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Dr. Warren S. Casey, Director
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for the Evaluation of Alternative Toxicological Methods
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Sent via email to warren.casey@nih.gov

Dear Dr. Casey:

People for the Ethical Treatment of Animals (PETA) appreciates being given time to voice our thoughts at the 2015 ICCVAM public forum, and would like to provide feedback on the discussion that occurred following the presentation of my comments relating to the training of USDA inspectors and the alternative method for *leptospira* vaccine potency testing.

Oral comment: "Additionally, we encourage ICCVAM member agencies to work to create guidance on searching for alternatives to painful experiments and to create more transparency around the search process. It would also be beneficial to provide training opportunities to USDA reviewers on available non-animal methods to equip them with the ability to determine whether alternatives exist."

In our written comments submitted to ICCVAM, we noted the continuous development and updating of *in vitro* and *in chemico* methods, as well as the continuous changes to the ways these methods can be used in integrated approaches to testing and assessment. In our oral comments, we suggested that training should be provided to APHIS inspectors and veterinary medical officers on available non-animal methods to assist them in evaluating instances in which animal methods have been used instead.

The discussion following our oral comments indicated a misunderstanding of our point regarding training at USDA. The comment was not in regards to training companies how to conduct literature searches. The comment was in regards to concerns that it is not uncommon for Category E justifications, submitted by USDA-registered facilities in an annual report, to state that alternatives are not available even when alternatives exist. Thus, our comment was meant to suggest training of USDA APHIS inspectors so that they may better identify inadequate alternative searches by companies. I'd like to reiterate our concern that training is needed for regulatory agency inspectors and reviewers on *in vitro* and *in chemico* methods. These training sessions could be in the form of presentations by speakers from NICEATM, industry, or NGOs such as the Institute for In Vitro Sciences.

Oral comment: "There is also a need to focus efforts on reducing the number of animals used in vaccine testing, which accounts for more than half of the animals reported to the USDA as experiencing pain without relief. For example, Leptospirosis is an urgent target. An alternative is available that has been used safely in Europe for several years but USDA policy prevents its use in the US."

In our oral statement, we recommended that ICCVAM focus efforts on reducing the number of animals used in vaccine testing, which accounts for more than half of the animals reported to the USDA as experiencing pain without relief. We stated that non-animal methods for *leptospira* vaccine batch potency testing have been used safely in Europe for several years, but that USDA policy prevents their use in the U.S.— despite their codification into supplemental assay methods (SAMs) 624—627.

The USDA representative to ICCVAM, Dr. Carol Clarke, responded to this comment by reiterating the availability of these SAMs. However, there remains an urgent need for the USDA to address the fact that U.S. companies are unable to meet USDA requirements for use of these SAMs, such as parallelism. USDA requirements for using these SAMs are more stringent than the requirements in the European Pharmacopoeia (Ph. Eur.). The Ph. Eur. requirements made it feasible for one major E.U. *leptospira* vaccine producer, for example, to move away from the use of animals for vaccine batch potency testing *almost five years ago*.

The USDA acknowledged U.S. companies' difficulty in meeting the requirements for use of the SAMs as far back as 2012 at the USDA CVB-sponsored workshop on alternatives for *leptospira* vaccine testing, and that requirements for using the same non-animal methods are more feasibly met in the E.U. USDA announced plans to address this discrepancy and other *leptospira* vaccine testing issues at the close of this 2012 workshop, but no updates have been forthcoming and companies report that seeking further guidance from USDA on the matter have not been addressed adequately or in a timely manner.

Dr. Clarke stated that *leptospira* testing is part of USDA's initiative to reduce animal use, and we ask that USDA ensure that its initiative focus on achieving wide implementation of the *leptospira* SAMs. Although the 2008—2012 ICCVAM five year plan helped validate the methods described in the SAMs, companies report that they have applied to CVB with requests to use these non-animal methods but have not been successful. Dr. Clarke mentioned that an update will be provided at SACATM, and we look forward to seeing real progress on the part of the USDA on this issue.

We look forward to continued collaboration on these important matters.

Sincerely,

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