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The Nuances Of 'Nano' In Pesticide Products

Law360, New York (June 30, 2011) -- On June 17, 2011, the U.S. Environmental Protection Agency released a much-anticipated notice describing possible approaches for obtaining information on the potential presence of nanoscale materials in registered pesticide products.

The EPA has repeatedly, and legitimately, expressed its need for information relating to the existence of nanoscale materials in the composition of registered pesticide products where the presence was unknown to the EPA at the time it registered the product. The need is driven in no small measure by concerns expressed by the International Center for Technology Assessment, a not-for-profit environmental group, relating to the inclusion of nanosilver and nanocopper in existing registered pesticide products.

The notice is much anticipated because the EPA's previously expressed option of choice for collecting such information was a controversial interpretation of its authority under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) to require registrants to submit information under Section 6(a)(2), frequently referred to as the FIFRA "adverse effects" reporting provision.

While the notice is well written and reflects solid work on the EPA's part, the agricultural and biocidal chemical community continues to be troubled with the unintended consequences of the use of FIFRA Section 6(a)(2) to obtain information and the inadvertent linking of "nano" material composition in pesticides with affects considered "adverse."

FIFRA Basics

Under FIFRA Section 6(a)(2), pesticide registrants must immediately report certain information to the EPA if that information: (1) is additional; (2) is factual; and (3) regards unreasonable adverse effects on the environment of the pesticide.

Pursuant to 40 C.F.R. Section 159.195, this includes information that, if correct, a registrant knows, or reasonably should know, would be regarded by the EPA, either alone or in conjunction with other information about the pesticide, as raising concerns about the continued registration of a product or about the appropriate terms and conditions of registration of a product.

The EPA clarifies in the notice that the applicability of FIFRA Section 6(a)(2) to collect information about nanoscale materials in pesticides "would not mean that EPA is expanding its interpretation of FIFRA Section 6(a)(2) or changing its regulations." Instead, "EPA would be merely identifying a set of information that

adds to the subset of reportable section 6(a)(2) data explicitly identified at present under the section 6(a)(2) regulations."

The EPA notes that the identification of information as reportable under FIFRA Section 6(a)(2) "does not mean that any particular pesticide or group of pesticides, to which such information pertains, poses a risk," but rather, "merely indicates that EPA has determined that a particular type of information is relevant to, and may improve the Agency's ability to assess, whether the pesticide would cause an unreasonable adverse environmental effect."

The agency defines "nanoscale material" in the notice as "an active or inert ingredient and any component parts thereof intentionally produced to have at least one dimension that measures between approximately 1 and 100 nanometers (nm)."

To address industry's strong push back when the EPA originally announced its Section 6(a)(2) interpretation over a year ago, the agency offers two "approaches" for obtaining the information the EPA believes it needs concerning nanoscale materials in pesticide products.

Under the first approach, the EPA would use FIFRA Section 6(a)(2) to obtain information regarding what nanoscale material is present in a registered pesticide product and its potential effects on humans or the environment. According to the notice, the EPA believes FIFRA Section 6(a)(2) "is the most efficient and expedient administrative approach to obtaining information about nanoscale materials in pesticides and EPA would prefer to use this approach."

Under the second approach, the EPA would obtain such information using a data call-in (DCI) under FIFRA Section 3(c)(2)(B). Under FIFRA Section 3(c)(2)(B), the EPA has authority to issue a DCI notice to a pesticide registrant directing them to provide data "required to maintain in effect an existing registration of a pesticide ..."

The DCI notice is addressed to an individual registrant, specifically identifies the information or data that the registrant must provide, prescribes an initial response deadline of 90 days, and, if data are to be generated, it may prescribe a timeframe for generating and providing that data. Under FIFRA, the EPA can suspend the registration of a pesticide if the registrant fails to respond to a DCI.

The EPA readily acknowledges the concern stakeholders expressed over the use of Section 6(a)(2) for these purposes, explicitly noting the "stigma" the nanotechnology industry could sustain occasioned by the "adverse effects" reporting requirement.

In response, the EPA contends that the agency's "longstanding interpretation" of Section 6(a)(2) is that it is not limited to requiring reporting only of actual "adverse effects" of pesticides, but instead "requires reporting of 'additional factual information regarding unreasonable adverse effects on the environment,' where 'unreasonable adverse effects on the environment' is specifically defined as a risk/benefit standard."

According to the EPA, use of FIFRA Section 6(a)(2) would have only a minimal overall administrative burden for both the EPA and industry. Only registrants who know that their products contain nanoscale materials would be required to report,

and they would be required to report only the information about which they know. Registrants and applicants whose products do not contain nanoscale materials, or who do not know that their products contain nanoscale materials, would have no reporting obligation.

As comforting as these expressions are intended to be, they miss the mark. Section 6(a)(2) has been a fact of life for the pesticide community for years, and is synonymous with adverse effects. The EPA's efforts to rebrand it now as merely a value-neutral "information gathering tool" ring hollow, and certainly will not prevail when such notices are offered up in tort or other legal actions as proof of injury or other claim adverse to the manufacturer, distributer, or user of the pesticide that is the subject of the Section 6(a)(2) notice.

