to be exempted from the requirements of the Directive from industry. These requests need to be evaluated in order to assess whether they fulfil the above mentioned requirements of Article 5 (1) (b). Where the requirements are fulfilled the Commission proposes a draft decision amending the RoHS Directive.

Against this background Öko-Institut e.V. and Fraunhofer Institute for Reliability and Microintegration IZM have been commissioned by the European Commission with technical assistance for the evaluation of requests for exemptions submitted according to Article 5 (1) (b). The main objective of this technical assistance contract consists in a clear assessment of whether the requests for exemptions are justified in line with the requirements listed in Article 5 (1) (b) and in a subsequent recommendation on whether or not to grant the exemption – including a precise wording. These recommendations as well as the description of the proceeding will be included in monthly reports between October 2006 and October 2007.

2 General Procedure

For details on the general procedure please refer to monthly report 1.

3 Scope

On 10 November 2006 the sixth stakeholder consultation round was launched by the Commission and closed on 10 January 2007. The requests open for comments of this sixth consultation round represent the scope of this fourth monthly report and of the current and forthcoming evaluation. Stakeholder comments have been posted on the consultation website concerning requests 1, 7, 15, 18, 22 and 23 as well as one general comment.

Table 1 below gives an overview over the corresponding set 6 of requests for exemption and their current status.

Table 1: Overview status of requests set 6

No.	Title	Applicant	Status
1a	Lead used for shielding of x-radiation emissions for CRT	VDC Display Systems	WITHDRAWAL 11/12
1b	Hazardous materials and lead in solders in components and assemblies used in non-consumer products	VDC Display Systems	WITHDRAWAL 11/12
1c	Electronic equipment where reliability, durability and longevity of the equipment is paramount	VDC Display Systems	WITHDRAWAL 11/12
2	Lead as soldering alloy in high performance communication electronic board and hexavalent chromium (Cr-VI)	Clarity SAS	WITHDRAWAL 18/12
3	GemCore 410 EMV	Gemplus	Questions sent out 4/12/06. Reply received. Recommendation in process.
4	SAVBIT solder	Roband Electronics PLC	Questions sent out 16/02/07. Reply received. Recommendation in process.
5	Sn-Pb soldering used in Ground-based Aeronautical Communication Equipment Manufacturing	Telerad	Questions still to be sent out.
6	Transducers used in professional loudspeaker systems, using tin-lead solder	Gemini Sound products Corp.	Recommendation in process.
7	Tin-lead solder in the manufacture of professional audio equipment	Gemini Sound products Corp.	Recommendation in process.

No.	Title	Applicant	Status
8	Inventory of special ICS having tin-lead solder on/in leads/balls, used in specialist/professional equipment	Gemini Sound products Corp.	WITHDRAWAL 02/01
9	Crystal Stones within the battery operated watch	Zeon Ltd.	WITHDRAWAL 10/01
10	EEE used for the broadcast and homeland security sector	Tieline Technology	Questions sent out 16/02/07. No reply yet.
11a	AM186ES-V40 containing lead in used in the leads over plating and AM79C961AKC containing lead in used in the leads over plating	Digigram	Questions sent out 5/12/06. Reply received. Recommendation in process.
11b	Audio board manufacturing process	Digigram	Questions sent out 5/12/06. Clarification on possible withdrawal ongoing.
12	Cadmium sulphide or cadmium selenide in polymer based thin film transistor	Silk Displays Inc.	Questions sent out 5/12/06. Reply received. Clarification on scope issue in progress with Commission.
13	Lead used in the soldering for surface finishing at the electric pole terminal on the electronic parts	ICOM Incorporated	Questions still to be sent out.
14	Cadmium contained in the cadmium oxide of a thick film ceramic substrate	ICOM Incorporated	Questions still to be sent out.
15	All electronics assemblies using lead in solder	RoHSUSA Inc	Draft recommendation given in third monthly report.
16	Lead in electric overblankets for Hot Spot detection	Beurer / Especialidades Eléctricas Daga S.A.	Draft recommendation possible (cf. section 5.1).
17	MPC10 used in automatic vending machines to achieve the payment by card	Sagem monetel	Questions sent out 07/12/06. No reply received yet (although two reminders have been sent out). Recommendation in progress with original application document.
18	Hexavalent Chrome Cr-VI when used as a passivate	Amphenol Limited	Questions sent out 09/01/07. Reply received. Recommendation in process.

