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Annex to the

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

**amending Council Directive 76/769/EEC relating to restrictions on the marketing of
certain measuring devices containing mercury**

IMPACT ASSESSMENT FORM

{COM(2006) 69 final}

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1. INTRODUCTION

On 28 January 2005 the Commission adopted a communication on the Community strategy concerning mercury¹ underpinned by an Extended Impact Assessment (ExIA)². The Strategy considers the impacts of mercury on a global basis and proposes measures to protect human health and the environment from the release of mercury based on a life-cycle analysis taking into account production, use, waste treatment and emissions.

With the aim of reducing the demand for mercury used in products and to speed up the substitution of mercury, the ExIA indicated that it would be appropriate to introduce a Community level marketing restriction on mercury-containing measuring and control equipment for consumer use and, with some exemptions, in the healthcare sector. While most control equipment for household use, e.g. thermostats, falls in general within the scope of Directive 2002/95/EC³ (RoHS directive), measuring devices such as fever and room thermometers, barometers, blood pressure gauges and manometers do not depend on electric currents to work properly and therefore fall outside of the scope of the RoHS Directive. These measuring devices are the subject of the present proposal (compare Action 7 of the Strategy).

The impact assessment for the present proposal is based mainly on the findings of the ExIA made for the Mercury Strategy, complemented by the results of further consultation on the scope of the proposed restrictions.

2. ISSUE THAT THE PROPOSAL TACKLES

Mercury and its compounds are highly toxic to humans, ecosystems and wildlife. Initially seen as an acute and local problem, mercury pollution is now also understood to be global, diffuse and chronic. Mercury is persistent and can change in the environment into methylmercury the most toxic form. Exposure to methylmercury occurs mostly via diet. Methylmercury collects and concentrates in the aquatic food chain in particular, making populations with high intake of fish and seafood particularly vulnerable (especially in the coastal areas of the Mediterranean). Direct exposure to mercury via inhalation of vapour and absorption through the skin is also a health risk.

Although some mercury is released by natural sources, additional releases from anthropogenic sources like coal burning and its use in products have led to significant increase of concentrations in the environment. It is therefore important to reduce anthropogenic mercury releases to the environment either through measures relating to the control of emissions or through measures at earlier stages of the mercury cycle such as supply and use.

Demand for mercury stands at around 3,600 tons per year globally, including around 300 tons in the EU. The main global uses, accounting for over 75%, are artisanal gold mining, batteries and the chlor-alkali industry. Of these, only the chlor-alkali industry remains a significant user in the EU, although the mercury cell process is now being phased out. The next most significant application in the EU is in dental amalgam, which is addressed by Community

¹ COM (2005) 20 final, 28.01.2005

² SEC (2005)101, 28.01.2005

³ Directive 2002/95/EC of 27 January 2003 on the restriction of the use of certain hazard substances in electrical and electronic equipment, OJ L 37 , 13.2.2003

legislation on medical devices and on waste management. Among other major product groups, Community legislation covers electrical and electronic equipment (RoHS Directive). The main mercury product group not yet covered by Community law is non-electrical or non-electronic measuring and control equipment. An overview of mercury uses in products is given in Annex I.

3. MAIN OBJECTIVES THAT THE PROPOSAL IS EXPECTED TO ACHIEVE

A key long term aim is that levels of mercury in the environment will be reduced to a level such that there is no longer any need for concern over methylmercury in fish. The Community has already taken much action to reduce mercury emissions and uses, although some such measures have not yet taken full effect. Possible further policies that have been assessed conclude that additional action on the use of mercury in measuring and control equipment is an appropriate component of a larger strategy to reduce mercury emissions.

The objective of the Directive is to provide a high level of protection of the environment and human health, whilst preserving the internal market, as required by Article 95 of the Treaty. It does so by introducing harmonised provisions with regard to mercury to restrict its use in measuring devices, and thereby preventing significant amounts of mercury entering the waste stream.

4. MAIN POLICY OPTIONS AVAILABLE TO REACH THE OBJECTIVE

Measuring equipment is the largest mercury-using product group in EU not covered by Community legislation on mercury. Although some measuring and monitoring equipment will be restricted under Directive 2002/95 this would not include some of the more significant mercury-using products such as thermometers, barometers sphygmomanometers since Directive 2002/95 only covers electrical and electronic equipment.

