UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: **Section 18 - Specific Exemption** for Use of Clothianidin on Immature Citrus Trees for Control of Asian Citrus Psyllid to Manage Transmission of Huanglongbing Disease in Florida (22FL01)

FROM: Marietta Echeverria, Acting Director
Registration Division

TO: Ed Messina Esq., Director
Office of Pesticide Programs

I. APPLICANT REQUEST

Applicant: Florida Department of Agriculture and Consumer Services

Chemical: Clothianidin (CAS No. 210880-92-5)

Product: Belay® Insecticide (EPA Reg. No. 59639-150) manufactured by Valent U.S.A. Corporation

Site: Immature (young) Citrus Trees

Pest: Asian Citrus Psyllid, a vector for Huanglongbing Disease

Rate: Belay Insecticide® may be applied via soil drench at a single maximum application rate of 0.2 lb a.i./A (12.0 fl oz per acre) to immature citrus trees (3 to 5 years old), with a maximum of 0.4 lb a.i./A (24.0 fl oz per acre) per 12-month period regardless of tree size, tree count per acre or application method.

Restrictions:

Acreage: 125,376 acres of immature citrus trees

Use Season: October 15, 2022 through October 15, 2023

II. BACKGROUND

According to the Florida Department of Agriculture and Consumer Services (FDACS), citrus growers have an urgent and critical need for clothianidin, (Belay® Insecticide, EPA Reg. No. 59639-150), a season-long tool to manage the transmission of Huanglongbing (HLB) disease caused by the Asian citrus psyllid (ACP) in immature citrus trees. In 2005, HLB (also known as citrus greening disease) was first identified in Florida. The disease is caused by the pathogen *Candidatus Liberibacter Asiaticus* and is spread by ACP, an invasive pest first discovered in Florida in 1998. HLB is considered the most serious disease of citrus worldwide and has greatly limited commercial production of citrus in countries where it is present. Since its discovery in Florida, this disease has spread rapidly and extensively throughout all commercial citrus production areas in the state.

Approximately 90% of Florida citrus harvest is processed for juice. With the rapid decline of HLB-infected mature trees and falling yields, Florida's citrus is nearing a critical point where the supplies of fruit may become inadequate to sustain the U.S juice-processing infrastructure. Economic analysis shows that losing as few as five percent of young citrus trees currently planted in the ground to HLB will result in lost viability of long-term production. The applicant asserts that the only mechanism presently available to prevent HLB disease transmission to young trees is the soil-application of neonicotinoid insecticides at a frequency adequate to ensure protection from infected ACP. A unique attribute of soil applied neonicotinoid insecticides (clothianidin, imidacloprid, and thiamethoxam) is their ability to deter the feeding behavior of the psyllid vector, preventing its ability to inject HLB bacteria into the host tree tissue. The systemic protection provided by soil application of neonicotinoids lasts longer and is superior to that provided by foliar applied neonicotinoids.

FDACS states the trees that would be treated with clothianidin under the emergency exemption (3 to 5 year-old trees, 5 to 9 feet tall) can be expected to reach production levels that would approximate the level of yields in young trees prior to introduction of the pest and diseases (approximately 2 to 3 boxes of fruit per tree). Without the protection afforded by the use of clothianidin, the trees will not reach market maturity before succumbing to the symptoms of HLB disease, resulting in the complete loss of any productive value. The only manner known at this time to assure tree life and viability of the industry is by sustaining protection of young trees with the use of clothianidin.

Progress Toward Registration: This is the first year that a request for use of clothianidin to manage Asian citrus psyllids on immature citrus trees has been requested under section 18 of FIFRA. At this time, progress toward registration is adequate. On the advice of Office of General Counsel, EPA has placed a hold on all new Section 3 uses of clothianidin, which includes the section 18 use on citrus, while the Agency is responding to a lawsuit from the Center for Food Safety and other Non-Governmental Organizations as it relates to clothianidin use and imminent risks to bees.

Crisis Exemption: On April 8, 2014, the FDACS authorized a crisis exemption for use of clothianidin on immature citrus trees to manage transmission of Huanglongbing disease caused by Asian Citrus Psyllid. In addition, FDACS had submitted a specific exemption request which allows the use to continue beyond the 15 days allowed under a crisis exemption because the use is needed until October 31, 2014.

