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CHILDREN'S HEALTH

Court dismisses DNT test guidelines lawsuit

A district court judge Sept. 11 granted EPA's motion to dismiss a suit challenging the agency's position on Developmental Neurotoxicity Test (DNT) guidelines.

The suit was filed last year by the Physicians Committee for Responsible Medicine (PCRM), People for the Ethical Treatment of Animals (PETA) and three individuals after EPA denied their petition to repeal the DNT guidelines. The suit requested that the district court force EPA to reverse its denial, but the judge ruled that the plaintiffs lacked standing.

PETA and PCRM argued that EPA's DNT procedures were never scientifically validated to verify the reliability of extrapolating data from animal experiments to accurately predict developmental neurotoxic effects of a pesticide in humans. Furthermore, the suit argued that EPA has used DNT results to justify exposing children to pesticide levels higher than mandated by the Food Quality Protection Act's tenfold children's health safety factor.

(see ***Lawsuit***, *Page 16)*

EPA

Sen. Boxer ready to block EPA inspector general nominee

The Bush administration's nominee for EPA general counsel faced a relatively easy confirmation hearing last week, but the same cannot be said for Alex Beehler, the nominee for EPA inspector general.

Sen. Barbara Boxer (D-Calif.) sharply criticized Beehler's record as a top environmental official with the Department of Defense (DOD) and said she plans to block his confirmation.

Boxer said Beehler is a poor choice for the position because he has fought for DOD exemptions from environmental laws — including the Clean Water Act, Clean Air Act, the Endangered Species Act and the Superfund law — and also helped with DOD efforts to weaken federal standards for perchlorate and trichloroethylene (TCE).

(see ***Hearing***, *Page 12)*

CHILDREN'S HEALTH

Groups still divided over FQPA implementation

EPA was charged with a daunting task when the Food Quality Protection Act (FQPA) was signed into law in 1996. FQPA fundamentally changed how pesticides are regulated and gave the agency ten years to reassess all food-use pesticide tolerances to ensure they met federal safety standards and met additional safety requirements for infants and children.

A decade later, EPA has completed reassessments of more than 99% of food-use pesticide tolerances and is finishing up work on the few remaining substances. But while the agency gets an "A" for meeting its deadline, what kind of grade does FQPA get from stakeholders ten years down the line? How successful has FQPA been in improving the safety of foods over the last ten years? *Pesticide & Toxic Chemical News* spoke with representatives of both pesticide industry groups and public interest groups, and found that both sides concede that FQPA has reduced children's risks from dietary exposure to pesticides. However, that's about the only thing they agree on.

FQPA History

Before FQPA, EPA regulated pesticides solely under FIFRA and the Federal Food, Drug and Cosmetic Act (FFDCA). Under FIFRA, the agency registered pesticides for use in the United States and provided labeling requirements to prevent unreasonable adverse effects on health and the environment. Under FFDCA, EPA established pesticide tolerances, which are the maximum legally allowed levels for pesticide residues in food.

The FQPA was prompted in part by the 1993 National Academy of Sciences report "Pesticides in the Diets of Infants and Children" that recommended changes to the then-pesticide regulatory process that emphasized average adult exposure by taking into account the diets of children, children's non-dietary exposure to pesticides, and the different physiology of children. The law mandated that EPA reassess all existing food-use pesticide tolerances by Aug. 3, 2006 to ensure they met federal safety standards. Both the House of Representatives and the Senate unanimously passed FQPA, and President Clinton signed the act into law Aug. 3, 1996.

EPA still uses FIFRA and FFDCA to regulate pesticides, but FQPA amended both statutes to "establish a more consistent, protective regulatory scheme grounded in sound science," according to the agency.

FQPA laid out specific requirements for EPA to ensure the protection of infants and children from pesticide exposure, including assessing the risk of a pesticide based on available data on the neurological differences between children and adults and the effects of pesticide exposure on a fetus. The statute also required the agency to consider the available information on the cumulative effects of pesticides that shared a common mechanism of toxicity, such as organophosphate (OP) or carbamate pesticides.

Advocacy groups find EPA lacking

Environmental and health proponents have found EPA's efforts in implementing FQPA and improving the safety of children lacking and have outlined their specific concerns and recommendations.

Margaret Reeves, senior scientist at Pesticide Action Network North America, told *PTCN* that there are two big priorities EPA needs to address to better implement FQPA and protect children's health, and both relate to the agency's cumulative reassessment of the OP pesticides. The agency needs to better assess risk by considering certain neurotoxic effects of OPs and also needs to consider residential exposure to agricultural OPs, she said.

EPA has only focused on cholinesterase inhibiting neurotoxic effects in assessing risk, and there is "growing literature" that non-cholinesterase inhibiting effects of OPs are also neurotoxic, Reeves said.

Cholinesterase is an enzyme which aids the breakdown of the neurotransmitter acetylcholine into choline and acetic acid, which allows neurons to return to a resting state. OPs work by suppressing the enzyme cholinesterase, thus causing neurotoxic effects.

Reeves also said EPA hasn't considered residential exposure to agricultural pesticides in its cumulative risk assessment of OPs. There's a growing "interface" between agricultural areas and suburbs. Pesticide drift from fields is causing the population to be exposed to OP pesticides by inhaling dust contaminated with the pesticides, Reeves said.

Chuck Benbrook, senior scientist at The Organic Center, concedes that FQPA has made children safer from dietary pesticide exposure. "Our estimates of overall risks have gone down," Benbrook told *PTCN*.