Proposed Policy Regarding Classification of Applications under FIFRA and PRIA for Products Containing Nanoscale Active and Inert Ingredients

The EPA proposes also to apply an initial presumption that active and inert ingredients, that are the nanoscale versions of non-nanoscale active and inert ingredients already present in registered pesticide products, are potentially different from those conventionally sized counterparts.

For purposes of registration under FIFRA and the Pesticide Registration Improvement Act (PRIA), the EPA would initially classify any application for registration of a pesticide product containing an active or inert ingredient that is a nanoscale material as an application for a "new" active or inert ingredient, even when another registered pesticide product contains a non-nanoscale form of the ingredient or a nanoscale form of the ingredient with different size dimensions or other properties.

PRIA is relevant because under PRIA, "new" active ingredients are assessed a substantial fee (typically greater than $500,000) and require many months, if not years, for the EPA to review a registration application for a new active ingredient. Thus if the agency determines a pesticide is "new," the fee and review time are substantial, the imposition of which inspire formidable commercial barriers to commercialization.

Registrants could rebut this initial presumption, however, on a case-by-case basis through the submission of bridging data or other information demonstrating to the EPA's satisfaction that the nanoscale material's properties, which are relevant to assessing the potential risks to human health and the environment, are substantially similar to the properties of the already-registered non-nanoscale or already-registered nanoscale form of the material.

Similarly, registrants could prove that the nanoscale material differs only in ways that do not significantly increase the risk of unreasonable adverse effects on the environment, and that approving the registration in the manner proposed would not significantly increase the risk of any unreasonable adverse effect on the environment.

If an applicant could make this showing to the EPA's satisfaction, then the agency would process the application as a "me-too" application within the timeframes prescribed for such applications. Of course if an applicant could not make this showing, then the EPA would process such products as new active ingredients or

new inert ingredients and would complete its review within the timeframes prescribed for such applications.

Discussion

Long in gestation, the document represents a significant departure — and considerable improvement — over the EPA's initial description of its intended approach to obtain information on nanopesticides. The original approach appeared to focus exclusively on Section 6(a)(2) reporting to obtain information and disallow other available options under FIFRA, all of which were believed by many to be more appropriate, including FIFRA Section 3(c)(2)(B) DCI approach.

The document reflects a more nuanced and thoughtful articulation of what the EPA hopes to achieve. Even with a stated bias in favor of the EPA's original FIFRA Section 6(a)(2) approach, the list of issues and questions about which the EPA invites public comment is an opportunity for the public — industry advocates and public health and environmental advocates alike — to weigh in on the difficult and important substantive issues at hand.

As the pesticide industry vocally urged the DCI approach, among other options, as preferred alternatives to the Section 6(a)(2) approach, the policy document identifies issues that make the DCI alternative less than a straightforward equivalent.

Given the comprehensive discussion of the issues presented, the notice opens the door for the registrant community to educate itself, the EPA, and the public on the state of nanopesticides, what the technology means for the pesticide industry, and what reporting, registration, and other risk management options should apply to address potential risks derivative of nanoscale components of pesticide products, as well as how the benefits of nanopesticides should be identified, communicated and nurtured.

In particular, the discussion of how best to avoid the "stigmatization" of pesticide nano-components as necessarily representing an adverse effect is a clear concession to the manufacturers of pesticides that forcefully raised significant concerns over the EPA's initial assurances about its plans regarding implementing and communicating the Section 6(a)(2) reporting policy.

That said, the EPA's comforting words in the notice are of no real consequence when Section 6(a)(2) notices themselves are the stuff of lawsuits and product deselection strategies. Stakeholders have now been invited to participate in how to approach this difficult issue. FIFRA registrants and other stakeholders are urged to step up, meet the challenge, and comment coherently and cogently on the best way to proceed.

One last point would be to note the possible implications of the PRIA issues mentioned appropriately in the policy document. The PRIA category designation as a new chemical could result in a PRIA fee of more than $500,000, and perhaps more for any nano product declared as new and not "old" (me-too).

The price distinction is obvious, but the underlying point is that policy determinations outside of PRIA, driven by how the EPA articulates a final policy for reporting or to define the parameters of its regulatory vigilance, could have significant and far-reaching impacts on the development of the nanomaterials

industry or the adoption of nanotechnologies in the pesticide industry.

The notice seeks comment on many of the important elements here, even as simply as what PRIA category should apply. The issue here is that more interest in the short term will likely be devoted to the broad issues of data reporting, "stigmatization," and appropriate controls, whereas the biggest impact a few years from now on nanopesticides may be driven by the PRIA fees' imposed derivative of these more visible (and controversial) elements of the public debate today.

Given the breadth and significance of the issues, and the potential complexity, legal vulnerability, and burdens presented by the different options, it is critically important for potentially affected entities to consider carefully the issues and approaches discussed and offer strong and compelling comment of a caliber comparable to the quality and thoughtfulness of the EPA's notice.

It will be important in this regard to recognize that the targets for the comments include both the EPA and other federal agencies, including the Office of Management and Budget, that likely were influential in shaping the contours of the policy. While comments may or may not sway the EPA's views, they will be available for consideration by other agencies during the interagency review process.

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