



US Environmental Protection Agency Office of Pesticide Programs

**Spirotetramat -
Comments received on the sale,
distribution, and/or use of existing stocks**

Updated on March 4, 2010

Note: This document contains comments received in response to a Notice of Intent to Cancel the federal registration of the pesticide spirotetramat. Because of the short time-frame required by the court-ordered vacatur of the spirotetramat registration, EPA did not publish a *Federal Register* notice announcing its intent to cancel. As a result, no docket was created for this action, which is the standard way by which comments could be viewed by the public. Instead, the Agency published the notice on its Web site, and announced an opportunity for interested parties to comment on how they believe EPA should treat the sale, distribution, and/or use of existing stocks of spirotetramat in the cancellation order. The purpose of this document is to make the comments received by the Agency publicly available in the absence of a *Federal Register* notice and its associated docket.

Because the invitation for comments did not specify that comments submitted would be made public, all personally identifying information has been removed. Information identifying organizations, however, remains.

Finally, comments were submitted in a variety of formats, not all of which were amenable to copying and pasting into one comprehensive list. Every effort has been made to ensure that the text submitted by commenters is included even though some formatting features might have been lost. Because some commenters chose to send their comments in encrypted or protected formats, they are not included in this summary.

Comment

I believe that the use of existing stocks of Movento should be allowed, given that safety issues are not the reason for the upcoming product cancellation (if the current stay is not extended). It is reasonable that existing stocks be required to be used in accordance with the current attached labeling. The benefits of the continued use of existing stock include a reduction in the use of more toxic organophosphate insecticides such as oxydemeton-methyl, fewer pesticide applications and a reduction in the use of tankmixed products.

Comment

I am writing to request that EPA allow the continued sales and use of the insecticide Kontos on ornamental plants. This product is one of very few that will control key pests of crops raised by the U.S. nursery industry. The loss of Kontos would have a significant negative economic impact on the nursery industry in the United States.

Respectfully,

Comment

I would like to request continued use of the spirotetramat product "Kontos" registered by the Bayer Company. This is the only product that is available to the greenhouse industry that has systemic activity relating to mites. The ability to use a product that is drenched on is safer for laborers and has a longer effective time for prevention of pest activity.

Comment

Please continue to allow the sale and use of spirotetramat (Kontos). We use it in our rotation of chemicals, along with good management practices, to control spider mites. We need a good arsenal of control methods to keep insect damage to a minimum.

Comment

It is the position of the Pennsylvania Department of Agriculture that the cancellation of spirotetramat products must allow for the continued sale and use of products currently in the marketplace. Since the basis of this cancellation is a procedural error, and no basis exists for the use of this active ingredient to be suspended based upon concerns for human health, or an imminent hazard to the environment, there is no justification to burden businesses, and individuals currently in possession of products thought to be properly registered. In addition, if legal use is terminated by EPA it will create a disposal and enforcement dilemma for State Lead Agencies at a time when states are facing extremely challenging economic circumstances.

Comment

Bayer has told us that we are the ONLY state (which I find hard to believe) that is not allowing the sale/distribution of Movento and Ultor until this issue is resolved. We have not yet registered the product for sale/distribution in 2010. It is unclear why people simply can't wait until a decision is made around Feb 16 (uses do not even take place until May/June). Any advice?

Comment

I would just like to let you know how important Spirotetramat (Movento) is to our program of onion production. I produce 350 acres of onions annually. Without Movento, our growing costs would not only increase, but more importantly the liability of growing onions would increase due to additional spraying and the risk of Iris Yellow Spot Virus (IYSV). We have found this past year by using Movento in our thrip control, we can reduce the number of total spraying by possibly two per season thus reducing the exposure of our neighbors and surrounding crops to other chemicals on a weekly basis. I would much rather spray once every 2-3 weeks than to be spraying every 10 days throughout the season. IYSV can reduce production of an onion crop from an average of 750 cwt per acre to less than 250cwt per acre with a chance the crop will not be marketable. IYSV is a big enough threat to our area that I can't take a chance on losing our crop of onions. As a grower, I can tell you that we have enough problems growing crops in the US without any additional burdens. I have seen the Ag chemicals transition from old chemistries of the organophosphates to the new pyrethroids. I can see we are getting safer for human exposure of handling, but we will be spraying more often and increasing the risk to humans around the infected fields if we lose products like Movento. Movento is a product that has great promise of safe handling with a longer interval of spray applications. Movento is a product the EPA and growers can all benefit from.

Best regards,

Comment

i am a whole sale grower, and in the short time that i have used kontos I've had to use less of other more dangerous products; to achieve the same or greater control of my targeted pest.this chemical seems to really work and it would be a huge lose to the ornamental plant industry if it was to be taken off the market.please consider keeping this product on the market.

Comment

I am a crop consultant in west Texas. I have been working with crops and pesticides since I graduated from Texas Tech University with a degree in Ag Science in 1985.

I am writing to air my concerns about the product Movento being removed from the pesticide market.

Movento is an excellent product because it is effective at controlling the target pest (potato psyllid) while not adversely affecting the beneficial insects or assorted wildlife that live in and around our crops. Without Movento we will be forced to take a step backward and go back to using more broad spectrum, harsher chemistry's.

Please reinstate Movento as it is the type of chemistry that all concerned parties (E.P.A. consumers, farmers, environmentalists, scientists) are trying to move toward.

Thank you for your consideration.

Comment

District Court Judge Denise Cote rendered the wise and only possible decision in ordering Spirotetramat's registration cancelled. It needs to be said, however, that the \$90 million that BayerAg invested in that chemical is a drop in the bucket compared to the \$15.4 billion of ag produce that is put at risk by not only that chemical, but by all chemicals which were not properly studied before they were put into the environment.

If a defense contractor loses a \$15.4 billion weapons deal, the engineers just move on to some other weapons project that they will concoct. That is not so with the loss of agricultural products because that loss must be made up somewhere. Do you think China will put its people at risk sending us food products because the EPA has failed since its inception to determine the lethal and sub-lethal dosages that pesticides cause in the environment?

Just this week two leading beekeepers in California stated that for the first time ever, there will be a shortage of enough bees to adequately pollinate California's almond crop. As one almond grower stated, without the bees all we have are shade trees. In a program called Nature on PBS, it was shown that the Chinese have experimented with a program in hand-pollinating pears. They concluded that even with their large population, it is not economically feasible to do that.

I am 60 years old, having been a beekeeper since my mid-twenties. Men who were old when I started warned me of the futility of doing battle with the chemical companies because they use their wealth to influence both government and researchers. The Land Grant college in our state, CSU, is heavily funded by pesticide and herbicide manufacturers. One of the worst instances of their influence was obvious when I testified in the mid-seventies to the Colorado Senate Agricultural Committee about one of our members who was sprayed in the field with the state apiary inspector present at the time, and nothing was done then or since about our problems. Instead, we have been called assholes in public meetings for complaining to the ag

commissioners about these problems. Most recently, this year, after about a year and a half of constant complaining to the current commissioner, with help from a State Representative, the Boulder County Beekeepers Association was only able to extract a pitiful \$400 fine for a sprayer spraying blooming alfalfa in violation of the label, and in conditions which were causing drift.

California, where 40% of our fruit and vegetables come from, should quickly ban all uses of pesticides and herbicides so that California beekeepers can increase their numbers enough so that other states won't have to export bees to California. Banning the pesticides will eliminate one of the biggest stressors for bees. Eliminating stresses for bees will help their immune systems combat viruses. It will also eliminate the stress of bees traveling over the road. Eliminating herbicides addresses the nutrition problem bees have with monoculture crops. An almond grower wants the dandelions eliminated so the bees will only work the almond blossoms. That's understandable from a human standpoint. The bee, however, needs variety in his diet, and that includes a whole category of flowering plants which those who market chemicals have vilified as "weeds" in order to sell their product.

Lastly, the EPA is transparently taking the side of BayerAg when the EPA threatens to allow BayerAg to turn loose the entire product that's already on the market for whatever use Bayer sees fit. A cancellation has to mean a recall to the manufacturer. It should be Bayer's responsibility to take all that stuff back and dispose of it according to guidelines that are already in place.

Comment

I am sending this as a response to EPA's decision re; Spirotetramat. We strongly urge you to at least allow the use of material in growers hands. This is a valuable tool in our arsenal for the control of aphids. Despite what has been said about spirotetramat and bees, it is a VERY safe material when used around bees and is a very safe material when considering worker safety.

Thank you for allowing me to comment,

Comment

Please accept our comment in support of releasing all stocks available of Spirotetramat (Movento, EPA registration number 264-1050). This is especially important to this year's Section 18 use in onions to control thrips for growers and farmers.

Comment

To: Ms. Meredith Laws,

Re: **Continued sale and use of spirotetramat (Kontos)**

As a U.S. producer of houseplants, I strongly urge the Environmental Protection Agency to allow continued sale and use of the chemical Kontos (spirotetramat).

I am a wholesale grower of potted interior foliage. I'm north of San Diego with almost an acre of greenhouses employing 5 people full time. I do the spraying myself and was so happy to have Kontos added to my product rotation, especially for Mealy bug! With the neonicotinoids, we have a good chance to control them but [even with 4 or 5 products – Safari, Tristar, Marathon, Flagship, etc] it's still only one chemical as far as rotation is concerned...and we certainly don't want the bugs to become resistant to these wonderful – systemic – chemicals. That's why Kontos was such a welcomed weapon. It's a different chemical class and systemic to boot! Awesome!

As a producer, it is very important for me to have a variety of chemicals available to fight insects. Mealy bug and Whitefly are particularly troublesome, in that continued use of a single active ingredient can lead in a relatively short period of time to the development of resistance in their populations. The ornamentals industry has worked together with the cotton and the fruit and vegetable industries to adopt management plans for the rotation of chemicals with differing active ingredients, in order to avoid resistance development in whitefly populations. If resistance develops in whitefly populations, devastating economic losses can and do result, severely impacting growers in all segments of agriculture. Thus, the continued availability of Kontos provides another alternative in the rotation scheme developed in the Whitefly Management Plan to help avoid development of chemical resistance in whitefly populations.

Kontos gives growers one more active ingredient in the arsenal of chemistries from which good management rotations can be established. Its loss would be significant for the ornamentals industry.

Systemic chemicals are twice as valuable as translaminar and four times more valuable than non-systemic chemicals. This is because my plant canopy is so tight, it's nearly impossible to cover all leaf surfaces [certainly not economically or efficiently].

As a responsible producer and employer, I am careful to ensure that all chemicals, including Kontos, are applied in strict accordance with its label requirements. It is my understanding that Kontos was approved by EPA for use following EPA's normal procedures to ensure worker, consumer and environmental safety, and that because the original registration request was not published for public comment, the court has now cancelled the registrations effective February 16, 2010. This product is environmentally more friendly than some of the alternatives, and the ability to continue its production and use is important not only to the economy, but also for our environment. Just as one example, the product is more compatible with IPM strategies including beneficial insects.

Since the chemical has already been approved by EPA and stocks of it are currently in the hands of growers and distributors, I ask that those stocks be allowed to be used. If possible, we would urge that continued manufacture of the chemical be allowed. For EPA to decide otherwise would be not only to harm our pest management strategies, but also cause economic damages resulting from loss of sales and/or loss of ability to use product already purchased. Furthermore, the risks and costs of disposing of

existing stock are unknown, and could be significant. Pending the re-registration of this important product, this step is the most practical one for EPA to take.

I therefore urge that this chemical be allowed to be legally sold and used.

Thank you for your consideration of my comments.

Comment

Re: Spirotetramat Cancellation

To Whom It May Concern:

The following comments are provided on behalf of the National Potato Council (NPC) in response to the Environmental Protection Agency's (EPA) request for input on the "Spirotetramat - Notice of Cancellation Order; Opportunity for Public Comment" posted on your website. NPC represents more than 90 percent of the growers of potatoes in the United States. The consistent availability of EPA registered crop protection products is critical to economically viable potato production due to the devastating impact that insect pests and other diseases can have on the crop.

The litigation driven decision to cancel Spirotetramat creates added decision making related uncertainties, forces unnecessary adjustments to pest management plans and puts pressure on the availability of competing products that could leave growers without adequate replacement products. We strongly urge EPA to take actions to insure that growers will have access to the existing stocks of Spirotetramat that are in the possession of the grower or have been distributed to dealers, custom applicators and distribution centers.

It is our understanding that EPA has adequately reviewed the data submitted by the registrant and concluded based on that review that there are no substantive worker safety, environmental or human health concerns that would not allow the safe use of the product based on the label approved by the Agency. We also understand from a review of the decision by the U.S. District Court for the Southern District of New York that the issues raised concerning the registration of Spirotetramat relate solely to minor procedural inadequacies in the initial stages of the product review that ultimately lead to an affirmative decision to register the product. Based on those facts, the use of existing stocks of the product that is already in the distribution chain will avoid disruptions at the farm level and are justified on the record of product safety created during the substantive portions of the EPA review process.

In order to incorporate Integrated Pest management and other risk mitigation strategies into their farm operations, potato growers develop pest management strategies months in advance of planting. Decisions to incorporate new products into that system are not taken lightly. Once Spirotetramat was registered by the EPA, growers began to incorporate its use into their pest management programs. Providing for the continued use of existing stocks of Spirotetramat is critical to not needlessly disrupting the on farm decision making process due to procedural issues

in the legal system and with no demonstration of evidence against the safety of the use of Spirotetramat.

Sincerely,

Comment

Hello Ms. Laws,

I am writing in response to the EPA's solicitation of public comments re: Spirotetramat. As a beekeeper of some years' experience, the findings cited in the link below are very concerning to me and I implore you to consider removing the product from the market. I have personally experienced serious pesticide loss multiple times from existing pesticides; in addition to some products' inherent threat to honeybee colonies, pesticide misapplication is so frequent as to be the norm (significantly multiplying the threat due to off-label usage). If a product with these identified risks is allowed into use, I fear that the pesticide-related colony mortality that we already struggle with will expand dramatically. Please take strong action to remove the product from further production and prevent existing stocks from being used.

Comment

I wish to express my deep concern about the use of spirotetramat developed by the Bayer CropSource industry. As a beekeeper, I oppose unlimited use of existing stocks and unlimited sales of insecticides which contain spirotetramat. The EPA should be concerned about protecting the social, economical, and environmental benefits which bees provide. Permitting use of spirotetramat on agricultural land poses a particular risk. Thank you for the opportunity to comment.

Comment

Re: Continued sale and use of spirotetramat (Kontos)

As a U.S. producer of houseplants, I strongly urge the Environmental Protection Agency to allow continued sale and use of the chemical Kontos (spirotetramat).

I am a wholesale grower of potted interior foliage. I'm north of San Diego with almost an acre of greenhouses employing 5 people full time. I do the spraying myself and was so happy to have Kontos added to my product rotation, especially for Mealy bug! With the neonicotinoids, we have a good chance to control them but [even with 4 or 5 products – Safari, Tristar, Marathon, Flagship, etc] it's still only one chemical as far as rotation is concerned...and we certainly don't want the bugs to become resistant to these wonderful – systemic – chemicals. That's why Kontos was such a welcomed weapon. It's a different chemical class and systemic to boot! Awesome!

As a producer, it is very important for me to have a variety of chemicals available to fight insects. Mealy bug and Whitefly are particularly troublesome, in that continued use of a single active ingredient can lead in a relatively short period of time to the development of resistance in their populations. The ornamentals

industry has worked together with the cotton and the fruit and vegetable industries to adopt management plans for the rotation of chemicals with differing active ingredients, in order to avoid resistance development in whitefly populations. If resistance develops in whitefly populations, devastating economic losses can and do result, severely impacting growers in all segments of agriculture. Thus, the continued availability of Kontos provides another alternative in the rotation scheme developed in the Whitefly Management Plan to help avoid development of chemical resistance in whitefly populations.

Kontos gives growers one more active ingredient in the arsenal of chemistries from which good management rotations can be established. Its loss would be significant for the ornamentals industry.

Systemic chemicals are twice as valuable as translaminar and four times more valuable than non-systemic chemicals. This is because my plant canopy is so tight, it's nearly impossible to cover all leaf surfaces [certainly not economically or efficiently].

As a responsible producer and employer, I am careful to ensure that all chemicals, including Kontos, are applied in strict accordance with its label requirements. It is my understanding that Kontos was approved by EPA for use following EPA's normal procedures to ensure worker, consumer and environmental safety, and that because the original registration request was not published for public comment, the court has now cancelled the registrations effective February 16, 2010. This product is environmentally more friendly than some of the alternatives, and the ability to continue its production and use is important not only to the economy, but also for our environment. Just as one example, the product is more compatible with IPM strategies including beneficial insects.

Since the chemical has already been approved by EPA and stocks of it are currently in the hands of growers and distributors, I ask that those stocks be allowed to be used. If possible, we would urge that continued manufacture of the chemical be allowed. For EPA to decide otherwise would be not only to harm our pest management strategies, but also cause economic damages resulting from loss of sales and/or loss of ability to use product already purchased. Furthermore, the risks and costs of disposing of existing stock are unknown, and could be significant. Pending the re-registration of this important product, this step is the most practical one for EPA to take.

I therefore urge that this chemical be allowed to be legally sold and used.

Thank you for your consideration of my comments.

Comment

I wish to file a public comment on the spirotetramat matter. First, It was wrong of the agency to pass this matter without a period for public comment. Second, this pesticide was approved without adequate testing.

Do you have any idea what would happen to this country's food chain if the honeybee is wiped out? Perhaps you should read up on it. It is said that bees pollinate more than 15 billion dollars worth of US crops per year.

Please require more testing before spirotetramat is approved.

Comment

The Florida Department of Agriculture and Consumer Services (FDACS) appreciates the opportunity to comment on existing stocks provisions that the Agency is considering as a result of a court vacatur and subsequent cancellation of the federal registration of pesticide products containing the active ingredient, spirotetramat. We understand that spirotetramat registration cancellation has been stayed until February 16, 2010, and in the meantime, the Agency is seeking comments on the regulation of existing stocks in the possession of sellers, distributors, and users.

The Agency indicates its intent to cancel spirotetramat registrations under FIFRA Section 6(a)(1), noting that this section of the law provides that: "The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under [sections 3, 4 or 6 of FIFRA] to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of [FIFRA]." The Agency also points out that in such circumstances, USEPA orders can be issued that can, among other things, "...contain limitations or conditions on the sale, distribution, or use that the Administrator determines to be appropriate," and that, "one such limitation that EPA frequently applies to existing stocks is a condition that any authorization of use of such stocks is limited to use that is consistent with the previously-approved labeling accompanying the product."

The registration of spirotetramat products is being vacated and cancelled because the Agency failed to provide an opportunity for public comment prior to granting registration. Thus, the cancellation appears to be caused by a procedural misstep, rather than by the identification of significant and unacceptable product-related risk issues.

Spirotetramat products have been registered for sale and distribution in Florida since August, 2008. Our registration review included consideration of the toxicity and environmental fate of spirotetramat under Florida-specific conditions, with input by technical experts from FDACS, the Florida Department of Environmental Protection and the Florida Fish and Wildlife Conservation Commission. The products are registered for a wide array of agricultural crops, and they fill a niche needed by growers for "softer" chemicals to control serious economic pests such as white flies, mites and aphids.

We have received no complaints or other indications that spirotetramat has caused unreasonable adverse effects to non-target organisms in Florida when the product is used according to label

directions. Spirotetramat is not acutely toxic to birds, mammals, or several beneficial insects including honey bees. We are aware that the current label states that spirotetramat “is potentially toxic to honey bee larvae” based on previous field studies at higher application rates. To address these concerns, the registrant, Bayer CropSciences, has recently performed a field study with honey bees exposed to spirotetramat in a citrus grove in Florida. The researchers measured both mortality and hive condition while following these colonies as they were relocated from Florida to other field locations throughout the United States (typical for commercial bee hives). The registrant’s interim reports have been informally reviewed by our ecotoxicologist and, to date, they appear to allay rather than confirm concerns of honeybee larvae toxicity or decline in hive condition when the product is used according to label.

Given these observations and in view of the fact that the use season for insect control is approaching or upon is in some parts of the state, it is important that the USEPA allow for the continued distribution, sale and use of existing stocks that are in the hands distributors, dealers, and users in Florida. We strongly support the Agency issuing enforceable orders to allow such use, provided that spirotetramat products are used in accordance with the label. We request that Agency’s orders be crafted to enable the Department to continue to take enforcement action in the event of non-compliant applications. Additionally, it is important for the Agency to maintain food tolerances for spirotetramat, so that growers will be able to market legally treated crops without penalty.

We appreciate your consideration of our comments.

Comment

As an amateur beekeeper, I am extremely concerned about the potential negative impact of spirotetramat products on bee colonies. From what I have read, the EPA test showed "increased mortality in adults and pupae, massive perturbation of brood development, early brood development, and decreased larval abundance". Beekeepers around the world are struggling with Colony Collapse Disorder (CCD) and the potential loss of a large percentage of the world's honeybees with the resulting agricultural losses due to the lack of polenators. Pesticides have been identified as a highly likely source of CCD.

The approval and introduction of any new insecticides that show potential for decreasing bee colony's survival is extremely irresponsible, especially for a government agency like the EPA which is charged with protecting the environment and the helath and welfare of the public that depends on that environment.

Please enforce not only the de-registration of all products containing spirotetramat, but also the removal and safe disposal of all such products currently in distribution and use channels.

Thank you,

Comment

i have been a pest control adviser on the central coast of california for the past 33 years. i was recently informed by my bayer crop science representative that due to a technicality in protocol of the filing process in the federal registrar for public comment that the use of movento for 2010 may be in jeopardy. i have used the product movento with great success in the past 2 years especially in my brussel sprout crop where 2 types of aphids attack the plant causing severe damage and making the product unmarketable. without movento it is inevitable that the growers will suffer production and quality losses which in turn will create financial loss. since movento is a softer product which also has a different mode of action it can be used in an integrated pest management program as a rotation to the organophosphate products which in turn will prevent resistance issues from repeated applications of the same categories of chemistries. at this time i would like to ask you for your help to extend the use of movento into the upcoming and following years. sincerly yours

Comment

i am a bee keeper in Alberton Montana and was asked to comment on this. i was unable to find any information on the short or long term effects of this pesticide on honey bees or other beneficial insects. i would ask that studies be done and that information be made public before making this product available. i would also like to know more about how it affects soil and plants over time, what it becomes as it breaks down, if it poses any threat to species feeding on affected insects, and treated foliage. if this information is available i would also appreciate a version of it that i can understand with my limited understanding of chemistry. thank you for your time and patience,

Comment

Please consider my request for you to not allow Bayer to use, sell, transfer ,or dispose of this chemical as the bee population is vulnerable to it.
Thank you for taking the time to read this

Comment

Please, oh please, reconsider the problem of spirotetramat from the point of view of a beekeeper who pays close attention to the impact of chemicals upon the natural world. We are doing ourselves a great disservice when we bow to the wishes of the corporate world without a full investigation.

