Joint EDMA and Eucomed response to Section 6 of Öko Institute consultation on EEE newly in scope of RoHS

Scenarios proposed	Consequences	a. Possible costs for your organisation or other stakeholders tied with compliance of a specific product category, in relation to the above mentioned scenarios, one-time costs such as investments as well as annual costs, such as costs for purchasing resources.	b. Possible benefits that may incur to your organisation or other stakeholders in relation to the above mentioned scenarios – please clarify when or over what period benefits are expected.	c. Possible impacts to health and to the environment associated with the scenarios mentioned above	d. Possible impacts on employment that may be associated with the scenarios mentioned above (impacts on required skills; impacts on number of employees; etc.)	e. Possible impacts on competition that the various scenarios may have in regard to your organisations general activities or those tied with a specific product category. Please elaborate in this regard concerning impacts on import and export of products/ applications.	f. Possible impacts on the supply of certain products or components that are relevant to the various scenarios detailed above.
A. Article 2.2 wording unchanged	No secondary market operations would be permissable for products in all Categories 8, 9 and 11 after July 22 2019 such as leasing or refurbishment; Non compliant EEE would be allowed to remain with the current customer but would not be allowed any ownership change.	• Possible social, environmental and economic costs are laid out in the "Study to support the Impact Assessment of the RoHS Review Final Report" by Bio Intelligence (2008; "BioIS Report") and further analysed under the "Final Impact Assessment for RoHS Directive, by BIS (2012). EDMA and Eucomed consider that there is no need to repeat a cost analysis and that the figures provided by COCIR to the BioIS Report are comparable for other long-lifetime products in the medical device (MD) and in vitro diagnostic (IVD) medical device sectors. Should the Öko Institute need more detail however you are welcome to return to EDMA and Eucomed.	According to the BioIS Report, there are no potential benefits to leaving Art. 2.2 unchanged however there are significant potential economic, environmental and social costs to maintaining it. EDMA and Eucomed agree with this conclusion and further note that Art. 2.2 does not prevent non-compliant devices from being placed on the market but would bring them into the waste cycle before the end of their useful lifetime with consequent negative environmental, social and economic effects.	• Art. 2.2 would impact MD and IVD placed on the market 5 and 3 years respectively or more before the hard stop represented by Art. 2.2. Keeping this legal text unchanged would cut short the useful lifetime of devices and render them waste. The lifetime of a device will depend on operating conditions, frequency of use, maintenance etc. As examples: - The typical life of a new IVD instrument within a given laboratory is 5 to 7 years, at which time the laboratory will often upgrade its system for a newer or different model. Given that the instrumentation is usually designed to operate much longer, when it is removed	Loss of employment linked to non-RoHS compliant products for sales, field service, technical staff and customer service etc. is to be expected unless hospitals and clinical laboratories considerably invest in new systems to replace old systems made redundant as a result of Art. 2.2. However the BioIS study anticipates that hospital budgets are not likely to increase to the point where they will replace all old stock for new.	The competitiveness of the market would be affected as hospitals, health care professionals and clinical laboratories would no longer have the option to buy refurbished products as part of their investment in medical technology, nor would they have the option to renew leasing agreements with manufacturers. The European market in refurbished medical equipment and IVDs would be expected to shrink considerably.	Hospitals, health care professionals and clinical laboratories would no longer be able to maintain current stock via leasing contracts or buy non-RoHS compliant refurbished products from 22 July 2019 even if these are only 3-5 years old. The BioIS report points out that this scenario could lead to the average age of medical equipment and diagnostic instrumentation becoming older as the availability of refurbished replacement equipment is delayed (i.e. hospitals with budgetary constraints which would have bought an available non RoHS compliant refurbished unit would need to wait to replace their older equipment until a RoHS compliant refurbished unit
B. Article 2.2 wording amended to exclude impact to category 8 & 9	Addresses potential impact to categories 8 and 9, i.e. secondary market operations (leasing contracts and sale of refurbished EEE) would be allowed, however Category 11 (medical veterinary and forensic products; certain 'medical devices' intended for training or research use) would not have this capability; Category 11 EEE could not be repaired with noncompliant spare parts after July 22 2019 unless Art. 4.4 would be amended.	No costs are expected for Category 8 products. Costs are to be expected for Category 11 products with a longer life time which might include medical instrumentation and analysers for veterinary use, forensic devices, and certain 'medical devices' which are placed on the market for training or research use.	This scenario allows hospitals, health care professionals and clinical laboratories to renew servicing and leasing contracts for older technology and purchase newer technology through the secondary sale of older technology. The market in refurbished equipment provides hospitals and clinical laboratories with a viable alternative for keeping costs under control while at the same time maintaining critical technologies on site which ensure reliable results for the safe management of patients in the healthcare system. This scenario therefore supports the market	• This scenario avoids the early retirement of non-RoHS compliant instrumentation into the waste cycle. It therefore also avoids early and unnecessary waste for categories 8 and 9, in support of the principles laid down under the Waste of Electronic and Electrical Equipment Directive 2012/19/EU. It would not however avoid unnecessary waste for longer life products under Category 11 which may include medical veterinary and forensic products as well as certain 'medical devices' intended for training or research use.	No negative impact on employment is expected in the medical sector including in the European market for refurbished MD and IVD equipment.	Current market operations are expected to continue for Category 8 products, i.e. leasing contracts for hospital and clinical laboratory medical equipment/instrumentation, refurbish and resell of old equipment and sales of new devices. The European market in refurbished veterinary medical devices would be expected to shrink.	Hospitals, health care professionals and clinical laboratories would be able to maintain current stock via leasing contracts as well as sell and purchase non RoHS compliant refurbished products from 22 July 2019. Supply would not be adversely impacted for categories 8 and 9 EEE.
C. Delete Article 2(2) and amend article 4(3) with category 11 date.	Allows secondary market operations (leasing or refurbishment) for non RoHS compliant products placed on the market prior to compliance date for categories 8, 9 and 11, since Art. 2.2 would be deleted. However secondary market operations for Category 11 products would be limited from 22 July 2019, unless Art. 4.4 would be amended to include a spare parts provision.	No costs are expected for categories 8, 9 and 11 products. Category 11 would need a spare parts provision as foreseen by scenario E.	According to the BioIS study, the ability to conduct secondary market operations for non RoHS compliant products already placed on the market prior to compliance date for categories 8, 9 and 11 would have significant potential economic, environmental and social benefits. EDMA and Eucomed agree.	Negative impacts to health and the environment are not expected: • This scenario allows hospitals, health care professionals and clinical laboratories to purchase newer technology through the secondary sale of older technology and to purchase refurbished technology and also allows renewal of leasing contracts. Hospitals and clinical laboratories choosing to rely on existing technology – which may only be 3-5 years old – can ensure that their instrumentation is properly maintained throughout its useful lifetime. The useful lifetime of instrumentation varies	No negative impact on employment is expected in the medical sector including in the European market for refurbished medical equipment.	Current market operations are expected to continue for Category 8 products, i.e. maintenance and leasing contracts for hospital and clinical laboratory equipment/instrumentation, refurbish and resell of old equipment and sales of new equipment/instrumentation.	Hospitals, health care professionals and clinical laboratories would be able to maintain current stock via leasing contracts or buy non-RoHS compliant refurbished products from 22 July 2019.