Special Review/Reregistration: Clothianidin is not currently under registration review.

Notice of Receipt/Public Comment: A notice of receipt published in the Federal Register on May 21, 2014 (79 FR 29185) FRL-9909-94) with the public comment period closing on May 28, 2014 since this request is for use of a neonicotinoid. There were no significant comments received. Only one comment was received from a private citizen who opposed granting the exemption. The comment was not clothianidin specific but part of a group denial of pesticides that were banned 25 years ago.

III. EPA EVALUATIONS

BIOLOGICAL AND ECONOMIC ANALYSIS: The Biological and Economic Analysis Division (BEAD) reviewed Florida's emergency exemption request and determined that there are no effective available alternatives for season long protection of 3 to 5 year old citrus trees in Florida and that infestations of Asian citrus psyllid (ACP) are likely to result in yield/quality losses in excess of 20%, even with the use of currently registered insecticides. BEAD concludes that the current situation is urgent and non-routine and that citrus growers in Florida are likely to experience significant economic losses due to ACP transmission of huanglongbing (HLB).

***Biological Analysis*:** The Asian citrus psyllid, *Diaphorina citri*, is a tiny mottled brown insect, about the size of an aphid, which poses a serious threat to citrus trees. The psyllid feeds on all varieties of citrus (e.g., oranges, grapefruit, lemons, and mandarins) and damages citrus directly by feeding on new leaf growth (aka flush). Feeding on the new leaf growth twists and curls young leaves and kills or burns back new shoots. The degree of damage to young citrus trees is substantial. According to FDCAS, the insect is a vector of the bacterium *Candidatus Liberibacter asiaticus*, associated with the fatal citrus disease huanglongbing, also called citrus greening disease. The psyllid takes the bacteria into its body when it feeds on bacteria-infected plants. The disease spreads when a bacteria-carrying psyllid flies to a healthy plant and injects bacteria into it as it feeds.

Further, according to University of California researchers, HLB can kill a citrus tree in as little as five years, and there is no known remedy. The only way to protect trees is to prevent the spread of the HLB pathogen in the first place, by controlling psyllid populations and removing and destroying any infected trees.

***Economic Analysis*:** [SEQ CHAPTER \h \r 1][SEQ CHAPTER \h \r 1] For the analysis of an emergency exemption request, BEAD compares the losses to growers from the non-routine situation to the returns in a normal year. BEAD determines whether the loss from the non-routine situation meet the standard of a significant economic loss using a tiered approach. Tier 1 considers only yield loss, the most common source of loss for emergency exemption requests. For Tier 1, a yield loss of 20% or more qualifies as a significant economic loss. This situation reaches the threshold for a significant economic loss.

BEAD concludes that growers currently have no viable options for season long management of outbreaks of the ACP in young bearing trees. With other available treatments, the potential yield loss for infected young bearing trees is 100%, because the disease causes the complete loss of the tree before it reaches market maturity.

HEALTH EFFECTS RISK ASSESSMENT: The Health Effects Division (HED) conducted an exposure and risk assessment for the proposed emergency use of the insecticide clothianidin via soil drench on young citrus trees in Florida. To support the proposed section 18 use, HED completed a new acute dietary assessment. There are no human health risk issues that would preclude granting the requested emergency exemption or establishing a temporary tolerance of 0.04 ppm on citrus.

Human Health Risk: In 2012, HED conducted an assessment for the section 3 use of clothianidin on citrus. The citrus uses in that risk assessment include similar soil applications to that proposed in the emergency exemption request from Florida. A recommendation for establishing a tolerance for residues in/on citrus at 0.6 ppm was made; however, the use on citrus has not been registered and the associated citrus tolerance has not yet been established. The time-limited tolerance required to support the section 18 use on citrus is 0.04 ppm (a much lower tolerance than the section 3 use on citrus, 0.6 ppm, which is driven by foliar uses). The higher application rates and concentrations associated with the pending section 3 use were used to evaluate dietary risks so that exposure and risk were not underestimated in the event those same uses were registered.