I live at the edge of the great farmlands of Weld County, Colorado. I see first hand the devastation upon the hives from cropdusting and treated seeds. I shudder at the unseen devastation in our children. After thirty-some years in public education I can say with assurance that we do NOT have healthier children than we had in the past.

Your decisions often go unnoticed by the populace; they are not unnoticed by nature.

Please consider the full import of this decision.

Comment

We are writing to express support for continued use of Bayer's Movento (spirotetramat) in US tree fruit crops in 2010.

Our consulting firm- agr.assistance- has provided crop production consulting services to fruit and vegetable growers in the northeast US since 1985. We currently provide services to approximately 15,000 acres of fruit and vegetable grower clients- including pest management and regulatory compliance programs. We first used Movento commercially on apples in New York in 2009- and we have been involved in research trials evaluating Movento since 2007 as well. Movento has consistently proven to be an exceptional tool for control of both San Jose Scale and woolly apple aphid on apples.

Key reasons why Movento apple registration is important to US apple growers:

- Movento is a key material for growers due to MRL concerns with other pest management products for our export apples which head to the United Kingdom. Residues of both endosulfan (Thionex) and diazotolpene are of particular concern in the UK- and these are two of our primary tools for control of woolly apple aphid and San Jose Scale. The continued use of Movento would allow US apple growers to maintain this key UK export market for their 2010 crop.
- Resistance management programs- Movento's unique chemistry makes it an ideal fit in resistance management programs- resulting in reduced need for follow-up treatments and pre-harvest applications of other materials.
- IPM program fit- Movento's safety to beneficials, exceptional bee safety and benign environmental profile make it an ideal fit in tree fruit IPM programs.
- Reduction in broad-spectrum pesticide usage- Rotating to Movento would allow fruitgrowers to reduce use of broad-spectrum insecticides- including endosulfan, diazotolpene and methomyl.

We hope that Movento remains available for US fruitgrowers to utilize in the 2010 growing season.

Comment

Dear Ms Laws,

I understand you are accepting comment from stakeholders regarding the use of Movento Insecticide, and comments are due by Feb 8, 2010.

I am a California licensed Pest Control Advisor working with wine grapes in the Central Coast of California.

I have been told by growers, suppliers, and researchers at the University of California that Movento is our best option for control of Ring Nematode in sites that I oversee. At this time we have no better option.

Our crop loss on one 5 acres infested block last year, alone, was more than \$15,000 .

Without this material, I would likely need to use Admire , and Enzone insecticides, both.

I feel that existing stocks of Movento should be available to growers . We will need to apply the material by the end of April. I would like to see EPA remedy the registration situation by the end of March at the latest.

Thank you for your consideration of this problem.

Comment

Please do not approve this chemical for agricultural use or any use that would affect our honey bees. It is hard enough to deal with the intricacies of beekeeping without having to battle chemicals that diminish our bee hives brood development. Please help us survive.

"The EPA's review of tests exposing honeybees to spirotetramat found, inter alia, "increased mortality in adults and pupae, massive perturbation of brood development, early brood development, and decreased larval abundance." The EPA further found that insecticides that inhibit lipid biosynthesis have "potential for chronic effects on bee broods and development" and "may adversely affect bee broods and development;" and in 2007 the EPA found there is "uncertainty regarding the potential chronic effects of spirotetramat on pollinators because no long-term data were available." By the time the EPA made its registration decision in June 2008, it had reviewed additional studies on spirotetramat's chronic effect on bees, but it still found the data lacking because the chronic effect studies tested spirotetramat at levels lower than the label-recommended application rate."

Comment

Subject: Please continue to allow sale and use of spirotetramat (Kontos) 2-6-10

As a U.S. producer of cut flowers, I strongly urge the Environmental Protection Agency to allow continued sale and use of the chemical Kontos (spirotetramat).

We grow gerbera daisies and they can have a real problem if we can not control white fly. My company employs over 100 employees and the majority of our sales come from selling the gerbera daisy flowers. If white fly can not be controlled we would loose more than \$3,000,000 in gross sales.

As a responsible producer and employer, I am careful to ensure that all chemicals, including Kontos, are applied in strict accordance with its label requirements. It is my understanding that Kontos was approved by EPA for use following EPA's normal procedures to ensure worker, consumer and environmental safety, and that because the original registration request was not published for public comment, the court has now cancelled the registrations effective February 16, 2010. This product is environmentally more friendly than some of the alternatives, and the ability to continue its production and use is important not only to the economy, but also for our environment. Just as one example, the product is more compatible with IPM strategies including beneficial insects.

As a producer, it is very important for me to have a variety of chemicals available to fight insects. Whiteflies are particularly troublesome, in that continued use of a single active ingredient can lead in a relatively short period of time to the development of resistance in the whitefly populations. The ornamentals industry has worked together with the cotton and the fruit and vegetable industries to adopt management plans for the rotation of chemicals with differing active ingredients, in order to avoid resistance development in whitefly populations. If resistance develops in whitefly populations, devastating economic losses can and do result, severely impacting growers in all segments of agriculture. Thus, the continued availability of Kontos provides another alternative in the rotation scheme developed in the Whitefly Management Plan to help avoid development of chemical resistance in whitefly populations. Further, it should be

noted that the whitefly management plan referred to in the previous paragraph is important in the ornamentals industry's continued ability to export plants to European Union countries – thus making retention and ability to continue to use Kontos important to our international trade. Kontos gives growers one more active ingredient in the arsenal of chemistries from which good management rotations can be established. Its loss would be significant for the ornamentals industry. Since the chemical has already been approved by EPA and stocks of it are currently in the hands of growers and distributors, it is only logical that those stocks be allowed to be used. If possible, we would urge that continued manufacture of the chemical be allowed. For EPA to decide otherwise would be not only to harm our pest management strategies, but also cause economic damages resulting from loss of sales and/or loss of ability to use product already purchased. I believe that there is no risk from allowing continued use, and the benefits resulting are considerable. Furthermore, the risks and costs of disposing of existing stock are unknown, and could be significant. Pending the re-registration of this important product, this step is the most practical one for EPA to take.

I therefore urge that this chemical be allowed to be legally sold and used.

Thank you for your consideration of my comments.

Comment

I am a hobbyist beekeeper and I am concerned, very concerned regarding the danger to bees in this world. I belong to a beekeeping club and have been at this for about 5 years. I am finding it to be quite challenging to keep bees alive! I do not have answers for all of the myriad problems that have wiped out my entire swarms year after year, but I know that we live in a toxic world. I feel most people do not think of pollinators when they scan the shelves at Home Depot for pesticides to cure their gardening problems. So I appeal to a higher power to keep these products off the shelves. We all stand to benefit or suffer from the outcome. Please do whatever you can to keep this danger at bay. And thank you very much,

Comment

Dear Ms. Laws:

The California citrus industry is responding to the U.S. Environmental Protection Agency's (EPA) Web site notice requesting comments on the potential cancellation of Spirotetramat and the application of the existing stocks policy.

The California citrus industry generated farm gate revenue totaling approximately \$1.4 billion from the production of lemons, oranges, mandarins, grapefruit and other specialty fruits. California marketers supply approximately 80 percent of domestic fresh citrus sales and exports citrus valued at approximately \$509 million to important markets around the world.

Spirotetramat (Movento®) is an important production tool that enables the California citrus industry to produce high quality fruit that meets the demands of American consumers and other consumers around the globe.

We have a keen interest in EPA's decisions regarding the cancellation of Spirotetramat and the use of any existing stocks of this product. Spirotetramat is widely used by California citrus producers in their pest regimens. Its use helps growers produce a high quality crop. Therefore, any action to preclude its continued use would only serve to significantly and needlessly disrupt our industry. Such an action could also adversely affect the reputation of California citrus in the market place, undermine confidence in the safety of California citrus and endanger the livelihood of thousands of California citrus producers.

We appreciate the opportunity to share our views regarding the potential regulatory actions under consideration concerning spirotetramat and intend to highlight the danger this process poses to all citrus producers who use spirotetramat. Our sincere hope is that the Agency will act in a prudent manner, taking into consideration the substantial review that has been conducted already by the Agency in considering the registration application filed, and the scientific assessment based on that extensive review. It is clear that this chemical does not pose a significant hazard and unreasonable restrictions regarding the continued use of existing stocks is not warranted and would be imprudent if imposed. The Agency should not compound an administrative mistake by harming growers who had no hand in committing the administrative error and who simply want to avail themselves of this important crop protection tool.

Spirotetramat is Needed to Control Asian Citrus Psyllid

In Florida, spirotetramat has been shown to be effective against the Asian citrus psyllid (*Diaphorina citri*), which transmits a deadly bacterial disease known as huanglongbing (HLB). There is no known cure for this disease which is spreading quickly in Florida and causing a devastating loss of citrus acreage in Florida. Currently, the primary method to slow disease spread is severe suppression of the psyllid using multiple insecticide treatments in combination with removal of infected trees. This program has been in effect in Florida since the disease was discovered in 2005, and already psyllids are showing signs of resistance to one of the major chemical classes used, neonicotinoid insecticides.

Spirotetramat is critically needed as a rotational product to control the Asian citrus psyllid and prevent resistance development. The psyllid arrived in California in 2008, and huanglongbing is known to occur in western Mexico. California growers are organizing a treatment program for the Asian citrus psyllid with the intention of suppressing this pest and spirotetramat is one of the treatments needed for this program. Spirotetramat will be a critical tool in fighting Asian citrus psyllid, because it controls the target pest without harming natural enemies, which are needed to control other citrus pests. In addition, spirotetramat plays a strategic role because it is a class of chemistry different from the other materials needed for the psyllid control program and it is critical that a variety of chemistry be used in this program so that the psyllid does not rapidly develop resistance, making control extremely difficult. Removing spirotetramat from the

program will quickly lead to resistance to the remaining insecticides making them useless in the long term campaign to control Asian citrus psyllid.

The Florida citrus industry is being ravaged by HLB, which is being spread rapidly by the Asian citrus psyllid. The long term viability of the California and Florida industries will depend on our ability to stop the spread of HLB and Asian citrus psyllid. Controlling HLB and eradicating Asian citrus psyllid are the highest priorities for the national and California citrus industries. The U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) manages a \$45 million national program with the objective of controlling HLB and managing the spread of Asian citrus psyllid. Citrus growers are desperate for methods to eradicate the Asian citrus psyllid. It is inconceivable to the California industry that EPA would cancel the use of spirotetramat when growers need it the most. In doing so, EPA should be aware that it is contributing to the most urgent threat the national citrus industry has ever faced.

Spirotetramat Controls Harmful Insects and Promotes Biological Control

Spirotetramat was registered for use on California citrus in 2008. Laboratory and field studies conducted by Drs. Beth Grafton-Cardwell and Joseph Morse from the University of California, Riverside, have shown that spirotetramat is effective against California red scale (*Aonidiella aurantii*), cotton aphid (*Aphis gossypii*), citrus leafminer (*Phyllocnistis citrella*), citrus red mite (*Panonychus citri*) and citrus thrips (*Scirtothrips citri*).

Dr. Grafton-Cardwell tested the effects on three natural enemy groups that are key biological control agents in citrus: parasitic Hymenoptera in the form of *Aphytis melinus* that attacks California red scale, predatory beetles in the form of *Rodolia cardinalis* that feeds on cottony cushion scale and the predatory mite *Euseius tularensis* that feeds on citrus thrips and citrus red mite. The data demonstrates that spirotetramat caused little or no toxicity to the parasites and predatory beetles tested, but spirotetramat use reduced predatory mite populations. It shows a greater level of selectivity favoring natural enemies than organophosphate (OP), carbamate, neonicotinoid and pyrethroid insecticides that are registered for use in citrus, making it an important tool for citrus integrated pest management (IPM) programs.

Spirotetramat is a Key Resistance Management Tool

The primary use of spirotetramat in California citrus has been against the California red scale. A number of California red scale populations developed resistance to organophosphate and carbamate insecticides in the 1990s. According to Dr. Grafton-Cardwell, growers switched to using the insect growth regulator pyriproxyfen (Esteem®) for California red scale in 1998. This helped to reduce OP and carbamate use by 70 percent in San Joaquin Valley California citrus. However, pyriproxyfen is highly toxic to predatory beetles and its use has caused outbreaks of cottony cushion scale in the San Joaquin Valley. Dr. Grafton-Cardwell has documented the beginnings of resistance to Esteem® in some California red scale populations. Spirotetramat is a unique chemical class that can be rotated with pyriproxyfen to reduce the rate of resistance to either insecticide. The use of spirotetramat in combination with pyriproxyfen prolongs the useful life of both chemicals.

Because of its efficacy against key pests, especially California red scale, Asian citrus psyllid, its unique mode of action making it useful for resistance management and selectivity favoring natural enemies, spirotetramat is a critically needed insecticide for California citrus pest management. Cancellation of this production tool clearly harms growers who need it to control significant pests of citrus and depend on it as part of IPM and resistance management programs. The California citrus industry urges the agency to quickly re-register spirotetramat, so it will be available for use when needed next spring.

Cancellation Impacts on Growers and IPM Programs

When deciding how to remedy the spirotetramat situation, EPA should understand that growers are planning between four and eight months in advance of actual treatments using recommendations provided by the University of California and pest control advisors. Spirotetramat, as previously stated, is valued for its use in IPM programs that are designed to control insects while maintaining beneficial insects that biologically control harmful insects. The removal of spirotetramat from the system will cause growers to substitute other chemicals that may be less desirable from an IPM perspective.

Additionally, growers may contract or make purchases for pesticides four to eight months before treating to ensure that they have adequate supplies or to leave sufficient time for suppliers to respond to bids or to negotiate purchases. EPA's proposed cancellation will confuse grower purchasing decisions and complicate logistics in determining product availability. EPA's action regarding spirotetramat is likely to increase grower risk and uncertainty related to purchases of spirotetramat for the next season, which will discourage future purchase of the product. Since growers need to plan in advance for their chemical needs they would be inclined to substitute another chemical for spirotetramat because they will not be guaranteed availability of the chemical.

However, if growers have some product on hand from the previous season, they expect to use it. Therefore, EPA should allow growers to use existing stocks according to label directions including the current label restrictions to protect bees.

EPA Should Highlight its Administrative Error

In its five page *Notice of Cancellation Order*, EPA states several times that the Court decided to vacate the registration of spirotetramat due to "EPA's failure to publish a notice of receipt of the registrations for public comment." Strangely, the agency does not explain in its notice that a notice of receipt of registration is widely accepted to be an administrative requirement that rarely, if ever, generates substantive public comment. EPA should do more to highlight the fact that its error, while requiring legal repair, was nothing more than an administrative error in the regulatory context. We urge the agency to clearly explain in future communications that the error was a process error that had no substantive impact on the regulatory validity of the registration or the safety of the chemical.

EPA Should Reaffirm the Dietary Safety of Spirotetramat

A multitude of agricultural crops, including California citrus have been treated with spirotetramat and are currently being harvested and consumed by domestic and international consumers. We urge EPA to collaborate with its sister agencies at the U.S. Department of Agriculture and Food and Drug Administration to appropriately communicate that spirotetramat treated crops are unequivocally safe. Failure to communicate this important information could compound the agency's error by causing consumer fear about spirotetramat-treated crops. EPA should be keenly aware that consumers may misunderstand the purpose of the cancellation order and how it affects food they consume. EPA bears the responsibility to ensure that consumers are not confused and it is clearly understood that the anticipated cancellation procedure is not driven by dietary or environmental risk.

EPA Should Exercise its Authority to Minimize Impacts of Error

The California citrus industry strongly recommends that EPA treat the cancellation as a special case in which the agency acknowledges that there are no significant risk concerns associated with the cancelled product, keeping in mind that the registrant did nothing through its own actions to cause the cancellation. EPA's administrative error was unfortunate, but as long as EPA maintains power to minimize the impact of the error on agricultural producers and the registrant it bears a responsibility to exercise that discretion to minimize the negative implications. As such, EPA should allow unlimited use of existing stocks for labeled uses and unlimited sale by all parties including the registrant for as long as it takes to register spirotetramat - again.

EPA Should Normalize Spirotetromat's Legal Status Within 60 Days

The California citrus industry believes the agency should announce on Feb. 16, using its Web site, that it will accept comments for 30 days on the issue of bee safety. Once the comment period is closed EPA should take no more than 30 days to evaluate the comments received and immediately reinstate the spirotetramat registration. This course of action would normalize the legal status of spirotetramat within 60 days of the cancellation and allow time to more deliberately evaluate the need for additional regulatory action regarding bees, while minimizing the impact on growers and the registrant.

Additionally, given the massive record of spirotetramat's safe and effective use, the extensive information regarding its safe use around bees and its status as a "safer" chemical, we urge the agency to establish an appropriately high standard that should be met before the agency would consider prolonging the "pending" registration status of spirotetramat.

The California citrus industry appreciates this opportunity to comment on the cancellation of spirotetramat. We believe the agency has the discretion to protect growers and the registrant from additional harm from this incident and we believe conditions warrant an expedited repeat registration of spirotetramat.

Sincerely

Comment

It has come to our attention that due to a registration glitch the Bayer product, Movento (spirotetramat), for which a grape label had recently been approved, will be pulled from the market and is being questioned as to the continued use of current stocks.

We have evaluated this product over the past couple of years for control of the foliar form of grape phylloxera and found it to be very effective. For many years the grape industry has depended on products like Timik, Furdan, and Endosulfan which are highly toxic. We were pleased to see the development and registration of a new product such as Movento which has demonstrated good efficacy against grape phylloxera and at the same time was softer on beneficial insects.

Through extension outreach we were just beginning to educate Ohio grape growers to the benefits of Movento when now we hear of the current situation with its registration. Our first concern is that some of our growers may already have this product in their current pesticide inventories and would like to be able to utilize their stock since it represents a monetary investment. Also, Movento's unique mode of action towards a specific pest complex makes it an environmentally safer product than many of the currently labeled alternatives.

We hope that you will work to overcome this current glitch in registration procedure and allow our growers to use their current stock in the upcoming season and also help to smoothly expedite the corrections needed in current registration protocol.

Thank you very much.

Comment

Dear Ms. Laws:

The Arizona Department of Agriculture is submitting comments on the existing stocks provisions that the Agency is considering because of a court vacatur and subsequent cancellation of the federal registration of pesticide products containing the active ingredient, spirotetramat. Based on information received, the spirotetramat registration cancellation has been stayed until February 16, 2010, and the Agency is seeking comments on the regulation of existing stocks in the possession of sellers, distributors, and users.

The Agency is going to cancel spirotetramat registrations under FIFRA Section 6(a)(1), noting that this section of the law provides that: "The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under [sections 3, 4 or 6 of FIFRA] to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of [FIFRA]." The Agency also points out that in such circumstances, USEPA orders can be issued that can, among other things, "...contain limitations or conditions on the sale, distribution, or use that the Administrator determines to be appropriate," and that, "one such limitation that EPA frequently applies to existing stocks is a condition that any authorization of use of such stocks is limited to use that is consistent with the previously-approved labeling accompanying the product."

The registration of spirotetramat products is being vacated and cancelled because the Agency failed to provide an opportunity for public comment prior to granting registration. The cancellation is not the result of identification of unacceptable risk issues but is being caused by a procedural misstep by the agency.

We have one product with the A.I. spirotetramat registered for sale and distribution in Arizona, Movento. This product has been registered since 2008. The product is registered for a wide array of fruits and vegetables grown here and I learned through educational seminars from University of Arizona researchers, of the importance of this product to our growers. This product is used to control serious economic pests such as white flies, aphids, scale and thrips. We have received no complaints or other indications that spirotetramat has caused unreasonable adverse effects to non-target organisms in Arizona when the product is used according to label directions. Given these observations and in view of the fact that the use season is now in full swing in Arizona, it is important that the USEPA allow for the continued distribution, sale and use of existing stocks that are in the hands distributors, dealers, and users. We strongly support the Agency issuing enforceable orders to allow such use, provided that spirotetramat products are used in accordance with the label. We request that Agency's orders be crafted to enable the Department to continue to take enforcement action in the event of non-compliant applications. Additionally, it is important for the Agency to maintain food tolerances for spirotetramat, so that growers will be able to market legally treated crops without penalty.

We appreciate your consideration of our comments.

Comment

Dear Ms. Laws,

I am an Associate Professor in the Department of Entomology at Cornell University and I am responsible for developing vegetable insect pest management programs. I have worked with a number of vegetable crops over the past 20 years in New York and the Mid-Atlantic states. Currently, I have been developing integrated pest management programs for onion, snap bean and dry bean, cucurbit crops and pepper.

A significant portion of my applied research program at Cornell seeks to evaluate new insecticide products that will replace broad-spectrum products such as those in the organophosphate, carbamate and pyrethroid classes. One of these new products is spirotetramat (Movento). My experience with Movento has been limited to evaluating it on onion for onion thrips, *Thrips tabaci* Lindeman, control. Thus, my focus will be on the value of Movento to onion growers, the environment and the public.

Economic losses attributed to onion thrips and diseases they spread in the US may reach \$90 million. If the costs to control thrips with insecticides are considered, total economic damage estimates would increase by an additional \$12.5 million. Insecticide use is the primary tactic for managing onion thrips, but control is becoming less effective as populations develop resistance to insecticides and as products are lost through FQPA. To address the US onion industry's needs, broad-spectrum insecticides must be replaced with selective ones like Movento. Because Movento is highly effective against onion thrips, it can be applied less frequently than many of the broad-spectrum products. Additionally, Movento is selective against a narrow group of insects, so it conserves natural enemies and other non-target insects within onion fields. Finally, growers prefer to apply Movento over broad-spectrum products because it is a much safer product to use.

In 2009, EPA granted a Section 18 for Movento on onion for onion thrips control in New York and several other states. The product was terrific against onion thrips and was used extensively by onion growers throughout New York as well as other onion-producing states in which it was labeled. My

colleagues from other states and I have requested a Section 18 for Movento on onion for the 2010 season, which is quickly approaching.

In my opinion, it is vitally important to keep Movento available for vegetable growers in general and onion growers in particular in 2010 and the future.

Comment

I would like to comment on the decision of the U.S. District Court for the Southern District of New York to vacate all registrations issued by EPA for pesticide products containing the active ingredient spirotetramat and any further sale effective 01-15-10.

