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28 July 2020

AMCA REQUEST FOR INTERPRETATION

BACKGROUND

Mosquitoes are a vector for all sorts of deadly diseases for humans as well as animals. A tremendous amount of effort from chemical companies, private operators, and government entities is expended toward controlling mosquitoes. Traditional mosquito control uses a range of control strategies to limit adult mosquito abundance and disease transmission including the application of EPA-registered mosquito adulticides and larvicides. Biological or biorational methods of mosquito control using bacteria or mosquito predators is also common. Recently there is renewed interest in the use of adult mosquitoes that have been altered to either be sterile or reproductively incompatible with wild populations. This technique requires dispensing live sterile male mosquitoes into the target area on a regular basis over long periods of time to suppress reproduction. In agriculture, unaltered live insects are commonly aerially released in biological control programs to disrupt pest populations, usually through predation. In mosquito control, the goal of live male mosquito releases is generally to disrupt reproduction. There are two different approaches currently in use to prepare the live mosquitoes that will be released: 1) Sterile Insect Technique (SIT) where irradiation or genetic modification is used to make the mosquitoes sterile, and 2) Incompatible Insect Technique (IIT) which uses a bacteria called *Wolbachia* to make the mosquitoes reproductively incompatible with wild-type mosquitoes. SIT mosquitoes using irradiation have been used for decades and are generally treated, from a regulatory perspective, like any other live insect. Using IIT mosquitoes infected with *Wolbachia* is a more recent methodology with accompanying technology that has been subject to the US EPA regulatory process. The result is that some *Wolbachia*-infected live mosquitoes have become or are in the process of becoming registered with the US EPA as products, similar to a pesticide, which brings into question whether or not they are simply live insects or must be considered a “pesticide.”

CASE STUDY

In October 2022, the U.S. Fish and Wildlife Service and the State of Hawai’i proposed using the Incompatible Insect Technique (IIT) to reduce

mosquito populations within forest reserves, state parks, and private lands on the Hawai'ian islands of Maui and Kaua'i, with eventual expansion across the state. In response to this, the Birds, Not Mosquitoes (https://www.birdsnotmosquitoes.org/native-forest-birds-1) project is working to suppress mosquitoes known to transmit diseases to native forest birds in critical higher-elevation native forest habitat by aerially releasing male mosquitoes from a UAS platform. The goal is to protect Hawai'i's forest birds from extinction due to avian malaria transmitted by non-native mosquitoes that have decimated native forest bird populations, as a single bite from an infected mosquito can be deadly. Of Hawai'i's 50 native honeycreepers, most are now extinct with only 15 species remaining in the main Hawai'ian islands. Many of them are listed under the Endangered Species Act as threatened or endangered and some are nearing extinction. This important and high-profile project requires a clear understanding of FAA regulations for their UAS operations for them to ensure that they are in full compliance.

THE LAW

Part 137 applies when agricultural aircraft operations happen. "Agricultural aircraft operation means the operation of an aircraft for the *purpose* of (1) dispensing *any economic poison*, (2) dispensing *any other substance intended* for plant nourishment, soil treatment, propagation of plant life, or *pest control*, or (3) engaging in dispensing activities *directly affecting* agriculture, horticulture, or forest preservation, but not including the dispensing of live insects." 14 CFR 137.3 (emphasis added).

"Economic poison means (1) *any substance or mixture of substances intended* for preventing, destroying, repelling, or mitigating *any insects*, rodents, nematodes, fungi, weeds, and other forms of plant or animal life or viruses, except viruses on or in living man or other animals, which the Secretary of Agriculture shall declare to be a pest[.]" 14 CFR 137.3 (emphasis added).

When Part 137 was originally created (1965), the Secretary of Agriculture was designated as the office declaring things to be pests. This made sense in 1965 since the USDA administered the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). "In 1970, with the formation of [Environmental Protection Agency] EPA, responsibility for administering FIFRA transferred from USDA to EPA"[2]. The EPA has declared mosquitoes as pests of significant public health importance[3].

THE ISSUES

I. All three categories or just the last one?

"Agricultural aircraft operation means the operation of an aircraft for the purpose of (1) dispensing any economic poison, (2) dispensing any other substance intended for plant nourishment, soil treatment, propagation of plant life, or pest control, or (3) engaging in dispensing activities directly affecting agriculture, horticulture, or forest preservation, but not including the dispensing of live insects." 14 CFR 137.3

It is unclear whether the live insect exemption applies to all three dispensing activities or just the last activity. This becomes important if the insects fit the definition of an economic poison.

II. Is a Wolbachia-infected mosquito an economic poison?

"Economic poison means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any insects[.]" 14 CFR 137.3.

Two IIT live mosquito products registered as biopesticides are Zap Males, EPA Reg. No. 89668-4, (Section 3 registration), and DBQ Males, EPA File Symbol 23HI01 (Section 18 label). Questions as to whether they constitute an "economic poison" have arisen because of the wording approved for the EPA labels. The labels specify the *Wolbachia* bacteria as the active ingredient and the mosquitoes as other ingredients, implying a "mixture" (though the bacteria is natural and already present in >50% of all insect species, including in many of the targeted wild mosquitoes).

We argue that live mosquitoes, and live endosymbiotic bacteria inside the mosquitoes, are not substances; therefore, they could never be considered economic poisons since "Economic poison" means (1) any substance or mixture of substances"[.]

