COCIR CONTRIBUTION TO THE CONSULTATION ON THE DETAILED ASSESSMENT OF 3 SUBSTANCES

COCIR thanks the European Commission and Oeko for the opportunity to comment and contribute to the "Study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15)", in particular regarding the detailed assessment of:

- Tetrabromobisphenol-A
- Medium Chain Chlorinated Paraffins
- Diantimony trioxide

COCIR would like to focus in particular on the socio-economic impact analysis sections of the dossiers as such assessment provides a key information for the decision process.

Considering the Guidance released by the EC on the detailed assessment of substances and the comments previously sent by COCIR, we have to note that the socio-economic impact assessment is not as detailed as expected and therefore we conclude it does not provide useful elements for further decisions.

1. The impact of a restriction is different for different categories

RoHS applies to 11 categories of EEE, from mobile phones and washing machines (few Kgs and few years of life) to 8 tons medical imaging equipment with an expected service life of 15 years.

Medical Imaging devices are different from other categories of EEE	**Medical Devices Years** 	**Categories 1-7 Years** 
Innovation cycle	7	1
Service Life	15-20	2-5
Market availability	10+	2-3

A socio-economic impact assessment cannot consider such different products in one single group. There are several elements that make the impact on very complex and long-lived products higher than for simple ones:

2. Legacy Devices and redesign

New RoHS restrictions impact current designs not only new ones as for other categories. Medical device models are designed and priced according to an expected market availability time. The time a model is expected to be on the market and the market penetration over time are very important and critical elements of market strategy. The sales of the model also provide the cash flow to design and innovate new generations.

A) When a hazardous substance is restricted, existing designs on sale become "obsolete" and unless they can be redesigned in a technical and economical feasibly

manner, they have to be discontinued. This is especially relevant for products for which the end of production is scheduled around one or two years after the restrictions come into force. This does have a negative effect on human health because due to a shorter period of selling, the profit goes down which is resulting in less budget for R&D and innovation for new better medical devices.

B) Due to products getting obsolete ahead of time, hospitals need to purchase products with higher costs and/or lower patient benefits (as the successor model covering the gap can usually not be made available in time).

COCIR therefore believes that the claims made by TMC should have not been dismissed, as the problem of redesign and recertification of existing models (legacy) has not been considered properly:

1. *"Forced redesign and requalification testing of entire portfolio";*
   All current devices can become "non-compliant" with new restrictions and would need to be redesigned and recertified as, in the medical devices sector, substitution, most often than not, requires redesign, testing and requalification. For legacy products such costs are normally too high compared to the turnover generated by the products, and therefore the consequence is the phase out (connection to point 3).
2. *"Lost opportunity for introduction of new, cutting edge products";*
   The cost of redesign draws resources from R&D therefore delaying the release of new technology. In the Medical devices sector this can cause critical life saving technologies to be delayed. Moreover, current R&D projects, that may have been launched years ago, may have to be halted due to the need to recheck the presence of the newly restricted substances.
3. *"Withdrawal of products from EU market";*
   When redesign is not economically feasible or impossible. Only after assessing the use of the newly restricted substances with the supply chain (18 months minimum) it is possible to understand which products are impacted.

The issues touched upon by Oeko of "sufficient time" for redesign and testing is crucial. The problem of legacy equipment, obsolescence, impact on innovation and market withdrawal can only be solved by providing a transition time that is comparable with the service life and market availability of the involved devices.

3. The socio-economic impact is a function of the transition time:

The socio-economic impact is a function of the transition time. A restriction may have no impact at all if the transition time is long enough but can have a devastating impact on companies if the transition time is too short.

The socio-economic impact assessment should explore different options (3, 5, 7 years for instance) and provide estimations and recommendations for the different scenarios and for different categories.

COCIR is providing a study, together with this contribution, that applies a methodology to determine the time required for substituting the 7 chemicals under evaluation in different applications. The study clarifies that transition periods shorter than 5 to 7 years would have a very high impact on companies.

During the study COCIR assumed the restriction of all 7 substances proposed for assessment, therefore the conclusions reported below must be read under this perspective:

Conclusions of the study:

As shown by the timelines, it is expected that a full substitution in the medical devices sector would take from 10 to 15 years to be accomplished for all medical devices, both legacy (models being sold between now and the time compliance can be reached) and new devices that hopefully can achieve compliance before the end of the transition period.

A transition period of at least 10 years would be required for medical devices to substitute diantimony trioxide. While substitution can be achieved in a shorter period for one application as shown by the timelines, the huge number of possible applications would require more time.

Substitution of beryllium would require an even longer transition time as with the current state of the technology, no alternatives are known to exist for all uses.

