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TOP OF THE NEWS

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Challenges may lie ahead for potential nanosilver registrants

Recently released minutes of the FIFRA Scientific Advisory Panel meeting last November regarding nanosilver-based pesticide products' potential hazards and exposures has stakeholders bracing for challenges — be it preparing for expanded data requirements for registration or convincing EPA that it has already registered nanosilver.

Discussions during the November meeting detailed the vast amount of data the panel felt were needed to understand the potential risks of nanosilver-based pesticides — a signal to potential registrants that they may need to prepare to generate a whole lot of new data to get their products registered (see *PTCN* Nov. 9, Page 1). The minutes merely put that signal into writing.

"The panel stated that it 'strongly believe[s] that in addition to current data requirements under [the Federal Insecticide, Fungicide, and Rodenticide

(see ***Nanosilver**, Page 10)*

EPA

Legal questions abound over pesticide inert ingredient disclosure

Requiring pesticide manufacturers to publicly disclose inert ingredients could prove a legal headache for EPA, as some industry insiders believe the agency has questionable authority to force registrants to reveal such information.

The agency indicated its potential interest in requiring such disclosure in late December, when it released an advanced notice of proposed rulemaking (ANPR) and asked for public comment on options to increase disclosure of inert ingredients. EPA released its proposal in response to petitions filed in 2006 — one by a coalition of 15 states and another by a coalition of environmental groups — seeking greater disclosure of pesticide inerts. Although pesticide manufacturers must currently disclose to EPA the inert ingredients in their products, the agency generally does not require those ingredients to be listed on the product label.

(see ***Pesticide inerts**, Page 6)*

Preuss says the agency is "definitely going to try" to create a harmonized PBPK model and that agency staff are currently in the process of reading the NRC report in depth and will meet this week to discuss next steps.

Still likely to be a human carcinogen

The committee backed EPA's classification of PERC as "likely to be carcinogenic to humans," noting data to support the classification, including increased incidence of liver tumors, leukemia and kidney tumors in lab animals, and to a lesser extent, epidemiological data, meet the criteria in EPA's Guidelines for Carcinogen Risk Assessment.

"EPA's decision to characterize tetrachloroethylene as likely to be a human carcinogen as opposed to 'carcinogenic to humans' appropriately reflects the possibility that there are deficiencies or potential inaccuracies in interpretation of the data," the report notes.

But the committee could not agree on the type of cancer that should serve as the critical end point for estimating PERC's cancer risk. EPA chose the most sensitive response — the incidence of mononuclear-cell leukemia (MCL) in a strain of rats. "Our practice is to choose the endpoint with the highest potency," Preuss notes, meaning the cancer that is caused by the least amount of exposure.

The majority of members felt uncertainties associated with MCL — particularly a poor understanding of mode of action, the high incidence in the rat strain without PERC exposure and uncertainty about the dose-response relationship — were too great to support using MCL data instead of data on liver or kidney tumors to estimate cancer risk.

"Those members judged that the use of the MCL data could be justified only if it is EPA's policy to choose the most conservative unit risk when considering options but that such justification should be distinguished as a policy decision, not a scientific one," the report states. "They believed that a more scientifically defensible approach would be to use the dataset that has the least uncertainty rather than the dataset that yields the highest estimate of risk."

Therefore, the liver tumor data, which has the least uncertainty, should be used, followed by kidney tumor data and leukemia data, the report notes.

EPA can still include MCL data to estimate cancer potency, but it should have the least weight because it is the least relevant to humans, notes W. Caffey Norman, a partner with the law firm Patton Boggs.

But some committee members agreed with EPA that MCL data should be used to estimate human cancer risk because not only were the increases in the cancer in rats reproducible, statistically significant and above background levels, it was the cancer that resulted at the lowest level of exposure.

Nonetheless, Norman, who previously submitted comments on the draft assessment on behalf of the Halogenated Solvents Industry Alliance, which represents makers of PERC and other halogenated compounds, says the NRC report is "excellent and contains advice EPA is going to need to heed."

And heeding that advice means EPA will have to rewrite the PERC risk assessment so that it relies on all studies — not just those that find an association between the solvent and adverse health effects — and gives the appropriate weight to relevant studies, Norman tells *PTCN*. That means new reference values and cancer risk estimates, he concludes.

Preuss says he doesn't believe heeding the recommendations will result in a substantial rewrite of the assessment — "Changing the part on non-cancer effects is very straightforward," he notes. But he acknowledges such changes will impact the proposed RfC, and if EPA is successful with harmonizing the PBPK model, the RfD will be affected as well.

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Pesticide inerts, *continued from Page 1*

The ANPR outlines two general approaches — one would require all or most inert ingredients to be labeled, the other would require registrants to list the identities of all potentially hazardous inert ingredients on product labels. EPA is taking comments on the ANPR through Feb. 22.

CropLife America and many pesticide manufacturers generally oppose either approach, arguing that disclosure of inert ingredients would harm pesticide manufacturers by releasing valuable intellectual property to competitors and do little to help the public make informed choices about the safety of pesticides.

