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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 21.2.2006
COM(2006) 69 final

2006/0018 (COD)

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**

(presented by the Commission)

{SEC(2006) 194}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

- **Grounds for and objectives of the proposal**

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 for use 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 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 non-electrical measuring devices are the subject of the present proposal (compare Action 7 of the Strategy).

The objective of the Directive is to introduce harmonised provisions with regard to mercury by imposing restrictions on measuring devices and thus, by preventing considerable amounts of mercury entering the waste stream, to contribute to a high level of protection of the environment and human health, whilst preserving the internal market, as required by Article 95 of the Treaty.

- **General context**

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

¹ COM (2005) 20 final, 28.1.2005

² SEC (2005) 101, 28.1.2005

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, p. 19

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 goldmining, 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 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.

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.

The levels of emissions of mercury to the environment have decreased 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. 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 land filled with the potential for slow but long term leaching. Some mercury-containing instruments are subject to spills in dwellings in the case of breakages.

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.

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 (RPA 2002). Europe is the

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

principal manufacturing area for instruments for technical or scientific applications, the other main source being the Far East.

For the measuring devices used by private households, substitutes are available at similar prices and in fact the substitution process is already fairly well advanced. The available studies and information 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.

- **Existing provisions in the area of the proposal**

Various mercury containing products have been already banned or restricted in a number of countries such as Denmark, France, the Netherlands and Sweden. Although the scope of the restrictions varies, most of the specialist professional uses are excluded from the scope of this national legislation in almost all cases.

- **Consistency with other policies and objectives of the Union**

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.

2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT

- **Consultation of interested parties**

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 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/EEC (Limitations Directive)⁵ 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 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 the healthcare sector (with the exemption of strain-gauges). They also urged the Commission in the short term to continue to work towards a

⁵ OJ L 262, 27.9.1976, p. 201

phase out of mercury containing products within the scope of the Limitations Directive, and not to rely on the authorisation procedure in REACH⁶.

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. Four Member States requested widening the scope to include sphygmomanometers used in the healthcare sector whereas one had the opposite opinion.

The Commission referred the question of a potential restriction on sphygmomanometers used in 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 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 and by two manufacturers of barometers.

Further details on comments received are included in the accompanying Impact Assessment [SEC(2006) 194 of 21.2.2006].

- **Impact assessment**

Measuring equipment is the largest mercury-using product group in EU not covered by Community legislation on mercury. For this product group two main options were examined: the “no additional action” option and the “marketing and use restrictions” option. The latter 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

⁶ 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, 29.10.2003

available, and most specialist professional uses are outside the scope of most national legislation. The costs and benefits for this option are briefly presented below:

– Costs

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 enterprises. 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. The measure can be therefore regarded as cost efficient by comparison with some other measures already in place (e.g. restriction of mercury in batteries or in lighting).

The expected social impact from the proposed restriction is largely limited to potential job losses with the producers that cannot switch to the production of substitutes. The comments received in the consultation process indicate that the negative effects on employment would be very limited.

The impact will be neutral as far as trade is concerned. Some external suppliers would lose a market for their products although at the same time any external suppliers manufacturing mercury-free substitutes would find their market expanded.

– Benefits

The main benefit of a restriction on the marketing of certain measuring devices would be a reduction of mercury in the municipal waste stream. There would also be benefits to the healthcare waste stream. The overall result would be to have more effective waste management and a reduction of emissions from landfill and incineration.

The key long term benefit of reducing mercury emissions will be decreased levels of mercury in the environment. This, in turn, will lead to lower levels of human exposure to mercury including methylmercury in fish with resultant health benefits. The measure will also reduce the impacts of mercury in soils and on biodiversity.

A reduction in the use of mercury containing measuring devices in households will, in addition, avoid mercury spills in dwellings. Although such spills rarely have a direct effect on human health they are a source of exposure and of emissions which should be minimised.

In view of the global and transboundary nature of the environmental and health impacts of mercury, this proposal would also support EU initiatives at international level to promote a global of reduction of mercury use.

Further details on the options examined and the results of the economic, social and environmental impacts of the proposal are included in the accompanying Impact Assessment [SEC(2006) 194 of 21.2.2006].

