

[Clarification of FDA and EPA Jurisdiction Over Mosquito-Related Products \(Guidance\)](#)

Provides nonbinding recommendations for industry and other stakeholders regarding regulatory oversight for mosquito-related products.

Updated last **November 9, 2017**
for the 10/05/2017 guidance.

WHAT IT DOES

The Food and Drug Administration (FDA), in partnership with the Environmental Protection Agency (EPA), issued [guidance](#) (noticed via [82 FR 46500](#)) that provides clarity on regulation of mosquito-related products. Mosquito-related products, defined as articles, including substances, for use in or on mosquitoes, have been gaining increased attention as [mosquito-borne diseases](#), such as the [Zika virus](#), create pressing public health issues.

The FDA is charged with protecting the public health by ensuring that animal drugs are safe and effective ([21 U.S.C. 393\(b\)\(2\)\(B\)](#)). Under the [Federal Food, Drug, and Cosmetic Act](#) (FD&C Act), the FDA is required to protect human health when approving drugs, including “new animal drugs”, for use by humans or other animals. New animal drugs are defined as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals” and “articles (other than food) intended to affect the structure or any function of the body of man or other animals” ([21 U.S.C. 321\(g\)\(1\)](#)).

Under the [Federal Insecticide, Fungicide, and Rodenticide Act](#) (FIFRA), the EPA is charged with protecting human health and the environment by ensuring that registered pesticide products result in no unreasonable adverse effects to man or the environment ([7 U.S.C. 136a\(c\)\(5\)](#)). The definition of “pesticide” under FIFRA purposefully excludes any products that would be considered a “new animal drug” (as defined above) and thus regulated under the FD&C Act.

In short, both the FDA and the EPA regulate products intended for use in or on animals, and both have charges of protecting human health. The two agencies acknowledge that products designed to limit mosquito population may lead to regulatory confusion. Mosquitos are “pests” as defined by FIFRA, suggesting that products limiting their population (i.e., pesticides) would be regulated under FIFRA. However, the FD&C Act may instead have jurisdiction over such products as they are animal drugs used by mosquitos, and any animal drug regulated under the FD&C Act cannot also be regulated by FIFRA. Thus, this guidance intends to clear up confusion over which regulatory framework should apply for mosquito-related products.

Through the guidance, the FDA clarifies that its definition of “new animal drug” in the FD&C Act does not include articles intended to function as pesticides through preventing, destroying, repelling, or mitigating mosquitoes for population control; in other words, the EPA via FIFRA has the exclusive authority to regulate such products. This recommendation reflects recent history in that EPA has routinely registered pesticides aimed to limit mosquito population. As a non-binding recommendation, this clarification does not change the definition of new animal drug in the FD&C Act.

RELEVANT SCIENCE

[Diseases can be transmitted by vectors](#), which are defined as living organisms. These vectors are often blood-sucking insects, such as mosquitoes, that take in viruses or microorganisms from animals and humans when feeding. These vectors carry the viruses or microorganisms and ultimately infect other animals, including humans, at a subsequent feeding. Vector-borne diseases account for more than 17% of all infectious diseases. Mosquitoes, and other vectors, transmit many diseases, including:

- [Malaria](#);

- [West Nile](#);
- [Zika](#);
- [Yellow fever](#); and
- [Dengue](#).

Traditional means of controlling mosquito population through use of chemical insecticides are being [phased out](#) in many countries due to insecticide resistance in the mosquito population. Instead, the use of naturally occurring bacteria that target mosquito larvae, such as [Bti](#) and [Bs](#), has increased. But beyond utilizing these bacteria in pesticides, stakeholders are looking for further ways to prevent resistance. A basic principle in resistance management states that several toxins with different modes of action being used in combination are less prone to resistance. Thus, creation of new pesticides for mosquito population control naturally led to efforts combining two or more modes of action.

One result of such efforts has been investigation of the toxic genes in Bti, Bs, and other mosquitocidal bacteria to create recombinant strains; in other words, to combine parts of the DNA from one mosquitocidal bacterial with another. Typically, this occurs by identifying genes with toxic properties from one bacterium and inserting that gene of interest into the genome of another mosquitocidal bacterium. Many of these attempts lead to unstable or ineffective recombinant strains, but efforts are ongoing to create safe and more effective bacteria to control mosquito population at the larval stage.