No.	Title	Applicant	Status
19	Lead contained in circuit boards, obsolete and non-compliant Intel 80c188/86 EA\XL microprocessors, Analog Devices ADMC300 DSP, and NEC uPD7101 DART and hexavalent chromium	NBS Technologies Inc.	Questions sent out 09/01/07. Clarification on inclusion of RoHS scope still in process with applicant.
20	Component used in the manufacture of electric blankets and heating pads	Thermocable (Flexible Elements) Limited	Draft recommendation possible (cf. section 5.2).
21	Request to delete exemption for "Lead as impurity in RIG (rare earth iron garnet) Faraday rotators used for fibre optic communications systems	Integrated Photonics	No questions. Recommendation in process.
22	Lead in Trimmer Potentiometer elements	Tokyo Denshi Ltd.	Questions still to be sent out.
23	Cadmium in opto-electronic components	Marshall Amplification plc	Questions still to be sent out.

4 Results

Some requests are currently still being looked at in more depth before sending out questions that need to be answered in order to clarify some aspects of the requests (5). For the other part of the requests questions already have been sent out. Concerning this part most applicants have replied and drafting of recommendations is in progress. Apart from the draft recommendation giving concerning request no. 15 in the last monthly report (monthly report 3), the current report contains draft recommendations for the requests no. 16 and no. 20 (cf. section 5).

Most of the evaluation work has up till now consisted in asking the applicants the relevant questions in order to clarify whether (i) the application for which an exemption is requested falls under the scope of the RoHS Directive, (ii) an existing exemption would cover the application concerned and (iii) the use of the substance in an application can be described in more detail. This process sometimes takes up quite extensive e-mail exchanges and telephone calls. The fact that this is nevertheless an important part in the evaluation before beginning with drafting a recommendation is reflected in the many withdrawals (6) that are brought forward by applicants when they subsequently realise that the exemption request is not valid within the context of the RoHS Directive and its exemptions in force.

For example, with regard to exemption request no. 19, it is currently clarified whether the application for which an exemption was requested falls under the term "fixed installation" and

would thus be out of scope of the RoHS Directive. The applicant has been asked to confirm this and to formally withdraw the exemption request.

One interesting question was raised when the applicant of request no. 12 was sent the questions for clarification: can an exemption be granted for a product that is still under development and not yet on the market? This is one example for an issue that needs to be dealt with carefully before starting the drafting of the recommendation. The issue is currently being checked by the Commission.

5 Recommendations

5.1 Lead in electric overblankets for Hot Spot detection– Beurer (set 6 request no. 16)

5.1.1 Description of requested exemption

The company Beurer requests an exemption for the use of lead in PVC used for the insulation of heating wires in flexible heating overblankets. The applicant considers flexible heating overblankets to belong to category 2 WEEE Directive. Heating overblankets are – unlike heating pads or underblankets – often used in a folded or rucked way¹. The lead doped PVC is a conductive plastic material which is used for the detection of so-called hot spots. These occur when the heating overblanket is folded or rucked and an overheating takes place. Such an overheating may lead to skin burns.

An overheating can take place in two ways:

1. Either the heating wire is folded in such a way that in the areas of bending (thermal and mechanical stress), the plastic will melt thus causing a short circuit (preventing harm for the user since then current does no longer run and the appliance stops heating) or
2. the heating overblanket is folded in such a way that several layers of heating wire are on top of each other thus leading to local temperatures of around 90 – 100°C which may cause skin burns.

The hot spot detection is necessary for the second case.

The European Standard EN 60335-2-17 is applicable for flexible heating appliances and defines tests conditions to insure the safety of flexible heating appliances during normal use

¹ As opposed to heated underblankets which are designed to be placed flat on the mattress, heated overblankets are designed to be wrapped around the user.

and foreseeable misuse. The standard calls for the „most unfavorable folding condition“ during test. According to Beurer flexible heating overblankets can only meet the standard's requirements if they have a hot spot detection.

According to the applicant Beurer and the Spain-based manufacturer Daga own 90% of the European market for heating overblankets. Beurer says to have put all overblankets concerned by the RoHS Directive to the EU market before the closing date of July 1st, 2006.

Beurer uses heating wires manufactured by “Thermocable” (cf. set 6 request no. 20) and “Heatsolve”. Both have started research for alternatives where not PVC but another conductive plastic material not containing lead would be used. However, these alternatives are not yet on the market. Beurer expects to be able to purchase an alternative by end 2007 / beginning 2008 thus using this alternative in time for the 2008 production. An exemption is requested for the 2007 and part of the 2008 production.

The annual production volume of blankets with lead-containing heating wire in the EU is estimated by Beurer to be approximately 80.000 blankets with 1.5 kg each. The amount of lead per blanket is 0.4 grams. The corresponding annual amount of lead within these blankets is thus approximately 30-40 kg.

