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DEPARTMENT OF AGRICULTURE
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U.S. EPA Office of Pesticide Programs (7505P)
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RE: Emergency exemption for the use of hop beta acids (HopGuard) in honey bee colonies to control Varroa mites in Idaho, Oregon and Washington.

Section 18 of the amended FIFRA provides the Administrator may exempt a state or federal agency from provisions of FIFRA if a determination is made that emergency conditions exist which require such exemption. The Idaho State Department of Agriculture (ISDA), the Oregon Department of Agriculture (ODA) and the Washington State Department of Agriculture (WSDA) are applying for a regional specific exemption for the use of hop beta acids (HopGuard) to control Varroa mites in honey bee colonies in Idaho, Oregon and Washington. This regional request is being submitted by the WSDA on behalf of all three states. This is the first year that the ISDA, ODA and WSDA have made this request.

A. GENERAL INFORMATION

1. Type of exemption:

Specific Exemption

2. Contact persons:

a) Technical and Scientific Aspects:

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b) Economic Aspects:

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3. Description of the pesticide:

Brand Name: HopGuard
EPA Reg. Number: Not registered (draft CSF included with request as attachment #1)
Active ingredient: Hop beta acids 16%
Manufactured by: BetaTec Hop Products
Wholly Owned Subsidiary of
John I. Haas, Inc.
P.O. Box 1441
Yakima, WA 98907

4. Description of proposed use (draft labels included with request as attachment #2):

a. Sites to be treated:

Use of hop beta acids is requested for honey bee colonies located in all counties in the Pacific Northwest (Idaho, Oregon and Washington).

b. Method of application:

Applications will be made by inserting cardboard strips treated with hop beta acids between brood frames within the honey bee colony.

c. Rate of application:

Two strips per brood super, with each strip containing approx. 1.92 grams of hop beta acids.

d. Number of applications:

A maximum of three applications per year (spring, summer and fall).

e. Total number of honey bee colonies to be treated:

The total number of honey bee colonies in the PNW that could be treated with hop beta acids is estimated to be approx. 181,000 (USDA-NASS data).

f. Total amount of pesticide to be used:

Assuming that 100% of the approx. 181,000 honey bee colonies in the PNW are treated with four strips (two brood supers x two strips per super) three times per year (spring, summer and fall), a maximum of 2,172,000 strips will be used. If 100% of the honey bee colonies in the PNW are treated, then the total amount of hop beta acids applied in the PNW will be 4,170 kg (2,172,000 strips x 1.92 grams of hop beta acids per strip), which is equivalent to 9,194 lb.

State	***Number of Honey Bee Colonies***	***Number of Strips Needed (three treatments)***
Idaho	90,000	1,080,000
Oregon	50,000	600,000
Washington	41,000	492,000

Number of colonies per state is from USDA-NASS data (2009).

g. All applicable restrictions, user precautions, qualifications of applicators, and other requirements concerning the proposed use:

Applicators will need to wear gloves when handling strips.

h. Use period:

Beekeepers in the PNW have requested that HopGuard be approved for use during the fall of 2010. WSDA understands that EPA approval of an emergency exemption for a new active ingredient in that time frame would be very difficult, and we are committed to providing all possible assistance to support your review of our request.

5. Alternative methods of control:

There are seven pesticides currently approved for control of Varroa mites in the PNW, but none are providing acceptable control when used in commercial beekeeping operations. Varroa mites have developed resistance to two of these pesticides, rendering them useless in most areas in the continental USA. The other five pesticides are reported to cause bee mortality, provide inconsistent mite control and/or have use limitations that make them impractical for large commercial beekeeping operations. Additional information regarding alternative pesticides is included with the request (attachment #3).

Fluvalinate (Apistan) is one of the two EPA-registered pesticides that is formulated in a contact strip that has been available to beekeepers since the late 1980s. This pesticide worked well to control Varroa mite until repeated usage for the many years allowed the Varroa mite to develop resistance to the chemical and it is, with few exceptions, no longer effective against the Varroa mite in the PNW. This pesticide is routinely detected

in the wax combs in honey bee colonies, creating an additional negative impact on colony health.

