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Submitted via e-mail to EU TBT Enquiry Point

ACC Comments on G/TBT/N/EU/329

To whom it may Concern:

The American Chemistry Council (ACC)[1] appreciates the opportunity to provide the following comments on WTO TBT notification G/TBT/N/EU/329. These comments express deep concern regarding the recent draft Decision communicated to the WTO from the European Commission to list four substances as Substances of Very High Concern (SVHC) on the basis of endocrine disruption. This Decision applies to benzyl butyl phthalate (BBP), dibutyl Phthalate (DBP), bis-(2-ethylhexyl) phthalate (DEHP), and diisobutyl phthalate (DIBP). Specifically, each phthalate is proposed as a Substance of Very High Concern (SVHC) for inclusion the REACH Candidate List in accordance with Article 57 (f) of the REACH regulation on the basis of endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health that give rise to an equivalent level of concern to those substances identified as carcinogenic, mutagenic and/or toxic to reproduction.

These substances are already listed on the REACH Candidate List as SVHCs for reproductive effects (based on their classification as Category 1B under the EU Classification Labelling and Packaging Regulation). The reproductive effects are the adverse endocrine effects and in addition a threshold does apply for these effects as confirmed by the ECHA Risk Assessment Committee which has developed DNELs (Derived No Effect Levels) for these substances. Given the existing SVHC identification and listing already covers the adverse reproductive effects which may be related to an endocrine mechanism and for which there is data to show a threshold, a second listing as an endocrine disruptor for what are the same adverse effects is not justified or necessary. No new additional data relevant to human health (e.g. animals studies) are presented in the scientific reports that underlie this decision that were not in the detailed evaluation carried out by the ECHA Member State Committee (MSC) on DEHP and the other three LMW classified phthalates. No justification can be envisaged to subject a substance twice to Candidate Listing and Authorisation on the basis of the same health data. In addition the regulatory consequences of being listed on the Candidate List and Annex XIV are already being applied for these substances (requirement for Authorisation of uses; for DEHP and DBP Authorisation applications are in progress; for DBP and BBP no Authorisation applications have been made and all REACH regulated uses were phased out as of February 2015). It should also be noted that

[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 an $801 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.

there is no need to demonstrate equivalent level of concern when that level of concern is already agreed for the reproductive effects which are the adverse endocrine effects.

In addition to the above points on regulatory duplication, the scientific validity of the conclusions is questionable as the evaluations (i.e. the Annex XV reports) failed to adhere to key principles of scientific inquiry for evaluating cause and effect for endocrine-mediated toxicity. According to the WHO/IPCS definition, an "endocrine disruptor" is "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations." Therefore, for a substance to be concluded as an endocrine disruptor requires 1) evidence supporting endocrine activity; 2) evidence supporting an adverse effect; and 3) evidence supporting that the endocrine activity is the most likely explanation for the observed adverse effect and is causally related to the adverse health effects. The Annex XV reports for these substances focused on only the first two considerations of this cited definition. As such, the important distinction between endocrine active and endocrine disruptive was overlooked. This distinction is significant because endocrine activity (i.e. a simple biological interaction) is not an adverse effect per se, but represents the biological mechanism that may lead to an adverse effect. Therefore, an observation of endocrine activity in cell based systems or in whole animals is not on its own demonstration of endocrine disruption. Endocrine disruption only results when exposure to a substance goes beyond a simple interaction and results in an adverse health effect.

Furthermore, a substance may lead to an adverse effect by a number of diverse biological pathways many of which are not endocrine-relevant. Therefore it is critical to determine if there are other data that suggest the substance is more likely to lead to an adverse effect through another, non-endocrine pathway (i.e. causality assessment). The internationally recognized Mode of Action/Human Relevance (MOA/HR) framework has been developed by the WHO/IPCS for this purpose. Application of this framework or any type of systematic evaluation of the weight of evidence in support of a casual endocrine mode of action is not apparent in these Annex XV reports. As such, these reports fail to objectively and transparently establish the evidence basis for a link between the purported endocrine activity and the adverse effects. Additionally, there is no discussion of key considerations (potency, severity, threshold) important for establishing equivalent level of concern which is a clear requirement for an SVHC according to Article 57(f) of the REACH Regulation. Considering the significant regulatory implications the Annex XV SVHC proposals have on the availability of a particular chemical in the market, the significant short-comings call into question the appropriateness of this approach for the identification of a substance of very high concern according to the criteria set out in REACH Article 57(f) on the basis of endocrine disruption. It should also be noted that in the Annex XV dossiers for the four substances it is often unclear whether cited effects are adverse, adaptive or non-adverse i.e. there is no clear definition of adversity being used such as the WHO IPCS definition of adverse effects. Without an apparent clear reference point for what is adverse or not it is not possible to determine whether a substance meets the WHO IPCS definition of ED or whether it does not meet such a definition.