D. Delete Art. 2.2 and amend Art. 4.3 with an earlier compliance date (note the date is not specified but is to be agreed upon with the EU COM); revised date would not impact Category 8 or 9 products.	Same as Scenario C. but brings products in Category 11 earlier in scope than 22 July 2019.	No costs are expected for categories 8 and 9 products. However we note that this scenario would retroactively shorten the only given compliance deadline applicable to Category 11 products. This could lead to market confusion for products falling under this category and therefore loss of revenue for their manufacturers, particularly given that the current legal deadline of 22 July 2019 is just over 5 years from now.	This scenario allows hospitals, health care professionals and clinical laboratories to purchase newer technology through the secondary sale of older technology, purchase refurbished technology and allow the renewal of leasing contracts. This means that hospitals and clinical laboratories choosing to rely on existing technology – which may only be 3-5 years old – can ensure that their instrumentation is properly maintained throughout its useful lifetime. The useful lifetime of instrumentation may vary (depending on function, conditions and frequency of use, maintenance etc.) but could perform up to 20 years or longer. This scenario supports the market in continuing to advance in technology and 'current standard of care' for patients.	Negative impacts to health and the environment are not expected: • This scenario allows hospitals, health care professionals and clinical laboratories to purchase newer technology through the secondary sale of older technology and to purchase refurbished technology and also allows renewal of leasing contracts. Hospitals and clinical laboratories choosing to rely on existing technology – which may only be 3-5 years old – can ensure that their instrumentation is properly maintained throughout its useful lifetime. The useful lifetime of instrumentation varies depending on function, conditions and frequency of use, maintenance etc. but could perform for up to 20 years or even longer. This scenario supports the market in continuing to advance in technology and 'current standard of care' for patients. • Non-compliant devices will not enter the waste cycle from 22 July 2019 before the end of their useful lifetime but may be gradually phased out of the market at their end of life for newer technologies.	No negative impact on employment is expected in the medical sector including in the European market for refurbished medical equipment.	Current market operations are expected to continue for Category 8 products, i.e. leasing contracts for hospital and clinical laboratory equipment/instrumentation, refurbish and resell of old equipment and sales of new equipment/instrumentation.	Hospitals, health care professionals and clinical laboratories would be able to maintain current stock via leasing contracts or buy non-RoHS compliant refurbished products from 22 July 2019.
E. Addition of spare part provision for Category 11 in Art. 4.4	This would permit the repair of Category 11 products after July 2019 with non-compliant spare parts (as already granted for categories 8 and 9), if this non-compliant EEE was rightfully placed on the market before the date it came into RoHS scope. However, Art. 2.2 would need to be changed as envisioned under scenarios C or D to allow secondary market operations for Category 11 products for this scenario to have an impact.	No impact on categories 8 and 9 products is expected. Inclusion of a spare part provision for Category 11 products would enable those products which may fall under this category to be refurbished, thereby extending their useful lifetime. This may include medical veterinary devices, forensic products and certain 'medical devices' intended for training or research purposes. Without this provision, secondary market operations for Category 11 products, including those with a longer lifetime, would be limited to functioning products only. Consequent costs are described in the BioIS study.	The BioIS study does not foresee any potential benefits from the earlier disappearance of products containing RoHS substances from the market.	The BioIS study does not foresee any potential benefits from the earlier disappearance of products containing RoHS substances from the market and therefore recommends the inclusion of a spare parts provision for Category 11 products.	No negative impact on employment related to the market in refurbished Category 11 products would be expected as a result of this scenario.	No adverse impact on competition expected.	Maintenance of current equipment with spare parts and supply of refurbished goods would continue.