For the non-electrical measuring equipment product group, two main policy options were examined in the ExIA: the “no additional action” option and the “marketing and use restrictions” option. The latter would have direct and relatively predictable impact in the EU.

No additional action option

In this option, no Community action is taken for the time being. Measures are left to Member States and to the private sector. A number of Member States already have national legislation in place banning or restricting various mercury-containing products; the scope of those restrictions varies. In addition more recent studies show a progressive substitution of mercury in thermometers, barometers and blood pressure gauges especially for use in private households.

Marketing and use restriction option

This option would prohibit the marketing of measuring and control devices by means of an amendment to the Directive 76/769/EEC. The scope of a limitation under that directive must take into account the feasibility and proportionality of the risk management measure proposed. The information available to the Commission can be considered as sufficient to support a ban on all fever thermometers and other measuring devices for consumer uses. Specialist applications are excluded from the scope of this proposal. Adequate substitutes are

not always available, and most specialist professional uses are outside the scope of most national legislation.

5. IMPACTS EXPECTED FROM THE DIFFERENT OPTIONS IDENTIFIED

Traditionally mercury has been used in a wide variety of measuring devices and control equipment. The most common items are thermometers, blood pressure gauges (sphygmomanometers), barometers and manometers. From a risk management perspective it is appropriate to distinguish between measuring devices for consumer use and those for professional uses in science and industry. The professional uses are highly specialised. While the mercury content per item can be quite high, the numbers are quite limited and this equipment is typically used in systems with well established control procedures on safety at work place and management of dangerous waste. In contrast, it has proved extremely difficult to keep used measuring devices for consumer uses out of the waste stream. Some Member States (e.g. NL, FR) report that the mercury from products is the main source of mercury in surface water.

5.1. Environmental impacts

5.1.1. No additional action

The information available shows that 80-90% of all mercury used in measuring and control devices is used in medical (fever) thermometers and other thermometers for household use. Although the use of mercury is declining, the quantities remain significant; 33 tons of mercury is estimated to be used for measuring and control devices per year in the EU, and on an annual basis some 25-30 tons of mercury enters the cycle via thermometers alone². Annex II provides an overview of the most recently documented data on the consumption of mercury in measuring equipment.

The levels of emissions are lower as an increasing share of the equipment is collected and the mercury is recovered, but nevertheless emissions are still significant. RPA 2002⁴ has suggested that the emission to air will be about 8 tons per year from a consumption of 33 tons of mercury per year in new measuring and control equipment plus 27 tons entering the waste stream from old equipment (Annex III). However, it is difficult to quantify the disposal over time as most of this equipment has long service lifetime.

Many of the consumer products containing mercury will end up being landfilled with the potential for slow but long term leaching. Some mercury-containing instruments are subject to spills in dwellings in the case of breakages.

5.1.2. Marketing and use restriction

The main advantage of a restriction on the marketing of certain measuring devices would be a reduction of mercury in the municipal and healthcare waste streams. In medium terms the overall result would be to have more effective waste management and a reduction of emissions from landfill and incineration. A reduction in the use of mercury containing measuring devices in households will, in addition, avoid mercury spills in dwellings.

⁴ RPA (2002). Risk to health and the environment related to the use of mercury products. Report by Risk and Policy Analysts Ltd. For DG Enterprise of the European Commission

Although such spills rarely have a direct effect on human health, they are a source of exposure and emissions which should be minimised.

5.2. Economic impacts

5.2.1. No additional action

Results from a study by RPA from 2002 indicate that most measuring equipment for consumers (around two thirds) is now imported into the EU. Many thermometers and other measuring equipment are imported from China, India and Japan. Within the EU there are major manufactures in the UK and Germany. Europe is the principal manufacturing area for instruments for technical or scientific applications which are outside of the scope of the proposed restrictions, the other main source being the Far East. There is a modest economic benefit associated with the production of measuring and control devices in the EU, which would be unaffected in this option. However, this benefit is becoming less important as mercury is substituted more and more.

