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USDA Presses EPA To Reconsider Fluoride Pesticide Ban, Seeks NAS Review

The U.S. Department of Agriculture (USDA) is pressing EPA to examine options to maintain some uses of a fluoride-based pesticide instead of banning the chemical as EPA has proposed, and is also urging the agency to delay action until the National Academy of Sciences (NAS) can review the science EPA is using to justify its proposal.

"It is USDA's position that EPA should strongly reconsider its proposal to revoke tolerances for [sulfuryl fluoride] and examine whether the authorizing statutes offer any discretion to allow continued use of sulfuryl fluoride as a post-harvest fumigant," USDA writes in undated comments to EPA.

EPA in 2011 proposed revoking food tolerances for sulfuryl fluoride, effectively barring its use, because it deems exposures from naturally occurring, pharmaceutical and other sources of fluoride already too high. EPA has said sulfuryl fluoride use could add to this aggregate fluoride exposure because the fumigant breaks down into fluoride. Many observers have said that the 2011 proposal marks a novel and potentially precedent-setting use of EPA's authority under the Federal Food, Drug and Cosmetic Act, because it is the first time the agency has proposed revoking tolerances on the grounds that people are already overexposed to a chemical under the law's aggregate risk provisions.

USDA, however, questions EPA's aggregate exposure assessment — required under FFDCA — arguing that it "should be refined to better reflect current data," and suggesting that NAS review it.

"[B]efore the use of this valuable crop protection tool is removed, a thorough and independent review of the science supporting EPA's decision should be undertaken in advance of a costly and unnecessary disruption to domestic and imported agriculture," USDA writes. "The dose-response and the relative source contribution documents should be evaluated by the National Academy of Sciences as both these documents rely on historical dose reconstruction to fill critical data gaps."

The department says that EPA's aggregate exposure assessment relies on fluoride concentrations reported in foods and beverages in the 2010 Relative Source Contribution Analysis from the agency's Office of Water. USDA argues that the OW analysis "relies primarily on historical fluoride exposure data, often from a small number of individuals under special circumstances (i.e., hospitalization) in a limited geographic scope, rather than current data."

USDA argues that the OW analysis as a result is outdated and perhaps not nationally representative. USDA writes that it "cannot state that the science underlying EPA's proposed action is sound."

USDA's suggestion for an NAS review is not new — other agencies have jointly sponsored reviews of draft EPA Integrated Risk Information System (IRIS) assessments in the past, such as those of dioxin and perchlorate. Calls for such a reviews, however, delay decision-making because NAS reviews are generally scheduled to last about two years.

Still, a former EPA official says the bottom line is that a significant number of people are overexposed to fluoride and that examining EPA's dose-response and aggregate exposure analyses might not address that issue. "It may be relevant to knowing the precise exposure, but not relevant to the problem of overflowing the risk cup," the former EPA official says.

The concerns about the sulfuryl fluoride aggregate risk assessment add to those raised by others, including industry groups and Republicans, who have argued that EPA lacks consistent criteria for when to include non-pesticidal substances in those assessments and that EPA should develop a set of criteria.

Dow AgroSciences LLC, which makes sulfuryl fluoride, has argued that revoking its tolerances would create a "patently absurd" outcome that FFDCA did not intend because fluoride exposure from the pesticide itself is so small, or *de minimis*, that removing that exposure source would only negligibly reduce risks while banning a crucial fumigant that has no viable alternatives. Dow and other stakeholders have called on EPA to grant a novel *de minimis* exemption for sulfuryl fluoride from the strict food-safety limits. EPA reopened the comment period to further consider the argument but expressed skepticism at many of industry's arguments.

USDA, while echoing concerns raised by Dow, does not explicitly call for a *de minimis* exemption. USDA instead suggests that EPA might have other FFDCA authority under 21 U.S.C. section 321 to regulate the chemical because jurisdiction over fluoride is split between EPA and the Food and Drug Administration (FDA). "USDA strongly recommends that EPA undertake a careful examination of the data, the public comments, and the underlying discretion afforded

the Agency under FFDCA," USDA writes.

Under 321(q)(3), EPA can exempt a chemical from the definition of a pesticide or pesticide residue — and thus exempt it from tolerance requirements — if two criteria are met: "its occurrence as a residue on or in a raw agricultural commodity or processed food is attributable primarily to natural causes or to human activities not involving the use of any substances for a pesticidal purpose in the production, storage, processing, or transportation of any raw agricultural commodity or processed food," and if EPA in consultation with the Department of Health and Human Services determines it would be better to regulate the pesticide under that provision instead of others.

USDA argues that "[t]he occurrence of fluoride as a residue in or on raw agricultural commodities or processed foods" is satisfied by naturally occurring fluoride or community fluoridation programs.

USDA qualifies its argument, saying, "Of course, EPA is constrained to select from regulatory alternatives that are to the 'extent permitted by law,' and so it is USDA's position that EPA should re-examine its legal discretion under FIFRA and FFDCA." Moreover, USDA notes that it could not locate any case law interpreting 321(q)(3).

But one environmentalist and a former EPA official are arguing that USDA's argument could be a stretch.

"It might be a difficult argument to sustain, but they're throwing it out there for a larger point of, 'There's flexibility in the statute, why don't you go try it out?'" the former EPA official says.

Under the Food Quality Protection Act of 1996 (FQPA), which amended FFDCA, a food tolerance is considered "safe" — and therefore the pesticide can be used on the food — only if there is "reasonable certainty of no harm" to consumers of the food. Environmentalists have suggested that statute lacks the flexibility for a *de minimis* exemption — a suggestion EPA has pointed out and asked stakeholders to comment on.

A lawyer with the environmental law nonprofit Earthjustice, which has filed comments criticizing the idea of applying a *de minimis* exemption to an FQPA tolerance as illegal and setting a bad policy precedent for future pesticide decisions, says that FQPA's inflexibility would extend to USDA's suggested solution.

"These are balancing issues that aren't appropriate in the context of the FQPA," said Erin Tobin, staff attorney with Earthjustice and author of the group's July 30 comments to EPA. "The concern here is that public health has to be the overriding concern. That's what Congress said with FQPA."

Moreover, "I don't see how that provision applies here," Tobin said of 321(q)(3). "I've never seen it used that way, and I know that EPA certainly didn't take comment on whether this particular statutory provision was relevant."

— Puneet Kollipara