To the kind attention of: **Mr. Carl-Otto Gensch**
Öko-Institut e.V.
P.O. Box 17 71
D - 79017 Freiburg
Germany

COCIR Contribution to the "Stakeholder consultation to provide additional input to the commission impact assessment for a review of the scope of provisions of the RoHS 2 Directive pursuant Article 24(1)"

Dear Mr. Gensch,

COCIR is pleased to contribute to the ongoing consultation on RoHS 2 scope provisions, in particular regarding article 2.2 and the proposed options to amend it.

At the outset, we would like to emphasize COCIR's position, that medical devices are not affected by Art. 2.2 of RoHS 2 for the following reasons:

- Art. 2.2 only applies to EEE outside the scope of Directive 2002/95/EC, which would not comply with RoHS 2. Medical devices containing substances listed in Annex II of RoHS 2, but placed on the market before 22 July 2014, comply with all provisions of RoHS 2 and are therefore out of scope of Art. 2.2.
- According to Art. 4.3, medical devices containing substances listed in Annex II of RoHS 2 cannot be placed on the market from 22 July 2014. It would be contradictory if they could be made available on the market until 22 July 2019, because placing on the market means making available for the first time (see definitions of "placing on the market" and "making available" in Art. 3).
- It is the logical consequence of Art. 4.3 that medical devices containing substances listed in Annex II and placed on the market before 22 July 2014 can be continued to be made available thereafter (also after 22 July 2019).
- The legislative history shows that it was never intended to restrict the making available of medical devices placed on the market before 22 July 2014 (see Commission Proposal COM(2008) 809 final and Commission statement commenting on the EP position adopted on 24 November 2011).

Accordingly, Art. 2.2 has no scope of applicability for medical devices. COCIR understands that the European Commission has, in the past, interpreted Art. 2.2 differently (see BIO IS Report "Measures to be implemented and additional impact assessment with regard to scope changes, pursuant to the new RoHS Directive", page 346). COCIR does not share this interpretation and invites the Commission to reconsider its interpretation of Art. 2.2.

It is important to emphasize that the current review process should not only clarify that medical devices containing substances mentioned in Annex II of RoHS 2 and placed on the market before 22 July 2014 can be made available thereafter (also after 22 July 2019), but it should also result in an extension of the date by which such medical devices can be placed on the market.

In light of the above, COCIR would like to provide the following comments:

Already in 2012, COCIR provided to BIO IS evidence of the huge impact article 2.2 is going to have on manufacturers and users of category 8 equipment. The contributions have been used to compile the above-mentioned BIO IS Report, which you already referenced in the guidance to this consultation.

BIO IS also took into account the contribution sent by COCIR on July 2012, regarding an additional unwanted impact of RoHS 2 on refurbishment activities (Annex to the BIO IS Study, page 15 and 16). Medical Devices manufactured in Europe but sold outside (placed on the market in non-EU countries) cannot be imported back, refurbished and made available on the EU market as they would be considered "new product" and not "re-used" ones.
As RoHS 2 scope is under review, COCIR believes this issue, which is hampering refurbishment activities as much as article 2.2 (in its present interpretation) has to be addressed as well.

COCIR carefully analysed the proposed options and would like to submit the following comments:

1. **RoHS 2 legal text to remain unchanged;**
   In COCIR's view, Art. 2.2 in its current version does not restrict the making available of medical devices placed on the market before 22 July 2014.

   COCIR would like to highlight the adverse impacts and consequences should the RoHS 2 legal text remain unchanged and the interpretation prevail that medical devices containing substances mentioned in Annex II cannot be continued to be made available on the Union market from 22 July 2019. Such adverse impacts and consequences have been extensively discussed and analysed in the BIO IS report of 2012. Both manufacturers and healthcare providers (hospitals and clinics) of all Europe would face a huge impact which will end in reduced access to imaging diagnostic services and healthcare. Moreover the Medical Industry is focusing on promoting and developing the refurbishment business as a key towards a sustainable healthcare. An unchanged Article 2.2 interpreted to exclude the making available of medical devices from 22 July 2019 would halt those activities making refurbishment impossible for years and therefore hampering a promising business which brings important social, economic and environmental benefits.
   In the light of past interpretation of Art. 2.2 as including medical devices, a clarification that medical devices can be continued to be made available on the market seems required. COCIR supports an amendment of Art. 2.2 and Art. 4.3 which allows the placing on the market (and does not restrict the continued making available of medical devices) for an extended period (i.e. options 3 and 4, see below).

2. **Amendment of Article 2(2) to exclude Category 8 and 9;**
   This option is suited to avoid unwanted impacts on the Medical Industry and healthcare providers for category 8 products. Nonetheless there are other products for medical use which are not strictly medical devices which can fall under category 11 which would be affected negatively by article 2.2 (i.e. equipment for training). Therefore COCIR believes that options 3 and 4 are preferable.

3. **Incorporation of Article 2(2) into Article 4(3) with the 22.7.2019 as compliance date, thus allowing secondary market operations for non-conform products newly placed on the market before July 2019;**
   This option is suited to avoid unwanted impacts on the Medical Industry and healthcare providers, therefore COCIR supports it. Moreover this option is better aligned with the New Legislative Framework and re-instates the principle that EU legislation applies to the moment products are made available for the first time (or put into service if indicated in the relevant legislation). It corrects an unnecessary deviation from EU principles.

4. **Incorporation of Article 2(2) into Article 4(3) with an earlier compliance date (to be agreed upon with the EU COM) thus allowing secondary market operations for non-conform products newly placed on the market before the respective date**
   This option is suited to avoid unwanted impacts on the Medical Industry and healthcare providers, therefore COCIR supports it.

5. **The addition of a spare part provision for non-conform products newly coming into scope and placed on the market before 2019**
   The possibility to reuse spare parts to repair non-compliant products is already contained in the RoHS Directive, therefore COCIR has no opinion on this option.

COCIR consider the revision of RoHS scope and the amendment of article 2.2 as vital for ensuring the medical industry and their clients (healthcare providers) will not be affected by serious impacts which negative consequences are going to hit the environment and the health of EU citiziens, not to mention the Medical Industry.

Please do not hesitate to contact Riccardo Corridori at corridori@cocir.org for any additional clarification or data you may need.

Best regards

Nicole Denjoy
COCIR Secretary General