3. LEGAL ELEMENTS OF THE PROPOSAL

- **Summary of the proposed action**

The objective of the present proposal 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.

- **Legal basis**

The proposal is an amendment to Directive 76/769/EEC relating to restrictions on the marketing and use of dangerous substances and preparations for which the legal basis is Article 95 of the Treaty.

In compliance with Article 95 of the Treaty, the proposal is submitted to the European Parliament and Council under the co-decision procedure. The European Economic and Social Committee is also consulted.

- **Subsidiarity principle**

All Member States that expressed an opinion have supported Community restrictions on mercury at a discussion in the Working Group for implementation of Directive 76/769EEC, 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.

- **Proportionality principle**

The relatively large amounts of mercury which are still used for the production of measuring devices, and the high risks associated with those uses justify Community action in this area. 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 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. 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.

- **Choice of instrument**

The proposed instrument is a directive amending Directive 76/769/EEC.

4. BUDGETARY IMPLICATIONS

There are no budgetary implications from the proposed Directive.

5. ADDITIONAL INFORMATION

The present directive restricts the placing on the market of new measuring devices. This restriction does not apply to devices that are already in use, or which are sold second hand. The short term aim is to reduce the amount of mercury released to the environment. 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 (reference Action 10 of the Strategy) to address this issue.

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).

Proposal for a

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission⁷

Having regard to the opinion of the European Economic and Social Committee⁸,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁹,

Whereas:

- (1) The Commission communication of 28 January 2005 on the Community strategy concerning mercury¹⁰, which considered all uses of mercury, concluded that it would be appropriate to introduce Community-level marketing restrictions on certain non-electrical or electronic measuring and control equipment containing mercury, which is the main mercury product group not covered by Community action so far.
- (2) There would be benefits for the environment, and in long term for human health, by preventing mercury from entering the waste stream, if limitations on the marketing of measuring devices containing mercury were introduced.
- (3) Taking into account technical and economic feasibility, available evidence concerning measuring and control devices indicates that restrictive measures should cover only those measuring devices intended for sale to the general public and in one area of the healthcare sector.
- (4) By the present Directive only the placing on the market of new measuring devices should be restricted. This restriction should therefore not apply to devices that are already in use, or sold second hand.

⁷ OJ C xxx

⁸ OJ C xxx

⁹ OJ C xxx

¹⁰ COM (2005) 20 final, 28.1.2005

- (5) The disparities between the laws or administrative measures adopted by Member States as regards restriction on mercury in various measuring and control devices could create barriers to trade, distort competition in the Community and may thereby have a direct impact on the establishment and functioning of the internal market. It therefore appears necessary to approximate the laws of Member States in the field of measuring and control devices by introducing harmonised provisions with regard to those products containing mercury thus preserving the internal market whilst ensuring a high level of protection of human health and the environment.
- (6) Council Directive 76/769/EEC¹¹ of 27 July 1976 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 should be amended accordingly.
- (7) This Directive should apply without prejudice to Community legislation laying down minimum requirements for the protection of workers contained in Council Directive 89/391/EEC¹² of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work and individual directives based thereon, in particular Council Directive 98/24/EC¹³ of 7 April 1998 on the protection of workers from the risks related to chemical agents at work.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 76/769/EEC is amended as set out in the Annex to this Directive.

Article 2

1. Member States shall adopt and publish, by xx xx 200x [*one year after the date of its entry into force*] at the latest, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

They shall apply those provisions from xx xx 200x [*eighteen months after the entry into force of this Directive*].

When Member States adopt those provisions, the provisions shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

¹¹ OJ L 262, 27.9.1976, p. 201 Directive as last amended by Commission Directive 2004/98/EC (OJ L 305, 1.10.2004, p. 63)

¹² OJ L 183, 29.6.1989, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1)

¹³ OJ L 131, 5.5.1998, p. 11-23.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

ANNEX

The following point 19a is inserted in Annex I of Directive 76/769/EEC:

“19a Mercury CAS N° 7439-97-6	May not be placed on the market: (1) in fever thermometers (2) in other measuring devices intended for sale to the general public (e.g. manometers, barometers, sphygmomanometers, thermometers other than fever thermometers). ”
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