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DAILY NEWS FROM INSIDEEPA.COM - THURSDAY, JULY 10, 2008 - ADJUST TEXT SIZE +

EPA Draws Data Quality Challenge Over Key Endocrine Testing Method

An industry-funded watchdog group, in a just-filed Data Quality Act (DQA) petition, is asking EPA to correct its statements on the validity of a key test for evaluating whether pesticides and other chemicals are endocrine disrupting compounds. If the move is successful, one informed source says, it could call into question the agency's ability to proceed with its endocrine screening program, which Congress has ordered EPA to launch next month.

The Center for Regulatory Effectiveness (CRE) July 10 filed its petition with EPA over a frog assay that is a key component of EPA's upcoming endocrine disruptor screening program (EDSP), which is intended to narrow a list of chemicals that require additional testing to determine their endocrine disrupting effects.

The informed source, who is familiar with the petition, says that the agency is making “inaccurate and misleading” comments on the accuracy of the frog study, and scientific uncertainty renders the entire first tier of the EDSP “useless.”

An EPA spokesman was not immediately available for comment.

Endocrine disruptors are chemicals that mimic or block normal functioning of hormones, inducing a variety of developmental and other health effects. The chemicals have been shown to cause developmental problems in many animals, including the development of mixed-sex organs in aquatic species. The findings raise the question of whether the chemicals cause similar effects in humans, though little evidence is available for many suspected endocrine-disrupting compounds.

In a bid to improve understanding of the compounds, Congress ordered EPA in the 1996 Food Quality Protection Act to assess the endocrine-disrupting potential of all pesticides. But EPA has struggled to create the program. In EPA's fiscal year 2008 appropriations bill, Congress ordered the agency to issue in August orders for industry to begin the screenings. EPA also must finalize in August the list of pesticides that will go through the screening program first. Industrial and other chemicals will be tested later.

Earlier this year, EPA won lukewarm approval from its Scientific Advisory Panel (SAP), enabling the screening program to move forward as the agency’s Office of Pesticides, Prevention and Toxics pushes to meet the August deadline. The advisors declared some of EPA's tests outdated, but also rejected industry arguments for replacing some of the proposed tests with industry's preferred alternatives (see related story).

In its proposal, the frog assay is one of the assays that EPA proposes to require companies to use during the first tier of the EDSP. The assay is key to EPA's effort because it is the only one of the first tier testing assays to focus on the chemical's harmful effects on the thyroid gland, which regulates hormones in the body.

The agency has said that, “Overall, it is concluded that the amphibian metamorphosis assay is valid for its intended purpose” and that is “validated and ready for use.”

But the source familiar with the DQA petition says if CRE can successfully challenge EPA's statements about the validity of the amphibian metamorphosis assay, then the entire first round of the screening program would be invalidated, because the frog study is the only one of the 12 assays to look at the thyroid. If the DQA challenge succeeds, then EPA “will not be able to issue an order requiring companies to test their products. If they proceed with the remainder of the tests, the test data will be incomplete,” the source says, adding, “If this one assay being challenged falls, then the whole [EDSP] falls.”

The DQA allows parties to challenge the quality and accuracy of information released by the government, including statements and other findings issued by EPA. The law was passed as part of the fiscal year 2001 Treasury Department appropriations law. CRE's move is one of just a handful of DQA petitions filed by outside groups since the law took effect in 2001, though federal courts have so far declined to review agencies' denials of petitions.

In the petition, obtained by *Inside EPA*, CRE ask the agency to correct its public statements that the frog assay is reproducible and properly validated.

CRE says EPA's statements are “inaccurate and misleading” and the agency should correct them by stating that: external peer reviewers concluded the assay's intra- and inter-laboratory reproducibility has not been demonstrated; the peer reviewers concluded that the frog assay is not valid for its intended purpose; and all other EPA statements that the assay is reproducible and validated “should also be corrected to say just the opposite.”

CRE says the agency cannot use the frog assay in the program unless EPA first demonstrates it is valid for its intended endpoints. In order to do this, the agency must demonstrate the assay is reproducible both in a single laboratory and among different laboratories, according to the petition.

CRE says one EPA peer reviewer, responding to the question of whether the assay is reproducible, said, “This is a major flaw of the material provided.” The reviewer also said that there were inter-laboratory inconsistencies in the assay that “would convince any reviewer for a reputable scientific journal to recommend rejection” of the validation study. The petition cites other peer reviewers who echoed concerns about inconsistencies in the assay.

A fifth and final peer review wrote, “There is simply not enough detail in this methodology to be confident that the assays can be executed with adequate amounts of reproducibility,” the petition says.

Several industry representatives who made presentations to the SAP in March argued that the frog assay gave too many false positives, inaccurately flagging too many chemicals as potential endocrine disruptors. Chemicals flagged in the tier one screening as possible endocrine disruptors go on to a tier two screening, estimated to cost $1 million or more per test.

CRE says the peer reviewer comments show that the frog assay's overall intra- and inter-laboratory reproducibility has not been demonstrated. CRE says EPA's claims about the validity of the assay violate the DQA guidelines because the DQA's objectivity standard requires that agencies ensure that information they disseminate is reproducible and “accurate, reliable, and unbiased.”

“Because the [frog assay] does not meet the [DQA] standards, EPA cannot use, rely on, or otherwise disseminate any information generated by the [assay],” the petition says. -- *Anthony Lacey*

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