The stay on this decision should be lifted and the ban on sales should go into effect on 02-15-10 and all further sales and use of this pesticide should cease. The possible exception might be the use of existing stocks in closely controlled greenhouse situations where there would be no release of the pesticide to the environment, but that should be subject to a further court decision allowing for that use.

While the call for comments portrays the court decision as being based solely on the EPA's failure to properly announce a period of public comment in the Federal Register, a reading of the actual court decision shows that the court had serious questions about the failure of the science to assure the safety of spirotetramat before it was granted a "conditional" registration.

This is not the first pesticide released to the environment in recent years with inadequate testing and with serious unresolved questions as to safety. The EPA's responsibility is to assure the safety of these products for man and the environment, and instead beekeepers and the general public are being repeatedly put at risk and subjected to uncontrolled experimentation with disastrous consequences. Of equal concern is the fact that these questionable "conditional" registrations seem to be accomplished at the hands of the same cast of characters.

The sale and use of any products containing the pesticide spirotetramat should cease on 02-15-10 in accordance with the court decision. If there is an attempt to reregister this pesticide it must go back to the beginning of the process and sound science should assure its safety before it is registered, not after.

Sincerely,

Comment

Please consider and allow existing inventories of these products to be sold to the end user; fine to not allow Bayer to sell product to distribution until the issue is resolved, however please allow product in the channel to be moved to end users.

Thank you,

Comment

We are faced with the following set of facts.

1) Spirotetramat sale and distribution could become unlawful, despite its current legal presence and use within desert vegetable systems. All quoted text from EPA documents.

“In the absence of any action by EPA, all sale and distribution of formerly-registered sprirotetramat products will be unlawful under FIFRA once the vacatur goes into effect.”
“Without action by EPA, the termination of the registrations could thus make illegal not just any sale, but any further movement of material currently in the hands of distributors or retailers (FIFRA section 12(a)(1)(A) (7 U.S.C. §136(j)(a)(1)(A)) makes it a violation of FIFRA for any person to sell or distribute an unregistered pesticide), and subject any seller/distributor to potential civil or criminal penalties under FIFRA section 14 (7 U.S.C. §136l).”

2) This change in status could leave the user community with ambiguous market and regulatory signals, and may lead to use patterns that do not conform to currently in force label requirements.

“Thus, in the absence of EPA action, users of unregistered pesticides are not obligated to follow the labeling (which, for registered pesticides, prescribes enforceable conditions for using the particular pesticide, among other things) accompanying the product. Therefore, once the registrations are terminated, unless EPA takes action, persons holding stocks of spirotetramat will not be legally precluded from using those stocks without following label directions, including the restrictions on timing of applications that EPA required in order to protect bees.”

3) EPA has the authority to develop guidelines for sale and use of existing stocks that could allow the safe and effective use of spirotetramat currently in marketing channels and in users hands.

“The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under [sections 3, 4 or 6 of FIFRA] to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of [FIFRA].”

4) While the procedural anomaly that led to this court decision is unique, the EPA has ample guidance from previously established policy for handling cancelled pesticides.

“Regarding cancelled pesticides, the existing stocks policy identifies particular considerations relevant to five different cancellation scenarios: 1) cancellations where the Agency has identified particular risk concerns; 2) cancellations where a registrant has failed to comply with an obligation of registration; 3) cancellation of products while subject to data call-in notices under section 3(c)(2)(B) of FIFRA; 4) cancellation of registrations subject to reregistration requirements and label improvement programs; and 5) other voluntary cancellations.”

“Thus, EPA identified in the policy statement six criteria it might consider in making such risk benefit decisions, including: 1) the quantity of existing stocks at each level of the channels of trade; 2) the risks resulting from the use of the existing stocks; 3) the benefits resulting from the use of such stocks; 4) the financial expenditures users and others have already spent on existing stocks; 5) the risks and costs of disposal or alternative disposition of the stocks; and 6) the practicality of implementing restrictions on distribution, sale, or use of the existing stocks.”

Our goal in commenting on spirotetramat end of stocks use in Arizona is to prevent unacceptable economic, environmental and public safety risks consistent with EPA guidelines in the registration of any pesticide.

“That determination, like the initial decision to register a pesticide, will focus on the social, economic, and environmental risks and benefits associated with such sale and use.”

Spirotetramat is recently registered and available for use in desert vegetables grown in Arizona. Despite its recent appearance in the marketplace, researchers have been examining this active ingredient in Arizona production systems for more than four years. As a reduced-risk, selective insecticide, spirotetramat affords users a novel chemistry for controlling aphid and whitefly pest species without disrupting natural controls of other species and creating better safety for the user and consumer. All quoted text that follows is from a recently published scientific paper by Drs. John Palumbo and Steve Castle in *Pest Management Science* (2009).

“Many of the modes of action for these new chemistries exploit alternative nerve receptor sites, novel physiological processes and other key biochemical functions specific to insects.³² This has not only made them safer for the user and consumer, but in many cases more efficacious than the neurotoxins used in the past.”

However, the fully systemic action of this foliar pesticide is virtually unique among pesticides registered for use against this pest complex.

*“Another systemic insecticide, spirotetramat (ketoenol), was recently registered for use on desert produce crops. Although it has no practical soil activity, following foliar application and uptake, the insecticide is translocated acropetally and basipetally within the entire vascular system.³⁶ Research to date has shown excellent residual activity against aphid species such as *Nasonovia ribisnigri* Mosely and *Aulacorthum solani* Kaltenbach in lettuce that typically require repeated applications for economic control.³⁷ Again owing to its foliar systemic activity, spray coverage with spirotetramat is not as critical as with many older, conventional compounds.”*

The opportunities for efficient control and therefore lower exposure of users and the environment to a suite of broad-spectrum neurotoxic chemistries is very important in our production system and consistent with our local efforts to transition growers to safer, more selective IPM systems.

“...the changeover of IPM to safer and more effective insecticides from highly toxic, broad-spectrum insecticides of previous decades has been a welcome development. In addition to the positive attributes already described, many of the newer compounds are used at greatly reduced rates in lettuce and leafy vegetables that result in lower pesticide loads in the environment.”

The transition in our desert vegetable industry to lower risk, selective chemistries is key to the reduction of broadly toxic insecticides in our system, more efficient and economical control of target pests, and creating more safety for users, consumers, and the environment.

“Overall, the use of newer, selective compounds over the past decade in desert produce crops has certainly reduced the risk of exposure to toxic insecticide residues for consumers and farm

workers....Perhaps the most telling sign has been the overall reduction in the number of foliar spray applications made to desert lettuce crops over the years, [where] in the 1980s, an average of 12 – 15 sprays were applied to lettuce annually.... in 1996, growers applied an average of nine foliar insecticide applications to lettuce. Most recently, ... a range of 4 – 7 foliar sprays were applied to lettuce crops in 2007.”

“These data suggest that overall usage of the broadly toxic chemistries on head lettuce has declined steadily over the past 5 years, but, more importantly, since 1996 the usage of organophosphates and carbamates on desert head lettuce alone has declined significantly. In contrast, the use of the selective insecticides on lettuce has increased almost twofold over this same 14 year period.

In addition, our most recent history (2009) shows a major shift in insecticide use patterns in desert head lettuce. Our most broad spectrum chemistries (endosulfan, acephate, diazinon, and dimethoate) have decreased by over 50%. In fact without exception, all active ingredients declined precipitously in 2009 once spirotetramat (and two other selective active ingredients) was introduced to the marketplace (see Table 1 from Palumbo & Castle, 2009). Spirotetramat was used on nearly 3/4ths of the lettuce acreage last year.

“Results from the 2009 University of Arizona pest management workshop estimated that, for the first time, these broadly toxic compounds were actually applied to fewer acres of desert head lettuce than the selective insecticides (Palumbo JC, unpublished data).”

Our current work to examine non-target effects of spirotetramat in cotton is beginning to show the selective advantages of having such chemistry in our desert systems. While data analyses are ongoing, spirotetramat appears to be as selective as its related chemistry spiromesifen in our system. We determined in prior work that spiromesifen is “fully selective” in our cotton system affording users a new option for conserving the significant natural controls and pollination services present in cotton (Ellsworth & Naranjo, unpubl. data).

In short, spirotetramat is not only a safe and efficient insecticide in our desert vegetable systems, it is helping the entire industry transition to a more completely selective and therefore superior IPM system for these fresh market commodities. **We urge EPA to preserve the legal use of spirotetramat through the end of stocks period. All indications are that there are no new risks associated with this important product. On the contrary, the data are compelling that we are creating an environment where more reduced-risk chemistries are used than the broadly toxic conventional compounds. EPA, by acting now to insure the organized and legal use of this active ingredient, will be protecting the public and environment from the risks of increased usage of broadly toxic insecticides that will otherwise have to be used in place of spirotetramat in our fresh market vegetable systems.** This would be a large step backward for our industry and represent a major economic hardship as well. Furthermore, we support EPA in taking swift action to restore all previously approved Section 3 uses of spirotetramat. We also look forward to new labels for this critical active ingredient coming forth quickly in 2010 (e.g., in cotton and other agricultural crops).

References

Palumbo J.C. & Castle S.J. 2009. IPM for fresh-market lettuce production in the desert southwest: the produce paradox. *Pest Management Science* 65: 1311-1320. Available online: <http://www3.interscience.wiley.com/cgi-bin/fulltext/122653066/HTMLSTART>.
Submitted 2/8/2010

Table 1. Estimated usage of broadly toxic (organophosphates, carbamates, cyodienes and pyrethroids) and selective (reduced- and low-risk) insecticide chemistries on head lettuce in Arizona, based on NASS and PCA surveys^{18,25}

Insecticides	Estimated number of head lettuce acres treated (<i>total acres in production</i>)					
	1996 (55 000)	2005 (50 000)	2006 (48 000)	2007 (45 500)	2008 (46 000)	2009 (46 000)
Broadly toxic chemistries						
Pyrethroids	256 960	182 030	169 894	148 376	150 739	147 726
Methomyl	207 900	45 150	48 114	30 986	22 523	16 555
Thiodicarb	23 595	0	0	0	0	0
Endosulfan	36 630	17 760	17 566	20 020	16 480	8 118
Acephate	27 720	9 433	6 376	11 386	14 128	9 396
Diazinon	10 285	15 800	21 758	9 646	12 150	5 075
Dimethoate	56 760	14 656	8 050	3 829	3 487	0
<i>Total usage</i>	<i>619 850</i>	<i>284 829</i>	<i>271 758</i>	<i>224 243</i>	<i>219 507</i>	<i>186 870</i>
Selective chemistries						
<i>Bacillus thuringiensis</i>	74 250	1 125	288	0	0	0
Abamectin	11 495	0	0	0	0	0
Imidacloprid	11 550	36 443	40 488	22 818	29 973	19 890
Emamectin benzoate	–	4 483	11 928	16 124	10 670	6 989
Methoxyfenozide	–	32 728	33 926	28 494	27 141	16 740
Spinosad/spinoteram	–	114 438	103 144	82 257	98 382	85 590
Indoxacarb	–	6 363	10 609	8 395	9 994	2 475
Pymetrozine	–	7 508	3 755	1 081	432	0
Acetamiprid	–	–	10 654	19 963	9 118	1 238
Spiromesifen	–	–	1 272	1 145	2 800	585
Flonicamid	–	–	–	10 385	17 738	3 420
Spirotetramat	–	–	–	–	–	33 953
Chlorantraniliprole	–	–	–	–	–	16 509
Flubendiamide	–	–	–	–	–	4 500
<i>Total usage</i>	<i>97 295</i>	<i>203 088</i>	<i>216 064</i>	<i>190 662</i>	<i>206 248</i>	<i>191 889</i>

Comment

Reference above, Virginia recommends, for the pesticide products currently in the possession of the end user, the EPA allow the use of the existing stocks. Regarding those existing stocks in the channels of trade but which are not in the possession of the intended end user, we defer to the EPA to determine how best to handle those stocks and shall cooperate with the EPA in support of whatever action is taken.

We appreciate the opportunity to comment. Should you have any questions or require additional information, please do not hesitate to contact me directly.

Thank you.

Comment

Dear Ms. Laws:

I am writing with respect to the order to vacate all pesticides containing the chemical spirotetramat

While the “Opportunity for Public Comment” suggests that the reason for the opportunity is to address the failing of the EPA to properly post the registrations in the Federal Register, the actual court order indicates that there was inadequate testing of the chemical before it was granted preliminary approval.

I am extremely concerned about the disposition of current stocks already in the pipeline. I do not believe the EPA should, in any way, intervene in the established process of vacatur. All sales should be immediately deemed unlawful.

The “use” argument demands EPA action. The circular logic for the EPA’s failure to impose the requirements for proper use, application and disposal of improperly registered pesticides is ludicrous. Had the EPA properly registered the product, then this argument would be moot. As the EPA is at fault for the improper registration, the EPA needs to be held accountable for the proper use, application and disposal of all products containing spirotetramat that currently exist in the pipeline. I suggest that, at its most generous, the EPA limits its use to greenhouse applications where any misapplication or misuse would not cause any potential damage to our beleaguered pollinators. There is, however, a strong argument to stopping the use of spirotetramat for all applications due to the lack of strong science supporting its use at all.

In the event that Bayer resubmits an application for approval of spirotetramat, I am advocating for the consideration process for spirotetramat to essentially start from ground zero with the potential effects upon the environment properly assessed and the testing conducted with the recommended application quantities by agencies that do not have a vested financial interest in the product’s success. Per the court decision “if the product merits registration it should survive FIFRA’s notice and comment period and reexamination by the EPA, and it will return to the market. If it does not, then it should never have been registered and sold. The fact that Bayer has already begun reaping the rewards of the outcome of a flawed regulatory process does not prevent the EPA’s registration from being vacated and that regulatory error from being corrected.¹¹”

Sincerely,

Comment

The following comments are in response to the announcement for an open public comment period regarding the topic listed above.

The Wisconsin Department of Agriculture, Trade and Consumer Protection (DATCP) notes that the Notice of Cancellation Order did not address tolerances previously established for spirotetramat. Users and State lead agencies would benefit from clarification of the future status of the established tolerances in the existing stocks provision. If the Agency were to revoke any tolerances in conjunction with the cancellation order, DATCP requests that the Agency establish an end date for those uses and provide reasonable advance notice to users and State lead agencies.

From an enforcement standpoint, DATCP requests that the existing stocks provision provide users with a reasonable use timeframe to allow for attrition of products in the channels of trade. If the Agency were to establish an end date for spirotetramat use, DATCP requests that the Agency provide users and State lead agencies with reasonable advance notification in order to allow for realistic compliance and enforcement.

DATCP notes that the Notice of Cancellation Order did not specifically address uses of spirotetramat authorized under Section 18 emergency exemptions. In 2009 EPA granted Wisconsin a specific emergency exemption under FIFRA Section 18. The exemption authorized the use of Movento™ on dry bulb onions for control of onion thrips. The exemption provided a valuable new tool for onion producers; its unique mode of action provided producers with an additional, effective, chemistry class to use as part of a resistance management program. The EPA Section 18 team previously determined that this use is eligible for recertification in 2010 and DATCP intends to submit a recertification request. DATCP requests that the Agency develop the existing stocks provisions in a way that does not negatively impact the 2010 recertification request or the ability of onion producers to use Movento in 2010.

Thank you for considering these comments.

Comment

On behalf of the Florida Farm Bureau Federation, the state's largest general agricultural association representing over 140,000 member-families statewide, I am submitting these comments with regards to the Notice of Cancellation Order of spirotetramat (the active ingredient in Movento and Ultro by Bayer CropScience). Agriculture continues to be Florida's second most lucrative industry providing over 750,000 jobs and \$100 billion dollars a year of direct and indirect income to the economic sector. Florida's mild climate allows the state to produce crops year-round, but also causes the state to be more susceptible to pests, weeds, and diseases.

Having access to and being able to legally use important crop protection products, such as spirotetramat, gives Florida's agriculturalists the confidence to produce commodities that feed people all over the world. Spirotetramat is an important and widely used insecticide in Florida on many agricultural commodities including citrus, potatoes, peppers, tomatoes, cabbage, and numerous others to help combat attacks by white flies, aphids, citrus psyllids, and certain scale insects. Also, in circumstances where other crop protection chemicals have shown resistance, spirotetramat has been a proven alternative. Spirotetramat products can be sprayed at a lower volume, resulting in time and labor savings, as well as more timely applications to the entire area to be treated. These products also have a high level of residual efficacy and help protect new plant growth. Because of the benefits listed above, being able to legally use effective crop protection tools allows the agriculturalists in the United States to provide the most affordable, safest, and most abundant food supply in the world.

The Florida Farm Bureau Federation is concerned that there has not been an urgent response by the Environmental Protection Agency to resolve the procedural issues linked with the failure to publish notification of the receipt of the intent to register spirotetramat in 2006. Products containing spirotetramat were registered after enduring widespread reviews both domestically and internationally and we feel that the current approach by the Environmental Protection Agency may impede a timely re-review and registration of the product. There is also concern about the potential impacts on growers who depend on, and have made substantial investments to obtain, these important crop protection tools. The Environmental Protection Agency should use its discretion in such a manner that allows the sale and distribution of spirotetramat that is currently in the marketplace and allow its use by growers in accordance with the current labeling.

Once again, the Florida Farm Bureau Federation strongly believes that having access to important crop protection products such as spirotetramat is vital to the success of providing a safe, affordable, and abundant food supply. We would encourage the Environmental Protection Agency to very carefully examine their options and choose the one that allows the timely movement of agricultural crop protection chemicals that were legally purchased. We also ask that the Environmental Protection Agency take into account the economic impacts to stakeholders of any proposed action. Thank you for your consideration and please contact me if you need further information.

Comment

The National Honey Bee Advisory Board represents both the American Beekeeping Federation and the American Honey Producers Association. On issues related to pesticide enforcement and regulation, we are empowered to address policy issues facing our industry. Collectively, our two organizations represent most of the nation's beekeepers through our membership.

Managed honey bee colonies are at risk today as never before. Our industry is faced with a crisis the likes of which we have never seen before. The very viability of an entire industry is imperiled. The NHBAB believes that pesticide misuse is a critical part of the problem we find ourselves in today. Regulations regarding pesticides, including risk management and risk assessment, have been lax. Many products have been registered without sufficient field studies to prove adequate safety. Safe use practices in many states do not ensure that environmental cautions, including the Bee Warning, are properly adhered to.

Systemic pesticides as a class, and GMO pesticides as a class, are two of the primary fields of concern. Simply put, there is no way to keep the nectar and pollen of the bloom "away" from the chemical. Chemicals, which rely on these two methods of delivery generally, move through the plant and are present at bloom. Therefore, prevention is no longer an option with these forms of delivery. Many of these compounds have long half-lives in both soil and plant tissue of woody shrubs and trees.

The NHBAB believes that Movento poses a known danger to pollinators. This is clearly shown in the bee cautions offered by EPA. Movento received conditional registration with the environmental warning for honey bees as follows:

“This product is toxic to bees. Direct exposure to treatment or residues on Blooming crops or weeds can lead to effects on colonies. Do not apply this product or allow it to drift if bees are visiting the treatment area.”

Product label in use today reads

“This product is potentially toxic to honey bee larvae through residues in pollen and nectar, but not to adult honey bees. Exposure of adult bees to direct treatment or residues on blooming crops can lead to effects on honey bee larvae. See the ‘Directions for Use’ section of this label for specific crop application instructions that minimize risk to honey bee larvae.”

This brings us to the issue at hand, what should be done with existing stocks, and if these stocks are to be used how are they to be used? EPA offers two questions below.

1.) “The term “distribute or sell” is defined very broadly in FIFRA section 2(gg) (7 U.S.C. §136(gg)), and includes, among other things, any “shipment” of unregistered pesticide. Without action by EPA, the termination of the registrations could thus make illegal not just any sale, but any further movement of material currently in the hands of distributors or retailers (FIFRA section 12(a)(1)(A) (7 U.S.C. §136(j)(a)(1)(A)) makes it a violation of FIFRA for any person to sell or distribute an unregistered pesticide), and subject any seller/distributor to potential civil or criminal penalties under FIFRA section 14 (7 U.S.C. §136l)”.

2.) “There is no corresponding provision of FIFRA that prohibits *use* (as opposed to distribution or sale) of unregistered pesticides (*see* FIFRA section 12 (7 U.S.C. §136j)). Furthermore, section 12(a)(2)(G) (7 U.S.C. §136j(a)(2)(G)) only makes it a violation of FIFRA for any person to “use any **registered** pesticide in a manner inconsistent with its labeling” (emphases added); there is no provision that requires that unregistered pesticides (including formerly-registered pesticides) be used according to their labels.

Thus, in the absence of EPA action, users of unregistered pesticides are not obligated to follow the labeling (which, for registered pesticides, prescribes enforceable conditions for using the particular pesticide, among other things) accompanying the product. Therefore, once the registrations are terminated, unless EPA takes action, persons holding stocks of spirotetramat will not be legally precluded from using those stocks without following label directions, including the restrictions on timing of applications that EPA required in order to protect bees.”

The NHBAB believes that Spirotetramat represents a threat to insect pollinators and specifically managed honey bee colonies. Unrestricted use is clearly NOT an option.

NHBAB is requesting that EPA require the registrant (Bayer) to recall all existing product.

NHBAB believes that Bayer should be allowed to transport both recalled product and product on hand out of the United States for distribution and sale in other countries where Spirotetramat is legally registered. This approach would seem

reasonable since Spirotetramat is “registered” for use in several other countries. This approach would seem to us as the most in keeping with the intent of FIFRA and would present the least danger to the environment.

We hope that EPA will find these suggestions helpful in the decision making process to deal with this unprecedented situation.

Sincerely,

Comment

Florida Fruit & Vegetable Association has observed with interest the Agency's response to the Ruling by the Ninth District Court for the Southern District of New York that vacated the registration of the insecticidal active ingredient spirotetramat. This active ingredient is marketed under the trade names Movento®, and Ultor® by Bayer CropScience has become a critical component of the pest management programs for several of the crops grown by our membership. This is especially true for those crops attacked by the citrus psyllid, whiteflies, aphids and certain scale insects. We welcome the opportunity to comment on the proposed cancellation of the registrations that allow the sale and distribution of these products.

Substantive and detailed comments on this proposed cancellation order were prepared and submitted on behalf of the Minor Crop Farmer Alliance by its Counsel, Mr. Edward Ruckert, McDermott, Will and Emery. FFVA endorses those comments and encourages the Agency to follow the recommendation for unrestricted distribution and sale of any product remaining in the channels of trade.