Coumaphos (Checkmite) is the other EPA-registered pesticide that is formulated in a contact strip that has been used by beekeepers since the late 1990s. This product also worked well at controlling Varroa mite until repeated usage for the many years allowed the Varroa mite to develop resistance to the chemical and it is, with few exceptions, no longer effective against the Varroa mite in the PNW (similar to Apistan). This pesticide is routinely detected in the wax combs in honey bee colonies, creating an additional negative impact on colony health.

Thymol (Apiguard) is a vapor-action pesticide that is formulated as a gel. It was effective in controlling Varroa mites for some years but has lost its efficacy according to beekeepers in some areas. The product is useful only within a certain temperature range and if the temperature suddenly becomes too high, bee mortality occurs if the treatment is not quickly removed. This renders the product too labor intensive for the large-scale commercial beekeeping operations.

Thymol / eucalyptus oil / menthol (Api Life Var) is another vapor-action pesticide that is formulated as a tablet. It is dependent on optimum temperatures and thus becomes too labor intensive for the large-scale beekeeper. This product is not being used because it is reported by beekeepers to be ineffective in killing Varroa mites. In addition, bee mortality has been reported (similar to Apiguard).

Formic acid (Mite Away II) is another vapor-action pesticide that is formulated as a pre-soaked pad. The product is hazardous to the applicator unless it is handled very carefully. Use of the product requires installing a rim under the cover of the hive, and control of mites may not be adequate even when the temperature falls within the recommended range. If the temperature is too cold, then the product is not effective. If the temperature is too hot, then the bees can be driven out of the hive by the vapor. It is reported that the pad formulation of formic acid is no longer being produced, and availability is likely to be very limited.

Note - ODA is currently reviewing an application for SLN registration of an unregistered formulation of formic acid (Mite Away Quick Strips). There is concern that this proposed SLN registration may not meet the criteria for a special local need.

Sucrose octanoate esters (Sucrocide) is a contact pesticide that is formulated as a liquid and may be useful for hobby beekeepers with a few colonies. However, it is not useful for large commercial beekeeping operations because of the need to remove each individual frame and spray with product, thus making the procedure too labor intensive. This product can be very harmful to bees if not applied at the correct rate.

Fenpyroximate (Hivastan) is a contact action pesticide that is formulated as a patty. This unregistered product recently became available to beekeepers in the PNW under Section 18 emergency exemptions. However, beekeepers are reluctant to use the product because when used at the recommended rate it causes high bee mortality, depending on weather conditions. Furthermore, the user has to sign a waiver acknowledging there may be significant bee loss for which the manufacturer will assume no liability. Some brood mortality and queen failures have been observed and it is also reported to be ineffective

against the Varroa mite by some beekeepers in the PNW. Information from California suggests that adverse effects of Hivastan on queen development are synergized by exposure to fungicides used in crop production.

WSBA sent a letter to WSDA stating that they want to withdraw their request for a Section 18 emergency exemption for Hivastan, and apply for a Section 18 emergency exemption for HopGuard.

6. Efficacy data:

Dr. Jeff Pettis of the USDA-ARS Bee Research Laboratory in Beltsville, MD, Dr. Gloria DeGrandi-Hoffman and Fabiana Auhumada-Segura of the Carl Hayden Bee Research Center in Tucson, AZ conducted tests with HopGuard on Varroa mite on honey bees and showed good results for efficacy in the commercial beehive setting against the mite, with no harmful effects against the honey bee (attachment #4).

7. Residue data:

In 2010, USDA-ARS in Tucson, AZ conducted two studies using HopGuard to control Varroa during the honey flow period and then tested honey samples for the presence of hop beta acids in the honey. Study #1 – April and May: Honey samples taken from frames in the honey super (above the brood super where the strips were inserted) did not contain any hop beta acids. Honey samples taken from frames in the brood super (where the HopGuard strips were inserted) showed that 23% of the honey samples contained hop beta acids (amount ranged from 0.27-9.52ppm). Study #2 – June and July: Honey samples taken from frames in the honey super (above the brood super where the strips were inserted) did not contain any hop beta acids (attachment #5).

During commercial treatment, HopGuard strips will not be placed in a honey super, and it is anticipated that there will be no residues of hop beta acids in a honey super when the product used as directed.