Article 2(2)

2. Without prejudice to Article 4(3) and 4(4), Member States shall provide that EEE that was outside the scope of Directive 2002/95/EC, but which would not comply with this Directive, may nevertheless continue to be made available on the market until 22 July 2019.

Article 4 (1-3)

Article 4

Article 4

Prevention

1. Member States shall ensure that EEE placed on the market, including cables and spare parts for its repair, its reuse, updating of its functionalities or upgrading of its capacity, does not contain the substances listed in Annex II.

2. For the purposes of this Directive, no more than the maximum concentration value by weight in homogeneous materials as specified in Annex II shall be tolerated. The Commission shall adopt, by means of delegated acts in accordance with Article 20 and subject to the conditions laid down in Articles 21 and 22, detailed rules for complying with these maximum concentration values taking into account, inter alia, surface coatings.

3. Paragraph 1 shall apply to medical devices and monitoring and control instruments which are placed on the market from 22 July 2014, to in vitro diagnostic medical devices which are placed on the market from 22 July 2016 and to industrial monitoring and control instruments which are placed on the market from 22 July 2017.

4. Paragraph 1 shall not apply to cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the following:

(a) EEE placed on the market before 1 July 2006;

(b) medical devices placed on the market before 22 July 2014;

(c) in vitro diagnostic medical devices placed on the market before 22 July 2016;

(d) monitoring and control instruments placed on the market before 22 July 2014;

(e) industrial monitoring and control instruments placed on the market before 22 July 2017;

(f) EEE which benefited from an exemption and which was placed on the market before that exemption expired as far as that specific exemption is concerned.

Annex I

Categories of EEE covered by this Directive

1. Large household appliances.

2. Small household appliances.

3. IT and telecommunications equipment.
4. Consumer equipment.
5. Lighting equipment.
6. Electrical and electronic tools.
7. Toys, leisure and sports equipment.
8. Medical devices.
9. Monitoring and control instruments including industrial monitoring and control instruments.
10. Automatic dispensers.
11. Other EEE not covered by any of the categories above.