But Benbrook said he thinks that Congress, in passing FQPA, mandated EPA to reduce the risk to children from pesticides by as much as the risk to children from lead exposure has been reduced. EPA has "made a start" but hasn't finished the task, which the agency could do by reducing and revoking certain pesticide tolerances. "It's an admirable and fully achievable goal," Benbrook said.

According to Benbrook, the OPs dimethoate, methamidiphos, azinphos-methyl (AZM), and chlorpyrifos as well as the carbamates aldicarb and oxamyl and the organochlorine endosulfan "warrant significant, further tolerance reductions and revocations."

Benbrook is also concerned about what he calls "modest changes" in the level of OP metabolites in children. OP metabolites are "unequivocal evidence of exposure" to pesticides, he said. Benbrook attributes this modest exposure reduction to a shift in dietary risk from domestic produce to imported produce.

Benbrook said the shift began in 1999 when EPA began reducing the tolerances of ethyl and methyl parathion, which "brought about a reduction of toxicity in domestic produce" but increased the dietary risk of imports. "U.S. farmers switched to reduced risk chemistries and IPM systems which reduced dietary risk, while growers abroad shifted to other high-risk OPs and carbamates," Benbrook said.

In order to address this problem, EPA needs to "reduce and revoke tolerances of OPs and carbamates" because until it does, it is still legal for those residues to appear on imports, he added.

But industry doesn't agree.

"There's always some lingering concerns about products banned in the U.S. used on imports," Rebeckah Adcock, director of congressional relations at the American Farm Bureau (AFB) told *PTCN*. But that's "not an EPA issue," she added. It's an issue of the testing system at the border and whether "we are getting an accurate measurement [of residues] at the border to make sure [imports are] safe."

Tenfold protection for children

Industry and consumer groups are also deeply divided over FQPA's requirement that EPA use a tenfold safety factor to take into account both the possible toxicity of prenatal and postnatal exposure to pesticides and the potencial lack of data on a pesticide pertaining to infants and children. EPA must retain this factor unless reliable data supports using another factor. The children's tenfold safety factor sets pesticide tolerances ten times greater than those accepted for adults.

Industry representatives think EPA is using the tenfold safety factor appropriately on a case-by-case basis, tending to be cautious, but question whether it was necessary to begin with.

"Before FQPA, if a regulatory risk assessor had uncertainty about children, the 10X uncertainty factor would have been used anyway — with or without FQPA," said Mark Maier, health science policy leader at CropLife America. "FQPA made the 10X mandatory in dietary assessments whether scientifically justified or not, so it is called a 'safety factor.'"

In addition, industry proponents say the tenfold factor is rather arbitrary and based in politics.

"The tenfold factor is tradition," Ray McAllister, regulatory science and policy leader at CropLife America, told *PTCN*. It came out of "scientific discussions, not a scientific process."

Maier agreed. "The mandatory FQPA 10X is more a matter of political science being applied to exercise an abundance of caution."

But environmental and health advocates don't think the agency is adequately utilizing the tenfold safety factor. Richard Wiles, senior vice president of Environmental Working Group (EWG), said the agency has avoided the factor, and the Organic Center's Benbrook said EPA has been "overly conservative using 10X."

A group of 11 public interest groups brought a suit against EPA claiming the agency ignored some FQPA requirements, including failing to retain the tenfold safety factor, when reassessing certain pesticide tolerances; however, the suit was dismissed and the groups recently lost their appeal (see *PTCN*, Aug. 28, page 1).

When asked if the tenfold safety factor was excessive and if another factor would be more appropriate, EPA spokesperson Enesta Jones cited the National Academy of Sciences report, which recommended that a safety factor of "up to ten-fold … should also be considered when there is evidence of postnatal developmental toxicity and when data from toxicity testing relative to children are incomplete."

"The National Academy's recommendation was largely incorporated in the Food Quality Protection Act," Jones told *PTCN* via e-mail. "In ten years of making decisions on the FQPA safety factor, EPA has found that in many instances, due to the wealth of toxicity and exposure data it has on pesticides, that the additional 10-fold factor can be safely removed. In other instances, EPA has retained the full 10-fold safety factor or a lower factor, generally 3-fold. In a few cases, EPA has applied an additional safety factor greater than 10-fold," Jones said.

Although both industry and advocacy groups agree that FQPA has reduced risks for children from pesticides, industry, for the most part, believes EPA had already provided adequate protection to children before the statute's enactment, and doesn't see much need for improvement in EPA's implementation.

"The process was pretty darn safe to begin with," the AFB's Adcock said. "FQPA reinforced what we suspected — that EPA did a good job and will continue to do a good job."

Environmental and health proponents think the agency isn't doing enough under the mandates of the law.

"FQPA, in the beginning, worked," EWG's Richard Wiles said. "It's gone in the other direction with this administration. When [FQPA] was written, we thought it was tight. The agency has figured out ways to avoid compliance."

EPA has "artfully crafted a do-nothing strategy" and is "not faithfully implementing" the statute, Wiles added.

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Lawsuit, *continued from Page 1*

The groups further alleged that EPA's rejection of their petition to repeal the guidelines violated the Administrative Procedures Act (APA), and that the agency further violated the APA by issuing the guidelines without providing notice or a public comment period. (see *Pesticide & Toxic Chemical News*, July 11, 2005, Page 1).

This was not the first suit filed by PCRM and PETA challenging the DNT Guidelines. In the 2001 case *Helstosky v. EPA*, the plaintiffs claimed that the guidelines were not scientifically valid under TSCA. The court dismissed that case after determining the plaintiffs lacked standing, and *Helstosky* played a major role in this most recent decision.

"The plaintiffs' claims, while more detailed and developed than the claims in *Helstosky* regarding their injuries and the causal relationship between the