8. Risk information:

A. Human Health: HopGuard is made entirely of food grade, generally recognized as safe (GRAS) components and, therefore, no harm to the general adult population or infants or children is anticipated as a result of the approval of this request. Hops have been widely used in the brewing of beer and in animal feed for many years. Information regarding the use of hops in beer and animal feed, and the effects of hop extracts on humans is included with the request (attachment #6).

B. Ecological and Environmental Fate Effects: Specific studies have not been conducted with HopGuard, but since the components are all food grade, GRAS and commercially used on a global scale, there are no detrimental ecological or environmental impacts to be expected.

C. Endangered/Threatened Species: The proposed use of this product is intended to be

applied only to the inside of the beehive and therefore expected to have no adverse effects on the threatened and endangered species or their habitats in the PNW.

9. Coordination with other affected state/federal agencies:

The ISDA, ODA and WSDA will forward a copy of the request to the appropriate federal and state agencies in their respective states. Any comments received will be forwarded to the EPA.

10. Notification of registrant:

A letter from John I. Haas, Inc. discussing their support for this emergency exemption request in Idaho, Oregon and Washington is included with the request (attachment #7).

11. Enforcement program:

The ISDA, ODA and WSDA have provisions for enforcing restrictions under Section 18 emergency exemptions.

12. Previous use under Section 18:

There is no previous use of this product under a Section 18.

13. Progress toward registration:

Dr. Michael Braverman, Manager, Biopesticide and Organic Support Program, IR-4 Project has been contacted regarding the company's desire to obtain a Section 3 registration. IR-4 has received a Project Clearance Request (PCR) Form that was submitted to IR-4 by a member of the beekeeping industry as a completion of the first step in the process. The registering company (John I. Haas, Inc.) has been assigned an EPA Company Number 83623 and has thereby completed the second step. The third step is a work in progress as information is being gathered and presented to IR-4 for the purpose of getting the proposed pesticide classified into one of the EPA pesticide categories. The intent will be for hop beta acids to be classified as a biopesticide. Additionally, the registering company has developed a draft CSF for the product and is in the process of obtaining efficacy and toxicity data, in conjunction with USDA-ARS researchers. (Note - The CSF is confidential, and it will be submitted separately.)

B. REQUIREMENTS FOR SPECIFIC EXEMPTIONS BASED ON SIGNIFICANT ECONOMIC LOSS

1. Pests to be controlled:

Scientific Name: ***Varroa destructor***
Common Name: Varroa mite

2. Events which brought about the emergency condition:

The ectoparasitic mite *Varroa destructor* appeared in the U.S. in 1987 and is a highly destructive pest of honey bee *Apis mellifera* colonies. The mites live in the colony, reproduce in the cells feeding on the developing larvae by sucking hemolymph and emerge from the cells to feed on the adult bees. This parasitic action deforms and/or kills the young, shortens the life of the adults and adversely affects the colony through an overall reduction in population size, vigor and health.

Varroa is having a catastrophic effect on honey bee populations and the commercial beekeeping industry. Colony losses across the USA this past year were approximately 34% and USDA-ARS researchers believe that 75% of those losses could be attributed to the direct effects of Varroa. The parasitic mite is considered the number one pest of honey bees worldwide and its control is necessary for successful beekeeping; however control options are limited (attachment #3).

Two EPA-registered pesticides, Apistan® (fluvalinate) and Checkmite® (coumaphos), were initially used to successfully control the Varroa mite, however the repeated application of these products contributed to the widespread development of mite resistance to these products. Furthermore, fluvalinate and coumaphos are routinely detected in samples of wax combs used in honey bee colonies. The presence of these compounds in the combs has an additional negative impact in colony health and especially in queen rearing. With these two products no longer effective against the mites, additional products became available; however these additional products are reported to cause bee mortality, provide inconsistent mite control and/or have use limitations that make them impractical for large commercial beekeeping operations.

In the absence of an effective method of control for Varroa in the large commercial beekeeping operations, the need arises for a new product. The identification of a naturally occurring product extracted from hops (*Humulus lupulus*) having miticidal activity prompted the company BetaTec to conduct the necessary research to determine if this new product, HopGuard could be effective in controlling Varroa mites. The results obtained from *in vivo* studies have shown that HopGuard strips are effective in killing Varroa mites and do not harm the bees. Inside the colonies, HopGuard does not disrupt colony behavior, brood production or queen egg-laying.

