



CENTER FOR FOOD SAFETY

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Registration Division (7505T)
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Docket: EPA-HQ-OPP-2023-0103

Subject: Comments about the current approach to the oversight of various products regulated as pesticides by EPA or new animal drugs by FDA

To United States Food and Drug Administration (FDA) and United States Environmental Protection Agency (EPA):

The Center for Food Safety submits the following comments on behalf of its over 1 million members and advocates in response to FDA and EPA's requests for comments on their current approach to the oversight of various products regulated as either pesticides by EPA or new animal drugs by FDA.

For more than 25 years, the Center has been following the development of genetic engineering (GE), raising awareness about the environmental and health risks, and the need for more robust government oversight and assessment related to genetically engineered organisms including genetically engineered animals and insects.

1. What do you perceive as the strengths and weaknesses of each agency in regulating these types of products?

EPA does not have enough veterinarians to exercise effective oversight on pesticides that are also animal or insect drugs. FDA however does not have enough experience addressing the environmental problems raised by these drugs/pesticides. Both agencies would do a better job if they could clarify in regulations, guidance documents or MOI which applications each agency would take the lead on, but then have ways to draw on each other's expertise in the approval process.

2. Are there additional or different challenges that EPA and FDA did not identify in the whitepaper?

A general problem is that neither FIFRA or the New Animal Drug regulations require comparing the new products with other products on the market to make some assessment of the need for the product while assessing its risks.

3. How can EPA and FDA communicate with their stakeholders about the regulation of these products in a clearer and more transparent manner?

Both EPA and FDA need to stop allowing exceedingly broad claims of confident business information. They both need to look at the practice of EU countries which do not allow human health effects and environmental effects to be claimed as CBI. New kinds of pesticides/drugs need to be fully described for public comment. One of the applications to the EPA for experimental release of genetically engineered insects in two different states showed consumers only 4 pages of information about the releases of billions of mosquitoes. This kind of secrecy is unnecessary AND undermines the public trust in both the technology and the agency.

4. For regulated entities, how have you historically determined which agency to approach first to bring your product to market?

We are not a regulated agency, but it would be helpful to have USDA scientists involved in this discussion. USDA required more rigorous cage trials for the GE moth than EPA requires for the GE mosquito. Developing standards that all agencies can use would be helpful. Developing practices that model the kind of environments GE insects will be released into and require doing cage trials bit by bit, not allowing huge releases of the GE insects.

5. For consumers, do you know who is regulating the products you use on your animal(s)? If you have a concern or complaint about a specific product, do you know which agency to contact?

For the most part, consumers will go to their veterinarians for some of these products, but miticides for honey bees raise challenges for both agencies as the bees function as an ecological unit in their hives. This ecological trait needs to be better explored by both agencies.

6. How should EPA and FDA modify product oversight to better align with each agency's mission and expertise?

Again, many of these products need the experience of both agencies: EPA for its strong environmental expertise and FDA for its strong animal research veterinarians.

7. What difficulties would you envision if EPA and FDA were to modify product oversight to better align with each agency's mission and expertise, and how could they be mitigated?

EPA needs to develop new regulations that cover its work on GE insects, GE microbes. Using FIFRA to regulate GE insects and bacterially infected insects does not work. They are living, breeding organisms, not new pesticides. Likewise, more and more engineered microbes are being developed. They need their own regulations; they should not be considered new chemicals under TSCA.

FDA has developed extensive guidance documents for GE animals for food and for medicine. These need to be turned into regulations. FDA also needs separate regulations for GE insects/arachnids/etc.

While the US has not yet ratified the Convention on Biological Diversity (CBD) it would be helpful if the US could more rigorously apply the Precautionary Principle that is a part of both the CBD and the Climate Convention to its review of these products being regulated by both EPA and FDA.

Our members are quite concerned about USDA attempts to claim regulatory authority over GE animals. I am attaching comments from some 20,000 of our members.

Thank you for this review of products that overlap EPA and FDA authority. The coordinated framework started by the White House in 1986 has not coordinated work in this area well. We hope that the EPA and the FDA will be able to better coordinate with these steps in a way that allows consumers to support your work.

Sincerely,

Jaydee Hanson
Policy Director

Attachment: Comments from our members supporting FDA oversight of GE animals.

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