The wording proposed by the applicant is: “Lead in PVC used for giving a Negative Temperature Coefficient (NTC) behaviour to the PVC for the detection of hot-spots in flexible electric heating overblankets”.

5.1.2 Justification for exemption as submitted by applicant and stakeholders

The applicant justifies his exemption request according to the following technical and safety arguments:

- Currently there is no alternative (lead-free) plastic material on the market delivering hot-spot detection for flexible electric heating overblankets.
- Skin burns due to overheating of overblankets in folded or rucked condition can only be prevented by using a hot-spot detection system.
- For flexible electric heating overblankets, the fulfilment of the standard EN 60335-2-17 regarding the therein specified test conditions (“most unfavourable folding condition“) can only be achieved with an integrated hot-spot detection system.

5.1.3 Critical review of information as submitted by applicant and stakeholders

A critical review of the documents made available by the applicant and of further data and information given by other parties lead to the following observations and conclusions:

- The applicant has made clear with complete and comprehensive documentation that there currently is no lead-free alternative on the market for a hot-spot detection system to be used in flexible electric heating overblankets in order to prevent skin burns during use.

- Although there is no legally binding regulation prescribing the use of such a hot-spot detection system in the mentioned application, the applicant has justified the necessity of preventing overheating in such a way with valid arguments.
- There might be products on the market which wear the CE mark signalling conformity with EU legislation and standards that do not use such hot-spot detection. However, the applicant has made clear that these products represent a safety risk for the user and that these products represent a very small part of the market (thus not having to fear negative image problems should safety of users be endangered).
- Substitutes seem to be under development leading to the conclusion that in this case it is rather the question of phasing-out the use of lead in the short term rather than needing a long-term exemption.
- The argument that user safety can only be guaranteed with NTC hot-spot detection has not been confirmed by the heating wire supplier Thermocable (cf. set 6 request no. 20 and section 5.2). However, Thermocable has stated that an NTC hot-spot detection is the only system, that allows the device to be still operational after overheating has taken place while other safety systems (e.g. using an additional layer of low-melting polyethylene that would lead to melt-down in case of overheating and thus causing a short-circuit) would lead to failure of the device.
- Additionally Thermocable did also not confirm that the requirements of the standard EN 60335-2-17 can only be met with an NTC hot-spot detection for overblankets. However, here again, the argument of prolonging product life has been brought forward by Thermocable.

5.1.4 Draft final recommendation

Concluding on the above justification and critical review and in analogy to the recommendation given for exemption request no. 20, it is recommended to grant the exemption. Since substitutes will probably be available by latest mid 2008 it is however recommended to limit the exemption in time. The recommended wording of the exemption is thus (in line with the one recommended for exemption request no. 20 in section 5.2):

“Lead in PVC used for giving a Negative Temperature Coefficient (NTC) behaviour to the PVC in view of electronic shut down control of flexible electric heating appliances (overblankets, heating pads and underblankets) until 1 July 2008.”

The applicant has not yet agreed to this wording.

5.2 Component used in the manufacture of electric blankets and heating pads – Thermocable (set 6 request no. 20)

5.2.1 Description of requested exemption

The company Thermocable requests an exemption for the use of lead in Negative Temperature Coefficient (NTC) PVC used for the manufacture of heating wires used in flexible heating appliances (overblankets, heating pads, underblankets). The applicant considers flexible heating appliances to belong to category 1 WEEE Directive.

Flexible heating appliances operate at a certain temperature (e.g. 65°C - 70°C for overblankets). In cases where such flexible heating appliances are folded or rucked, the temperature can rise considerably (e.g. up to 160°C in one hour when blanket is 3-fold). The European Standard EN 60335-2-17 requires flexible heating elements to fail safe prior to 165°C in order to prevent skin burns². According to Thermocable, this requirement can be met in different ways:

- Either an additional low-melting polyethylene layer is used that melts down at around 120°C – 130°C thus causing the device to shut down but also resulting in the device not being operational anymore or
- The NTC hot spot detection system is used which electronically shuts down the appliance at around 110°C before a melt-down takes place thus allowing the product to be further used³.

In the first case, according to the applicant, devices will usually fail within the first two years of use. Although Thermocable admits that this is more probable for overblankets than for underblankets. Hence, the second possibility is particularly used for overblankets.

Thermocable estimates the annual amount of lead used in flexible heating appliances in the EU to be approximately 26kg and 0,468 g per blanket.

Thermocable has started research for alternative materials as well as substitution of lead in the NTC/PVC⁴. Although R&D efforts have started late in the RoHS implementation process

² It defines tests conditions („most unfavourable folding condition“) to insure the safety of flexible heating appliances during normal use and foreseeable misuse. The standard does not give guidance to what means are used to achieve the fail safe requirement.