While we understand the underlying premise associated with the ruling, we do not understand the difficulty faced by the agency in moving quickly to resolve the procedural issues associated with the failure to publish notification of the receipt of the intent to register the product in 2006. This product underwent extensive review both domestically and internationally with the subsequent decision to register the uses in question. It appears to our association that the approach being proposed by the Agency totally ignores that extensive review process and would unduly impede the timely re-review and registration of the product.

We are also especially concerned by potential impacts on growers who depended on the use of these products if this situation is not resolved expeditiously with minimal disruption in their ability to use products that they legally purchased prior to the pending vacatur of the registration.

Of equal concern is the significant investments at the grower level for product that is already in the hands of the grower or that were scheduled for purchase under forward contracts for use later in the season. The ability to distribute those previously registered products through the normal marketing channel appears to be severely limited under many permutations of the current proposal described in the Notice. We look forward to working with the Agency to resolve this situation and would encourage the Agency to carefully consider the impact to downstream stakeholders of any proposed action.

Sincerely yours,

Comment

Representatives of Hawai'i's agriculture stakeholders were queried for their opinions about what should be done with existing stocks of spirotetramat, i.e., spirotetramat products which will remain in either the hands of end users or in the inventories of retailers or wholesalers after February 16, 2010.

There was unanimity that growers who possess existing stocks of spirotetramat should be allowed to use their products, according to existing labeling. There was a preference expressed for spirotetramat to be used until existing stocks are depleted. Otherwise, a timeframe should be defined during which growers can use their existing stocks and a procedure can be established to return or dispose of remaining spirotetramat products. Those who expressed an opinion indicated that retailers and wholesalers should be allowed to sell the remaining stock on hand—and that adequate time must then be allowed to use for those products to be used after purchase.

It would very costly to recall these products, nation-wide. The reason the judge vacated the spirotetramat registration was because EPA didn't follow proper procedures, and not because this material is particularly harmful to workers, non-target organisms, or the environment, when this pesticide is applied according to its labeling. Therefore, it does not appear necessary to recall existing stocks of spirotetramat.

However, there are benefits to allowing the remaining stocks of spirotetramat to be used. This systemic insecticide is very important for Hawai'i's growers to effectively control aphids and whitefly on fruiting vegetables, crucifers and leafy vegetables and two newly introduced and potentially very damaging pests, the macadamia felted coccid on macadamia nuts and the tomato yellow leaf curl virus (TYLCV) which is transmitted by the sweetpotato whitefly and the biotype B (or silver-leaf) whitefly. In some cases, there may only be one practical alternative chemical to spirotetramat.

Spirotetramat is an excellent insecticide for vegetable crops for resistance management. It is a very important chemical that is used with other mode of action insecticide classes in a rotation to prevent resistance. Due to Hawai'i's tropical climate, many insects such as aphids and whiteflies are serious, year-round pests for many diversified crop producers. The availability of spirotetramat in Hawai'i will help prevent or retard the development of insect resistance.

If EPA were to issue an order to stop using all existing spirotetramat products as of February 16, 2010, it would be unfair not to compensate—promptly—growers who have spirotetramat products remaining in their possession. Spirotetramat products are expensive. Many of Hawai'i's farms are very small operations. Many of them have extremely limited resources and many are immigrants. Those who selected spirotetramat did so reluctantly because they have few, if any, appropriate options that will enable them to manage their pests and grow marketable products.

There is another practical reason that EPA should expressly allow existing stocks to be used: enforceability of labels. The decision of the court did not identify any violations in the determination of use patterns for which spirotetramat was registered. If EPA specifies that existing stocks of spirotetramat may be used according to existing labeling, use and distribution of spirotetramat will be subject to the provisions determined by its registration process. Violations (including illegal distribution and mis-applications) would be clear and subject to normal sanctions.

It should be noted that growers are not the only end users of spirotetramat. Because of the serious need of some of Hawai'i's ultra-minor crops for pest management tools, the relatively safety of this chemical, and its usefulness for resistance management, research projects have been executed and were planned for spirotetramat. Existing stocks could be used for planned projects to proceed. Unlike pesticides which are cancelled by normal procedures, spirotetramat may be registered in the future. Researchers may, with the full understanding that spirotetramat may never be registered, decide to learn what they can to manage some intractable pest problems and, perhaps, be prepared with needed recommendations in the event that spirotetramat becomes registered.

Hawai'i's agriculture community recognizes that the registration of spirotetramat will be vacated on February 16, 2010, followed by a cancellation order from EPA. However, it is obvious that this legal decision does not mean that spirotetramat products that have been distributed and sold will cease to exist on that date. Growers and vendors did not contribute to the problem with the spirotetramat registration. And there should be a resolution that follows the ruling of the court but does not unduly punish those who purchased and sold the product in good faith.

This information has been provided by extension agents and specialists of the College of Tropical Agriculture and Human Resources, one representative, each, of Hawai'i's macadamia nut industry, and agricultural chemical vendors.

Comment

Ms. Laws,

I am the General Manager of Pacific Vineyard Co. I farm over 2,200 acres of wine grape vineyards and deliver the grapes to many wineries within California. Scott Williams is the Vineyard Manager of our company, responsible for all of the day-to-day decisions that are made in the vineyards. Erin Amaral is our Pest Control advisor and viticulturist for our company, responsible for all pesticide recommendations and applications to the vines.

All three of us have first hand experience with the use of Movento (Spirotetramat) due to our use of the product in 2009 on 1500 acres of vineyards for the control of mealy-bugs. Our vineyards have been infested with Mealy bugs for many years, and the problem has recently turned worse. This is due to the lack of safe and effective chemistry to treat this insect. When Movento became available for us to use, we asked a lot of questions, and with the proper answers, we proceeded to use the product to try to control our Mealy Bug infestation. We were glad to see better control of this insect with this Movento.

In previous years we have had to use the same chemistry of materials to try to achieve less than adequate control of Mealy Bugs. Previous to Movento becoming available, we were using Lorsban, a category 1 insecticide in our rotation. Even with the use of Lorsban, some of our grapes were unmarketable due to the highly explosive vine Mealy Bug numbers. Movento, being a much safer product to the environment, was highly desired to replace Lorsban, and numerous other alternatives.

With the help of UC Davis and UC Berkley scientists, we have developed a Biological control Program in our vineyards. We cooperate with these UC professors and student advisors to release predatory wasps, mealy bug destroyers, and other biological insects that prey on the mealy bugs in our vineyards. This has been an ongoing successful project for almost 10 years now. Complimenting this Biological program has been the placement of Pheromone traps used for mating disruption. The University, and our viticulture staff, have developed ant bait stations to control Argentine Ants due to the ants "farming and harboring" mealy bugs which increase the survival of both mealy bugs and ants.

All of these biological methods of controlling mealy bugs would be lost entirely if we can no longer use Movento. If we cannot use Movento, we would have to return to using Lorsban,

Applaud, and Venom. These last 3 products are toxic to the mealy bugs, and also toxic to any biological insects and programs that we have invested in over the years.

Our vineyards became certified Sustainable in 2008 through the Central Coast Vineyard Team's SIP program. We choose to certify our vineyards because we knew Movento was available in the near future, and we could cease applications of toxic category 1 chemicals. This has been a huge investment for the vineyards and wineries. The wineries have now changed all of their wine labels to include SIP certification on each label. Our investment in Sustainability and mealy bug control, would be lost if we lost our ability to certify our vineyards and wines under the SIP program. We could loose a large portion of our crop if Movento were not available due to mealy bugs infesting each and every cluster making them un-marketable. We could spray with the toxic Lorsban, but then we would no longer be certified as Sustainable, our vineyard workers would have to work within more hazardous chemicals, our wineries would loose their investment, and the vineyards could loose long term contracts that depend on delivery of clean fruit that is grown with a certification of Sustainability.

We would like to see the continued the un-restricted use of Movento. If this is not possible, growers should be able to use the product that has already been purchased and that we have in our inventory.

Time is of the essence. All of our farming budgets have already been approved. If Movento will no longer be available for use in 2010, all 29 of our budgets will have to be re-written and submitted to our banks for approval. There will be large increases in farming costs, and then each winery will have to also re-submit to their lender a new budget for changing marketing materials and labels etc.

Bud Break occurs near the end of February in many of our vineyards. We need to know now if Movento is not going to be available to use in this season so that we can apply a pre-bud break application of an alternate chemical.

Please consider how this would effect our operation in your decision.

Comment

Dear Ms. Laws:

The following comments are submitted on behalf of the California Specialty Crops Council in response to the request for comments regarding the subject Notice of Cancellation Order which appeared on the Office of Pesticide Programs website on January 25, 2010.

The California Specialty Crops Council (CSCC) is a grower supported partnership of over 20 commodity organizations representing stonefruit, strawberries, root crops, vegetables, leafy greens and beekeepers. We also are supported by licensed pest control advisors, shippers, packers, handlers, and processors of various agricultural commodities. The CSCC engages in activities and projects which support sound pest management and stewardship for California growers. Our members are extremely interested in the development of pest management tools that are both efficacious and environmentally sound; many of our growers use the reduced risk insecticide spirotetramat.

We are contacting you today to urge the Agency to reconsider the cancellation of Spirotetramat and existing stocks provision as published on your website; we are particularly concerned that action by the Agency will be precedent setting action impacting not only this particular crop protection tool, but many others. We specifically ask that the Agency immediately publish the missing information, establish a public comment period, and then proceed with a process to address the submitted comments. In addition, the CSCC encourages the Agency to issue a full authorization for the distribution and use of existing stocks of the product until supplies are exhausted.

As we understand this matter, it is one of administrative oversight, and not one in which harm to users, consumers or the environment is at stake. As a group that is involved with the registration process and IR-4 Minor Use Registration Program, we are aware that a thorough review of all the available data confirmed that there is no significant risk associated with the use of Spirotetramat.

The California Specialty Crops Council looks forward to the Agency's decision on the existing stocks as well as the necessary publication of the notice for public comment necessary to proceed with the registration of Spirotetramat.

For your convenience, a signed copy of this letter on our letterhead in PDF format is attached to this e-mail.

Respectfully submitted,

Comment

EPA pollinator protectors, (bee team) how can this be?

<http://www.hortweek.com/channel/EdiblesProduction/article/981584/Bayer-CropScience-introduces-new-insecticide-Brassica-salad-growers/>

Comment

Dear Ms. Laws:

I am the major owner and general manager of CSS Farms. We grow chipping potatoes in TX and NE. In recent years, a new disease called Zebra Chip has caused major problems for our production, particularly in TX. The vector is the potato psyllid.

Through collaborative and interdisciplinary efforts by USDA ARS, Texas Agri-Life Extension, and a consortium of growers and Frito-Lay, we have developed an IPM approach to controlling psyllids. Movento is a cornerstone of that approach, as it is one of the chemicals with the greatest efficacy on psyllids (in part due to its improved translaminar and systemic activity in the plant), while doing little or no damage to beneficials.

To effectively control Zebra Chip, we need to control psyllids throughout the growing season. In addition, it is important to avoid the development of resistance by rotating chemicals. Before we had Movento, we were forced to use harsher chemicals that were hard on the beneficials, and as a result, we ended up with ineffective psyllid control despite the application of numerous chemicals. This led to severe problems with

Zebra Chip, which had severe economic impacts on all of the chip growers in TX, NM, and KS, as well as less severe impacts in CO, NE, WY, and CA. The significance of this problem is evidenced by the fact that USDA recently approved a \$6.9 million Specialty Crop Research Initiative grant to help develop solutions to the problem.

Because of the Zebra Chip problem, Frito-Lay and other chip processors have moved some of their chip potato production further north, which has the negative impact of increasing the distance to their processing plants, with the attendant negative impacts in terms of carbon footprint, etc.

Frito-Lay has four chip manufacturing plants in TX. They would like to source the potatoes for those plants from growers in TX if possible in order to meet their customer's demands for more "Local Grown" produce and a reduced carbon footprint. Movento is a critical resource for the growers in TX to be able to control psyllids.

As EPA works to correct the deficiencies in the Movento label, we would ask that EPA allow the continued use of existing stocks, as it will have less negative impact than the other chemicals that we will be forced to use in the absence of Movento.

Thank you for your consideration.

Comment

The U.S. Apple Association (USApple) is the national trade association representing all segments of the domestic apple industry. Members include 36 state apple associations representing 7,500 apple growers throughout the country, as well as over 300 individual firms involved in the apple business. USApple appreciates this opportunity to comment on the disposition of existing stocks of spirotetramat as described in EPA's announcement of its intent to issue a registration cancellation order.

On January 25, 2010, the EPA published an announcement of intent to issue a cancellation order for the registration of spirotetramat in response to a ruling by the U.S. District Court for the Southern District of New York that vacated the registration issued by the EPA in June 2008. The agency cites the FIFRA provision that allows them to issue enforceable orders governing the sale, distribution, and use of existing stocks of cancelled pesticides. Reference is made to section 6(a) (1) of FIFRA (7 U.S.C. §136d (a) (1)) that provides: "The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under [sections 3, 4 or 6 of FIFRA] to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of [FIFRA]."

The agency's description of applicable law further explains that "if the Agency has no significant risk concerns associated with a cancelled product, the policy statement suggests that the Agency will generally allow unlimited use of existing stocks, and unlimited sale by persons other than the registrant. A registrant will generally be allowed to continue to sell existing stocks for 1 year after the date cancellation is requested, or 1 year after the date the registrant has ceased to

comply with the responsibilities that are placed upon registrants, whichever date is sooner. 56 Fed. Reg. at 29362, 29364. . . .The Agency believes the criteria outlined in the existing stocks policy are generally appropriate for use in existing stocks situations, and may well be appropriate for use in the case of spirotetramat.” USApple agrees that the agency has the authority, and that the situation regarding the spirotetramat registration is appropriate for application of the existing stocks policy.

Sudden cancellation of spirotetramat could have significant unintended consequences. The economic impact of a sudden withdrawal of spirotetramat could extend far beyond the obvious impact on the registrant. Distributors and growers with unusable inventory for which they have paid face the loss of precious capital at a time of serious stress in the national economy. In the relatively short time since spirotetramat was registered for use by the EPA, anecdotal data provided by growers and university extension entomologists indicates that it provides effective control of a number of significant apple pests including the Apple Aphid, Rosy Apple Aphid, Whiteflies, and San Jose Scale. It has significant potential for use in IPM and IRM programs. Growers with inventory of spirotetramat not only face the inability to use an effective pest management tool, but would be forced to expend additional capital on alternatives.

As the agency noted in the announcement of the intent to cancel, this is a unique situation, with the proposed cancellation directly tied to the court actions and not based on risk concerns. In fact, the agency has stated that it “intends to treat Bayer’s earlier-filed applications for registration as now pending before the Agency.” The U.S. Apple Association has been a consistent advocate for an environment that allows for the widest possible variety of pest management tools available for growers to utilize as part of their individual pest management strategy. Spirotetramat has demonstrated the potential to be a significant addition to pest management tools available to growers.

The agency has the statutory authority to substantially mitigate the negative economic consequences to innocent third parties arising from the sudden cancellation of spirotetramat. By allowing the utilization of existing inventories by growers, as well as allowing maximum flexibility to the registrant and distributors to sell and distribute existing stocks, the threat of market disruption and serious economic consequences would be reduced. It is in the public interest that the EPA exercises its statutory authority to allow for the distribution, sale, and utilization of existing stocks during the period from when the cancellation notice takes effect until the reconstituted registration process is completed. The U.S. Apple Association urges the agency to allow for the sale and use of existing stocks of spirotetramat throughout the distribution chain.

Comment

Has anyone submitted public comments on EPA's spirotetramat cancellation order? If so, could I get copies of the comments? Thank you.

Comment

Given the weather paralysis of the government and entire Washington area this week, can you accept late comments on the “Spirotetramat - Notice of Cancellation Order”?

Comment

I recently submitted comments to your office on the pending ban on the sales of products containing spirotetramat. I would like to review the other comments that have been submitted. Can you tell me how I can do this?

Comment

Dear Ms Laws:

CropLife America is pleased to comment on the action that EPA should take regarding disposition of the existing stocks of spirotetramat. CropLife America is the national crop protection association that represents the companies that develop, manufacture, formulate and distribute crop protection chemicals and plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers. The precedents emerging in the litigation regarding the insecticide spirotetramat and the corresponding actions being taken by EPA have potentially far-reaching implications for other pesticide products as well. Hence CropLife America takes the unusual step of commenting on regulatory actions involving a specific product.

The registrations for products containing the active ingredient spirotetramat were vacated by a recent court order in the case of *Natural Resources Defense Council, Inc. v. EPA*. However, existing stocks of spirotetramat products are currently in the channels of trade. EPA's notice and solicitation of comments indicates that the Agency believes it may be appropriate to apply its longstanding existing stocks policy with respect to the existing stocks of spirotetramat products, and the Agency seeks public comment on this question. In a recent letter to the court, Natural Resources Defense Council, the plaintiff in the litigation, has stated its belief that EPA's existing stocks policy should not apply.

The issue raised by EPA's notice is whether, for purposes of EPA's policy on the disposition of existing stocks, a court's order vacating a registration because of EPA's lack of adherence to a procedural requirement of FIFRA should be treated any differently than a cancellation of a registration. Whether there is any meaningful difference between a court's order vacating a registration because the registration process allegedly did not comply with the provisions of FIFRA, and an EPA order pursuant to FIFRA section 6(b) canceling a registration because the pesticide product "does not comply with the provisions of this Act" can be argued. Nevertheless, in both cases, the practical effect is to nullify the existence of the registration because of a failure to comply with a provision of FIFRA. The criteria articulated in EPA's 1991 existing stocks policy are equally appropriate regardless of whether the cancellation is caused by a court order or an EPA order.

The grant of authority to the Administrator to act in such situations is extremely broad, demonstrating that Congress intentionally committed the shaping of remedies for disposition of existing stocks to the Administrator's discretion. ("The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or cancelled . . . to such extent, under such conditions, and for such uses as the Administrator determines that such

sale or use is not inconsistent with the purposes of this Act.” FIFRA section 6(a)(1)). It is difficult to imagine a broader grant of authority, or a delegation that warrants more judicial deference to the Agency’s determination.

NRDC argues that the court’s order in that case is dispositive and precludes EPA’s authority to determine what to do with existing stocks. CropLife disagrees. By revoking the spirotetramat registrations the court’s order may preclude any sales of newly produced pesticide by the registrant. However, it does not purport to address the subject of how a finite quantity of existing stocks of pesticide in the channels of trade should be treated. The authority to issue a registration, and the authority to dispose of existing stocks, derive from entirely different provisions of FIFRA. The power to grant registrations arises under FIFRA section 3(c). The power to dispose of existing stocks arises under FIFRA section 6(a). In the *NRDC* litigation the plaintiff did not raise any challenge to the Administrator’s authority under section 6(a) to dispose of existing stocks, and the court’s order did not speak to that issue. The complaint was limited solely to a challenge to the propriety of the issuance of the spirotetramat registrations under section 3. Therefore, the scope of the Administrator’s authority to dispose of existing stocks was not before the court in the *NRDC* case and is not affected by the court’s order.

NRDC has also made the argument that the provisions of FIFRA section 6(a) do not apply to pesticides like spirotetramat because those registrations were never lawfully issued in the first place. While this court opined that spirotetramat products had not been “lawfully registered” based upon a procedural violation by EPA, the fact is that the registrations were issued and sales of the products took place while the registrations were in force. Any procedural violation does not negate that fact. As noted above, once existing stocks of a pesticide are introduced into the channels of trade, the Administrator is empowered under FIFRA section 6(a) to determine their disposition.

In deciding how to treat existing stocks, the Agency’s 1991 existing stocks policy gives great weight to whether the use of the existing stocks would pose significant risks. CropLife agrees that this should be the principal focus of the Agency’s decision in situations such as this. Where the information before the Agency does not indicate that significant risks are presented by use of the existing stocks, it seems appropriate that the further sale and use of the limited quantities of those pesticides in the channels of trade should be permitted. It should be recognized that where a registration is involuntarily cancelled due to no fault of the registrant and without any finding of imminent hazard, efforts should be made to minimize economic harm to persons in the channels of trade holding the pesticides, and such persons should generally be permitted to sell, distribute or use the existing stocks until they are exhausted.

CropLife America appreciates the opportunity to submit comments on these issues. We would welcome the opportunity to discuss these comments further.

Sincerely,

Comment

Dear Mr. Owens,

Movento has been an excellent tool, allowing us to reduce our use of Metasystox-R by 60-70% over the last two years. While not suitable to completely replace Metasystox-R, it's hard to fathom that substituting less-toxic Movento, where able, is not better for the environment. Additionally, the longer residual of Movento allows us to reduce the number of pesticide applications, reducing the use of other tankmixed products in the process.

Comment

Good Morning,

Our organization, representing 80,000 acres, is dedicated to sustainable winegrowing and is currently a EPA PRIA2 Grant recipient and recipient of the EPA's Sustained Excellence in IPM Award in 2009.

We have been working on reducing pesticide risk since 1995, including researching and demonstrating alternatives to organophosphates, whose use increased with the introduction of the Vine Mealybug. OP have been identified as a serious threat to water quality on the Central Coast of California by the Regional Water Quality Control Board.

Attached is a letter voicing strong concern regarding the withdrawal of Movento registration. This material is critical in a reduced risk pesticide strategy as an alternative to organophosphates for Vine Mealybug control in vineyards.

Movento represents the only OP alternative not in the neonicotinoid class, so is critical for an reduced risk IPM program addressing resistance management.

In addition, OP's are prohibited in the Sustainability in Practice (SIP) Certification program. Without alternatives to OP's, many growers may face losing their certification, which would be a significant problem for them in terms of winery contracts that require certification.

Thank you in advance for your consideration,

Comment

Dear Steve,

Several of us with the IR-4 Project have recently become aware that the Southern District Federal Court in New York has responded to a lawsuit to invalidated the spirotetramat registration due to a technicality. We clearly recognize that this is a decision of the courts and the Agency has to abide by this decision. The purpose of this message is to let you know the impact of this action on specialty crops grown in the United States and minor uses.

Spirotetramat is critically important product for specialty crops. It is registered on many fruit and vegetable crops. This product is needed for control of pests such as aphids whiteflies, scales, mealybugs, and some thrips and offers a lower risk alternative for growers when compared to older technology. This material is also a great tool in insect resistance management strategies and data indicate that it has relatively low pollinator toxicology.

We urge you and your staff to do anything possible to revalidate the registration as quickly as they can to minimize the disruption of newly established pest management systems which utilize spirotetramat for specialty crops.

Thank you for your consideration of the urgency of this request. Please let us know if there is any data or information that we can provide to assist the Agency.

