EPA Publishes New Webpage to Answer Frequently Asked Questions on the EPA/FDA Whitepaper on Modernizing Oversight of Products for Animals Regulated as Pesticides or New Animal Drugs

The U.S. Environmental Protection Agency (EPA) and the U.S. Food and Drug Administration (FDA) are publishing new web content to provide an overview of the topics raised during the public comment period and to answer frequently asked questions about EPA and FDA's whitepaper, "A Modern Approach to EPA and FDA Product Oversight."

In February 2023, EPA and FDA released a whitepaper describing approaches for updating the agencies' oversight of various animal products regulated as either pesticides or new animal drugs. It describes challenges with the way EPA and FDA currently regulate these products and highlights the potential benefits of a modernized approach for oversight, particularly the transfer of product oversight for topically administered flea and tick products from EPA to FDA. Any change to regulatory jurisdiction, however, has not been formally proposed or finalized by the agencies. Rather, through the whitepaper, the agencies sought public input on whether to potentially transfer oversight of these products and, if so, how best to do so.

EPA and FDA opened a 60-day public comment period on Feb. 23, 2023. The agencies received over 18,000 comments from environmental organizations, veterinarians, industry, pet and livestock owners, and other members of the public. In addition to the comment period, the agencies also collected stakeholder feedback during a public meeting on March 22, 2023. All comments received during the comment period and the public meeting, are posted in docket EPA-HQ-OPP-2023-0103.

In reviewing the comments, EPA and FDA identified common questions from stakeholders, such as:

- How do EPA and FDA currently regulate products and review animal safety and incident data?
- How could EPA and FDA coordinate more closely on animal health, environmental, and efficacy considerations for these products?
- If products are transferred to FDA, how would products—particularly those used to protect livestock and honeybees—move from EPA to FDA? What would it cost for product manufacturers, how could it impact consumer access to products, and what would the FDA approval process look like?

EPA and FDA also identified some general comments and concerns from stakeholders, including:

- Support for an approach that would enhance animal safety for products used on pets, such as flea and tick products applied to cats and dogs.
- Recognition that FDA has a more robust regulatory infrastructure for regulating products used on or in animals.
- Support for a modernized approach to regulate genetically engineered pest animals used for population control (such as genetically engineered mosquitoes).
- Desire for continued agency transparency and outreach as the modern approach is developed and possibly implemented.

As an initial step, the agencies have published a new website to answer some of the public's most frequently asked questions.

At this time, the agencies do not have a timeline for formalizing any of the approaches discussed in the whitepaper and anticipate that if the agencies implement any such changes, it could take several years to come to fruition. EPA and FDA appreciate the stakeholder engagement received to date and look forward to continuing the conversation.