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From:	General Secretariat of the Council
To:	Permanent Representatives Committee (Part 1)/Council
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Subject:	Commission Delegated Regulation (EU) .../... of 4.9.2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 - Intention not to raise objection to a delegated act

STATEMENT BY DENMARK

The Commission's draft delegated Regulation setting out scientific criteria for the determination of endocrine disrupting properties pursuant to Regulation (EU) No 528/2012 has been discussed in a number of expert group meetings (the 'Biocides CA meeting') consisting of representatives of Member States' competent authorities for biocidal products. During these meetings and in written comments, Denmark has expressed a major concern regarding the unprecedented high level of evidence required to identify endocrine disruptors compared to other problematic substances, such as CMR-substances, and stated that the proposed criteria do not properly reflect today's scientific knowledge on endocrine disruptors.

Denmark has further pointed out that the new derogation introduced by the Commission as point 3 under Section B of the Annex to the delegated Regulation (that is, "If the intended biocidal mode of action of the active substance being assessed, consists of controlling target organisms other than vertebrates via their endocrine systems, the effects on organisms of the same taxonomic phylum as the targeted one, shall not be considered for the identification of the substance as having endocrine disrupting properties with respect to non-target organisms.") is not a scientific criterion for the determination of endocrine disrupting properties. The derogation mixes identification of substances with endocrine disrupting properties with managing the risks that may be a consequence of those properties.

Against this background, Denmark intends to object to the entry into force of the Commission's delegated Regulation.

STATEMENT BY SWEDEN

Sweden regrets that the Commission Regulation provides that substances which have an intended endocrine disrupting effect on a target organism shall not be identified as substances having endocrine disrupting properties with respect to non-target organisms of the same taxonomic phylum. This is not a scientific criterion for the determination of endocrine disrupting properties but a policy choice. Sweden is of the opinion that in this respect, the Commission goes beyond the delegated powers in this delegated Regulation.

Sweden is further of the view that the proposed criteria require an unprecedented level of evidence in order to identify endocrine disrupting properties, in comparison with other problematic properties – carcinogenic, mutagenic and repro-toxic properties – and do not properly reflect today's scientific knowledge on endocrine disruptors. This may lead to substances, for which there are substantial data pointing towards endocrine disrupting properties, not being covered by the cut-off criteria. This is contrary to the actual wording of the Regulation and the legislators' intention. In conclusion, we believe that the criteria will fail to meet the level of protection foreseen by the co-legislators.