Comment

To whom it may concern,

I have used Movento to control Psyllids on peppers and to control Aphids on celery. In all the situations where I used Movento it provided better long lasting control than other materials available. The grower was able to save money, there were less overall pesticide inputs made to the crop and Movento does not disrupt the beneficial insect populations.

If you have any questions or require further information please let me know.

Comment

I would like to express my concerns over the pending issue of having Movento Insecticide pulled from the market place.

Movento, produced by Bayer Crop Science, is a very novel insecticide that has gained wide acceptance within the market place in a very short time period. This is due to the products superiority in controlling food crop pests that prior to the products registration, were extremely difficult to control. The use of Movento, in almost all cases, has reduced the total amount of pesticides applied to crops for the control of these certain pest. Without Movento being available, growers will need to fall back on the few remaining pesticides and apply more frequently. The end result leads to more pounds of pesticides being applied and less quality food products being available for consumption.

I understand the stance that U.S. district Judge Denise Cote took, in that the citizenry of the United States, looks to EPA to assure food crop safety as well as human safety. And I fully understand the importance of bees and pollination. And not only for food and fiber production, but the balance of nature as well.

Under the law, as I understand it, the products registration will need to go back for review by EPA. However in the meantime, it is advisable that the product remain available for the control of certain pests and the ability to deliver fresh and wholesome food products to the public.

I'm hoping the issue can be resolved and Movento remain in the market place based upon science.

Comment

I am alarmed to hear about the Movento registration possible being suspended. Movento has been an excellent tool for intergrated pest control in our area. It is highly effective, soft on beneficial insects, and is very safe for pesticide loader / applicators.

To replace this product we will have to rely on very toxic VOC materials such as Metasystox-R, Diazinon, Dimethoate etc. Movento.

Comment

To Whom It May Concern,

I am a Pest Control Adviser and Pest Control Business owner in the Salinas Valley. I have been a licensed and practicing PCA for 20 years, advising vegetable growers on their pesticide and nutritional crop needs. I am writing to you, with great concern, regarding the pending Movento registration problem.

As you know, the Foxglove and Lettuce aphid are serious economic pests on lettuce crops in the Salinas Valley and require diligent and diverse spray programs for proper control and to avoid resistance. The Green Peach aphid, over the last couple of years, has also become quite a challenge to control in cole crops. The recent registration of Movento, on cole crops and

lettuce, has been a much-needed addition to the limited tools we have available for aphid control in those crops. As we continue to lose old chemistries and have to deal with label restrictions, we are forced to spray more times with inferior pesticides. If we are allowed to use new products like Movento in our spray rotation, we can cut back on the number of sprays per crop and get better pest control while decreasing pest resistance. Movento's systemic action works well on the aphid pests I have listed above and has low mammalian toxicity, is non-toxic to bees and is easy on beneficials.

As we move towards more "Environmentally Friendly" products, Movento is a necessary tool for PCA's to have. It's loss would be a step backwards for our industry.

Sincerely,

Comment

Dear Mr. Owens:

It has come to my attention that the Environmental Protection Agency (EPA) has recently been involved in a lawsuit regarding the approval and use of spirotetramat. The decision on December 23, 2009, by U.S. District Court Judge Denise Cote to order the EPA to rescind approval for spirotetramat will have tremendously negative implications for many growers who depend on the insecticide to produce their crops.

Spirotetramat, a product of Bayer CorpScience, is the active ingredient in Movento and Ultar brand insecticides which the lawsuit now labels as toxic to the environment, specifically harmful to bees. Effective January 15, 2010, it will be illegal for farmers to use Movento and Ultor on their crops due to the court's ruling. It is my understanding that the ruling was based solely on EPA's procedural error in which the Agency did not publish a notice in the Federal Register when the application for registration was submitted. Ironically, EPA has made public the scientific data analysis supporting its conclusion that Movento and Ultor pose no unreasonable risk to human health or the environment, including bees. Therefore, EPA has no substantive concern about the safety of the product to the environment or to bees.

I am writing to urge your Agency to act on behalf of farmers who use these insecticides to protect their crops. Primarily, EPA needs to ease the concerns of producers by making clear that those who use spirotetramat will be allowed to continue to trade and export any treated products without fear of legal reprimands. Growers should be allowed to use any product already in their possession according to the label on the container. I would suggest that the EPA act in a timely manner to correct its procedural error before the product is needed for the spring. In addition, the EPA needs to protect its science-based registration decisions in court to highlight the importance of environmentally safe products such as spirotetramat.

Again, I urge you to act expeditiously in regards to addressing the issue involved with the case to avoid unnecessary delays and confusion. I greatly appreciate your attention to this important matter.

With warmest regards, I remain

Sincerely yours,

Comment

This is a important chemical in our rotation as it is affective on whiteflies and mites. Please allow us continued use.

Comment

Dear Ms. Laws:

This is in response to the Agency's website notice requesting comments on the potential cancellation of spirotetramat and the application of the existing stocks policy.

The Northwest Horticultural Council represents over 4,000 growers, packers and shippers of deciduous tree fruits in the Pacific Northwest states of Idaho, Oregon and Washington. Since its relatively recent registration, spirotetramat has become an important tool in the management of aphids and pear psylla (*Psylla pyricola*), some of which—such as woolly apple aphid (*Eriosoma lanigerum*)—are pests of quarantine concern. Growers and researchers value the use of spirotetramat given its relative safety to workers, low impacts on beneficial insects and the advantage of its use as part of an insecticide resistance management strategy in tree fruit IPM programs. These benefits are the reason for the concern we have with the proposed cancellation order.

The Northwest Horticultural Council strongly recommends that EPA treat the cancellation as a special case in which the agency has no significant risk concerns associated with the cancelled product. EPA's administrative error was unfortunate, but as long as EPA maintains power to minimize the impact of the error on agricultural producers and the registrant it bears a responsibility to exercise that discretion to minimize the negative implications. As such, EPA should allow unlimited use of existing stocks for labeled uses and unlimited sale by all parties including the registrant for as long as it takes to register (again) spirotetramat.

A number of Northwest tree fruit crops have been treated with spirotetramat and are currently being consumed by domestic and international consumers. We urge EPA to collaborate with its sister agencies at the U.S. Department of Agriculture and Food and Drug Administration to appropriately communicate that spirotetramat treated crops are unequivocally safe. Failure to communicate this important information could compound the agency's error by causing consumer fear about spirotetramat-treated crops. EPA should be keenly aware that consumers may misunderstand the purpose of the cancellation order and how it affects food they consume. EPA bears the responsibility to ensure that consumers clearly understand that any cancellation procedure is not driven by dietary or environmental risk and the anticipated agreement to allow the use of existing stocks is safe.

Once the appropriate administrative action takes place on February 16 we would urge EPA to move quickly to register spirotetramat to allow its use as soon as possible in the 2010 growing season. Given the usefulness of this material in tree fruit pest management programs and its relatively low mammalian toxicity, we urge the agency to seek comments and any additional existing data on concerns that might be raised regarding its registration and move quickly to consider those comments and reinstate the registration.

We appreciate the opportunity to comment on this matter. If there are any questions regarding our position on this unfortunate error or its resolution please feel free to contact us.

Sincerely yours,

Comment

Dear Ms. Laws:

Bayer CropScience is submitting comments in Response to the Spirotetramat – Notice of Cancellation Order that was published January 25, 2010 on the EPA Pesticides website (<http://www.epa.gov/pesticides/index.htm>).

On December 23, 2009, due to EPA's failure to publish a notice of receipt of the spirotetramat registration applications in the *Federal Register* under Section 3(c)(4) of FIFRA, the U.S. District Court for the Southern District of New York issued an order vacating the spirotetramat registrations that the Agency issued in 2008, and remanding the matter to EPA for further proceedings in accordance with FIFRA and the Administrative Procedure Act. In early January, the court extended the original January 15 deadline for vacatur until February 16 at the request of EPA. EPA has since decided that instead of taking steps to remedy its procedural error before the deadline for vacatur, they will proceed with a "cancellation order" following review of comments received during a second public comment period.

Bayer CropScience is deeply disappointed in EPA's failure not only to publish a notice of receipt for the spirotetramat registration application at the appropriate time, but also its failure to act promptly to remedy a situation that stems from its own error. We continue to believe that the most appropriate remedy to address the Court-mandated vacatur order is for EPA to simply review and address the public comments EPA has already received in response to its remedial notice and 30-day comment period, published on August 6, 2009 (74 Fed. Reg. 39321). It is our understanding that EPA was in the process of reviewing those comments when the Court issued its ruling. If EPA had simply acted diligently to complete that review, that straightforward course of action would permit resolution of the whole situation prior to the vacatur deadline. Instead, the EPA has elected to make the process yet more complex and time-consuming by indicating its intention to reissue yet another 30-day comment period, as well as initiating this existing stocks review as part of an "Intent to Cancel" process.

This entire approach is entirely out-of-proportion with the procedural failure, and runs counter to the statutory scheme's consistent emphasis that EPA's decisions and actions are to be based on sound science and consistent with the nation's substantive environmental and agricultural interests. Further, the Agency's election to instead issue a "cancellation order" creates the unjustified appearance that the safety of spirotetramat is in question, when it is not. The net result of these unnecessary procedures is to take away from growers a reduced-risk pesticide that is critical to controlling several key insect pests, such as the Asian citrus psyllid, the lettuce aphid and the vine mealybug. Spirotetramat has been extensively studied and its environmental and agricultural benefits well documented by EPA. It is ironic, in light of the irresponsible allegations of some, that spirotetramat is one of the most extensively studied insecticides on the market concerning bee safety, and is more "bee safe" than existing alternatives used today. This

has been confirmed by the additional field studies that Bayer, on its own accord, has undertaken including several on flowering crops.

Regardless of EPA's failure to publish the notice of receipt of the spirotetramat registration applications, Section 3(c)(7)(C) of FIFRA states that a pesticide may be conditionally registered if the Administrator determines that use of the pesticide will not cause any unreasonable adverse effect on the environment and that use of the pesticide is in the public interest. The EPA, in complete compliance with Section 3(c)(7)(C) of FIFRA, approved the conditional registration of spirotetramat because it met or exceeded all criteria necessary for registration including the lack of any significant risk concern.

The EPA and its two joint review partners, Austria and Canada, plus the states of California, Florida and New York, thoroughly reviewed all studies submitted by Bayer CropScience in support of spirotetramat and each regulatory agency independently determined that spirotetramat and the end-use products satisfied all of the criteria required for registration and, therefore, each regulatory agency approved the registration of spirotetramat technical and the end-use products. The scientific reviews, risk assessments, and regulatory decisions by the above mentioned agencies are conclusive evidence that the studies submitted in support of spirotetramat product chemistry, environmental fate, ecotoxicology, toxicology, and residue tolerances justify registration. The decision of the U.S. District Court to vacate the registrations was explicitly based solely on a procedural error by EPA rather than any failure to meet any requirement of registration or any concern about risk to humans or the environment.

It is important to note that EPA classified spirotetramat and its end-use products as reduced risk products and concluded that: (1) Spirotetramat minimizes the risk of pesticides to human health by reducing the use of Category I insecticides, class C carcinogens, and developmental and reproductive toxicants; (2) Spirotetramat poses less risk to non-target organisms than primary competitor products; (3) Spirotetramat reduces the potential for contamination of groundwater and surface water because the application rates and leaching potential for spirotetramat are much lower than for most competitor products; and (4) Spirotetramat brings a new insecticidal mode of action to a wide range of crops, providing a much needed resistance management tool to extend the life of other important and useful pesticides which results in fewer insecticide applications and a lower environmental burden.

As the record amply testifies, there are no significant risk concerns associated with the current uses of spirotetramat. Under these circumstances, at a minimum, EPA should fully apply its established policy regarding disposition of existing stocks for pesticides showing no significant risk (56 Fed. Reg. 29362, 29364). Under that policy, EPA allows unlimited use of existing stocks, and unlimited sale by persons other than the registrant, and allows the registrant to continue to sell existing stocks for one year after the date of EPA's "cancellation order." The most closely analogous category in the policy appears to be "Other voluntary cancellations." Although this circumstance arises due to a court order rather than a voluntary request for cancellation, it is otherwise the same since EPA has identified no risk concerns regarding the product, and Bayer has applied with all applicable obligations and conditions of registration.

Bayer CropScience believes there is no legal basis for EPA not to apply its established existing stocks policy, and the Agency can and should design a program that fits this unprecedented

situation and minimizes further damage to Bayer CropScience. Accordingly, we note that EPA is not obligated to entitle its order as a “Cancellation Order.” It would be more appropriate and equally consistent with FIFRA Section 6(a) to title EPA’s action an “Existing Stocks Order,” even if the Agency deems that action in substance to also constitute a “cancellation order” within the meaning of Section 6(a)(1). *See* 7 U.S.C. § 136d(a)(1)(“Existing stocks”).

While the Court determined that the registrations should not be allowed to continue unless and until EPA makes a decision on the registration following the process set forth in Section 3(c)(4) of FIFRA (7 U.S.C. §136a(c)(4)), as EPA has noted, neither the question of what should happen to existing stocks nor the status of domestic and foreign crops destined for US consumption that have been recently treated with spirotetramat in reliance on the registrations and tolerances were before the court.

Growers should be assured by EPA that they can apply all end-use products without concern about salability of treated commodities. Bayer CropScience has received several inquiries from foreign countries that are significant trading partners with the USA regarding the treatment of agricultural commodities with spirotetramat and the importation of these treated commodities into the USA. It is Bayer’s understanding, which we have conveyed to our foreign trading partners, that all USA tolerances for spirotetramat will remain in place, unaltered, that spirotetramat may continue to be used to control damaging insects, and that importation of treated agricultural commodities will not be impacted by any decision EPA makes on the proper path forward concerning the registrations.

EPA additionally stated that there is no provision in FIFRA that requires unregistered pesticides (including formerly-registered pesticides) be used according to their labels and implied that, in the absence of EPA action, users of unregistered pesticides may not follow the labeling accompanying the product. EPA concluded that unless they take action, persons holding stocks of spirotetramat will not be legally precluded under FIFRA from using those stocks without following label directions, including the restrictions on timing of applications that EPA required in order to protect bees.

To the extent EPA is suggesting that this may create a practical problem, rather than merely a theoretical gap in EPA’s enforcement authority under FIFRA, Bayer disagrees. Growers are responsible businessmen as well as stewards of the environment. They are highly unlikely to stray from the labeled use directions due to concerns for the environment, costs, practical pest management practices, and the need to maintain residues below existing tolerances. Pesticide users are fully aware of the need to apply all pesticides according to directions on the label. Bayer and the industry expend significant resources to educate users regarding the safe use of pesticide products. Pesticide users attend meetings conducted by Bayer and other pesticide producers where they learn about the products and are encouraged to follow all label directions.

EPA has required that all comments to the Notice of Cancellation Order be submitted to Meredith Laws rather than, as customary, to a public docket. In the spirit of transparency Bayer CropScience is requesting that EPA promptly provide us with copies of all comments received in response to this Cancellation Order. Please forward all comments to larry.hodges@bayercropscience.com.

If you have any questions regarding this submission you may phone or email me.

Sincerely,

Comment

Dear Ms. Laws:

The following comments are submitted on behalf of my client, the Minor Crop Farmer Alliance (MCFA) in response to the request for comments regarding the subject Notice of Cancellation Order, (the Notice) which appeared on the Office of Pesticide Programs website on January 25, 2010.

The Minor Crop Farmer Alliance (MCFA) is an alliance of national and regional organizations and individuals representing growers, shippers, packers, handlers, and processors of various agricultural commodities, including food, fiber, nursery, and horticultural products, and organizations involved with public health pesticides. Our members are extremely interested in the development of pest management tools such as Spirotetramat and techniques that are environmentally sound. While our commodities are often called “minor crops,” they are vitally important components in our diets and they contribute to safe and aesthetic surroundings for our homes, schools, and places of business. U.S. farmers grow more than 250 types of fruit, vegetable, tree nut, flower, ornamental nursery, and turf grass crops in addition to the major bulk commodity crops. Specialty crop production accounts for more than \$45 billion, or greater than 40% of total U.S. crop receipts.

Many MCFA members use Spirotetramat. They are very much interested in and affected by the regulatory decisions concerning its registration, including the disposition of existing stocks of the chemical. MCFA strongly encourages the Agency to issue as part of its cancellation order, authorization for the distribution and use of existing stocks of the product until such stocks are exhausted. Such action would be in the public interest.

Overview

The Notice concerns the Agency’s intention to issue a cancellation order for the pesticide Spirotetramat, an insecticide which is relied on by an ever increasing number of growers to assist them in addressing plant pest problems. The Notice arose out of litigation in which the National Resources Defense Council (NRDC) successfully challenged the Agency’s pesticide registration decision on the grounds that an administrative procedural requirement specified in section 3 © (4) of the Federal Insecticide, Fungicide and Rodenticide Act, as amended (FIFRA) and its implementing regulations, was not met for Spirotetramat. Specifically, the Agency neglected to publish for public comment a notice of receipt of pesticide application.¹ The district court determined that the remedy for this administrative error is to cancel the registration of the

¹ It is believed that in almost all cases, few if any substantive comments are ever received in response to such a notice.

product immediately. The court determined that essentially the registration should be considered void *ab initio*. Apparently the court believed that the impacts from its decision were not significant enough to moderate its response to the administrative misstep.²

The Agency Should Allow The Sale And Use of Spirotetramat Existing Stocks

The members of the MCFA strongly believe that the response of the court is unreasonable and that based on all the relevant facts and circumstances, a more appropriate response would have been to require the Agency to immediately publish the missing notice, request public comment, and address any substantive comments received. If, after reviewing such comments, the Agency concluded that there was a need to modify or cancel the registration, steps could be taken in a timely manner to accomplish this. Instead, the court's decision places the Agency in the unenviable position of having to "un-ring the bell". It ignores the fact that this product has been available and used for over a year and a half. The court's action has the potential to significantly disrupt the carefully developed integrated pest management plans of MCFA grower members, leading to growers using crop protection tools that potentially may be harsher on the environment, undermining chemical resistance efforts being taken by growers, and creating potential negative economic impacts for them.³

MCFA appreciates that there may be little that the Agency can do at this juncture to convince the court to reconsider its decision based on the potential impacts of its decision when juxtaposed against the administrative error involved. However, the Agency does have significant discretion in fashioning the appropriate approach to be used concerning the disposition of existing stocks associated with a cancellation order. In this instance, the Agency should exercise its discretion in such a manner that allows the distribution of Spirotetramat that is in the channels of trade, and its use by the grower in accordance with its labeling. Issuing such an existing stocks order would be in the public interest. It would help assure that the product would be used in accordance with its labeling. Failure to follow such an order is actionable by the Agency pursuant to section 12 of FIFRA. It would also avoid needless waste and cost in either the disposition of the stocks or unnecessary governmental outlays in the repurchase of such stocks. The best disposition of such existing stock is its use for its intended purposes.

In registering Spirotetramat originally, the Agency performed a risk/ benefit analysis. At that time, its exhaustive review of all the available data confirmed that there is no significant risk associated with the use of the product. Regardless of the court decision, that analysis is equally applicable today to the question of addressing the appropriate disposition of existing stocks of the product. In previous situations involving other cancelled products for which the Agency did

² The court acknowledges that a substantial body of scientific studies and information were submitted in support of the Spirotetramat registration. Those data demonstrated to the satisfaction of the Agency that when used in accordance with label directions, it would not cause unreasonable adverse effects on man or the environment. Similarly, the pesticide met the requisite safety requirements to support the issuance of tolerances addressing the product's potential residues on human and animal food. It is recognized that the plaintiff NRDC disputes the adequacy of this exhaustive Agency review. It would prefer to substitute its opinion for the Agency's conclusions of that exhaustive review. MCFA believes that but for the administrative error involved herein, the plaintiff's likelihood of prevailing in its litigation was remote. No reliable evidence was presented establishing that the Agency's review of the registration application was not objective or based on anything other than sound science.

³ See e.g., the use of the product to address whiteflies in the cotton and ornamental industries, and California red scale in the citrus industry.

not have significant risk concerns, the Agency has allowed the unlimited use and sales of such products in the channels of trade. That same approach should be adopted in this instance. The administrative error which serves as a basis for the cancellation order should not deter the Agency from adopting a reasonable approach to the disposition of existing stocks of Spirotetramat.

MCFA does not know the exact amount of product in the channels of trade. However, regardless of the amount, the risks resulting from the use of product in the channels of trade are not meaningfully different from those which identified and considered by the Agency when the product was initially registered. The benefits of use of such stocks are substantial, as reflected in the Agency's original registration decision.

Obviously, growers have purchased product and have it on hand for use in 2010. Given the very short time allotted to provide comments, we are not in a position to quantify the financial expenditures that have been made by growers or the investment in inventory that has been made by the dealers and distributors of the product. In the absence of some scientifically substantiated and reliable evidence of harm that is associated with the use of the product, imposing restrictions precluding the continued sale distribution and use of the product in the channels of trade would be unreasonable.

The Agency has the opportunity to minimize the adverse effects on growers from the administrative error that was committed in the issuance of the initial registration. It should use that opportunity to fashion a responsible response to the court's decision. It should appropriately consider the risks represented by the distribution and use of the existing stocks of the product. It should rely on the exhausted review of the product that it previously conducted, at this time not to necessarily support the registration of the product but rather in fashioning an appropriate response for handling existing stocks impacted by the court's decision. The Agency should not compound its original administrative mistake by unnecessarily restricting product that is in the channels of trade. Growers will follow the label on the product. There is no incentive for them to act otherwise.

MCFA appreciates the opportunity to provide these comments. We look forward to the Agency's decision on the existing stocks issue as well as the publication of the notice for public comment necessary to proceed with the registration of Spirotetramat. This crop protection tool can serve a very important role in the growers' attempts to implement integrated pest management strategies in addressing the plant pest problems that they face.

Very truly yours,

Comment

This letter is intended to provide additional comment of the use of Spirotetramat. I am a licensed Pest Control Advisor in California and I have been using Spirotetramat for over one year now. In my experience, this material is far superior to many other aphicides available today. I believe that the continued use of existing stocks is the most appropriate path for the EPA to take in this instance for these reasons.