5.2.2. Marketing and use restriction

The economic impact of the proposed restriction is expected to be small. For measuring devices used by private households substitutes are available at similar prices. According to the information available, the number of remaining producers in the EU is limited to a small number of small and medium sized enterprises although determining the precise scale and extent of the mercury business has proved difficult. In one study the existence of about a dozen SME's in the former EU 15 has been mentioned, although unfortunately without indication of the source. This is also illustrated by the fact that no sectoral organisation exists on a European or Member State level.

The negative impact on the producers has to be balanced against the avoided costs of removing mercury in waste management and of dealing with the impacts of emissions. While it would be somewhat artificial to quantify the avoided collection and separation costs, even a rough estimation shows that the costs of avoiding mercury emissions are lower in this area than emission reduction costs in other sectors (like coal combustion) or in relation to some other measures already in place (e.g. restriction of mercury in batteries or in lighting). The measure can be therefore regarded as relatively cost efficient.

The available studies and contributions from industry show that for specialist industrial and scientific measuring devices the situation is far less clear cut. In quite a number of cases, adequate substitutes are not available, or have considerably higher costs. This has forced those governments that have implemented restrictions in this area to provide for numerous exemptions. On the other hand, collection and recovery of the mercury discarded from this area can be assumed to be much cheaper as the sources are limited in number and should have suitable waste management systems in place. The proportionality of restrictions in this comparably small area is therefore at least questionable.

5.3. Social impacts

5.3.1. No additional action

There is some employment associated with the production of measuring and control devices in the EU, although many such products are now made outside the EU.

5.3.2. Marketing and use restriction

The expected social impact from a restriction of consumer uses is largely limited to some job losses with the producers in the case that they cannot switch to the production of substitutes. Despite efforts at getting information from the most relevant industry associations (Eucomed) it proved extremely difficult to obtain precise number of jobs involved that could be affected by the restrictions. Nevertheless, a thorough examination of all comments received in the consultation process indicates that the negative effects on employment, if any, would be very limited.

5.4. External impacts (i.e. outside the EU)

5.4.1. No additional action

It has been reported that a large proportion of mercury thermometers is imported from Asia, in particular China (RPA 2002). This could continue to be the case under this option. However, taking no additional action in this product group, despite the possibility of significant substitution, could negatively affect the EU's credibility in any international or bilateral discussions concerning mercury. In particular, it could be taken as a sign in other countries that mercury is not a problem that needs to be taken seriously.

5.4.2. Marketing and use restriction

Under this option, the restriction on marketing certain products would apply regardless of whether those products were made in the EU or externally. As a result, some external producers would lose a market for their products, although at the same time any external producers manufacturing mercury-free substitutes would find their market expanded. This option would also support any broader action the EU took or advocated to promote global reduction of mercury use. In addition there is an international understanding in view of the global and transboundary nature of the mercury problem that the use of mercury should be avoided where appropriate.

5.5. Subsidiarity and proportionality

5.5.1. No additional action

There are no subsidiarity and proportionality issues to address in this option.

5.5.2. Marketing and use restriction

All Member States that expressed an opinion have supported Community restrictions on mercury at a discussion in the Working Group for implementation of Directive 76/769/EEC, as well as in responses to the Commission consultation document on mercury. Furthermore it is not appropriate to address this issue by way of targets ; such an approval would result in diverse measures at Member State level with resulting distortions in the internal market and less effective health and environment safeguards overall. Establishing a restriction on certain measuring devices containing mercury at Community level would have a higher effectiveness than leaving such measures to the Member States alone. The proposed Directive would establish uniform rules for the circulation of products within the internal market. The measure proposed also contributes to a high level of protection of health and the environment. In summary the proposed amendment to Directive 76/769/EEC is the only way to fully meet these goals.

As regards proportionality, the relatively large amounts of mercury which are still used for the production of measuring devices, and the high risks involved indicate the importance of Community action on this application. This action would be in line with legislation for this substance used in other applications such as electrical and electronic equipment. It would also contribute to implementing the Water Framework Directive which considers mercury as one of the priority hazardous substances. The proposed Directive would yield benefits in terms of protecting human health and the environment as part of the overall risk management measures on this substance. This will be achieved at comparatively little cost.

