COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMISSION STAFF WORKING PAPER

accompanying the

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the restriction of the use of certain hazardous substances in electrical and electronic equipment

(recast)

Summary of the Impact Assessment

{COM(2008) 809 final}
{SEC(2008) 2930}

SUMMARY

RATIONALE FOR THE REVIEW

Directive 2002/95/EC aims to restrict hazardous substances in electrical and electronic equipment so as to contribute to the protection of human health and the environmentally sound recovery and disposal of waste electrical and electronic equipment. Its review is being carried out for two main reasons:

1. The Commission is committed to developing a **better regulatory environment**, one that is simple, understandable, effective and enforceable. The regulatory environment in which businesses operate influences their competitiveness, and their ability to grow and create jobs. The aim for better regulation is an important element in the EU's Partnership for Growth and Jobs (Lisbon) strategy. There is room to improve the Directive in terms of implementation, enforcement and coherence.

2. The RoHS Directive calls on the Commission to review the measures provided for in the Directive in particular with regard to the inclusion of two additional categories of equipment in the scope (categories 8&9 : medical devices and monitoring and control instruments) and the adaptation of the list of restricted substances.

PROBLEM AND OBJECTIVES

Achievement of the RoHS Directive's objectives is hindered and made more costly by problems related to uncertainties in implementation such as lack of harmonisation in interpretation of definitions and diverging requirements for demonstration of product compliance; problems with enforcement such as suboptimal market surveillance activities; and problems related to perceived inconsistency with other Community legislation or technical/scientific progress, such as potential overlaps with REACH or EuP and need for extending the scope to cover medical devices and control and monitoring instruments.

The objectives of the review are: improved implementation and enforcement of the Directive, enhanced consistency with related Community product legislation, improvements in cost effectiveness of the Directive and increased environmental benefit.

THE REVIEW PROCESS

Two stakeholder consultations and several studies were carried out. These dealt with the topics of the review as well as the policy options within each topic. These consultations and studies helped define and analyse a number of specific options as outlined below.

OPTIONS

The options are grouped in three main classes:

1. Clarify and simplify the Directive

2. Improve enforcement at national level

3. Adapt the Directive to technical and scientific progress

Within each of these main groupings a number of options were considered and an analysis of costs and benefits was carried out for each option.

SELECTED OPTIONS

In summary, the following options are recommended:

Changes in the legal text to clarify scope and definitions, in particular by creating a list of products defining the scope of the RoHS Directive which is binding and not dependent on the scope of the WEEE Directive

Introduction of all relevant provisions already used in the EU "Marketing of products" package of legislation concerning:

- national market surveillance activities;
- mechanisms for assessing the conformity of the product prior to its placing on the market based on the self declaration by the producer;
- presumption of conformity of the product on the basis of harmonised standards and CE marking.

Adaptation of the procedure for exemptions, for instance by introducing through comitology a requirement for applicants to analyse the substitutes before submitting a request, and the introduction of additional criteria for granting an exemption;

Inclusion in a staged manner in the scope of RoHS of medical devices and control and monitoring instruments; no changes in the list of restricted substances.

BENFITS and COSTS

An overview of the costs and benefits of these options is as follows:

There is little experience of actual **compliance costs for industry;** for products currently included in RoHS estimates are it would vary from 1-4% of turnover. More recent surveys give an average overall cost related to RoHS of 1,9% of turnover (past cost and one-off future costs).

In the case of medical devices and control and monitoring instruments some of which are produced in low numbers or have critical applications and hence increased testing and reliability requirements, approximate yearly compliance cost is estimated to 400-1600 million €; it is even claimed that cost of RoHS compliance for some complex products could be as high as 7-10% of turnover (new product) or 1-10% (modification of existing product). A large part of this cost is attributable to the long development, testing and approval cycles of the more complex products. This is why a **staged introduction** for these products is proposed allowing the compliance conversion to take place in the framework of existing resources and product development cycles.

The RoHS Directive does not foresee explicit reporting obligations for Member States or information supply requirements by manufacturers and in most cases Member States have not introduced such legal obligations at national level. The process for granting exemptions is considered lengthy for products with short innovation cycles; harmonising the requirements

for the contents of the application and clarifying the period of validity of exemptions will **speed up the process**, increase legal security and reduce administrative burden for both authorities and the applicants.

The introduction of harmonised requirements for scope, definitions, assessment of product conformity and market surveillance which are in line with other product-related EU legal requirements will **increase legal certainty** and thus **reduce the administrative burden.**

Initial implementation of these revised provisions could create **additional administrative burden** for Member States and producers dependent on the Member State's current level of preparation for proper enforcement and on the adequacy of measures taken by producers for ensuring product compliance.

The Commission services estimate that overall net benefits, albeit modest, will ensue. Moreover, the recommended options will have an important cumulative effect in clarifying the Directive and harmonising its implementation and enforcement with a positive contribution to better regulation.

Environmental benefits are likely to be significant: several tonnes of the heavy metals banned under RoHS (>1400 tonnes of lead, approximately 2,2 tonnes of cadmium) are used in medical devices and control and monitoring instruments, which account for 0,2-03% of waste from electrical and electronic equipment by weight; these substances by improper waste management may be released to the environment (only 49,7% of waste medical devices and 65,2% of waste control and monitoring instruments are separately collected); restricting the use of these substances through RoHS will in the medium to long term eliminate their presence in the products and in the waste thereof; further analysis shows that even in scenarios assuming much higher recycling rates there is some environmental benefit from including these categories of equipment in the scope of RoHS.

Taking into account that current Member States checks revealed that up to 44% of EEE checked were not fully compliant, effective market surveillance mechanisms at national level and enhanced cooperation among Member State authorities for removal of non-compliant products are expected to increase considerably the environmental benefit of RoHS by minimising the number of non-compliant products on the market.

Concerning the adaptation of list of hazardous substances regulated by RoHS, the preparatory studies identified candidate substances, but given the lack of sufficient information on substitutes, which does not allow a clear view on whether they are environmentally safer or, in cases where environmentally safer alternatives do exist, whether replacement costs are proportionate to environmental benefits, **it is not considered feasible to propose new hazardous substances in the scope of RoHS.**