AMCHAM EU
AMERICAN CHAMBER OF COMMERCE TO THE EUROPEAN UNION
SPEAKING FOR AMERICAN BUSINESS IN EUROPE

POSITION STATEMENT

Meglena Mihova
Chair of the Environment Committee
American Chamber of Commerce to the EU
Ave des arts 53
B-1000 Brussels

28 June 2012

Dear Ms. Münchmeyer,

I am writing on behalf of AmCham EU in response to your report on the European Commission's Impact Assessment of Directive 2011/65/EU (RoHS2) and on Article 2.2 in particular. AmCham EU members agree that Article 2.2 of RoHS 2, if unchanged, will have significant negative economic, environmental and legal impacts. We endorse all of the points you raised in your factsheet, including specifically **the proposed solution outlined in Option 3,** to amend Article 2.2. This option in alignment with that of a number of other trade associations, which are also concerned about this issue.

We include below our key arguments for supporting option 3.

Amending Article 2.2

We support the proposal to change Article 2.2 to replace the term "making available" with the term "the placing on the market of the product". This horizontal solution would to ensure legal consistency, proportionality and avoid the negative economic and environmental impacts built into the current text of Article 2.2. Furthermore, we understand that using the term "placing on the market" was the original intent of stakeholders during the negotiation of the final text of Directive 2011/65/EU.

This issue should be addressed as soon as possible in both your final report on RoHS' impact assessment, and in the Commission's upcoming FAQs. Industry needs legal certainty on this point as soon as possible to comply with RoHS 2's timelines, to continue providing the service its customers expect, and the environmental benefits which come from the refurbishment of EEE.

Specific impact of Article 2.2 on Category 8 & 9 Equipment

The typical life of some medical instruments (e.g. an In-vitro diagnostic device) within a given laboratory is 5 to 7 years, at which time the laboratory will upgrade its system for a newer or different model. The instrument is designed and maintained to operate much longer. Therefore when it is removed from the laboratory, it is typically refurbished and placed into another lab.

Re-use of devices through refurbishment is environmentally sound. If the refurbishment of all RoHS2 non-compliant devices becomes impossible after 2019, it will lead to tonnes of equipment becoming waste – a consequence which would clearly contradict the principles of the Waste of Electric and Electronic Equipment Directive 2002/96/EC.

Clinicians continuously rely on fast, accurate results when they are monitoring or treating their patients. Many of the results are needed in just a few minutes in order to have a positive impact; which means, having diagnostic systems on site is critical. In some cases, the use of refurbished instruments is the preferred option. It is a viable alternative for hospitals and clinical laboratories to keep costs under control and provide reliable results and care, and limit the costs of the healthcare system.

AmCham EU kindly asks that you consider strongly the economic, legal and environmental impact of Article 2.2 on categories 8 & 9 equipment, as well as on our consumers (laboratories, hospitals, and ultimately patients) into account in your final report. In this context, we ask that your report and the RoHS FAQ send a strong signal at the earliest opportunity. Such an amendment would address the environmental objectives of the RoHS Directive, provide regulatory certainty for industry, while also supporting the ability of hospitals and laboratories to use and purchase refurbished equipment.

Yours sincerely,

Meglena Mihova
Chair of the Environment Committee
American Chamber of Commerce to the EU

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