The acute and chronic assessments for clothianidin are both based on the screening-level input assumptions, including tolerance-level residues, 100% crop treated, and high-end estimates of residues in drinking water. These inputs resulted in risk estimates that are, at most, 28% of the population-adjusted dose for all population subgroups for both the acute and chronic assessments; the maximum risk estimate is for children 1-2 years of age. All dietary risk estimates are below HED's level of concern.

There are no new residential exposures as a result of the proposed section 18 use on citrus in Florida. However, existing uses of clothianidin on turf, ornamental plants, and/or indoor surfaces may result in human exposure in a residential setting.

For clothianidin, residential handler risk estimates are considered to be of potential concern when the dermal MOE is less than 100, the inhalation MOE is less than 1000, and/or the aggregate risk index (ARI), reflecting combined dermal and inhalation exposure, is less than one. The residential handler risk estimates are not of concern (ARIs range from 11 to 990).

The most recent aggregate risk assessment for clothianidin showed no risks of concern for any population subgroup. Since this use is restricted to citrus trees and the use does not result in residues of clothianidin in chronic drinking water greater than those already assessed, there are no concerns regarding chronic dietary exposure.

In addition, residues resulting from soil drench applications were significantly (10-100 times) lower than residues resulting from foliar uses, which were used in evaluating the citrus tolerance and for evaluating the dietary exposure and risk. Acute and chronic aggregate risk estimates are equivalent to the acute and chronic dietary risk estimates which are not of concern.

***Occupational Risk*:** The previously evaluated occupational exposure and risk assessment associated with soil application uses on citrus is similar to the proposed section 18 use. All occupational handler scenarios resulted in risk estimates equal to MOEs ranging from 5.4 (resulting from mechanically pressurized handgun) to 660 (resulting from mixing/loading for airblast) and are not of concern. The post-application dermal exposure and risk resulting from foliar applications of clothianidin on citrus fruit, which are considered to be a worst-case scenario resulted in a post-application dermal MOE of 22,000, which is significantly greater than HED's level of concern (LOC) of 100, and is not of concern. Further, post-application dermal exposures resulting from soil-directed applications of clothianidin on citrus were not assessed quantitatively due to the lack of representative unit exposure values. However, dermal post-application exposure for workers from the use of soil drench treatments is expected to be much lower than those associated with post-application exposure resulting from foliar uses. Post-application exposure from fruit harvesting is considered protective of potential exposure following soil drench treatment, and is not of concern.

ENVIRONMENTAL FATE EFFECTS ASSESSMENT: The Environmental Fate and Effects Division (EFED) concluded that the proposed use pattern is consistent with other currently registered soil application rates on brassica, cucurbit and fruiting and leafy vegetables uses of clothianidin. The application method, soil drench, was assumed to result in no spray drift. Based on the available data clothianidin is moderately toxic on an acute basis to birds and mammals and practically non-toxic to birds on a subacute dietary basis. There are potential risk concerns for aquatic invertebrates, small birds, small and medium sized mammals and beneficial terrestrial invertebrates.

Clothianidin is highly toxic to honey bees (*Apis mellifera*) on both an acute contact and oral exposure basis, and bees may be exposed to residues resulting from residues translocated in the plant to pollen and nectar. This ecological assessment attempted to quantify the risks to honeybees based on both modeled concentrations and empirical data.

Potential risk from the proposed use on citrus to Federally-listed threatened/endangered species (hereafter referred to as "listed" species) and non-listed species are as follows:

- Acute listed species and chronic levels of concern (LOCs) were exceeded for freshwater invertebrates who reside in the water columns.
- The proposed use pose acute risk to listed species of small birds feeding on short grass and broadleaf plants, acute risk to small and medium mammals feeding on short grass and chronic risk to all size classes of mammals feeding on short grass, small and medium sized mammals feeding on broadleaf plants and small mammals feeding on tall grass.
- The proposed use also poses risk to nonlisted and listed species of beneficial terrestrial invertebrates.

