



HCWH Europe’s response to the European Commission’s public consultation on the proposed scientific criteria for identifying endocrine disruptors for biocidal and plant protection products

We help the EU healthcare sector improve patient safety and care, reducing the sector’s environmental footprint. We have been very active in tackling the issues raised by endocrine disrupting chemicals (EDCS) in medical devices (MD). One of our major concerns that the proposed MD Regulation (2012/0266) should address is the presence of CMRs and EDCs contained in medical devices. We support a clear phase-out of these substance, in medical devices, when safer alternatives are available, technically feasible, and do not compromise the safety of patients and healthcare professionals. Sadly the proposed measures on EDCs in MDs stand or fall by the European Commission’s (EC) set of scientifically sound criteria for identifying EDCs. These are now defined by reference to the delegated Regulation of the Biocidal Product Regulation (BPR) (528/2012) presented on 15 June 2016. We are critical as they require such a high amount of evidence that it will be nearly impossible to identify more than fraction of substances posing a threat to human health and the environment from hormone disruption. They illegally restrict the scope of the approval mechanisms to substances having endocrine disrupting (ED) properties “known” to cause adverse effects, removing substances that “may” cause adverse effects.

As the approval mechanisms in the BPR excludes substances having ED properties that “may” cause adverse effects, while the draft criteria are limited to substances “known” to cause adverse effects, it follows that the draft criteria are deliberately excluding substances that are “presumed” to have ED properties. Also, there are no criteria for substances that are “suspected” to have ED properties. Consequently, this formulation: (a) exceeds the EC’s mandate in restricting the scope and objective of the Regulation; (b) is inconsistent with BPR, which applies the same approval mechanisms for substances with ED properties and substances that are carcinogenic, mutagenic and toxic for reproduction according to the CLP classification, since the CLP classification encompasses different categories, covering also “presumed” (and “suspected”) carcinogenic, mutagenic and repro-toxicants; (c) is inconsistent with the level of protection from endocrine disruptors set in the BPR, which in Article 5.1(d) also excludes substances “identified in accordance with Article 57(f) REACH as having ED properties”.

Since those endocrine disruptors “give raise to an equivalent level of concern” that substances that meet the identification criteria for carcinogenicity, mutagenicity and toxicity for reproduction, it follows that the determination of ED properties shall adopt similar method of identification and include presumed and suspected EDs; (d) fails to comply with the precautionary principle, to which “the provisions of the Regulation are underpinned by”; (e) fails to comply with the purpose of the BPR to ensure “a high level of protection of both human and animal health and the environment”, paying “particular attention” to the “protection of vulnerable groups” such as pregnant and nursing women, the unborn, infants and children, the elderly and workers and residents highly exposed over the long term. Also, the draft criteria lower the level of protection by limiting the scientific evidence that can be considered for assessment. The draft criteria ask for the adverse effect to be “relevant” for human health, excluding EDs, the effects of which have been demonstrated on animals only; the draft criteria also favour studies “primarily performed according to internationally agreed study protocols” above other studies, such as peer-reviewed independent studies that could bring stronger scientific evidence in identifying endocrine disruptors. This high burden of proof: (a) fails to comply with the precautionary principle; (b) fails to ensure a high level of protection for human and animal health and the environment, (c) is inconsistent with the CLP practice for classification and weight of evidence.