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April 24, 2023

Mr. Paul Di Salvo
Office of Chemical Safety and Pollution Prevention
Registration Division (7505T)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Re: **Docket ID No: EPA-HQ-OPP-2023-0103-0001 – Modernizing the Approach to the Environmental Agency (EPA) and Food and Drug Administration (FDA) Oversight of Certain Products**

Dear Mr. Di Salvo,

The National Association of State Departments of Agriculture (NASDA) appreciates the opportunity to submit comments on the Environmental Protection Agency's Request for Comments on Modernizing the Approach to the Environmental Protection Agency (EPA) and Food and Drug Administration (FDA) Oversight of Certain Products.

NASDA represents the commissioners, secretaries, and directors of the state departments of agriculture in all 50 states and 4 U.S. territories. State departments of agriculture are responsible for a wide range of programs, including food safety, combating the spread of disease, and fostering the economic vitality of our rural communities. Conservation and environmental protection are also among our chief responsibilities. In 43 states, the state departments of agriculture are co-regulators with EPA and responsible for administering, implementing, and enforcing the production, labeling, distribution, sale, use, and disposal of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Modernizing the Approach to EPA and FDA Regulatory Oversight

NASDA recognizes the challenges that EPA and FDA have faced in the review and oversight of topical pest control products and new animal drugs, particularly as innovative new technologies have emerged. The process for modernizing the regulation of these products is complex. EPA and FDA must engage in a transparent and risk-based process to determine if this modernization process is necessary. A modernization process that is burdensome, lacks clarity, or is otherwise inefficient will likely result in compromised pathways to innovation, reduced product availability, and potential detrimental impacts to both animal and human health.

NASDA is concerned that there has been a lack of adequate time for co-regulators, industry stakeholders, and applicators of these products to engage in a meaningful way given the large-scale regulatory changes being considered. According to the whitepaper, approximately 600 topically administered products for external parasites will be transferred to the FDA. A

regulatory change encompassing such a large volume of products should not occur in a vacuum without robust stakeholder input. Our concerns are further compounded by the lack of inclusion of the USDA Office of Pest Management Policy (OPMP) in the organization of recent listening sessions. This was a significant oversight given the regulatory oversight USDA-OPMP has for a number of biological and biotech products associated with the animal health space. Additionally, Administrator Regan's recent testimony in the House Agriculture Committee, where, when asked about justification for the change in jurisdiction, he stated that "that exact action has not reached my desk". This lack of familiarity with the issues outlined in the whitepaper demonstrates the need for further thoughtful consideration.

NASDA implores the agencies to extend this process before the next steps are developed. This extended process should include addressing questions posed in the initial responses to the whitepaper, allowing the agencies to fully understand all potential challenges before moving forward in a way that disregards critical stakeholder input.

Considerations of Agency Questions

Agency Strengths, Missions, and Expertise

When considering questions posed by the agency, NASDA is concerned that the transfer of the broad suite of animal health products is seen as an appropriate pathway to modernizing regulation. If EPA and FDA do move this process forward, then NASDA recommends a more narrowly targeted approach to ensure that agricultural producers and pesticide applicators do not suffer unintended consequences. Consideration of EPA's in-house experts on agricultural production who assess usage and benefits of pesticide use on animals of agricultural importance under FIFRA should be prioritized when determining appropriate next steps.

NASDA acknowledges that FDA houses significant veterinary experience, ensuring that new animal drugs are safe for the animals given the drug, humans consuming food derived from treated animals, and users administering the drug; and has a robust adverse event reporting system for animal health. However, the most holistic approach to evaluating these products currently resides with the EPA. Particularly in the case of agricultural animals, including bees, the existing infrastructure at the EPA is better suited to account for the wide variety of factors impacting the use of these products. As a part of the regulatory process, the EPA must determine that a product will not cause any unreasonable effects on the environment, including "water, air, land, and all plants, animals, and people living therein." (7 U.S.C. § 136(j), (bb)). This includes the assessment of a wide variety of potential human health and environmental effects associated with the use of the product, including aggregate exposure and environmental fate considerations.