Clothianidin use on citrus (based on estimated maximum application rates, exposure levels and available effects data) may lead to direct adverse effects on listed freshwater invertebrates residing in the water column from acute and chronic exposures, direct adverse effects on listed birds and mammals from acute and chronic dose-based exposure, and direct adverse effects on listed insect pollinators feeding on citrus nectar and pollen. There is a potential for indirect effects to listed animal and plant taxa that depend on those taxa directly at risk when exposed to clothianidin as pollinators or seed dispersers, mammal or reptile burrows for habitat, feeding, or cover requirements, and for survival, growth, or reproduction.

Applicant's Endangered Species and Pollinator Discussion

The applicant states that impacts to federally listed species are not expected from this use under the emergency exemption program. The Schaus swallowtail butterfly is located near Biscayne National Park, a considerable distance from any commercial citrus. In addition, the Florida leafwig and Bartram's hairstreak are located in the Everglades National Park and Big Pine Key and both areas are outside of commercial citrus production.

FDACS reviewed the potential for risks to pollinators. The product label carries a restriction prohibiting clothianidin from being applied to blooming, pollen-shedding, or nectar-producing parts of plants since residues are toxic to bees during application and up to 5 days following treatment. FDACS has repeated this language on the section 18 use directions, to stress to users that this restriction must be adhered to under section 18 use, as required. FDACS asserts direct spray exposure to pollinators is not expected since applications are controlled and targeted only to the soil at the base of the tree and FDACS believes that consumption of nectar (citrus is not a preferred pollen source) is the primary source of exposure to honey bees. Further, FDACS has developed an online mapping tool for beekeepers to register the approximate location of hives near citrus and facilitate communication between beekeepers and growers. The mapping tool includes the location of citrus groves planted in the past 5 years, which may assist beekeepers who use the tool to avoid use sites covered under this exemption program. The section 18 use directions carry information to access the website for this tool and advise growers to cooperate with FDACS to help communicate with local bee keepers.

I recommend that the Florida Department of Agriculture and Consumer Services (FDACS) be granted a specific exemption for the use of clothianidin on immature citrus trees to manage the transmission of Huanglongbing (HLB) disease caused by the Asian citrus psyllid (ACP). This recommendation is based on the following:

1. BEAD reviewed FDACS's emergency request and determined that the recent introduction and rapid spread of ACP and HLB make this an urgent non-routine situation. BEAD concludes that there are no effective available alternatives for season long protection of 3-5 year old citrus trees and that citrus growers in are likely to experience significant economic losses due to HLB.

2. HED concluded that there are no human health risk issues associated with the proposed use on citrus in connection with this emergency exemption program. The toxicological, residue chemistry, dietary-exposure, and occupational/residential exposure assessments are adequate to support a time-limited tolerance for residues of clothianidin of 0.04 ppm in/on citrus. In their review of the proposed use pattern, HED requested that an amended section 18 label include a PHI of 1-day for citrus, which is reflected in the citrus field trial data submitted in support of the application.

3. EFED reviewed the emergency exemption and concluded that the maximum proposed single application rate on citrus (bearing and non-bearing trees less than five years old) is similar to the maximum single application rate of other currently registered soil application rates on brassica, cucurbit and fruiting and leafy vegetables. Based on estimated maximum application rates, exposure levels, and available effects data, clothianidin use on citrus in Florida may lead to listed and non-listed species effects on freshwater and estuarine/marine invertebrates, birds, mammals and beneficial terrestrial invertebrates from acute and chronic exposures. However, it is unlikely there will be increased exposure or new species impacted from the proposed section 18 use on citrus than currently may exist from already registered uses of clothianidin. EFED has not proposed additional mitigation measures in connection with this section 18 outside of those already addressed on the section 3 label to address honeybee pollinators and environmental hazards to protect aquatic invertebrates.

4. This is the first year that a request for use of clothianidin to manage Asian citrus psyllids on immature citrus trees has been requested under section 18 of FIFRA. At this time, progress toward registration is adequate. On the advice of Office of General Counsel, EPA has placed a hold on all new Section 3 uses of clothianidin, which includes the section 18 use on citrus, while the Agency is responding to a lawsuit from the Center for Food Safety and other Non-Governmental Organizations as it relates to clothianidin use and imminent risks to bees.

_____

Jack E. Housenger, Director
Office of Pesticide Programs

Date: _____