HopGuard was developed as a quick mite knockdown contact application. The strips are made of biodegradable material (cardboard) coated with HopGuard which is made of components that are all food grade, GRAS and used commercially on a global scale. The strips are inserted between the frames and when the product has been delivered and is no longer on the strip; the bees chew the cardboard and remove it from the hive. The development and delivery system of HopGuard strips as a control for Varroa is compatible with commercial beekeeping because the strip delivery is a practice known to beekeepers, involves minimal labor and HopGuard is very safe for the bees and the beekeepers (attachment #8).

3. Discussion of the anticipated risks to the threatened or endangered (T/E) species, beneficial organisms, or the environment that would be remedied by the proposed use of the pesticide:

This emergency exemption is not expected to remedy any risks to threatened or endangered species or to the environment.

4. Discussion of economic loss:

Economic conditions in the beekeeping industry have become increasingly adverse since the Varroa mite was introduced into the U.S. in 1987. Control of Varroa in the colony became an added cost to beekeeping and during the early years of the pest, it was adequately controlled by two EPA registered pesticides (fluvalinate and coumaphos). However, subsequent long-term use of these two chemicals has allowed the mites to develop resistance to these chemicals and they are no longer effective controls. Other controls have since been approved, but none of these is adequately controlling the Varroa for the large commercial beekeeping operations. Consequently, commercial beekeepers are suffering large colony losses due to Varroa. In the meantime another phenomenon referred to as Colony Collapse Disorder (CCD) has appeared and added to the economic woes of the beekeeper. The cause of CCD has not been determined but the Varroa mite is certainly a part of the disorder. Annual colony losses in the U.S. have been greater than 30% per year for several years. While these losses are not entirely due to Varroa, Dr. Jeff Pettis (USDA-ARS) estimates that Varroa mites could account for as much as 75% of these annual losses (attachment #9).

The majority of colony losses occur during the winter months. Information on colony loss for the state of Washington was collected during the 2010 Honey Bee Loss Survey, which was conducted by the WSDA Apiary Advisory Committee (chaired by Eric Olson, a commercial beekeeper based in Yakima, Washington). The survey showed colony losses during the winter of 2009-2010 totaled 39% for commercial beekeepers in Washington (attachment #10).

Commercial beekeepers have three methods to replace lost colonies. (1) Buy full strength replacement colonies for a cost of approx. $150 apiece. This is the most expensive method, but it is also the quickest method. (2) Buy nucleus colonies for a cost of approx. $65 apiece. A nucleus colony is three frames of bees and a queen that are placed into an empty brood super. Over time, a nucleus colony will become a full strength colony. (3) Split existing parent colonies for a cost of approx. $60 apiece. This method involves buying a queen and taking half of the brood frames from an existing parent colony and put these frames into an empty brood super. Over time, a split colony will become a full strength colony. The Washington State Beekeepers Association believes that each of the three methods is used about equally to replace lost colonies.

Jan Lohman (Oregon State Beekeepers Association) stated that colony losses for 2009 were approx. 28% for commercial beekeepers in Oregon. Nick Noyes (Idaho Honey

Industry Association) stated that colony losses for 2009 were similar for commercial beekeepers in Idaho to the losses experienced by commercial beekeepers in Washington and Oregon.

Tier 2 Analysis, Commercial Beekeeping Operation in the PNW.

	Baseline	***Emergency***	***Change***	***% Change***
Pollination income ($200/colony)	$1,028,000	$801,676	-$226,324	
Honey production (42 lb/colony)	215,880 lbs	189,924 lbs	-25,956 lbs	
Honey income ($1.46/lb)	$315,185	$277,289	-$37,896	
Gross revenue ($261.32/colony)	$1,343,185	$1,078,965	-$264,220	***-19.7%***
Replacement colony cost ($150/colony)		$61,650	-$61,650	
Nucleus colony cost ($65/colony)		$26,715	-$26,715	
Split existing parent colony cost ($60/colony)		$24,660	-$24,660	
Total additional costs		$113,025	-$113,025	***-8.4%***
Total losses (% Change compared w/Gross revenue)			-$377,245	***-28.1%***

The baseline estimate for pollination income assumes that a commercial beekeeping operation in the PNW pollinates 2 crops per year with 5,140 colonies of honey bees: almonds in California ($150.30/colony) and apples in Washington ($49.70/colony). If a beekeeper pollinates an alternative crop in Oregon or Washington (such as berries, cherries, pears, or vegetable seed crops), then pollination income might be slightly higher or lower. Data on pollination income is from a 2009 survey of commercial beekeepers conducted by Dr. Mike Burgett, Oregon State University – emeritus (attachment #11).