1. Sending unused pesticide to a landfill is more environmentally harmful than using it safely according to labeling.
2. Since Spirotetramat became available I have been able to use one spray that previously required 2-3 sprays of 2 or more aphicides to accomplish the same level of control.
3. Many other nations around the world have registered Spirotetramat, or have tolerances established for use on crops intended for consumption by their citizens.
4. Some of the alternative pesticides are Organophosphates and Carbamates and have greater environmental/health hazard potential than Spirotetramat.
5. Since toxicology requirements have already been met, wouldn't it be better to allow full manufacture and use of Spirotetramat during the time period necessary to complete public posting requirements?
6. Financial aspects are significant to many farmers since many products (including Spirotetramat) are "price-bid" therefore, they hold many thousands of dollars worth of chemical in stock. To recall Spirotetramat only to resell it later, after public posting, would only mean an increase in costs
7. Spirotetramat has the ability to achieve a level of control no other single- use pesticide can.

Thank you, for your consideration in this matter

Comment

Ms. Laws,

I am the General Manager of Pacific Vineyard Co. I farm over 2,200 acres of wine grape vineyards and deliver the grapes to many wineries within California. Scott Williams is the Vineyard Manager of our company, responsible for all of the day-to-day decisions that are made in the vineyards. Erin Amaral is our Pest Control advisor and viticulturist for our company, responsible for all pesticide recommendations and applications to the vines.

All three of us have first hand experience with the use of Movento (Spirotetramat) due to our use of the product in 2009 on 1500 acres of vineyards for the control of mealy-bugs. Our vineyards have been infested with Mealy bugs for many years, and the problem has recently turned worse. This is due to the lack of safe and effective chemistry to treat this insect. When Movento became available for us to use, we asked a lot of questions, and with the proper answers, we proceeded to use the product to try to control our Mealy Bug infestation. We were glad to see better control of this insect with this Movento.

In previous years we have had to use the same chemistry of materials to try to achieve less than adequate control of Mealy Bugs. Previous to Movento becoming available, we were using Lorsban, a category 1 insecticide in our rotation. Even with the use of Lorsban, some of our grapes were unmarketable due to the highly explosive vine Mealy Bug numbers. Movento, being a much safer product to the environment, was highly desired to replace Lorsban, and numerous other alternatives.

With the help of UC Davis and UC Berkley scientists, we have developed a Biological control Program in our vineyards. We cooperate with these UC professors and student advisors to release predatory wasps, mealy bug destroyers, and other biological insects that prey on the mealy bugs in our vineyards. This has been an ongoing successful project for almost 10 years now. Complimenting this Biological program has been the placement of Pheromone traps used for mating disruption. The University, and our viticulture staff, have developed ant bait stations to control Argentine Ants due to the ants “farming and harboring” mealy bugs which increase the survival of both mealy bugs and ants.

All of these biological methods of controlling mealy bugs would be lost entirely if we can no longer use Movento. If we cannot use Movento, we would have to return to using Lorsban, Applaud, and Venom. These last 3 products are toxic to the mealy bugs, and also toxic to any biological insects and programs that we have invested in over the years.

Our vineyards became certified Sustainable in 2008 through the Central Coast Vineyard Team’s SIP program. We choose to certify our vineyards because we knew Movento was available in the near future, and we could cease applications of toxic category 1 chemicals. This has been a huge investment for the vineyards and wineries. The wineries have now changed all of their wine labels to include SIP certification on each label. Our investment in Sustainability and mealy bug control, would be lost if we lost our ability to certify our vineyards and wines under the SIP program. We could loose a large portion of our crop if Movento were not available due to mealy bugs infesting each and every cluster making them un-marketable. We could spray with the toxic Lorsban, but then we would no longer be certified as Sustainable, our vineyard workers would have to work within more hazardous chemicals, our wineries would loose their investment, and the vineyards could loose long term contracts that depend on delivery of clean fruit that is grown with a certification of Sustainability.

We would like to see the continued the un-restricted use of Movento. If this is not possible, growers should be able to use the product that has already been purchased and that we have in our inventory.

Time is of the essence. All of our farming budgets have already been approved. If Movento will no longer be available for use in 2010, all 29 of our budgets will have to be re-written and submitted to our banks for approval. There will be large increases in farming costs, and then each winery will have to also re-submit to their lender a new budget for changing marketing materials and labels etc.

Bud Break occurs near the end of February in many of our vineyards. We need to know now if Movento is not going to be available to use in this season so that we can apply a pre-bud break application of an alternate chemical.

Please consider how this would effect our operation in your decision.

Thank you,

Comment

I would like to make a few points regarding spirotetramat and its use on vegetable crops.

Spirotetramat has become an important tool in our overall IPM program. By using spirotetramat, we have been able to minimize the use of several Organophosphate insecticides, namely diazinon (which was removed several years ago) and dibrom. It has been an objective of ours to reduce OP's, and spirotetramat has made that reduction possible. Spirotetramat also allows us to use less pyrethroids, which we all know can result in aphid out breaks.

It is our hope that the paperwork issues around spirotetramat can be cleared up quickly. It is discrediting to the EPA PESP program and environmental groups that by restricting a product such as spirotetramat, that we must resort to using older aphicides such dibrom, crotoxyphos (oxydimeton), dimethoate and pyrethroids. This clearly goes against 1996 FQPA and the reduction of OP's and all the IPM programs and reduced risk programs that have been fostered by the EPA PESP program.

In short; yes we need this product registered and available for our use.
I would be happy to answer any questions you might have by phone or email.

Thank you.

Comment

Movento has been an excellent tool, allowing us to reduce our use of Metasystox-R by 60-70% over the last two years. While not suitable to completely replace Metasystox-R, it's hard to fathom that substituting less-toxic Movento is not better for the environment. Additionally, the longer residual of Movento allows us to reduce the number of pesticide applications, reducing the use of other tankmixed products in the process.

Comment

I would like to take a minute and comment on the proposed cancellation of Ultor. My name is Nathan Squires and I am the Field Staff manager for Northwest Wholesale, Inc. in Wenatchee Washington. I have great concern with the removal of Ultor from the approved list of chemicals we are able to use in the fruit industry. Pear growers in the Wenatchee River Valley are faced with a tough battle to control Pear Psylla. In the 2009 growing season Psylla control was as good as it could be. Ultor played a significant role in the control of psylla. The important part of the equation is that the Ultor was used in a petal fall spray. Pear growers usually spend in the neighborhood of \$1000.00 plus, per acre, in chemicals per season to grow clean pears. Last season that was reduced by around \$250.00 per acre due to better control with new chemistries such as Ultor. I don't feel that the petal fall spray is totally understood. We have removed bees from the orchard by up to two weeks at that time. If the problem is truly bee toxicity, how do you spray bees that aren't present? I fear that the cart is in front of the horse in this matter. I would love to have the opportunity to discuss this in person if possible. Thank you for your time and consideration.

Sincerely

Comment

I support allowing use and sale of existing stocks. The registration is being cancelled because of a legal technicality, the cancellation is not due to inadequate scientific review of the product's toxicological characteristics. It sounds like the 'error' in this registration was EPA's failure to provide public notice. I hope this can be rectified, and eventual reregistration of these products can occur.

I am an entomologist who works with the grape industry in NY.

Comment

Dear Ms Law

I am writing to express my opinion about the Spirotetramat - Notice of Cancellation Order - loss of Movento will be terrible for Florida vegetable production. Over the years with the development of new more environmentally friendly chemistry we have been getting growers to move successfully to softer chemicals approved to replace some of the other harsher chemicals! Spirotetramat is a major tool in the control of whiteflies, mites and aphids. Most of our many vegetable crops have to be treated for at least two of the three of these insects during any given season. Taking Movento out of the rotation is a terrible mistake in terms of resistance management as well as environmental stewardship. It is particularly needed in the case of whiteflies as many of the older neonicotinoid compounds are becoming less efficacious against this pest and spirotetramat provides growers with a viable control option.

I can only hope that this error will be quickly fixed and Movento will be back on the shelves as soon as possible

Sincerely

Comment

Dear Ms. Laws,

I am writing with great concern regarding the existing stock provision for the subject product. In contrast to what NRDC might think, there is actually a fair amount of this material in trade, especially in Florida. I am pasting under this the feedback from several people quite close to the situation:

I think the loss of Movento will be terrible for Florida vegetable production. I can't even comprehend how Bayer could have allowed such a thing to happen. AND I can't believe the EPA would take this action after finally getting softer chemicals approved to replace some of the other harsher chemicals!!! Whiteflies, mites and aphids. I don't know how many vegetable crops don't have to be treated for at least two of the three of these insects during any given season. Taking Movento out of the rotation is a terrible mistake. I can only hope that this error

will be quickly fixed and Movento will be back on the shelves within the year.

Comment

This is very bad news - this product was rapidly becoming a major tool against whiteflies replacing the neonics which are becoming less effective in many cases. Some growers are using Movento rather than Admire etc.

Comment

So as you can see this material is becoming an important part of specialty crop production here in Florida (where ag is worth a billion a year). Ironically, this is material that would substitute for a nicotinoid, which the bee activists seem to dislike more than tetronic acids. I would advise leaving existing stocks right where they are and pulling them off the shelf, putting them in the back, and then bringing back out once the comment period has been fulfilled. I truly hope that EPA moves as expediently as possible in making this reduced risk OP and carbamate replacement available again after 2/16/10.

Sincerely,

Comment

Ms. Laws,

I wish to leave a comment in reference to the Kontos cancellation. As I understand it, it is not that the product or manufacturer has violated any laws or done improper paperwork. But that the EPA had made a mistake in the paperwork and filing associated with this products' registration. Because of this, I do not feel the distributors and end users should be included in this cancellation. That the product that is in the channels of trade (out of the manufacturers hands) should be allowed for sales and use by the end user for whatever time the EPA sees fit. The product has proven to be a great tool to the grower in providing a product with good safety and unique chemistry for rotation and resistance management.

Comment

As a U.S. producer of ornamental crops, I strongly urge the Environmental Protection Agency to allow continued sale and use of the chemical Kontos (spirotetramat).

I, **Dave Matias**, represent **GroWest Nurseries** in Riverside, California. We are growers of large boxed ornamental trees on 250 acres and employ 75 employees. Having safe insecticide products such as Kontos that our employee's can work around is critical in our operation. As a responsible producer and employer, I am careful to ensure that all chemicals, including Kontos,

are applied in strict accordance with its label requirements. As a producer, it is very important for me to have a variety of chemicals available to fight insects.

Kontos gives growers one more active ingredient in the arsenal of chemistries from which good management rotations can be established. Its loss would be significant for the ornamentals industry.

It is my understanding that Kontos was approved by EPA for use following EPA's normal procedures to ensure worker, consumer and environmental safety, and that because the original registration request was not published for public comment; the court has now cancelled the registrations effective February 16, 2010. This product is environmentally friendlier than some of the alternatives, and the ability to continue its production and use is important not only to the economy, but also for our environment. Just as one example, the product is more compatible with IPM strategies including beneficial insects.

Since the chemical has already been approved by EPA and stocks of it are currently in the hands of growers and distributors, it is only logical that those stocks be allowed to be used. For EPA to decide otherwise would be not only to harm our pest management strategies, but also cause economic damages resulting from loss of sales and/or loss of ability to use product already purchased. I believe that there is no risk from allowing continued use, and the benefits resulting are considerable. Pending the re-registration of this important product, this step is the most practical one for EPA to take.

I therefore urge that this chemical be allowed to be legally sold and used.
Thank you for your consideration of my comments.

Comment

I have written to you earlier regarding agricultural use of spirotetramat and must also mention that the compound is used in ornamental production (as Kontos). Again, whitefly is a key pest that this material manages. The management of this pest, in this site, is worth millions of dollars in pest control benefit to the State of Florida.

It is extremely important that growers be able to use this product legally pending the new EPA registration. It is just as important that existing stocks in the hands of growers, distributors and resellers be able to be sold to growers during that time.

I would also recommend stocks being "held" in place until this process has been rectified - again as expediently as the Agency is able.

Regards,

Comment

I really appreciate you sending your comments to Ms. Laws. As you are probably aware, I am co-chair of the National Whitefly Management Task Force a group of scientists and regulators. We represent the vegetable, cotton and ornamental industries. Our ability to manage the various biotypes of *Bemisia tabaci* is very tenuous because of resistance to all but a couple active ingredients. Products that contain spirotetramat are critical. If we loose just one of our tools we could loose the rest very quickly due to resistance. This would result the type of economic losses experienced in the early 1990's when resistant whitefly populations caused losses estimated to be around 500 million dollars annually.

Comment

Dear Ms. Laws,

I have written to you earlier regarding agricultural use of spirotetramat and must also mention that the compound is used in ornamental production (as Kontos). Again, whitefly is a key pest that this material manages. The management of this pest, in this site, is worth millions of dollars in pest control benefit to the State of Florida.

It is extremely important that growers be able to use this product legally pending the new EPA registration. It is just as important that existing stocks in the hands of growers, distributors and resellers be able to be sold to growers during that time.

I would also recommend stocks being "held" in place until this process has been rectified - again as expediently as the Agency is able.

Regards,

Comment

As a U.S. producer of ornamental crops, I strongly urge the Environmental Protection Agency to allow continued sale and use of the chemical Kontos (spirotetramat).

EuroAmerican Propagators annually produces approximately 45 million rooted cuttings of herbaceous perennials and bedding plants for the wholesale nursery trade. We offer more than 900 varieties of plants and employ 200 to 400 people, depending on the season. It is very important that we supply insect and disease free plants to our customers and good chemicals such as Kontos are critical to that goal. In the short time that it has been available, we have found Kontos to be very effective and versatile, especially in the control of spider mites. Kontos is the only systemic miticide/insecticide available and has become well integrated into our pest control program. Kontos has also helped us decrease our dependence on other, less effective and more expensive miticides. It is also effective in the control of aphids and whiteflies and many other important insect pests, which makes this insecticide very useful. We would hate to lose the ability to use Kontos due to a procedural problem in the registration process.

As a responsible producer and employer, I am careful to ensure that all chemicals, including Kontos, are applied in strict accordance with its label requirements. It is my understanding that Kontos was approved by EPA for use following EPA's normal procedures to ensure worker, consumer and environmental safety, and that because the original registration request was not published for public comment, the court has now cancelled the registrations effective February 16, 2010. This product is environmentally more friendly than some of the alternatives, and the ability to continue its production and use is important not only to the economy, but also for our environment. Just as one example, the product is more compatible with IPM strategies including beneficial insects.

As a producer, it is very important for me to have a variety of chemicals available to fight insects. Whiteflies are particularly troublesome, in that continued use of a single active ingredient can lead in a relatively short period of time to the development of resistance in the whitefly populations. The ornamentals industry has worked together with the cotton and the fruit and vegetable industries to adopt management plans for the rotation of chemicals with differing active ingredients, in order to avoid resistance development in whitefly populations. If resistance develops in whitefly populations, devastating economic losses can and do result, severely impacting growers in all segments of agriculture. Thus, the continued availability of Kontos provides another alternative in the rotation scheme developed in the Whitefly Management Plan to help avoid development of chemical resistance in whitefly populations.

Further, it should be noted that the whitefly management plan referred to in the previous paragraph is important in the ornamentals industry's continued ability to export plants to European Union countries – thus making retention and ability to continue to use Kontos important to our international trade.

Kontos gives growers one more active ingredient in the arsenal of chemistries from which good management rotations can be established. Its loss would be significant for the ornamentals industry.

Since the chemical has already been approved by EPA and stocks of it are currently in the hands of growers and distributors, it is only logical that those stocks be allowed to be used. If possible, we would urge that continued manufacture of the chemical be allowed. For EPA to decide otherwise would be not only to harm our pest management strategies, but also cause economic damages resulting from loss of sales and/or loss of ability to use product already purchased. I believe that there is no risk from allowing continued use, and the benefits resulting are considerable. Furthermore, the risks and costs of disposing of existing stock are unknown, and could be significant. Pending the re-registration of this important product, this step is the most practical one for EPA to take.

I therefore urge that this chemical be allowed to be legally sold and used.
Thank you for your consideration of my comments.

Comment

Dear Ms. Laws,

I have heard you speak and support your efforts and the administrations actions on the environment. You are acting in the best interest of this great country.

Please continue to allow sale and use of spirotetramat (Kontos). This is a valuable tool we will need in the rotation of chemistry's we use in our integrated pest management program. I hope you can find that it makes good sense to allow this use and put our dollars and your resources toward more important environmental disasters and programs like West Virginia coal and ground water and air pollution.

Thank you.

Comment

As a U.S. producer of ornamental crops, I strongly urge the Environmental Protection Agency to allow continued sale and use of the chemical Kontos (spirotetramat).

We use Kontos in production of Ornamental Perennials for our mail order, retail and wholesale nursery business. We need Kontos for resistance management of insect pests, and this new chemistry is a valuable asset in resistance management of Whitefly. We use Kontos primarily on ornamental perennials for whitefly control. Our nursery is small, with only 4 employees, but being a small farm, we need the best tools available to manage our crops and environment with less and more environmentally sensitive insecticides, and since I am the chemical applicator, better products like Kontos free up more time to manage the nursery and complete other management duties.

As a responsible producer and employer, I am careful to ensure that all chemicals, including Kontos, are applied in strict accordance with its label requirements. It is my understanding that Kontos was approved by EPA for use following EPA's normal procedures to ensure worker, consumer and environmental safety, and that because the original registration request was not published for public comment, the court has now cancelled the registrations effective February 16, 2010. This product is environmentally more friendly than some of the alternatives, and the ability to continue its production and use is important not only to the economy, but also for our environment. Just as one example, the product is more compatible with IPM strategies including beneficial insects.

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populations. The ornamentals industry has worked together with the cotton and the fruit and vegetable industries to adopt management plans for the rotation of chemicals with differing active ingredients, in order to avoid resistance development in whitefly populations. If resistance develops in whitefly populations, devastating economic losses can and do result, severely impacting growers in all segments of agriculture. Thus, the continued availability of Kontos provides another alternative in the rotation scheme developed in the Whitefly Management Plan to help avoid development of chemical resistance in whitefly populations.

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I therefore urge that this chemical be allowed to be legally sold and used.

Thank you for your consideration of my comments.

Comment

We count on the EPA to ensure that science is the deciding factor as to whether a product is safe. The recent politicization of the EPA and what appears to be elevation of corporate profits over the protection of our shared resources means that even what might have been an innocent oversight sends up a red flag.

The decline in bee populations calls for extra caution in evaluating poisons which will negatively affect them.

I urge the EPA not to take any shortcuts which could ultimately cause irreversible harm to our environment.

Thank you,

Comment

I am writing to comment on the Notice of Cancellation Order for Spirotetramat. This is a very important material for the lettuce industry in California. It is used to control aphids, which are primary insect pests in all of our production areas. Not only do aphids damage the product, but they also transmit viruses which negatively impact production. I urge you to allow for the continued use of existing inventories of Spirotetramat.

Lettuce producers need to have tools for aphid control. We also need an array of materials with different modes of action to manage the development of resistance in aphid populations. Without Spirotetramat, other materials, typically with older chemistries, will be employed to a greater degree. We encourage you to allow for the continued use of this effective, less impactful material as a part of our pest management programs.

Please feel free to contact me if you have any questions or need more information.

Sincerely,

Comment

My name is ----- and I am a professor of entomology at Cornell University with research and extension responsibilities for grapes and small fruit crops. My research expertise is in insect ecology and integrated pest management. As part of my research and extension work, I have been investigating the efficacy and potential use of Movento in pest management for grapes in New York and surrounding states. I am certainly concerned with the potential loss of this insecticide due to what seems to be technicalities.

Movento has shown promise in my trials for managing grape phylloxera and grape mealybug, two important pests with the potential to limit grape production not only in New York, but also in other major grape-growing areas, such as California. Grape growers in New York have shown interest in Movento. Depending on specific circumstances, I believe it has a nice fit in an overall insecticide program. It's fairly selective and therefore will not harm biological control programs. Also, because it is systemic, it has longer residual than some other products and therefore its use may reduce overall amounts of insecticides applied. Grape mealybug and several other species of mealybugs and soft scale species found in New York, California, and other grape-growing regions are becoming increasingly problematic in that in addition to potentially contaminating fruit and reducing vine vigor, they are important vectors of several viruses that cause grapevine leafroll disease. Insecticide control of the vector may be one way to slow the spread of the disease, although it probably needs to be very effective. Because of its systemic activity,

Movento looks very promising, although we are still collecting supporting data. With respect to grape phylloxera, the root form of this pest is very difficult to target with insecticides, especially in New York where we typically do not have drip irrigation. Having a systemic insecticide that is applied to the foliage and translocated to the roots and has efficacy against root-form grape phylloxera is very desirable in some circumstances where using rootstock is either too expensive or not practical. Movento has these desirable traits.

Given the circumstances of the revocation of the EPA label for Movento, in which the issue is not environmental or human safety, I would request that the EPA allow the continued sale and use of Movento already in grower or dealer possession. Moreover, I urge the EPA to move quickly to resolve the issues quickly and hopefully reinstate the label so that Movento can continue to be have a role in the future as an important pest management tool in grapes and other crops.

Thank you for your consideration.

Comment

To whom it may concern,
We use and have used Kontos with great results and no issues. Please continue to allow sale and use of Kontos.

Thank you for your time.

Comment

We just recently began using Kontos in our operation and we have found it to be very effective. Kontos is an important chemical to our operation. . We have stock plants that are highly susceptible to insect pests. Shipping cuttings free of aphids, whiteflies and thrips is imperative. Unfortunately it is difficult to get adequate coverage and kill when spraying contact insecticides on stock plants with closed canopies. Drenching is the most effective application for control and there are few systemically active chemicals that can fill this role. Kontos allows us another chemical group to use in rotation with neonicotinoids like Safari and Marathon. Please continue to allow the distribution of Kontos for Greenhouse operations. Thank you for your consideration.

Comment

To whom it may concern,
Please allow the sale and use Kontos in commercial greenhouses. Kontos is very valuable in our chemical arsenal and would be very much missed.

Sincerely,

Comment

Hello my name is ----- and I am the owner of Trail Nurseries, a wholesale greenhouse in Dover, Pa. I am writing to express my deep concern about the possible removal of Kontos insecticide. At our greenhouse we actively participate in scouting and practice sound IPM strategies. We spray only when we see a problem and watch populations carefully. We also rotate chemicals, every two to three applications. We do this to ensure that the chemicals that are effective stay that way. Aphids have become a horrible battle at our operation, up until the introduction of Kontos onto the market we were forced to use harsher and more dangerous chemicals (many times with poor results) in our rotation. We began using Kontos in the spring of 2009 and finally we had a safe, long lasting new option to fight aphids. Kontos, timed right, can control Aphids through an entire crop cycle, lessening our need to spray additional chemicals that are not as effective.

Without the use of Kontos I know we would have an economic hardship, being forced to throw away plant material (and not selling it) due to aphid issues.

If you have any further questions on Kontos use in our operation, please feel free to call me at the below number.