III. Does biodegradable media trigger 137?

Some insect release programs release the insects directly into the air, but some live insects can be released inside media designed for transport and delivery. The IIT mosquitoes are sometimes packaged inside small biodegradable paper mache pods to protect their delicate bodies as they fall and contact the substrate.

Other beneficial insect programs outside of the mosquito control context have wrestled with this issue. For example, the green lacewing is a beneficial predatory insect for which broadcast applications may be done via aircraft to control common insect pests. Green lacewing larva are added to rice hulls or vermiculite as an aerial disbursement carrier along with a food source to sustain the developing insect.

Other insects are dispensed in media such as buckwheat, saw dust, leaves, or sticks because there needs to be some mass to transport the tiny insects to the intended treatment area, to prevent the insects from drying out, and/or it's the media they were raised in and it's just more practical to drop the inert media rather than sort out all of the insects.

14 CFR 137.3 says, "operation of an aircraft for the *purpose* of . . . (3) engaging in dispensing activities directly *affecting* agriculture, horticulture, or forest preservation, but not including the dispensing of live insects." (emphasis added).

We argue dropping biodegradable carrier media does not trigger Part 137 because (1) the *purpose* of the flight is to dispense live insects not for directly affecting agriculture, horticulture, or forest preservation and (2) the actual biodegradable material dispensed is *de minimis* and not to the level of affecting agriculture, horticulture, or forest preservation.

IV. Are Wolbachia bacteria and a biodegradable pod "other substances" triggering 137?

"Agricultural aircraft operation means the operation of an aircraft for the *purpose* of . . . (2) dispensing any *other substance intended* for plant nourishment, soil treatment, propagation of plant life, or pest control[.]" 14 CFR 137.3 (emphasis added).

There are questions as to whether the biodegradable paper pods and *Wolbachia* bacteria constitute "other substances" and would be captured under dispensing category 2.

We argue a live insect carrying bacteria it might otherwise have naturally within its body is not a substance. A biodegradable media could be argued to be a substance, but the *intent* of dropping the insects within biodegradable media is for insect protection, insect nutritional sustenance, resisting wind/turbulence while dropping the insects to their intended location, and/or the practicality of securing and organizing the insects for management operations. Therefore, without intent, Part 137 is not triggered.

V. Does naturally occurring bacteria or viruses in or on insects change the "live insects exception?"

Wolbachia is a bacterium that lives naturally in many species of insects, particularly in both wild and IIT mosquitoes. For example, in areas within Hawaii where IIT mosquitoes will be beneficial, the same species of mosquito and Wolbachia strain are already present in the wild. Anything inside or on the mosquito that is naturally occurring should be encompassed within the "live insects" exception. Otherwise, the live insects exception is meaningless as insects can naturally carry all sorts of bacteria and viruses inside and outside their bodies.

We argue that if the insect is alive, the dispensing of the live insects would not be captured by Part 137.

Questions

Question 1. Is the live insect exemption (", not including the dispensing of live insects.") referring to all three dispensing categories or to just the activities that fall into the last category?

Question 2. Are bacteria considered a "substance?"

Question 3. Is dispensing of live insects with bacteria inside their bodies considered an agricultural aircraft operation?

Question 4. Does the live insects having an EPA pesticide label change the answer for the scenario in question 3?

Question 5. Is dispensing of live insects inside a biodegradable paper mache pod into a forest considered an agricultural aircraft operation?

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[1] https://www.federalregister.gov/documents/2022/12/15/2022-27220/dqb-males-wolbachia-pipientis-dqb-strain-contained-in-live-adult-culex-quinquefasciatus-males

[2] https://www.epa.gov/enforcement/federal-insecticide-fungicide-and-rodenticide-act-fifra-and-federal-facilities#Basics%20of%20FIFRA

[3] https://www.regulations.gov/document/EPA-HQ-OPP-2020-0260-0017

Questions with Suggested Answers

To aid in responding, we have drafted suggested answers to the five questions presented.

Question 1. Is the live insect exemption ("..., not including the dispensing of live insects.") referring to all three dispensing categories or to just the activities that fall into the last category?

> Due to how the text is drafted, it could be read two different ways. At this moment, the FAA interprets that the live insect exception refers to all three categories. In the future, if this interpretation presents unforeseen safety issues, the FAA may narrow this interpretation.

Question 2. Are bacteria considered a "substance?"

> No, a substance is something that is not alive. Anything that is alive (bacteria, viruses, insects, animals, etc.) cannot be considered a substance.

Question 3. Is dispensing of live insects with bacteria inside their bodies considered an agricultural aircraft operation?

> No.

Question 4. Does the live insects having an EPA pesticide label change the answer for the scenario in question 3?

> No. The economic poison category refers to "substances" that are economic poisons. Live insects are not substances triggering Part 137 applicability.

Question 5. Is dispensing of live insects inside a biodegradable paper mache pod into a forest considered an agricultural aircraft operation?

> As long as the purpose of the flight is to do something else other than affecting agriculture, horticulture, or forest preservation, even though the dispensing or what is being dispensed may have an indirect or secondary effect on agriculture, horticulture, or forest preservation, Part 137 is not applicable. The FAA cautions pilots to not creatively repurpose the flight so as to get out from Part 137 safety regulations. If in the future the FAA determines this is being abused, the FAA may rescind this interpretation.
>
> If the biodegradable material is of *de minimis* amount and does not affect agriculture, horticulture, or forest preservation, Part 137 is not applicable. In the future, if this interpretation presents unforeseen issues, the FAA may narrow this interpretation.