Dear Sir/Madam,

I am writing to you on behalf of Health Care Without Harm (HCWH) Europe, whose objective is to help the EU healthcare sector to improve patient safety and care, whilst reducing the sector’s environmental footprint. As part of this broad mission, we have been active in tackling the health issues linked to endocrine disrupting chemicals (EDCs), specifically focussing on medical devices.

On 11th October 2016, we addressed a letter to Commissioner Bieńkowska and Commissioner Andriukaitis to share our deep concern regarding the on-going discussion on the elaboration of the EDC criteria as currently defined by the draft delegated act under the Biocidal Product Regulation (EU) No 528/2012 (henceforth referred to as BP EDC criteria). Specifically, we wished to alert them to the potentially damaging knock-on effects of the BP EDC criteria on the soon to be formally adopted Medical Devices Regulation (henceforth the new Medical Devices Regulation). The revised proposal that was issued in early November on the BP EDC criteria remains a source of concern, in particular the high burden of proof required to identify EDCs.

Annex I, 7.4.1 (b) of the new Medical Devices Regulation explicitly states that substances having endocrine disrupting properties will be identified either through the REACH process or through “those criteria that are relevant to human health of the criteria established in the delegated act adopted by the Commission pursuant article 5(3), first paragraph, of Regulation (EU) No 528/2012”, i.e. the Biocidal Product Regulation. It is therefore clear that the BP EDC criteria will be incorporated in the new Medical Devices Regulation.

Our concern is twofold. Firstly, the BP EDC criteria that were issued in November have now introduced a terminology that deviates from the wording of Option 2 in the EDCs Roadmap (agreed by DGs Environment and Santé) and from the wording used for the identification of CMR substances (“known and presumed effects”). This novel wording (“shows an adverse effect”) will lead to inconsistencies across EU legislation by introducing different identification requirements for EDCs and CMRs.

Secondly, the November BP EDC criteria are still seen by a significant segment of the independent scientific community and by the majority of NGOs as inadequate because they continue to require an unprecedented level of proof of evidence of adverse effects relevant to humans.
Indeed, only including those substances (as is proposed) shown to have “an adverse effect” substantially reduces the scope of the criteria as per the WHO/IPCS (2002) definition. As you know, the WHO/IPCS (2002) definition refers to substances “known or presumed to have caused endocrine-mediated adverse effects in humans”. The consequence of the November BP EDC criteria is plain to see: it will limit the number of substances that will be identified as EDCs and regulated as such by excluding substances that are ‘presumed’ to have adverse effects.

We, and we are not alone, struggle to reconcile this approach with the declared intention of the 7th Environmental Action Programme (7th EAP) that committed the EU to develop horizontal measures to ensure the minimisation of exposure to EDCs by 2015. There was also a political commitment in the 7th EAP to develop horizontal EDC criteria applicable to all current and future laws.

The new Medical Devices Regulation is a case in point. As indicated above, the BP EDC criteria will have a direct effect on the new Medical Devices Regulation. It will mean that the possibility of replacing harmful chemicals (such as EDCs) with safer alternatives in medical devices (See Annex I, 7.4.1 (b) of the new Medical Devices Regulation) will be watered down.

If not classified as EDCs, because of the exacting level of proof, there will be no need to replace these substances contained in medical devices that are put on the market. This will undoubtedly lower protection for EU citizens. And sadly, the EU citizens that will be most affected by the adverse effects of EDCs are particularly vulnerable: medical patients, foetuses, small children, and pregnant women.

As you know, the effects of EDC exposure are most critical during the important developmental phases of these vulnerable groups. EDCs can take the place of natural hormones, which can hinder the proper development of the endocrine system, possibly causing long-term negative health effects. So instead of straying from the precautionary principle, we would expect the November BP EDC criteria to uphold it.

More generally, we are concerned that that the November BP EDC criteria will lower the protection of not just human health, but also the health of animals and will affect the environment. This is why HCWH Europe would like to call on you to support EDC criteria that are aligned with Option 3, as defined by the 2014 Commission Roadmap. Option 3 uses the WHO/IPCS definition combined with three categories based on the different strength of evidence. This option is the one that is supported by most independent scientists, the European Parliament, the EDC-Free Europe coalition and, presumably, by any well informed EU citizen.

We are aware of the delays incurred by the European Commission which are attributed to strong representations made by affected sectors or by broader international trade considerations. These have all been well-documented but at this stage should only be given the attention they deserve in the face of the responsibility the EU carries in coming up with robust criteria. Now is the time to act.

As a last point, we also believe that the November BP EDC criteria will hamper innovation and deprive companies designing or manufacturing medical devices of scientifically reliable information on which to base a decision to use (or replace) a substance. In the long run, it will erode any chance of building a
competitive advantage for these companies and affect their reputation and brand. They will fail to address their customers' uses and needs.

To conclude, we would like to point out that in today’s climate, the EU is often regarded with mistrust, being ineffectual and too responsive to private corporate interests. Such scepticism would be further fuelled if, as a result of allowing inappropriate considerations to steer the discussion, adequate provisions to define the BP EDC criteria were peremptorily dismissed.

We trust that you will give this letter the attention it deserves. We remain at your disposal should you require any further information about this issue.

Yours Sincerely,

Anja Leetz,
Executive Director, HCWH Europe