Thank you for your time,

Comment

I read the article in Greenhouse Grower that the registration is being held up in court and might not be available for use this season.

Please continue to allow sale & use of spirotetramat (Kontos) while the registration issue is being straightened out. In Florida we have a very long insect season with whiteflies being the worst. We need to rotate chemicals each time we spray for whiteflies & by June we have to tank mix to attack more than 1 part of the life cycle. We used this product twice in our rotation last summer. Kontos was effective in controlling immatures of whiteflies.

Sincerely yours,

Comment

Dear Ted,

The impact to California table grape production has the potential to be significant. Just last year table grape producers lost an additional application/use of chlorpyrifos as an option to treat for vine mealybug as EPA's re-registrations continue to eliminate effective materials. Currently

there is no one single material that is proven as a stand alone control and the layering of different chemistries over several generations of vine mealybug can be an effective method for control. An additional concern is the loss of a rotation material, when control is gained thru applications of multiple materials and the key to maintaining an effective program is to rotate different modes of action as with the tetramic acid systemic in Movento.

A specific point we would like to make with the EPA is the need to understand that grower's put their own dollars in researching how or if newer chemistries can replace the ones that are lost or if further benefits may be achieved on additional target insects/diseases. Within the past few years, industry has invested \$65,000 in research with spirotetramat as an alternative to pre-plant treatments in vineyards to control soilborne pests and weeds. This is in part to address the loss of Nemacur. Research trials have indicated that spirotetramat may provide some control in root feeding pests; however without the opportunity to further investigate specific timings and application methods, the industry is stripped of an opportunity which may have provided an alternative and research dollars spent in vain if EPA is not able to remedy this situation.

Lastly, industry is the sole bearer of the limitations of allowable residue tolerances within their target export markets, and routinely participates within the regulatory process in facilitating that their commodity achieves the registered use with an acceptable tolerance so that they can maintain market access. The table grape industry funds these efforts through participation within the regulatory processes of Codex and the many foreign regulatory bodies.

Thank you very much for providing an opportunity to share these concerns, and we greatly appreciate the efforts to pass them along. If more information is necessary please do not hesitate to contact us.

Sincerely,

Comment

RE: Loss of registrations of Spirotetramat

I am a Professor and Extension Entomologist with the Georgia Cooperative Extension, The University of Georgia. My responsibilities are for insect management in commercial vegetable crops. I have over 20 years experience with applied research and education in vegetable IPM, with the last eight years in South Georgia. I am writing in support of continued registration of spirotetramat (sold as Movento in vegetable crops).

While I can not say that Movento is absolutely critical to current production, I believe it plays an important role in maintaining our production viability for fall production of multiple crops. This critical role is in insecticide resistance management in the sweetpotato whitefly (a.k.a. silverleaf whitefly). The whitefly is a severe pest of multiple crops in South Georgia. This pest typically overwinters in small numbers, but builds populations rapidly in cotton in the late summer, and invades fall vegetable crops in overwhelming numbers. Movento provides a highly efficacious insecticide for this pest, with a unique mode of action. Resistance is of great concern with this pest.

The neonicotinoid insecticides (e.g. Admire, Venom, Assail, etc.) have served as the cornerstone of whitefly management for well over a decade. In recent years, we have documented resistance to these insecticides. While they continue to provide good initial efficacy in most cases (some complete field failures have been documented), residual control has decreased dramatically (soil applications which initially provided control for 4 to 6 weeks now control this pest for 1 to 3 weeks depending on year and pest pressure). This shift in efficacy requires additional insecticide applications for whiteflies. While several different insecticide chemistries are available, I feel that the continued use of Movento will definitely enhance our grower's ability to manage potential resistance to all chemistries. Within the crops for which Movento is currently labeled, the primary alternatives to Movento are neonicotinoid insecticides, Knack (an insect growth regulator), and Oberon. The neonicotinoid insecticides have well documented resistance concerns as discussed previously. Knack continues to work well, but this product has become one of the primary insecticides used in cotton for this insect pest. The other primary product in cotton is bifenthrin. Bifenthrin does not control whitefly in fall vegetables, as those insects invading vegetable fields have apparently been selected for resistance in cotton. A similar concern exists with Knack; thus, while we continue to use Knack in vegetables, it is wise to utilize alternate chemistries where available to reduce the overall selection pressure. Oberon does offer an additional mode of action, as compared to Knack, but has the same mode of action as Movento with less efficacy against whiteflies. In general, lower efficacy is considered to allow greater survival and higher potential for resistance selection. Thus, Movento would be a better alternative for resistance management in those crops where it is currently labeled.

The potential impact of insecticide resistance in the whitefly goes well beyond those crops for which Movento is currently labeled. This pest has an extremely wide host range and readily moves from crop to crop. Resistance issues also follow this pest from crop to crop. A classic example is the lack of efficacy of bifenthrin against this pest in fall vegetable likely resulting from insecticide applications in cotton. While multiple chemistries for this pest are available, the reduced efficacy of the neonicotinoid insecticides places added selection pressure on all alternatives. The loss of Movento on the few crops where it is labeled would place even more severe selection pressure on the remaining alternatives, and as efficacy is lost on one crop it affects all subsequent crops.

Loss of Movento will remove both a highly efficacious insecticide and functionally remove a unique mode of action for resistance management. While our growers may survive this loss in the short term, the long term results could be severe.

If I can provide any further information or clarification, please let me know.

Sincerely,

Comment

Ted and Kent,

The attached letter relatively briefly addresses my perception of the needs

for the current Movento labels in Georgia vegetables. While Movento can be used for several pests, whitefly is probably our most critical need. The argument presented (resistance management) would apply to any of our more efficacious whitefly insecticides. While Movento is not necessarily critical to current production, I would hate to lose it for even one season and anticipate expanded registrations to help with whitefly management. The current reduction in efficacy of the neonicotinoid insecticides and the potential for loss of others is a MAJOR concern in South Georgia. If we lose control of whiteflies we will lose a great deal of our fall vegetables.

Comment

Dear Dr.,

Thank you for the opportunity to respond to the recent procedural issues concerning the registration of spirotetramat (Movento) and the proposed revocation of the existing registration. The loss of this material to our dry-bulb onion industry will certainly be significant. Very briefly, adult and larval onion thrips feed on dry bulb onion using rasping-sucking mouthparts which drain cellular contents resulting in a total loss of photosynthetic area. When this occurs, cells become necrotic and enlarge into large patches of dead tissues which result in insignificant yield loss and loss of quality due to a lack of bulbing. It is common for onion thrips infestations to reduce yields by as much as 25 to 50%, especially with increased levels of insecticide resistance. In particular, when conditions are hot and dry, onion thrips infestations are much more difficult to control than when conditions are cool and wet. Specifically, several generations can be completed within a short period of time leading to exponential population growth.

During these hot and dry years (which have experienced with greater frequency in recent years), Wisconsin onion growers will apply as many as 4 to 5 different insecticides to manage onion thrips resulting in 8 to 10 foliar applications in each field. Another major problem faced by onion growers is onion thrips resistance to insecticides. Onion producers in Wisconsin have experienced field control failures similar to that which has recently been documented in New York populations as a result of insensitivity.

Very recently, spinetoram (Radiant SC) was registered as a new federally labeled product that is highly effective against onion thrips on onion and a label was issued in Wisconsin in the September of 2007 and available for use in 2008. Because of its effectiveness as a thrips control product, Dow AgroSciences wants this product to remain viable in the marketplace for as long as possible. Thus, it is extremely important to secure registrations for different mode-of-action (MoA) classes of chemistry to conserve the integrity of existing registrations. As indicated above, Wisconsin onion growers average 4 to 5 different insecticide applications per season. By labeling law, onion growers will apply Radiant twice (maximum number suggested) during the season, requiring an additional 3 to 4 insecticide applications to control thrips for the remainder of the season. The problem is that there are no effective labeled products available for these four applications.

Spirotetramat (Movento) is a highly effective and novel MoA class used against onion thrips on onion. In 2009, the state of Wisconsin, along with several other onion producing states (NY, MI, WA, and CO) requested and received a Section 18, Emergency Exemption use for spirotetramat (Movento). The proposed use for Movento is identical to Radiant - no more than two (5 fl oz / acre) applications per field per season. If three to four highly effective products are available to control onion thrips on onion (i.e., Radiant, Movento and Agri-Mek), with each applied a maximum of two times, Wisconsin onion growers will have the minimum sprays needed to control onion thrips for the entire season. With the proposed removal of Movento as a foliar control option, onion producers will be left with little alternative and may have to consider use of older active ingredients (methomyl, lambda-cyhalothrin, oxamyl) to try to hold populations at, or below established thresholds.

Field experiments have been conducted in commercial onion fields in Wisconsin in both 2008 and 2009 in which the efficacy of several registered products were compared with Movento for controlling a high infestation of onion thrips. Currently labeled products, Lannate, Vydate, and Warrior II failed to control the infestation after the successive applications. In contrast, applications of Movento (5 fl oz per acre) provided an extremely high and consistent level of protection making it an important control option for Wisconsin growers. As a result, complete loss of this material will likely impose additional pressure on new registrations hastening the time period over which insensitivity will likely develop. Furthermore, this loss will trigger far greater use of older MoA's which have been documented to have far less efficacy and greater impacts on non-target organisms.

Respectfully submitted,

Comment

TO:

Below are the responses I have received so far from the query I sent out on spirotetramat. If I get more responses, I will forward them to you. I received responses from Illinois, Michigan, Nebraska, Wisconsin, Indiana and North Dakota. The crops covered by the various responses are apples, blueberries, celery, Christmas trees, grapes, onions, ornamentals and potatoes.

Apples – Spirotetramat usage has just begun with apple growers. A small percentage (maybe 10%) used Movento in 2009. It was used to control woolly apple aphid and it is markedly more effective than the other products currently registered against woolly apple aphid. It is unique because it will translocate from the leaves to the roots, which may provide control of the root feeding aphids.

Blueberries – In Michigan, this product has great promise as an aphid and scale control. During 2009 two new virus diseases were found in Michigan and the most damaging of these is aphid vectored. Michigan entomologists have evidence of excellent control of aphids with spirotetramat and they have an “A” priority project tin IR-4 to get this product labeled for blueberry.

Celery - Celery growers in Michigan are using Movento to control aphids.

Christmas trees - This is a really new product for use in Christmas trees so the Michigan specialist doesn't have a sense of the impact of its loss. On the other hand, one of the challenges that Christmas tree producers continue to face is the lack of a broad collection of effective pesticides. For many of the major pests there are only a few registered pesticides that provide effective control. Accordingly, these products are used repeatedly thereby raising the possibility of developing resistance in the target pest. Also, an increasing dependency by growers on having current products remain available and it is important for Christmas to have new products labelled for use whenever possible.

Grapes – Three states, Michigan Illinois and Nebraska, responded that spirotetramat is used on grapes. Rufus Isaacs, Michigan State University entomologist, says, “In grapes, Movento's unique movement in plants portends an exciting new level of control for grape phylloxera. Currently endosulfan is a standard insecticide for control, so getting an alternative registered was an important development. In our 2009 trial against phylloxera, it was over 98% effective at controlling aerial damage to leaves by this pest using a 6oz/acre rate. I am planning to go back to the vineyard this summer to evaluate second year effects but would expect that the ability to move in the vascular system towards the roots would greatly improve our ability to control both aerial and root forms of this damaging insect. The applications for phylloxera are also expected to provide excellent leafhopper control, though I don't have data on that yet.”

Onions – You have already received a letter from Russell Groves on spirotetramat use on onions in Wisconsin. (I have also attached it to this letter.) Along with Wisconsin, Michigan has also requested a Section 18 for Movento to control onion thrips so there is definitely a need in these two states.

Ornamentals – In Indiana, spirotetramat is an important product because of its efficacy and because it has an alternative mode of action compared to the neonicotinoids. As a result, having this product will help to delay the development of resistance especially with whiteflies.

Potatoes – North Dakota and Nebraska both responded on potatoes. In North Dakota, zebra chip has become a huge issue in potato production and this insecticide is critical to help manage the psyllids that vector the pathogen, a Liberobacter. Neil Gudmestad says, “It is the critical most important insecticide we have to control psyllids and to help manage zebra chip.”

In general, specialists said things such as, “For many pests, Movento has very quickly become the product of choice because of its efficacy and we would hate to lose this valuable product.” And “Resistance management issues are also relevant, and it seems to make great sense for EPA's mission to be replacing broad-spectrum insecticides applied at pounds per acre with a new reduced-risk insecticide applied at ounces per acre. I hope this can be resolved and this AI be brought back for insect control in fruit crops.”

If you have any questions, or would like to speak to any of the respondents directly, please let me know and I can get their contact information. These are the people that responded to this request:

Sincerely,

Comment

Dear Mr.,

Vino Farms, Inc. is a family-owned and run winegrape growing business farming over 13,000 acres across 8 counties in California. As a company, we strive to use the most environmentally friendly practices possible while at the same time maintaining worker and environmental safety. In fact, all of our vineyards are managed using an intensive Integrated Pest Management (IPM) system and we have nearly 4,500 acres certified Green under the Lodi Rules for Sustainable Viticulture program.

Unfortunately, many of our vineyards have recently become infested with a relatively new and devastating exotic pest known as Vine Mealybug (VMB). VMB proves to be a difficult insect to control because it can survive on all parts of a grape vine including the roots and under the bark. Because of this fact and the lack of highly effective biocontrol agents, the University of California treatment recommendation for VMB has been a post harvest application of Chlorpyrifos followed by a delayed dormant application of the same material. Chlorpyrifos is a highly toxic chemical known to be a water contaminant and deadly to pollinators. Fortunately, since the registration of Movento, we have eliminated Chlorpyrifos use in all of our vineyards. With Movento, we only need to make one application a year saving us money and increasing worker and environmental safety.

In conclusion, if we are not allowed to use Movento in the coming year, we will be left with little alternative than to use Chlorpyrifos again. Please consider this letter as our enthusiastic endorsement of Movento and do whatever it takes to ensure that we are able to use this product in 2010 and beyond.

Sincerely,

Comment

Dear,

This is a very important material in CA. It is a key material for control of the recently introduced Asian Citrus Psyllid, which vectors Citrus Greening disease. It is also important for other tree, vine and vegetable crops as it has a unique mode of action and fits nicely into resistance management programs.

I do not have any use statistics, as it was registered in CA fairly recently (July 14, 2008). However, I have received many inquiries and concerns about this court decision.

We definitely want to see this resolved and the registration continued.

Regards

Comment

Subject Please continue to allow sale and use of spirotetramat (Kontos). As a U.S. producer of ornamental crops, I strongly urge the Environmental Protection Agency to allow continued sale and use of the chemical Kontos (spirotetramat). This chemical is very important to my business, Newton Greenhouse in Newton, NH. We grow cut flowers as well as potted ornamentals for the New England region. We have 10 employees and Kontos is an important part of our pesticide rotation to ensure that we produce safe and healthy crops.

As a responsible producer and employer, I am careful to ensure that all chemicals, including Kontos, are applied in strict accordance with its label requirements. It is my understanding that Kontos was approved by EPA for use following EPA's normal procedures to ensure worker, consumer and environmental safety, and that because the original registration request was not published for public comment, the court has now cancelled the registrations effective February 16, 2010. This product is environmentally more friendly than some of the alternatives, and the ability to continue its production and use is important not only to the economy, but also for our environment. Just as one example, the product is more compatible with IPM strategies including beneficial insects.

As a producer, it is very important for me to have a variety of chemicals available to fight insects. Whiteflies are particularly troublesome, in that continued use of a single active ingredient can lead in a relatively short period of time to the development of resistance in the whitefly populations. The ornamentals industry has worked together with the cotton and the fruit and vegetable industries to adopt management plans for the rotation of chemicals with differing active ingredients, in order to avoid resistance development in whitefly populations. If resistance develops in whitefly populations, devastating economic losses can and do result, severely impacting growers in all segments of agriculture. Thus, the continued availability of Kontos provides another alternative in the rotation scheme developed in the Whitefly Management Plan to help avoid development of chemical resistance in whitefly populations.

Further, it should be noted that the whitefly management plan referred to in the previous paragraph is important in the ornamentals industry's continued ability to export plants to European Union countries - thus making retention and ability to continue to use Kontos important to our international trade.

Kontos gives growers one more active ingredient in the arsenal of chemistries from which good management rotations can be established. Its loss would be significant for the ornamentals industry. Since the chemical has already been approved by EPA and stocks of it are currently in the hands of growers and distributors, it is only logical that those stocks be allowed to be used. If possible, we would urge that continued manufacture of the chemical be allowed. For EPA to decide otherwise would be not only to harm our pest management strategies, but also cause economic damages resulting from loss of sales and/or loss of ability to use product already purchased. I believe that there is no risk from allowing continued use, and the benefits resulting are considerable. Furthermore, the risks and costs of disposing of existing stock are unknown,

and could be significant. Pending there-registration of this important product, this step is the most practical one for EPA to take. I therefore urge that this chemical be allowed to be legally sold and used.

Thank you for your consideration of my comments.

Comment

RE: COMMENTS OF CROPLIFE AMERICA ON THE SPIROTETRAMAT CANCELLATION ORDER AND DISPOSITION OF EXISTING STOCKS

Dear Ms Laws: CropLife America is pleased to comment on the action that EPA should take regarding disposition of the existing stocks of spirotetramat. CropLife America is the national crop protection association that represents the companies that develop, manufacture, formulate and distribute crop protection chemicals and plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers. The precedents emerging in the litigation regarding the insecticide spirotetramat and the corresponding actions being taken by EPA have potentially far-reaching implications for other pesticide products as well. Hence CropLife America takes the unusual step of commenting on regulatory actions involving a specific product.

The registrations for products containing the active ingredient spirotetramat were vacated by a recent court order in the case of Natural Resources Defense Council, Inc. v. EPA. However, existing stocks of spirotetramat products are currently in the channels of trade. EPA's notice and solicitation of comments indicates that the Agency believes it may be appropriate to apply its longstanding existing stocks policy with respect to the existing stocks of spirotetramat products, and the Agency seeks public comment on this question. In a recent letter to the court, Natural Resources Defense Council, the plaintiff in the litigation, has stated its belief that EPA's existing stocks policy should not apply. The issue raised by EPA's notice is whether, for purposes of EPA's policy on the disposition of existing stocks, a court's order vacating a registration because of EPA's lack of adherence to a procedural requirement of FIFRA should be treated any differently than a cancellation of a registration. Whether there is any meaningful difference between a court's order vacating a registration because the registration process allegedly did not comply with the provisions of FIFRA, and an EPA order pursuant to FIFRA section 6(b) canceling a registration because the pesticide product "does not comply with the provisions of this Act" can be argued. Nevertheless, in both cases, the practical effect is to nullify the existence of the registration because of a failure to comply with a provision of FIFRA. The criteria articulated in EPA's 1991 existing stocks policy are equally appropriate regardless of whether the cancellation is caused by a court order or an EPA order.

The grant of authority to the Administrator to act in such situations is extremely broad, demonstrating that Congress intentionally committed the shaping of remedies for disposition of existing stocks to the Administrator's discretion. ("The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or cancelled . . . to such extent, under such conditions, and for such uses as the Administrator determines that such

sale or use is not inconsistent with the purposes of this Act.” FIFRA section 6(a)(1)). It is difficult to imagine a broader grant of authority, or a delegation that warrants more judicial deference to the Agency’s determination.

NRDC argues that the court’s order in that case is dispositive and precludes EPA’s authority to determine what to do with existing stocks. CropLife disagrees. By revoking the spirotetramat registrations the court’s order may preclude any sales of newly produced pesticide by the registrant. However, it does not purport to address the subject of how a finite quantity of existing stocks of pesticide in the channels of trade should be treated. The authority to issue a registration, and the authority to dispose of existing stocks, derive from entirely different provisions of FIFRA. The power to grant registrations arises under FIFRA section 3(c). The power to dispose of existing stocks arises under FIFRA section 6(a). In the NRDC litigation the plaintiff did not raise any challenge to the Administrator’s authority under section 6(a) to dispose of existing stocks, and the court’s order did not speak to that issue. The complaint was limited solely to a challenge to the propriety of the issuance of the spirotetramat registrations under section 3. Therefore, the scope of the Administrator’s authority to dispose of existing stocks was not before the court in the NRDC case and is not affected by the court’s order.

NRDC has also made the argument that the provisions of FIFRA section 6(a) do not apply to pesticides like spirotetramat because those registrations were never lawfully issued in the first place. While this court opined that spirotetramat products had not been “lawfully registered” based upon a procedural violation by EPA, the fact is that the registrations were issued and sales of the products took place while the registrations were in force. Any procedural violation does not negate that fact. As noted above, once existing stocks of a pesticide are introduced into the channels of trade, the Administrator is empowered under FIFRA section 6(a) to determine their disposition. In deciding how to treat existing stocks, the Agency’s 1991 existing stocks policy gives great weight to whether the use of the existing stocks would pose significant risks. CropLife agrees that this should be the principal focus of the Agency’s decision in situations such as this. Where the information before the Agency does not indicate that significant risks are presented by use of the existing stocks, it seems appropriate that the further sale and use of the limited quantities of those pesticides in the channels of trade should be permitted. It should be recognized that where a registration is involuntarily cancelled due to no fault of the registrant and without any finding of imminent hazard, efforts should be made to minimize economic harm to persons in the channels of trade holding the pesticides, and such persons should generally be permitted to sell, distribute or use the existing stocks until they are exhausted. CropLife America appreciates the opportunity to submit comments on these issues. We would welcome the opportunity to discuss these comments further.

Sincerely,

Comment

To:

Subject: Spirotetramat: Impact of Loss of Registration — Hawai‘i The following comments are being submitted in response to email message of January 14, 2010 regarding the impact of the loss of this spirotetramat on production of commodities and agriculture in general. These

comments are being submitted on behalf of the Western Integrated Pest Management Center and provide input on the use and importance of spirotetramat to the production of macadamia nut, various vegetables and other commodities in Hawai‘i.

Spirotetramat is an effective insecticide against many insect pests in Hawai‘i. It has a long term residual effect and is relatively safe for pesticide applicators and farm workers, many of whom are immigrants for whom English is a second language. These characteristics make spirotetramat ideal for our tropical climate and production environment. The loss of this product would greatly affect the sustainability and profitability of many small scale agricultural operations in Hawai‘i. Testament to the efficacy of this expensive, new chemistry is that, growers buy it—grudgingly—because they lack options to produce marketable products.

