

Comments from Patricia Bishop, Humane Society of the United States

On behalf of the Humane Society of the United States and our members and supporters, we thank the Chartered Science Advisory Board for the opportunity to provide input on topics to be discussed during this meeting. Our comments focus on the white paper describing “New Approach Methods and Reducing the Use of Laboratory Animals for Chronic and Carcinogenicity Testing.”

We applaud and wholeheartedly support EPA for its ongoing efforts to end the use of animals in chemical safety testing by 2035. The carcinogenicity studies in the rat and mouse are just two of a standard battery of tests that have been required by EPA for decades when registering a single pesticide. The mouse study, in particular, has been identified as a largely superfluous test. In a paper published ten years ago that analyzed 202 pesticide evaluations, researchers in the EU showed that the mouse test contributed little or nothing to risk assessment. If there are bases for waiving tests that are not needed, or promising new approaches that can provide the necessary information through other means, then these should be pursued.

Conducting the two rodent carcinogenicity tests really involves the use of animals in four tests. The sub-chronic 90-day rat and mouse studies are typically used to set the doses for the longer-term chronic tests. While the 90-day mouse study is not a requirement under Part 158, it is strongly encouraged by EPA; however, its results are rarely used in any other capacity during risk assessment. The short-term, repeat dose study in rodents being proposed to derive a transcriptomic-based POD is an appealing intermediate step between performing the multiple animal-intensive studies already mentioned and no animal studies at all. While the short-term study is still an animal test, it uses much fewer resources in terms of time, cost, and animal lives. If this approach does prove successful in providing the information necessary for risk assessment, we urge the workgroup to also consider how it could eventually lead to a NAM that replaces animals altogether.

With regards to the draft risk-based weight of evidence framework proposed for supporting a chronic/carcinogenicity waiver, we understand that it is important to gather as much information as possible upon which to base a decision. However, a large portion of the information listed in Attachment 1 is derived from animal tests, such as ADME and toxicokinetics data and results of acute, sub-chronic, reproductive and developmental animal studies. Based on our review of numerous pesticide human health risk assessments conducted by EPA in the past 20 years, a number of these studies are redundant and rarely used in setting pesticide exposure limits. While the focus here is on developing a waiver for just the chronic/carcinogenicity study, we would hope that in the near-term EPA could begin to move away from its standard battery of tests that then need waivers to avoid performing certain ones. Rather, we encourage EPA to transition to an integrated testing system whereby, after considering pesticide exposure patterns, usage, mode of action, read-across and so on, animal tests are only carried out to answer specific questions and fill specific data needs. Reviewing the utility of animal test data in past human health risk assessments would likely shed light on which tests offer the most useful information going

forward, which tests could potentially be combined, and which could be eliminated altogether without sacrificing human or environmental safety.

HSUS welcomes the opportunity to assist with these or future EPA efforts to eliminate unnecessary animal tests for pesticides.