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EPA Registers New Active Ingredient Fluazaindolizine

The U.S. Environmental Protection Agency (EPA) is registering fluazaindolizine, a new pesticide active ingredient for agricultural use. Fluazaindolizine can be used to control nematodes (also known as roundworms) on vegetables such as carrots, squash, tomatoes, eggplant, potatoes and taro, and on some fruits, including oranges, peaches, almonds, and grapes.

EPA expects fluazaindolizine will help delay the further development of nematicide resistance. Nematode pests are important to control because they can cause damage to the quality and quantity of crops. According to the U.S. Department of Agriculture (USDA), nematodes are estimated to cause at least $10 billion in crop damage annually in the United States.

In addition to the registration decision, EPA has finalized the biological evaluation for fluazaindolizine under the Endangered Species Act (ESA). This action furthers the goals outlined in EPA's April 2022 ESA Workplan by identifying potential effects to listed species, implementing necessary mitigation, and initiating the ESA consultation process with the U.S. Fish and Wildlife Service prior to registration.

EPA's Human Health and Ecological Risk Assessments

Prior to this registration decision, EPA assessed whether exposures to these products would cause unreasonable adverse effects to human health and the environment, as required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).

Based on EPA's human health risk assessment, there are no human health risk concerns from the uses of fluazaindolizine. However, EPA's ecological risk

assessment identified risks of concern for mammals and honeybees near use sites. These risks will be mitigated with measures such as soil incorporation (mixing the pesticide into the soil) and restrictions that limit pesticide spray drift.

EPA's Final ESA Biological Evaluation

The Agency evaluated the effects of the registration on listed species and critical habitats. EPA's final effects determination found that fluazaindolizine is likely to adversely affect (LAA) 18 listed species and three critical habitats.

An LAA determination means that EPA reasonably expects that at least one individual animal or plant, among a variety of listed species, may be exposed to fluazaindolizine at a sufficient level to have an adverse effect. This is the case even if a listed species is almost recovered to a point where it may no longer need to be listed. The likely "take," which includes unintentional harm or death, of even one individual of a listed species, is enough to trigger such a determination. As a result, there are often a high number of LAA determinations. An LAA determination, however, does not necessarily mean that a pesticide is putting a species in jeopardy.

EPA further refined its analysis for the species and critical habitats where it made LAA determinations to predict the likelihood that fluazaindolizine use could lead to a future jeopardy finding for certain listed species or adverse modification finding for critical habitats. These predictions examine effects of fluazaindolizine at the species scale (as opposed to one individual of a species). EPA's draft biological evaluation predicted that, without additional mitigation, the proposed uses of fluazaindolizine would present a likelihood of jeopardy for one listed plant species, the Kern Mallow. EPA predicted no likelihood of adverse modification to critical habitats.

Given EPA's initial prediction for the Kern Mallow plant, EPA developed geographically specific pesticide use limitations. In areas within the four counties in southern California where Kern Mallow is known to occur, users cannot use micro-sprinklers to apply the pesticide on non-bearing orchard crops. This includes citrus trees (e.g., oranges, lemons, limes), stone fruit trees (e.g., peaches, plums, apricots), and nut trees (e.g., hazelnuts, almonds, walnuts) that are not yet bearing fruit or nuts. As directed on the label, users must check the Bulletins Live Two! website to identify whether these restrictions apply to their geographic area. With these mitigations in place, EPA's final biological evaluation predicts the use of fluazaindolizine will not present a likelihood of jeopardy to the Kern Mallow.

Next Steps

Since EPA's final biological evaluation found that fluazaindolizine is likely to adversely affect some listed species and critical habitats under the jurisdiction of the Fish and Wildlife Service (FWS), EPA has initiated formal consultation and shared its findings

with FWS.

During formal consultation, FWS uses the information in EPA's final biological evaluation (i.e., the final effects determination, predictions of the likelihood of jeopardy/adverse modification, and EPA's mitigations to avoid jeopardy and minimize take) to inform their biological opinions. While EPA has made predictions about the likelihood of jeopardy and adverse modification as part of its biological evaluation, FWS is responsible for making the final jeopardy/adverse modification findings and have the sole authority to do so. If FWS determines in its final biological opinions that additional mitigations are necessary to address any jeopardy or adverse modification determination or to address any incidental take, then EPA will work with the registrant to ensure that any necessary registration or labeling changes are made.

The registration decision and final biological evaluation are available in docket EPA-HQ-OPP-2020-0065 at www.regulations.gov.