The significance of this proposed classification with regard to international trade is that, because it is not based on an a robust analysis and documentation of the scientific data demonstrating that DEHP, DBP, DIBP and BBP are endocrine disruptors according to the WHO IPCS definition, it

could lead to inconsistent and very different regulatory conclusions in different regions leading to the disruption of trade of articles made with these substances and thereby constitute a barrier to trade. For example for endocrine disruptors it has been proposed that a no safe threshold approach would be applied on a blanket basis; this would lead to certain countries or regions banning the import of articles containing those substances based on the application of a non-robust scientific standard.

If this non-robust weight of evidence scientific evaluation approach is more broadly applied in the assessment of endocrine disruptors, this could result in major impacts on trade. For example, agricultural produce can also be impacted by such scientifically unjustified assessments, since crop protection agents, which may be present as residues in foodstuffs and which could considered as endocrine disruptors under EU regulation. This would impact international trade of such produce being impacted through restrictions and bans, particularly if a no threshold approach is applied. In view of these potential trade impacts it essential that robust scientific standards of evaluation and assessment are rigorously applied in determining which substances are and which substances are not endocrine disruptors. Without such an approach there will be widely differing conclusions in different regulatory jurisdictions with the associated confusion, chaos and impact on trade.

Specific comments on the text from the European Commission

The following statement from the European Commission text is particularly concerning as it states that multiple listing of the same substance for the same adverse effects but different modes of action is not precluded by REACH:

> *"(10) The Commission notes further that Article 57 does not preclude identifying a substance as being of very high concern based on the same effect on human health several times, in order to specify the mode of action."*

The objective of REACH is to provide a high level of protection for health and the environment, which surely means identifying potential adverse health and environmental effects and assessing the risks associated with such effects. The statement from the European Commission has significant implications with regard to regulatory duplication and the efficient use of resources, if the same substance can be listed repeatedly for the same adverse effect but different potential modes of action. It is important to note that double listing creates the obligation for companies that have already gone through the REACH Authorization process once to apply again for Authorization, with the significant costs and administrative burden that this process implies and the likely negative impact on the import of these substances and their use in many applications, which would further impact the business of foreign companies importing these substances into the EU. Additionally, the double listing gives scope for the EU to further strengthen restrictions on these substances in articles, which would directly impact non-European companies' ability to sell their products and final articles made with the substances in question in the EU.

Double listing and duplication of regulatory requirements also have implications with respect to the use of animals and animal welfare considerations, since such requirements could drive companies and regulators towards additional animal testing. With respect to international trade it also places demands on other regulatory jurisdictions to consider multiple modes of action for

the same substance for the same adverse effect, with the associated impacts for regulatory duplication and the efficient use of resources.

We would also note the following statements in the text:

> *"According to four members of the MSC the effects for human health pointed out in the Annex XV dossiers were the same effects, caused by the same mode of action, as those already taken into account when the substances were included in the candidate list due to their toxicity for reproduction according to Article 57(c) of that Regulation."*
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> *"The Commission also notes that the majority of members of the MSC considered that the level of concern of those effects is equivalent."*

In a committee which operates on a consensus basis to a significant degree it is relatively unusual for members to oppose proposals in this formal manner. The fact that four Member States opposed the double listing of the four LMW phthalates for the same adverse effect is very notable, and this point should be given much greater weight by the European Commission rather than dismissed as a minority. In the voting it should also be noted that five Member States abstained. The following point should also be noted (extract of the minutes of the ECHA MSC meeting of December 8 – 11, 2014):

> *"Referring to the minority position arguments presented after the vote, several MSC members raised concerns that new elements were introduced, particularly regarding Risk Assessment Committee (RAC) deliberations, which were not raised during the MSC discussions. These members expressed a concern that by introducing the link to RAC at such a late stage, MSC was denied an in-depth scientific discussion on these objections."*