August 31, 2016

Submitted via e-mail to EU TBT Enquiry Point

ACC Comments on G/TBT/EU/N/383 and N/384

To whom it may Concern:

The American Chemistry Council (ACC)[1] appreciates the opportunity to provide the following comments on WTO TBT notifications G/TBT/EU/N/383 and N/384. These comments express concerns over the proposed criteria to identify endocrine disrupting chemicals under the biocide (BPR) and pesticide (PPR) regulations.

ACC is concerned that the proposed criteria to identify endocrine disrupting chemicals (EDCs) may trigger negative and far-reaching impacts on global commerce. Lack of alignment in regulatory approaches has the potential to result in disagreement between the EU and other countries in identifying EDCs. ACC notes that the proposed criteria do not reference the U.S. Endocrine Disruptor Screening Program (EDSP) or any other regulatory approaches being taken around the world. This is a particular oversight considering the EDSP has overseen considerable work in screening and testing chemicals for adverse endocrine activity. The EU's proposed approach could lead to trade disputes, and marketplace and consumer confusion.

The proposed criteria also fall short by not considering potency or other elements of hazard characterization in identifying EDCs, and as they stand are not sufficient for the purposes of regulatory decision making. While ACC supports a robust systematic review of relevant scientific evidence using a weight-of-the-evidence approach (which, in stark contrast to some alternatives now being proposed by others, e.g. SYRINA, strikes an appropriate balance between not requiring conclusive proof, yet ensuring that there is reasonable scientific evidence for causation), this in itself is not sufficient to determine whether a substance may cause harm to human health or the environment. In contrast, the EDSP mandates the collection of new data to determine whether a substance has the potential to interact with estrogen, androgen and thyroid pathways in mammals or amphibians. If activity is identified, US EPA uses a weight-of-the-evidence evaluation of these results along with other available data to determine whether

[1]The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $797 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for fourteen percent of all U.S. exports. Chemistry companies are among the largest investors in research and development. Safety and security have always been primary concerns of ACC members, and they have intensified their efforts, working closely with government agencies to improve security and to defend against any threat to the nation's critical infrastructure.

additional testing to determine adverse effects is warranted. Potency is a fundamental principle of toxicology and hazard characterization. Without it, substances that have been demonstrated to pose no unacceptable risks to humans or wildlife in the U.S. may be banned from commerce in the EU.

While the WHO/ICPS definition is an appropriate starting point for the proposed criteria, without the addition of potency and other elements of hazard characterization (such as severity, reversibility, and lead toxicity) it **will not enable European authorities to differentiate for regulatory purposes between substances that are likely and unlikely to cause harm**. The decision to recommend Option 2 is disappointing given that DG SANTE's own impact assessment identified Option 4 as the best overall option, based on multivariate analysis. The impact assessment also concluded that all of the proposed policy options would provide the same level of protection for human health and the environment, so it would seem self-evident that the most scientifically valid option (Option 4) is the most appropriate choice. The goal in regulatory decision making should be to adopt recommendations that have the highest prospect of meeting the stated objective: identifying which substances are EDCs and which are not. Option 2 does not meet this test.

ACC agrees that categories (Option 3) are not relevant for the proposed criteria. The adoption of categories risk identifying a broad range of substances as potential EDCs which may not pose an actual risk to human health and the environment. As the Commission points out, categories would reduce "legal certainty" for regulators and other stakeholders, and may result in public confusion over which substances are or are not EDCs. It could also result in substances being identified as potential EDCs in Europe that have been determined not to be EDCs in the U.S., with resulting trade and marketplace effects.

In summary, ACC urges:

- An explicit acknowledgement of the work of U.S. and other regulators in assisting with the identification of EDCs and a commitment to international cooperation and coordination in this area.
- The incorporation of potency and other elements of hazard characterization to ensure a more accurate determination of which substances are, and are not EDCs.
- The continued rejection of categories in the proposed criteria, since they are not relevant to meet the stated objective.