Shorter timescales than the ones proposed, would create a critical situation:

- *Due to the impossibility to test and approve so many different applications and alternatives, including redesign, it would not be possible to be compliant by the deadline and it would also not be possible to submit exemption requests if alternatives are available.*
- *The knowledge on alternatives and their suitability and reliability would not be sufficient by the deadline to submit exemptions. Dossier would not be corroborated by sufficient evidence.*

It is also important to note that R&D programs in the medical device sector are normally longer than 5 or 7 years, therefore any shorter period than 7 years would also impact innovation as the investment risk would be too high (manufacturers will not invest if there is a risk that they cannot sell the products).

An example of timelines from the COCIR study is reported below. It shows that substitution of MCCP from special purpose cables could require from 4 to 7 years (best and worst case scenario) and that enough information on alternatives' performance to submit an exemption request would not be available for at least for 3 years after the entry into force of the ban. The alternative must be tested first at component level and then at system level. A classic example is the plastic used in the imaging area of MRI, for instance in MRI coils, that must be tested for mechanical and physical properties, prototyped first and then tested for signal interference and image quality degradation.

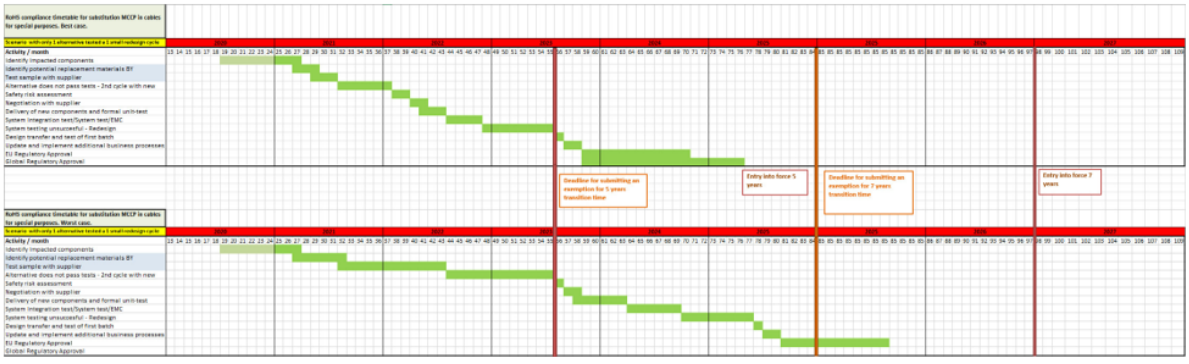
Additional RoHS substances

Review of impact of potential new RoHS substance restrictions on the medical sector

MCCP in special purpose cables: best- and worst-case scenarios

As for previous cases, even the best-case scenario shows that a 5 years transition time could be extremely dangerous for medical imaging devices, in particular as it would be virtually impossible to submit exemption requests for applications that are found to be technically impossible to substitute.

The worst-case scenario, which is still based on the assumption that an alternative can be found at second iteration, including a short redesign cycle, shows that 5 years may not even be enough to achieve compliance. The issue of legacy devices (medical devices that were designed and were being sold before a restriction took effect) would impact companies and healthcare providers directly.



4. Impact on innovation

The "Draft Manual Methodology for Identification and Assessment of Substances for Inclusion in the List of Restricted Substances (Annex II)" indicates that the impact on innovation has to be considered in the socio-economic impact assessment.

We have to note that the impact on innovation has not been considered in the dossiers and no information is reported as if new restrictions have no consequences for innovation. While this may be true for some sectors, it is not definitely true for the medical imaging devices one. Any RoHS restriction, as mentioned above, has a clear negative impact on innovation in the medical imaging devices sector, due to several factors:

Investment risk

A serious problem caused by new RoHS restrictions is the uncertainty for investments in R&D. The time between the proposal for a restriction and the actual end of the transition time is normally shorter than the duration of R&D projects in the medical imaging devices sector where design cycles of 7 to 10 years are normal.

The substances assessed in the study for this consultation are a clear example. The work on the 7 substances was launched middle 2018 and a short transition period may put at risk all current R&D programs and delay products almost ready for market access that should be re-assessed and maybe redesigned. This increased risk for long-term investment impacts negatively innovation.

The short duration of certain exemptions and at the same time, the time required by the EC to grant a new exemption request, that has grown significantly since 2006, are adding additional problems.

Diverted resources

COCIR estimated the cost for companies for compliance to comply with RoHS in around 300 million euros (between 2010 and 2014) up to 860 by 2021. The cost, while expressed in millions of euros, is mostly represented by human resources' time, such as engineers, technicians and researchers that have been diverted from innovation in more valuable medical devices for EU citizens.

5. Recommendations

COCIR remain at disposal of Oeko and the EC to provide additional clarification about the impacts of restrictions on the medical imaging sector, so that the detailed assessment report could provide a more complete representation of the socio-economic impact involved with new restrictions. Decisions about transition periods for individual categories, should be based on proper assessment of consequences.