The baseline estimates for honey production and income assumes that a commercial beekeeper produces honey from 5,140 colonies of honey bees. Estimates are based on a weighted average of the yield and price information for Idaho, Oregon and Washington from annual statistics published by USDA-NASS (attachment #12).

The emergency estimate for losses of approx. 24% of commercial honey bee colonies in the PNW due to Varroa mites is based on an adjusted average of the estimated colony losses from WSBA, OSBA and USDA. WSBA indicates that colony losses in Washington were approx. 39%. OSBA indicates that colony losses in Oregon were approx. 28%. USDA indicates that national colony losses were greater than 30% a year, and that Varroa mites could account for as much as 75% of the losses. The average estimated loss of commercial colonies is approx. 32%, and the estimated loss due to Varroa mites is assumed to be approx. 24%. For a commercial beekeeping operation with 5,140 colonies, the estimated colony losses due to Varroa mites are assumed to be approx. 1,237 colonies.

The emergency estimates for income losses and additional costs are based on information from WSBA. The emergency estimates for income losses assume (1) no income from almond pollination for replacement colonies, (2) no income from almond pollination or apple pollination for nucleus colonies, (3) no income from almond pollination, apple pollination or honey for split colonies, and (4) loss of 50% of honey income for parent colonies. The emergency estimates for additional costs assume that a commercial beekeeper buys 412 replacement colonies ($150/colony) to replace one-third of the losses, buys 412 nucleus colonies ($65/colony) to replace one-third of the losses, and splits 412 existing parent colonies ($60/colony) to replace one-third of the losses.

The emergency estimates do not include long-term negative impacts on honey bee colonies from Varroa mites (or from alternative pesticides used to control Varroa mites), or negative impacts on crop pollination from lack of available honey bee colonies.

Based on our analysis of the above information, WSDA strongly believes that an emergency condition exists in the PNW. Honey bee colonies are critical to the production of numerous fruit, nut and seed crops grown in the PNW and California. Failure to have an effective pesticide to control Varroa mites would be disastrous to commercial beekeepers, and to the crops that depend on honey bees for pollination. In 2008, the value of crops pollinated by PNW honey bees, including almonds grown in California, was in excess of $4.5 billion (USDA-NASS).

If you have any questions, please contact Erik Johansen of our office at (360) 902-2078 or email ***ejohansen@agr.wa.gov***.

Sincerely,

PESTICIDE MANAGEMENT DIVISION

Ted Maxwell
Program Manager, Registration Services

cc: Lloyd Schantz, John I. Haas
Gene Probasco, John I. Haas
Dr. Gloria DeGrandi-Hoffman, USDA
Fabiana Ahumada-Segura, USDA
Dr. Jeff Pettis, USDA
Dr. Steve Sheppard, WSU
Dr. Ramesh Sagili, OSU
Dr. Mike Burgett, OSU (emeritus)
Dr. Eric Mussen, UC Davis
Jerry Tate, WSBA
Eric Olson, WSBA
Jan Lohman, OSBA
Nick Noyes, IHIA

Attachments:

1. Proposed CSF for HopGuard (confidential)
2. Draft labels for HopGuard
3. Information regarding alternatives to HopGuard
4. USDA - Efficacy data
5. USDA - Residue and honey bee toxicity data
6. Information on use of hops in beer and animal feed, and effects of hop extracts on humans
7. Letter of support from John I. Haas
8. USDA - Need for effective pesticide compatible with commercial beekeeping practices
9. USDA - Colony loss estimates due to Varroa mite
10. WSBA - Survey on colony losses
11. OSU - Survey on pollination income for the PNW
12. USDA - Data on honey production and prices for PNW