ENDOCRINE DISRUPTORS

PETA weighs in on endocrine testing proposal

An animals rights group is urging EPA not to expand its plans to gauge the endocrine disrupting potential of pesticide ingredients.

People for the Ethical Treatment of Animals issued its warning in response to an agency request for comments on its chemical selection process for Tier 1 tests (67 FR 79611) (see PTCN, Jan. 6, Page 1). The group believes that EPA has already expanded its Endocrine Disruptor Screening Program far beyond the mission specified in the FQPA.

That’s because EPA is proposing to validate tests on animal species (like shrimp and minnows) without any relevance to humans, said PETA Science Policy Advisor Troy Seidle, adding that FQPA directed EPA to find out if pesticides substances mimic hormones in humans — not wildlife.

“Four out of the five Tier 2 tests proposed by EPA are only relevant to the species being tested,” Seidle told PTCN, noting that the fifth test — the only potentially relevant one, in his opinion — would use rats. The other tests would serve only to “satisfy scientific curiosity” without leading to any regulatory consequences, Seidle argued.

Redundancy blasted

The Tier 2 rat test — a two-generation reproduction study — is already required for every pesticide on the market, Seidle added, pointing out that the addition of non-relevant wildlife tests, along with redundant tests, has quadrupled the size of the EDSP program.

Seidle is particularly incensed by the redundant tests.

“It’s a classic definition of insanity,” he said. “You’re doing the same test over and over and expecting a different result.”

What follows is some of the comments Seidle submitted to EPA on behalf of PETA.

Limited use of effects data

EPA believes that the available toxicology data on endocrine effects is insufficient to support a determination of endocrine disruption for most pesticides. Consequently, it’s proposing to use effects data solely for the purpose of excluding chemicals that are clearly endocrine disruptors (although these would be subjected to Tier 2 tests), and those that clearly aren’t.

“It’s a classic definition of insanity: You’re doing the same test over and over and expecting a different result.”

— Troy Seidle, People for the Ethical Treatment of Animals

PETA strongly disagrees with this approach, arguing that EPA should evaluate all exposure and effects data to determine if there’s any “value added” to further testing. Noting that pesticides are particularly “data rich,” the group said it’s “dumbfounded by the EPA suggestion that ‘it has not yet been established how the available data might be confidently used to predict the endocrine disrupting potential of [pesticide] chemicals.’

“If this is indeed the case,” PETA continued, “why has a two-generation rodent reproduction study — a required endpoint for all food-use pesticide active ingredients — been proposed as the definitive Tier 2 test to evaluate adverse effects to human health under the EDSP?”

Inerts testing

The EPA request for public comment noted that there are an estimated 600 High Production Volume chemicals with uses as inert pesticide ingredients. Besides their eventual testing under EDSP, these chemicals are already being tested under the HPV Chemical Challenge Program. That means there are plenty of available data on many or most of them.

PETA argues that information on the presence or absence of endocrine effects from these chemicals could be “mined” from the histopathological examinations of reproductive and other organs taken from animals subjected to 90-day feeding studies, “as well as the myriad of observations carried out in existing developmental toxicity studies on rodents.”

Last year, PETA points out, the Office of Pesticide Programs revised its inerts testing guidance to require some of the tests — i.e., the Screening Information Data Set, or SIDS — recommended by the Office of Pollution Prevention and Toxics for HPV Challenge testing.

“With respect to the generation of SIDS-type data under OPPT and OPP programs, we strongly urge
EPA program offices to ensure that chemicals are not subject to duplicative or redundant testing for the same or similar endpoint,” PETA says. “An example of the type of scenario that should be prevented would be for an HPV chemical/pesticide inert to undergo a screening-level reproductive toxicity study (675–1,300 animals) under either OPPT’s HPV program or OPP’s inerts reassessment strategy, and later be required to undergo one or more multigenerational reproduction studies (requiring more than 2,500 animals) under the EDSP. Such needless duplication could be prevented through early and careful coordination among the program offices.”

**PETA agreement**

Despite its criticisms of the EDSP program in general, and some of the EPA selection proposals in particular, PETA agreed with a number of the agency plans. Those plans include:

- **Deferring consideration of nominations of chemicals from the public.** PETA says this would preclude the expansion of the EDSP to include a large number of non-pesticidal chemicals, which aren’t named in the FQPA.

- **Deferring tests of mixtures.** PETA would like EPA to rule out mixtures-testing altogether because of a potentially massive program expansion. For example, says the group, testing just 10% of the chemicals in the TSCA inventory in combinations of three would require testing 85 billion mixtures.

- **Excluding chemicals no longer used or produced in the United States.** PETA would like EPA to formally state that these chemicals are exempted from EDSP screening and testing at any time — now or in the future.

PETA also wants EPA to eliminate screening and testing for chemicals listed as generally safe by FDA as well as those classified as non-toxic inerts by OPP. High molecular-weight polymers should also be excluded, PETA adds.

“On a more general note,” PETA concludes, “we strongly believe that the entire exercise being proposed … is highly premature” because many of the screens and tests proposed for EDSP haven’t been validated. Consequently, PETA warns, “the generation of Tier 1 data without the potential to confirm or refute the results could leave chemicals in regulatory limbo for months or years, pending the outcome of lengthy Tier 2 validation studies.”

— Phil Zahodiakin