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EPN Comments for the Public Meeting of the Science Advisory Committee on Chemicals Regarding the Draft 1,4- Dioxane Risk evaluation Under TSCA

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Good afternoon. My name is Penelope Fenner-Crisp. Today, and again on Wednesday, I will be presenting comments on behalf of the Environmental Protection Network (EPN). EPN is an organization comprised of over 450 U.S. Environmental Protection Agency (EPA) alumni volunteering their time to protect the integrity of the agency, human health and the environment. We harness the expertise of former EPA career staff and confirmation-level appointees to provide an informed and rigorous defense against current administration efforts to undermine public health and environmental protections.

I am a former EPA career employee, serving much of my time in senior management positions in the Office of Pollution Prevention and Toxics (OPPT) and the Office of Pesticide Programs (OPP). During my 12-year tenure in OPP, I had management oversight of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel, so I am very familiar with the requirements and procedures associated with the peer review process that provides the optimal environment for solicitation and provision of valuable expert scientific advice that is so critical to the development of sound and credible risk management decisions.

The staging of the Science Advisory Committee on Chemicals (SACC) meeting being held this week does not reflect best management practices, and is significantly at variance with the agency's own guidance on the conduct of peer reviews. While EPN expects to prepare more detailed comments on the 1, 4-Dioxane and Cyclic Aliphatic Bromide Cluster (HBCD) draft risk evaluations by the August 30 deadline, it is concerned that the SACC will have concluded their review before the public comment period closes. As a matter of policy, EPN finds it extremely disingenuous to hold the SACC meeting prior to the deadline for submission of the public comments, a departure from the way EPA traditionally conducts its business. This approach indicates that either the arbitrary deadline for a decision is more important than the integrity of the information going into the decision or this is a mechanism to discourage comments from the stakeholder community which desires to see a standardized risk evaluation process followed, or both. Furthermore, the relatively short time given for the Committee members to digest the extensive body of information on these chemicals before the public peer review meeting also sends the message that the Committee's input will not be given the serious and appropriate degree of consideration that this assessment process warrants.

Like the Committee and most public commenters, EPN has not had the time desired to conduct an in-depth analysis of the two draft risk evaluations slated for discussion at this meeting. Therefore, EPN is focusing its initial comments primarily on some of the critical policy issues that affect not only these two chemicals but all existing chemicals to be subjected to risk evaluations under the new Toxic Substances

Control Act (TSCA). I will highlight just one of them today, reserving discussion of the remainder for Wednesday.

The agency has received, and continues to receive, public comments criticizing its use of a systematic review process seen to possess serious flaws and at variance with other, accepted approaches. EPN, and others, have called for the draft guidance document entitled "Application of Systematic Review in TSCA Risk Evaluations" to be subjected to a credible external expert peer review BEFORE risk evaluation documents are drafted. OPPT has noted that it intends to arrange some type of consultation with the National Academies, but this is not expected to constitute a formal peer review and likely will not be completed before the first ten risk evaluations are. Once again, an example of discordance with accepted peer review principles.

I will close with two comments specific to 1.4-Dioxane. In its draft risk evaluation, EPA stated that no consumer product exposures will be considered because its regulatory tools under TSCA Section 6(a) are better suited to addressing any unreasonable risks that might arise from these products through regulation of the activities that generate 1, 4-Dioxane as an impurity or cause it to be present as a contaminant in the products. It is fine that EPA plans to prevent 1,4-Dioxane impurities in consumer products some day, but that does not eliminate the need to account for this pathway of exposure now as part of the cumulative exposure to the general population and to workers.

EPN was puzzled to see that EPA spent considerable effort evaluating a threshold cancer risk model for 1, 4-Dioxane when the 2013 IRIS assessment concluded that there was not sufficient evidence, at that time, to support a mode of action (MOA) of cytotoxicity and regenerative cell proliferation. EPA's cancer risk assessment guidelines are clear that evidence of a threshold MOA must be strong and convincing to justify departing from the presumption of a linear MOA. At first blush, given EPA's time constraints to deliver the first 10 chemical risk evaluations this year, it seemed unwise to spend time and resources to carry out a re-evaluation of this alternative cancer risk model. EPN will examine EPA's re-evaluation in greater detail before submitting its second set of more detailed comments in August.

Thank you for your attention.