6. MONITORING THE RESULTS AND IMPACTS OF THE PROPOSAL AFTER IMPLEMENTATION

Following the implementation of the directive the aim in the short term is to reduce the amount of mercury which is likely to be released to the environment by restricting the placing on the market of new measuring equipment.

As the amount of mercury in existing household equipment is greater than the amount represented by sales of new equipment, the Commission intends to undertake a further separate study on this issue (reference Action 10 of the Strategy).

7. STAKEHOLDER CONSULTATION

All the interested parties have been consulted through a very wide consultation process in the course of preparing the Mercury Strategy. In the course of the consultation the Commission has organised meetings with Member States and stakeholders and has launched an open public consultation on the internet where the specific issue of whether the EU should take additional action to limit the marketing of measuring and control equipment was addressed. Overall, there was strong support for EU action; further details can be found in the relevant part of the ExIA.

In addition, as a part of consultation exercise on 2 May 2005, DG ENTR circulated a preliminary draft of the proposal to all interested parties (Member States, industry representatives, NGOs). This draft was presented during the meeting of the Working Party under the Directive 76/769 (Limitations Directive) on 20 May 2005. The meeting provided an opportunity for stakeholders to give initial reactions to the consultation document; in general there was strong support for the proposal. All Member States (AT, FR, UK, DE, FI, SE, DA, NL) who took the floor favoured the proposal. Some of them asked the Commission to widen the scope of restrictions and to include at least the blood pressure devices used in healthcare sector (with the exemption of strain-gauges). They also urged the Commission in the short term to continue to work towards a phase out of mercury containing products within the scope of the Limitations Directive, and not to rely on the authorisation procedure in REACH.⁵

⁵ Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}, COM (2003) 644 final, 20.10.2003

Member States were asked to provide feedback to the analysis presented. In particular, if Member States requested a widening of the scope of the restriction, they were asked to supply the technical, scientific and economic information necessary to justify the restriction and to demonstrate the proportionality. Subsequently 5 replies were received. SE supported by AT, DA and NL repeated their request for widening the scope to more stringent restrictions in order to cover all measuring devices within the healthcare sector, or at least to include sphygmomanometers, with some few exemptions. In their experience, most of those devices are either already being phased out or can easily be done so. These Member States urged the Commission to continue to work towards a phase-out of mercury containing products within the scope of the Limitations Directive and not to wait for REACH to limit unnecessary uses and emissions of mercury. They have also asked for more legal clarity regarding the interrelation with medical devices directive. On the other hand, the UK would be highly concerned if the restrictions on sphygmomanometers were to be extended into the healthcare sector. According to their consultation with the Medicines and Healthcare products Regulatory Agency (MHRA) and on the basis of the draft report produced for this purpose, there are no currently suitable alternatives in terms of accuracy for all the uses, especially for clinical diagnosis and monitoring. In addition, there is a need to develop acceptable performance criteria against which automated non-invasive blood pressure monitors should be evaluated.

The Commission referred the question of a potential restriction on sphygmomanometers used in the healthcare sector to the Member State experts on medical devices. This consultation concluded that hospitals need a high level of accuracy to treat life-threatening conditions such as hypertension, arrhythmia and pre-eclampsia. Mercury sphygmomanometers provide the appropriate level of accuracy and reliability to maintain patient's safety. The same level of reliability is not yet achievable by alternative blood pressure monitors.

Whereas mercury sphygmomanometers will be needed for the foreseeable future for testing and calibrating other blood pressure manometers, the position should be reviewed if and when evidence becomes available that non-mercury sphygmomanometers are suitable not only for the measurement of blood pressure trends, but also for the diagnosis and treatment of hypertension and for clinical trials.

A group of four NGOs (EEB, Ban Mercury Working Group, EEN, Health Care Without Harm), said the proposal should be expanded to include all consumer and professional uses.