Recombinant DNA technology can also be used to create [sterile males](#). Various methods for this aim exist, but they typically include moving a non-native gene that humans use to manipulate the mosquito population into the mosquito genome. For example, in a process called “conditional lethality,” a toxic gene can be introduced that would not allow for growth past the larval stage.

RELEVANT EXPERTS

[Christopher Plowe, MD, MPH, FASTMH](#), Director of Duke Global Health Institute. Dr. Plowe is a malariologist and has a wide body of work establishing the molecular epidemiology of drug-resistant and vaccine-resistant malaria.

“Mosquito-related approaches to malaria elimination have some real promise, and it is essential to address the regulatory and social aspects of where and how they can be deployed very early in the development process.”

BACKGROUND

[Major outbreaks](#) of dengue, malaria, and Zika have afflicted populations since 2014, causing an increased interest in mosquito vector control. This guidance may be particularly useful for industry stakeholders who are developing mosquito-related products due to the recent breakouts of mosquito-borne illnesses.

Based off the clarification in the guidance, the FDA provides examples of new animal drugs regulated by the FDA under the FD&C Act:

- Products intended to reduce the virus or pathogen load within a mosquito; and
- Products intended to prevent mosquito-borne disease in humans or animals.

The FDA likewise provides an example of products regulated by the EPA under FIFRA:

- Products intended to reduce mosquito population, such as by killing them during the life cycle or interfering with reproduction or development. The guidance points out that this example includes mosquito control products involving [recombinant DNA technology](#).

ENDORSEMENTS & OPPOSITION

Endorsement

- Bergeson & Campbell PC, [regulatory development commentary](#), October 5, 2017: “The Guidance is a welcome addition to the growing body of work generated by federal agencies intended to assist stakeholders in sorting out the challenging jurisdictional issues that often arise in the context of procuring federal agency approval of products of biotechnology and synthetic biology.”

Opposition

- At present, there has not been any publicly reported opposition to this action.

STATUS

As a guidance document, this policy has no legal power and it does not create any enforceable requirements on agencies or the public. Individuals wishing to market a product designed to limit mosquito population still have a legal requirement to receive some form of governmental approval; this guidance recommends that such individuals submit those products under the FIFRA framework. Further Congressional or regulatory action would be necessary to legally establish these recommendations.

RELATED POLICIES

- [S 849](#) & [HR 1310](#) (115th Congress), “Strengthening Mosquito Abatement for Safety and Health Act” originally co-sponsored by Senators Richard Burr (R-NC), Bill Nelson (D-FL), and Marco Rubio (R-FL), currently passed the Senate and introduced in the House, amends the Public Health Service Act to expand the grant program for the Centers for Disease Control and Prevention for mosquito control programs;
- [California S 382](#) (2017–2018 Regular Session), “Pest control: mosquito abatement” introduced by Senator Richard Pan (D), currently pending in the Senate Appropriations Committee, creates the California Mosquito Surveillance and Research Program Account to fund surveillance and research on mosquitoes;
- Hawaii has introduced several bills on mosquito elimination that have all failed, most recently [Hawaii HR 57](#) (29th Legislature); and
- [Massachusetts HR 400](#) (190th General Court), “An Act relative to the Mosquito Borne Disease Control Board” introduced by Representative Thomas J Calter and currently pending, specifies members that will constitute the mosquito-borne disease control board. It also specifies that “[t]he board shall regulate and oversee all disease vector mosquito and related nuisance organism management activities in the commonwealth.”

POLICY HISTORY

Before 1975, both the FDA and EPA had authority to regulate substances that controlled mosquito population when the substance met the definition of both new animal drug and pesticide. In 1975, Congress amended FIFRA’s definition of pesticide to exclude new animal drugs. Since 1975, the EPA has registered pesticides that act to control the population by killing them or interfering with reproduction.

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RECOMMENDED CITATION

Duke SciPol, “Clarification of FDA and EPA Jurisdiction Over Mosquito-Related Products” available at <http://scipol.duke.edu/content/clarification-fda-and-epa-jurisdiction-over-mosquito-related-products-guidance> (11/09/2017).

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