The issue could prove thorny for EPA as FIFRA contains clear provisions for protecting confidential business information (CBI) — including inert ingredients — and the agency has rarely required disclosure of hazardous inerts.

"Any forced disclosure of CBI information is a sensitive legal issue," says Lynn Bergeson, an attorney with Bergeson & Campbell. "The tricky part for EPA is finding the balance between disclosure and protecting manufacturers."

Any move to require disclosure of inerts "across the board" is on shaky legal ground, adds Larry Ebner, a longtime pesticide industry attorney with McKenna Long & Aldridge.

Such a rule "would be vulnerable to a legal challenge from industry because it would flatly contradict FIFRA and EPA's own regulations." he tells *Pesticide & Toxic Chemical News*.

Ebner notes inert ingredients are specifically excluded from the provision that excludes safety and efficacy data from FIFRA's CBI protections — outlined in Section 10 of the statute.

EPA, however, asserts in the ANPR that it can revoke that exclusion because Section 10 of FIFRA only bars the agency from disclosing information "which in the administrator's judgment" contains or relates to trade secrets or is deemed confidential commercial or financial information. The agency suggests that CBI claims for inerts could also be undermined by technological advances, such as reverse engineering, that may allow competitors to determine the identity and quantity of inerts in pesticide products.

This "turns the notion of CBI on its head," says Ebner, who also questions whether listing inerts would benefit consumers or be consistent with EPA's past practices.

"I don't think there is any reason to think that most consumers and even commercial applicators would get anything from a list of additional chemical names on the label of a pesticide," he says. "It would add to label clutter, which EPA many times in the past has indicated ought to be avoided."

Ebner also takes issue with EPA's suggested use of Section 10 to claim authority to force registrants to list inerts on pesticide labels.

Furthermore, EPA's regulations on pesticide inerts, promulgated in 1975, clearly state that identification of inerts on pesticide labels is not required "and would be required only if a hazard determination was made," Ebner adds.

The 1975 rules allow EPA to require the name of any inert ingredient be listed on the ingredient statement if the agency determines that such an ingredient "may pose a hazard to man or the environment."

These regulations mean EPA must determine a hazard exists for each specific inert, Ebner explains.

"It is very questionable from a legal viewpoint whether EPA has the authority to require that all inerts be listed on the label versus those inerts that pose a real hazard if label directions are followed," Ebner says.

David Sarvadi, a partner with Keller and Heckman, agrees that broad disclosure of inerts would present EPA a "real statutory problem" and suggests such a rule could be vulnerable to legal challenges beyond FIFRA.

An inerts disclosure rule "would be vulnerable to a legal challenge from industry because it would flatly contradict FIFRA and EPA's own regulations."

— Larry Ebner, attorney, McKenna Long & Aldridge

"Trade secrets are recognized as property rights in the United States," he says. "You might argue that it is a taking [of private property] under the Constitution."

Sarvadi also suggests that forcing disclosure of hazardous inerts presents problems for the agency.

EPA can currently do this on a "case-by-case" basis, he says, but it is unclear how it would craft and legally support a rule requiring disclosure of all potentially hazardous inerts.

FIFRA does not contain any definition for hazardous inert ingredients, Sarvadi explains, and how it ultimately decides to categorize such inerts could prove a legal headache for the agency.

He contends the push for broad disclosure is a solution in search of a problem.

"The idea that these products are out in the marketplace without any regard for public health is just not true," he says. "EPA has plenty of authority to ensure the ingredients used in pesticides are safe."

Deference rules

Charlie Tebbutt, an environmental lawyer who authored one of the petitions that prompted EPA to issue the ANPR, rejects the claim that the agency may lack authority to force inert disclosure.

"The courts give agencies deference to interpret the statute," he tells *PTCN*. "Industry lawyers are salivating because they are looking for work — this is an industry that for decades has tried to get its way and taken advantage of a weak statute."

Tebbutt, who filed the petition on behalf of the Northwest Coalition for Alternatives to Pesticides and 21 other environmental and public health advocacy groups, says the public has every right to know what inerts are in pesticides.

"People know more about what is in the twinkies they are eating than what is in pesticides that are widely used," he says. "The public is the last to know — disclosure would allow them to make more informed choices."

The ANPR is a good start, Tebbutt says, but the agency should also be working on a separate rulemaking to determine how to disclose inert ingredients that have already been deemed hazardous under FIFRA and other federal statutes.

"We will have to see what EPA's substantive response will be," he says. "We want them to move quickly on this."

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>
> *— Charlie Tebbutt, environmental attorney*

Bergeson adds that pesticide manufacturers should view the inert issue within the wider context of the Obama administration's push to narrow industry claims of CBI.

The industry needs to see that "this is an issue that is important [to the administration] for policy, legal and appearance purposes and it is wise to find a way to move this forward," Bergeson says. "It is not going to go away."

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