NASDA also urges the agencies to consider the current relationships that the EPA holds with many state departments of agriculture that allow them to engage in cooperative federalism. This existing structure, as well as the financial models that allow for the states to engage in this body of work, plays a critical role in the regulation of these products that do not currently exist at the FDA.

Additional Challenges

As co-regulators with the EPA, NASDA recognizes there are a number of potential challenges that a blanket transfer of jurisdiction will create. We are generally supportive of the second component outlined in the modernized approach in the case of products that are deemed necessary to move to FDA jurisdiction, "…provide a seamless process for the transfer of oversight from EPA to FDA… this component should be designed to be minimally burdensome and not require an FDA approval for products previously regulated by EPA, except in the limited circumstance that products raise serious safety concerns." However, we have questions concerning specific elements of how a transfer may be administered. Our questions follow:

1. How will labeling requirements find alignment through a transition?
    a. As state departments of agriculture often serve as the enforcement branch of pesticide regulation, additional clarity will be critical to ensure state officials have time to educate their staff.
2. What product testing and manufacturing requirements will shift if products are transferred, and how will those necessary changes be communicated to the regulated community?
3. How will the framework for a transition from the EPA to the FDA ensure that products continue to move through the regulatory pipeline?
    a. In the absence of a transparent regulatory framework, we are concerned that product availability will decline, costs to end-use customers will increase, and innovation will be stifled on account of confusing and overly burdensome regulatory requirements.
4. How are the agencies' scope of expertise and legal authority being considered?
    a. FIFRA provides the EPA with broad authority to regulate a wide swath of pesticide risks, including environmental and occupational. Given the priority the Administration has placed on ensuring robust environmental protections, it seems counterproductive that the regulation of products would be transferred to an agency with a different charge.
5. Do the agencies have the necessary resources to make this transition without negatively impacting the veterinarians and consumers that rely on these products to protect their animals?
    a. NASDA is concerned that moving products at this time will result in additional burdens, creating a stall at a time when products intended to protect animal, human, and environmental health are critical to combat rising pest pressures.
6. How will the transfer of products, particularly those used on agricultural animals, impact U.S. producers in international markets?

NASDA also encourages EPA and FDA to consider the unique challenges that a blanket transfer may pose to beekeepers. Bees provide a valuable role in the economy, food security, and agricultural sustainability. NASDA supports scientifically-sound efforts to protect bees from disease, pests, parasites, and pathogens, and recognizes that the FDA likely does not have the existing infrastructure to support the needs of this group.

Stakeholder Communication

Substantial stakeholder communication is critical as the agencies determine how to best modernize their approach to the regulation of topical insecticides. It is important that product developers, consumers, applicators, and particularly state departments of agriculture who have staff with regulatory knowledge and practical experience, are consulted often and thoroughly. The EPA and FDA can communicate more clearly with their stakeholders through formal processes such as public hearings, Federal Register notices, or webinars. The agencies should also prioritize their engagement with other federal agencies with technical expertise such as USDA-OPMP who can assist in gathering stakeholder input.

Conclusions

The process for modernizing the regulation of topical insecticide products that play a critical role in the health and protection of pets and livestock, and indirectly people, by repelling and killing external parasites is complex and requires thoughtful consideration. If a transition or regulatory authority is deemed necessary, we implore the agencies to carefully consider the nuance associated with these products, and how the expertise and missions of the EPA and FDA may differ in their ability to provide holistic regulation of these products. In creating a path forward, an emphasis should be placed on engaging with all impacted stakeholders, prioritizing transparency, and ensuring that innovation is not stifled. As co-regulators, NASDA stands ready to work with the EPA and FDA to ensure safe animals, humans, and environment across the country.

Should you have any questions, please contact Josie Montoney-Crawford, Manager of Public Policy, at josie.montoney-crawford@nasda.org. Thank you for your consideration of our comments on this important topic.

Sincerely,

Ted McKinney
Chief Executive Officer
NASDA