³ Statement Thermocable: “The PVC/NTC has particular repeatable characteristics than can be electronically measured and used to switch off the heating appliance at any desired temperature prior to 165°C without activating the final safety circuits, which means the heating appliance can be still operated once the abnormal condition is removed.”

⁴ Substitution of lead in PVC without NTC characteristics is already being done according to the applicant. Only the substitution of lead in PVC with NTC characteristics is not yet feasible.

(mid 2005⁵), the applicant is confident that an alternative will be ready for market use within the next 18 months⁶.

The applicant has not proposed a wording. The following wording was submitted to the applicant for agreement: "Lead in PVC used for giving a Negative Temperature Coefficient (NTC) behaviour to the PVC in view of electronic shut down control of flexible electric heating appliances (overblankets, heating pads and underblankets) until 1 July 2008".

5.2.2 Justification for exemption as submitted by applicant and stakeholders

The applicant justifies his exemption request according to the following technical, environmental and safety arguments:

- Currently there is no alternative (lead-free) plastic material on the market delivering NTC characteristics for flexible electric heating appliances. Lead substitutes lead to problems with the long-term stability of the plastic material and problems in the extrusion process due to the material having low melting temperature. Therefore research efforts rather go in the direction of materials other than PVC able to deliver NTC characteristics without the use of lead. The applicant explains it as follows:
 - "In processing the lead free material, we experienced problems in extrusion where the processing characteristics were different to the standard version which led to the finish of the extrusion to be uneven and inconsistent in diameter. Various changes were made to achieve an acceptable finish in the short term to enable further testing to be carried out.
 - The NTC characteristics of the polymer were measured on the various samples in the laboratory and compared with past records. This showed a major change in the performance of the NTC properties.
 - Long term stability tests were carried out which again showed that the stability of the NTC properties in the polymer were unacceptable and that the resistance curve verses temperature would not allow for any accurate long term temperature control in heating appliances."

⁵ The applicant argues that due to an unclear or misleading interpretation of „homogeneous material“ it was not clear that the amount of lead in PVC would exceed maximum concentration values.

⁶ „We have currently completed processing and NTC characteristic testing. Long term stability and ageing testing of the product is under way and may require several more months of development dependant upon results. If this solution proves successful then the product could be introduced to our customers who would then have to develop modifications to their control circuits due to the NTC characteristics of the new polymer being different. These controllers would then have to be presented to European test houses for approval, all of which could take 12 to 18 months.“

- The safety characteristics delivered by NTC prolong the lifetime of the product since the product does not fail when overheating takes place but can rather be shut down in a controlled way thus making further use of the appliance possible.
- NTC/PVC allows for additional safety also for heating pads and underblankets.
- The amount of lead in the heating wire is very small. Thus, negative environmental effects due to the use of lead are supposed to be outweighed by the negative environmental effects due to appliances failing because of overheating (i.e. shortening product life).
- A phase-out period is required for the use of lead in NTC/PVC meaning that an exemption can be limited in time.

5.2.3 Critical review of information as submitted by applicant and stakeholders

A critical review of the documents made available by the applicant and of further data and information given by other parties lead to the following observations and conclusions:

- The applicant has made clear with complete and comprehensive documentation that there currently is no lead-free alternative on the market for a NTC/PVC to be used in flexible electric heating appliances in order to prevent devices to fail safe by melt-down.
- Although there is no legally binding regulation prescribing the use of such NTC/PVC in the mentioned application, the applicant has justified the necessity of preventing overheating in such a way with valid arguments.
- The applicant delivered information on efforts made for the development of alternatives leading to the conclusion that in this case it is rather the question of phasing-out the use of lead in the medium term rather than needing a long-term exemption.
- Ensuring a long product life and guaranteeing a maximum level of safety for the use of electric heating appliances is in line with Article 5 (1) (b).

5.2.4 Draft final recommendation

Concluding on the above justification and critical review, it is recommended to grant the exemption. Since substitutes will probably be available by latest mid 2008 it is however recommended to limit the exemption in time. The recommended wording of the exemption is thus (in line with the one recommended for exemption request no. 20 in section 5.1):

“Lead in PVC used for giving a Negative Temperature Coefficient (NTC) behaviour to the PVC in view of electronic shut down control of flexible electric heating appliances (overblankets, heating pads and underblankets) until 1 July 2008.”

The applicant has agreed to this wording.

6 Further proceeding

The next step will be to finalise sending out the first questions to applicants (for 5 of the 23 requests). Furthermore, recommendations for the requests for which they are already in progress will be finalised as well as clarifications on scope issues.

The next monthly report is scheduled for 24 March 2007.