Opposition to the proposal was expressed by the European Medical Devices Association (Eucomed) and by a few individual equipment manufacturers. In particular, Eucomed argued that the proposed measures might have a non-negligible impact not only on enterprises but on consumers also. They consider that the advantages of the fever thermometers containing mercury (ease of use, relatively cheap, no need of maintenance as is the case with some complicated electronic devices) outweigh possible risks for the patient, the user and the environment. Two manufacturers of mercury barometers located in NL strongly opposed to the proposal. They claim that mercury barometers, due to their design, cannot be easily become waste and consequently no benefits would be expected for the environment from this ban which only would lead to negative impact for the future of their business.

8. COMMISSION DRAFT PROPOSAL AND JUSTIFICATION

Based on the assessment of the impacts resulting from the different options and after a thorough consideration of the comments received, the Commission has decided to propose an amendment to Directive 76/769/EEC providing for harmonised rules on the restrictions of marketing of certain measuring devices containing mercury.

The restrictions on fever thermometers and other measuring devices intended for consumer use cover the major part of mercury use and emissions from this product group. The remaining specialised uses in science and industry either lack reliable alternatives or they are very expensive. Restrictions on this specialised product group would not be proportionate. In addition, systems are in place for the collection and recovery of the mercury discarded from this category. Such an approach is a technically and economically appropriate measure to exclude mercury from the municipal waste stream as the sources are quite limited in number. Furthermore, no additional data or information was made available to justify widening the scope of restrictions.

The proposed directive would therefore introduce harmonised provisions with regard to mercury in measuring and control equipment by imposing restrictions on the placing on the market of new fever thermometers and other measuring devices intended for consumer use. The proposal would yield benefits in terms of protecting human health and the environment as part of the overall risk management measures on this substance.

In the medium to longer term, any remaining use is likely to be subject to authorisation under the proposed REACH Regulation (see Action 8 of the Strategy).

ANNEX I

EU Mercury Consumption by Product Group (t/year)				
Product	mid-1990s¹	1996²	2000³	
			EU-15	3ACs
Dental amalgam	not given	69	70	20
Batteries	not given	5 - 8	8	1
Lighting	21	>12	5.2	0.7
Measuring and control equipment	56	<63	28	5
Electrical equipment	28	not given	8	1
Sub-totals	>105	c150	119.2	27.7
Other products	<2	73	c50	c5
All of the above	>107	c220	c170	c33

Sources:
(1) *WS Atkins (1998)*; (2) *Eurochlor (1999)* and (3) *based on information presented below where the 3ACs = Czech Republic, Poland and Slovenia.*

Source: RPA 2002

ANNEX II

Estimates of EU Mercury Consumption in Measuring & Control Equipment		
Product type	WS Atkins, 1998	KEMI, 1997
Medical thermometers	23 t/year	70 t/year*
Other thermometers	28 t/year	
Other measuring equipment	4 t/year	
Total	55 t/year	70 t/year*

**also includes thermostats and applies to all of Europe (i.e. not only EU Member States).*

Overall a 50% reduction in the consumption figures quoted by WS Atkins in 1998 seems a reasonable scenario. This would bring mercury consumption in measuring equipment in the EU to about 28t/year. For the three accession countries, a total of 5t/year (on the basis of Czech data) could also be suggested as reasonable.

Source: RPA 2002

ANNEX III

Mercury in Measuring and Control Equipment Emissions & End-Points (t/year)		
Parameter	Amount (t/year)	Comment
Consumption	33.00	See note in Annex II
End-points:		
Recycled	7.21	It has been assumed that 75% of mercury recovered from equipment is re-used
Water Course	0.12	
Agriculture	0.23	
Atmosphere	8.08	Atmospheric emissions dominated by emissions from landfill (58%) and incineration (39%)
Landfill/burial	44.43	
Accumulation ¹	-27.06	This represents the additional flow entering the waste stream from 'old' equipment. As such, this equates to a reduction in the overall "inventory" of mercury present in measuring and control equipment (within the EU and the three accession countries)
<i>Check Totals:</i>	<i>33.00</i>	
<i>Note:</i>		
<i>(1) Accumulation relates to the quantity of mercury in circulation within the product rather than to the total quantity of mercury present in the environment associated with the product.</i>		

Source: RPA 2002