Due to Hawaii's year-round tropical climate, many insects such as aphids and whiteflies are a serious economic concern for many diversified crop producers. Further, the loss of a registered crop protection chemical like spirotetramat can aggravate resistance issues in many of our minor crops for which only a few pesticides are registered. The availability of spirotetramat in Hawai‘i will help prevent development of insect resistance to one chemical; will give growers more choices of effective pesticides; and will encourage extension agents and pesticide education specialists to help growers with sustainable pest management programs.

Perhaps macadamia nuts is the single largest commodity in Hawai‘i for which spirotetramat is used. Spirotetramat is being used in macadamia nut to control macadamia felted coccid. Felted coccid can pose a threat to Hawai‘i’s entire macadamia crop and there are few tools to control this pest. Recently, these insects were infesting the upper branches of macadamia trees in one large orchard. Because spirotetramat is systemic, it was able to move in the plant and very effectively control this pest. Spirotetramat is used in large macadamia trees. A possible alternative chemical, petroleum oil (Safe-T-Side) is effective in small trees. Buprofezin (Applaud) is effective, but has negative impacts on Coccinellidae.

Vegetable crops. Because of its systemic activity, spirotetramat is very good for controlling aphids, whiteflies and other sucking insects on fruiting vegetables—eggplant, peppers, tomatoes and others; crucifers—broccoli, kai choy, gai lan and others; leafy greens—chard, lettuce, amaranth and others; and dasheen (dryland taro). Spirotetramat is an excellent insecticide for these crops for resistance management; it is a very important product that is used in spray rotations with other mode of action insecticide classes to add to a pesticide resistance rotation.

Spirotetramat is very effective in controlling root aphids on crucifers. For crops with thick canopies, like eggplants, spirotetramat provides good control of mealybugs. Other contact/translaminar insecticides do not control these pests well because these insects are on the stems of the eggplant. This product is also important to the lettuce industry for the control of red aphids in lettuce hearts.

There are current reports of huge infestations of whiteflies on beans, eggplants and peppers on O‘ahu. Populations of this insect pest vary a great deal; whiteflies baffle farmers when they appear again and again. There are other pesticides being used on this pest but recurring insect pests like whiteflies will most likely need new pesticides for effective control.

Tomato growers are likely to increase the use of spirotetramat because imidacloprid (Provado, Admire), a whitefly control product which is commonly applied, has been used for years and there have been reports of resistance. The sweetpotato whitefly (*Bemisia tabaci*) and the biotype B (or silver-leaf) whitefly (*Bemisia argentifolii*) are the primary vectors of the tomato yellow leaf curl virus (TYLCV). Tomato yellow leaf curl is a destructive viral disease of tomato. In tropical and subtropical regions, total losses of tomato crops have been reported. TYLCV is widespread and can be found in most places where tomato is grown. TYLCV was first discovered in Hawai'i on the islands of Maui and O'ahu, in November of 2009.

Research and uses in the pipeline. Because it is relatively safe for human handlers, but mostly its importance in the insect resistance management/control program and its effectiveness against various insect pests, spirotetramat has been a material selected for current and future research projects:

1. Papaya. Papaya Mealybug is a very important pest to Hawai'i's papaya production. Spirotetramat is very effective against this pest and papaya growers statewide were looking forward to having spirotetramat help meet the dire need for new pesticides for papaya pest management. Papaya growers would greatly benefit from this product to use in rotation with malathion, imidacloprid, buprofezin and a few others.

Mites are another serious pest of papayas. Spirotetramat is being tested on papaya with mite infestations, and there is a chance that this systemic pesticide may also be a good chemical to manage papaya mite pests.

2. Coffee. Green scale is one of the most important economic pests of coffee production in Hawai'i. (A more serious problem in dry environments, green scale, is becoming a major problem in the Ka'u District.) The ability to use spirotetramat will prove useful to the coffee growers. As for other commodities, spirotetramat will be useful in the resistance management program.

3. Banana. Banana bunchy top virus (BBTV) is one of the two most damaging diseases of bananas in Hawai'i. The banana aphid is a serious problem on banana because it is a vector of BBTV. Banana growers are anxiously waiting for spirotetramat as a tool to help control BBTV.

4. Taro and sweet potato. An extension agent has purchased spirotetramat in preparation for efficacy research for pests of taro and sweet potato. Taro, in particular, has few registered pesticides.

5. Ornamentals. Hawai'i ornamental crop extension agents were just introduced to the spirotetramat product, Kontos, in October 2009. Therefore, there are no critical uses identified. However, two of the agents reported that they were quite interested in researching the efficacy of this chemical for the nursery and landscape industry.

Hawai'i's agriculture producers in general and ornamental producers in particular have had problems with quarantine pests that have resulted in their products being refused by California.

Spirotetramat is effective against aphids, mealybugs, and other soft bodied insects that are targeted as quarantine pests.

Recently, the discovery of reniform nematodes has led to a suspension of all *Dracaena* shipments from Hawaii. This represents a \$4-5 M industry and a significant portion of Hawai'i's diversified agriculture. Work is presently underway to investigate nematicidal effects of spirotetramat. Should there be positive results, this would certainly add to the limited arsenal available as a post plant treatment for this industry.

This information has been provided by extension agents and specialists of the College of Tropical Agriculture and Human Resources, one representative, each, of Hawai'i's macadamia nut industry, the Hawai'i Farm Bureau Federation, and agricultural chemical vendors.

Comments

Dear Ms. Laws:

I believe that the Federal Insecticide Fungicide and Rodenticide Act has been the single most important law enacted in the last 30 years providing a valuable tool for the rational use of plant protection products by farmers while at the same time protecting the environment, and ensuring worker safety. We are now faced with a grave challenge to the spirit of this landmark legislation in the form of a lawsuit by the Natural Resources Defense Council v. EPA, 2009 WL 5033959 (Dec 23, 2009), which according to Judge Denise Cote's decision the registrations for spirotetramat (Movento & Ultor) will be terminated on February 16. This decision relates to EPA's failure to provide an adequate comment period in accordance with FIFRA and the Administrative Procedure Act, and as a result is now faced with the possibility of a "Stop Sale" on a significant amount of product already in channels of trade.

The question of whether or not the EPA issued a valid label for a plant protection product is not about the efficacy, residue studies, or environmental impacts of spirotetramat, but it is clearly about the interference of a well funded activist group attempting to disrupt conventional agriculture. In this case the EPA should grant an exception to Bayer CropScience and allow all products currently in channels of trade to be distributed and applied according to labeled directions. The fact that EPA or another regulatory organization may be concerned that this may constitute a use that is inconsistent with its labeling and may therefore authorize inadvertently applications while bees are actively foraging is completely outside the spirit of FIFRA. Growers know that bees are pollinators and that without pollination there will be no crop to sell.

Finally, it should be noted that EPA's failure to implement a public comment period has caused undue stress and harm for Bayer CropScience, distributors and growers. The possibility that a similar breach may have occurred on other product registrations should be fully investigated, rectified and prevented from future occurrences.

Comments

Dear Ms. Laws,

** EPA should allow product in the channels of trade and in the hands of applicators to continue to be distributed and used, with as little interruption as possible.

** We have recently submitted a repeat section 18 request to allow use of Movento in onions. So Bayer should be allowed to continue to manufacture and formulate product as necessary to support the section 18 request.

** Movento (EPA reg. no. 264-1050) and the distributor product Kontos (EPA reg. no. 432-1471-59807) are registered with CDA for distribution in Colorado. Under Colorado's Pesticide Applicators' Act, users are legally required to follow the label that came with the product. This will not be influenced by cancellation of the section 3 registration.

** If EPA grants our section 18, applicators using the product on onions will be required to follow both the "section 3" label on or attached to the product and the section 18 use directions. Users will also receive a copy of the EPA section 18 approval letter.

** We consider Movento to be a reduced risk pesticide, that has the potential to replace and reduce the use of more hazardous pesticides. For example, one applicator that used Movento under the onion emergency exemption in 2009 reported that the 2 applications of Movento allowed him to reduce use of Lannate LV (a carbamate insecticide) by 60%. We have not received any complaints or reports of adverse effects involving use of Movento.

Comments

To: Ms. Meredith Laws

As a U.S. producer of ornamental crops, I strongly urge the Environmental Protection Agency to allow continued sale and use of the chemical Kontos (spirotetramat).

We are a large greenhouse operation with over \$10 million in sales each year. We grow herbaceous perennials and annuals, vegetable transplants and herbs, as well as many potted plants. In springtime, we have over 200 employees and distribute throughout Oregon and Washington.

We are using Kontos on peppers, hanging baskets, all of our cuttings, gerbera, osteospermum, new guinea impatiens, dracaena, fuchsia, and will increase the crops as time goes on. We used Kontos some last year and planned to use it frequently this year. It is the only chemical we can use to effectively control spider mites in peppers! Two years ago we had difficulty controlling spider mites in our peppers. We had to do a lot of spraying with oil and M-Pede, both of which are contact only, where Kontos is tranlaminar/locally systemic. We found that it work very well to control spider mites in our hanging baskets above other crops. This is a big plus since we can drench it into baskets and not have to spray and have overspray drift down to the crop below which could stop sales. We our currently evaluating is use for aphids control. We also noticed that it works to control thrips and hope the label changes to add this option. The only effect chemicals we have for thrips are Conserve and Overture. Conserve is showing resistance in some areas such as Florida. It still works well here in Oregon, yet we are concerned about resistance. We hope to use it for early whitefly control in poinsettias.

As a responsible producer and employer, I am careful to ensure that all chemicals, including Kontos, are applied in strict accordance with its label requirements. It is my understanding that Kontos was approved by EPA for use following EPA's normal procedures to ensure worker, consumer and environmental safety, and that because the original registration request was not published for public comment, the court has now cancelled the registrations effective February 16, 2010. This product is environmentally more friendly than some of the alternatives, and the ability to continue its production and use is important not only to the economy, but also for our environment. Just as one example, the product is more compatible with IPM strategies including beneficial insects.

As a producer, it is very important for me to have a variety of chemicals available to fight insects. Whiteflies are particularly troublesome, in that continued use of a single active ingredient can lead in a relatively short period of time to the development of resistance in the whitefly populations. The ornamentals industry has worked together with the cotton and the fruit and vegetable industries to adopt management plans for the rotation of chemicals with differing active ingredients, in order to avoid resistance development in whitefly populations. If resistance develops in whitefly populations, devastating economic losses can and do result, severely impacting growers in all segments of agriculture. Thus, the continued availability of Kontos provides another alternative in the rotation scheme developed in the Whitefly Management Plan to help avoid development of chemical resistance in whitefly populations.

Further, it should be noted that the whitefly management plan referred to in the previous paragraph is important in the ornamentals industry's continued ability to export plants to European Union countries – thus making retention and ability to continue to use Kontos important to our international trade.

Kontos gives growers one more active ingredient in the arsenal of chemistries from which good management rotations can be established. Its loss would be significant for the ornamentals industry.

Since the chemical has already been approved by EPA and stocks of it are currently in the hands of growers and distributors, it is only logical that those stocks be allowed to be used. If possible, we would urge that continued manufacture of the chemical be allowed. For EPA to decide otherwise would be not only to harm our pest management strategies, but also cause economic damages resulting from loss of sales and/or loss of ability to use product already purchased. I believe that there is no risk from allowing continued use, and the benefits resulting are considerable. Furthermore, the risks and costs of disposing of existing stock are unknown, and could be significant. Pending the re-registration of this important product, this step is the most practical one for EPA to take.

I therefore urge that this chemical be allowed to be legally sold and used.

Thank you for your consideration of my comments.

Comment

Please accept the comments of the Society of American Florists and the American Nursery & Landscape Association with regard to continued sale and use of spirotetramat.

Thanks!

Comment

Dear Ms. Laws,

I am a citrus grower in Florida, and Movento is an important component of our pest control program. It has many positive characteristics, and is a good alternative in our rotation cycles to avoid pest resistance and protect the environment. As such, we would appreciate being allowed to continue using the existing stocks while the legal issues are being worked out. From the sounds of it, the problem seems to be with the fine print of the process, not the product itself.

Many thanks, and Enjoy Florida Citrus!

Comment

To: Ms. Meredith Laws

As a U.S. producer of ornamental crops, I strongly urge the Environmental Protection Agency to allow continued sale and use of the chemical Kontos (spirotetramat).

My farm produces 20 acres of nursery crops and employs the labor of 23 people.

As a responsible producer and employer, I am careful to ensure that all chemicals, including Kontos, are applied in strict accordance with its label requirements. It is my understanding that Kontos was approved by EPA for use following EPA's normal procedures to ensure worker, consumer and environmental safety, and that because the original registration request was not published for public comment, the court has now canceled the registrations effective February 16, 2010. This product is environmentally more friendly than some of the alternatives, and the ability to continue its production and use is important not only to the economy, but also for our environment. Just as one example, the product is more compatible with IPM strategies including beneficial insects.

As a producer, it is very important for me to have a variety of chemicals available to fight insects. Whiteflies are particularly troublesome, in that continued use of a single active ingredient can lead in a relatively short period of time to the development of resistance in the whitefly populations. The ornamentals industry has worked together with the cotton and the fruit and vegetable industries to adopt management plans for the rotation of chemicals with differing active ingredients, in order to avoid resistance development in whitefly populations. If resistance develops in whitefly populations, devastating economic losses can and do result, severely

impacting growers in all segments of agriculture. Thus, the continued availability of Kontos provides another alternative in the rotation scheme developed in the Whitefly Management Plan to help avoid development of chemical resistance in whitefly populations.

Further, it should be noted that the whitefly management plan referred to in the previous paragraph is important in the ornamentals industry's continued ability to export plants to European Union countries – thus making retention and ability to continue to use Kontos important to our international trade.

Kontos gives growers one more active ingredient in the arsenal of chemistries from which good management rotations can be established. Its loss would be significant for the ornamentals industry.

Since the chemical has already been approved by EPA and stocks of it are currently in the hands of growers and distributors, it is only logical that those stocks be allowed to be used. If possible, we would urge that continued manufacture of the chemical be allowed. For EPA to decide otherwise would be not only to harm our pest management strategies, but also cause economic damages resulting from loss of sales and/or loss of ability to use product already purchased. I believe that there is no risk from allowing continued use, and the benefits resulting are considerable. Furthermore, the risks and costs of disposing of existing stock are unknown, and could be significant. Pending the re-registration of this important product, this step is the most practical one for EPA to take.

I therefore urge that this chemical be allowed to be legally sold and used.

Thank you for your consideration of my comments.
Respectfully;

Comment

Hi Tom

I have been reading the links for Movento public comments. What does the paragraph below mean? The way I read it why would an applicator ever buy a registered pesticide? It would be much simpler to purchase all unregistered ones and then you would never ever get in trouble for applying against label. Isn't that what the paragraph means or am I missing something? If that is what it means, isn't that way outside the concept of prevention of unreasonable risk that EPA is charge with ?

The other question I have, I thought that as head of the bee team that you were going to keep NHBAB apprized of significant issues which potentially affect pollinators, why did I have to find out about this comment period through other sources?

Jeff Anderson
NHBAB

There is no corresponding provision of FIFRA that prohibits use (as opposed to distribution or

sale) of unregistered pesticides (see FIFRA section 12 (7 U.S.C. §136j)). Furthermore, section 12(a)(2)(G) (7 U.S.C. §136j(a)(2)(G)) only makes it a violation of FIFRA for any person to “use any registered pesticide in a manner inconsistent with its labeling” (emphases added); there is no provision that requires that unregistered pesticides (including formerly-registered pesticides) be used according to their labels. Thus, in the absence of EPA action, users of unregistered pesticides are not obligated to follow the labeling (which, for registered pesticides, prescribes enforceable conditions for using the particular pesticide, among other things) accompanying the product. Therefore, once the registrations are terminated, unless EPA takes action, persons holding stocks of spirotetramat will not be legally precluded from using those stocks without following label directions, including the restrictions on timing of applications that EPA required in order to protect bees.

Comment

Dear Ms. Laws:

I urge the Environmental Protection Agency to allow continued use of Kontos & Movento.

I am a licensed California Pest Control Advisor, and distributor of crop production chemicals. We have found a very efficacious tool for battling insects with spirotetramat. It is extremely important to have this unique chemistry so we may utilize resistance management programs. We plan on having this compound available for many years to come.

The loss of spirotetramat will hurt my business, and will lead to financial hardships for our customers. This is not the time to add to an already tenuous economic climate.

Whitefly continues to be a significant problem for our ornamental, and agricultural growers. If the EPA cancels registration of spirotetramat, I fear we may lose valuable ground. Our trading partners will not tolerate the insects presence.

Please consider my plea, and allow us to continue to safely use spirotetramat.
Regards,

Comment

Dear Ms. Laws:

I believe that the Federal Insecticide Fungicide and Rodenticide Act has been the single most important law enacted in the last 30 years providing a valuable tool for the rational use of plant protection products by farmers while at the same time protecting the environment, and ensuring worker safety. We are now faced with a grave challenge to the spirit of this landmark legislation in the form of a lawsuit by the Natural Resources Defense Council v. EPA, 2009 WL 5033959 (Dec 23, 2009), which according to Judge Denise Cote’s decision the registrations for spirotetramat (Movento & Ultor) will be terminated on February 16. This decision relates to EPA’s failure to provide an adequate comment period in accordance with FIFRA and the

Administrative Procedure Act, and as a result is now faced with the possibility of a “Stop Sale” on a significant amount of product already in channels of trade.

The question of whether or not the EPA issued a valid label for a plant protection product is not about the efficacy, residue studies, or environmental impacts of spirotetramat, but it is clearly about the interference of a well funded activist group attempting to disrupt conventional agriculture. In this case the EPA should grant an exception to Bayer CropScience and allow all products currently in channels of trade to be distributed and applied according to labeled directions. The fact that EPA or another regulatory organization may be concerned that this may constitute a use that is inconsistent with its labeling and may therefore authorize inadvertently applications while bees are actively foraging is completely outside the spirit of FIFRA. Growers know that bees are pollinators and that without pollination there will be no crop to sell.

Finally, it should be noted that EPA’s failure to implement a public comment period has caused undue stress and harm for Bayer CropScience, distributors and growers. The possibility that a similar breach may have occurred on other product registrations should be fully investigated, rectified and prevented from future occurrences.

Respectfully yours,

Comment

Dear Ms. Laws,

I am writing regarding withdraw of the registration of Kontos insecticide. This action increases risks to the environment and economic costs to the public and those involved in the production and marketing of Kontos.

My current position is Technical Support Specialist with Griffin Greenhouse and Nursery Supplies. My responsibilities include making greenhouse pest management recommendations throughout the Eastern U.S. Kontos is an important new product since it introduces a new mode of action, to use in pesticide rotations, to reduce the risks of resistant pest populations. Resistant pests such as aphids, whiteflies and thrips, originating in greenhouses are a significant risk to outdoor agricultural crops since they result in increased use of pesticides that have lost efficacy. I understand that an oversight in providing a public comment period has resulted in this action and there are specific concerns regarding safety to honey bees. As you may be aware, the same active ingredient has been registered for use as Movento which is commonly applied outdoors on fruit and vegetable crops. Also, please consider that the same honey bee precautions are listed on the Kontos label as on the Movento label under Environmental Hazards. Application of Kontos to indoor greenhouse crops presents fewer risks to honey bees since they are unlikely to forage inside greenhouses and their natural activity does not coincide with crop production for most of the year.

In order to avoid further environmental risks, unnecessary expense to the public and to those involved with manufacturing and marketing Kontos, I urge those involved to reconsider the withdrawal of this registration.



NATURAL RESOURCES DEFENSE COUNCIL

February 1, 2010

Meredith Laws
U.S. Environmental Protection Agency
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Re: EPA, *Spirotetramat – Notice of Cancellation Order; Opportunity for Public Comment*
(Jan. 25, 2010)

Dear Ms. Laws,

On behalf of the Natural Resources Defense Council, I am submitting this letter in response to EPA's Notice of Cancellation Order for Spirotetramat. EPA lacks authority to cancel the spirotetramat registration because that registration was vacated by court order.

On January 25, 2010, EPA noticed the "cancellation" of spirotetramat and invited comments on what action EPA should take with respect to existing stocks of the pesticide already in the channels of trade. This question was resolved by the Court's Order vacating the spirotetramat registrations, which renders illegal the continued sale, distribution, and use of the pesticide. *See* 7 U.S.C. § 136a(a); *Natural Res. Defense Council v. EPA*, No. 09-cv-4317, 2009 WL 5033959 (S.D.N.Y. Dec. 23, 2009). As NRDC previously advised EPA counsel by letter dated January 5, 2010, EPA must take affirmative steps to comply with the Court Order, including steps to prohibit further distribution and sale of spirotetramat and to proscribe further use of the pesticide after February 16, 2010.

EPA's Cancellation Order states that the agency will treat the Court's vacatur of the registrations as equivalent to a cancellation by EPA of a previously valid registration. Cancellation Order at 1. The agency asserts that the criteria outlined in its 1991 policy statement on existing stocks "may well be appropriate" in this case. Cancellation Order at 5. Under the existing stocks criteria, unless EPA finds "significant risk concerns" associated with spirotetramat, the agency will "generally allow unlimited use of existing stocks, and unlimited sale by persons other than the registrant" as well as continued sale by the registrant itself for one year after the date cancellation is requested. Cancellation Order at 4, citing 56 Fed. Reg. 29362, 29364 (June 26, 1991). EPA's attempt to use the cancellation process to permit further sale and use of spirotetramat contravenes the Court's Order, which renders illegal any further manufacture, sale, or use of spirotetramat. Only lawfully registered pesticides may be distributed, sold, or used. 7 U.S.C. § 136a(a).

Although FIFRA section 12(a)(1) regarding “unlawful acts” does not employ the word “use,” 7 U.S.C. § 136j(a)(1), when read in its entirety, FIFRA clearly prohibits the use of unregistered pesticides. *See* 7 U.S.C. § 136a(a) (“[N]o person in any State may distribute or sell to any person any pesticide that is not registered under this subchapter. . . . [T]he Administrator may by regulation limit the distribution, sale, *or use* in any State of any pesticide that is not registered under this subchapter” (emphasis added)). As the Court ordered, because spirotetramat was never “lawfully registered,” the agency lacks the authority to permit the use of existing stocks of the pesticide. 2009 WL 5033959, at *7. Although EPA may permit continued use of a previously registered pesticide after a suspension or cancellation proceeding, FIFRA does not confer on EPA the authority to permit use of a pesticide that was never lawfully registered in the first instance. *See* 7 U.S.C. § 136d(a)(1) (stating that EPA “may permit the continued sale and use of existing stocks of a pesticide *whose registration is suspended or cancelled* . . . to such extent, under such conditions, and for such uses as the Administrator determines . . . is not inconsistent with the purposes of this Act”) (emphasis added). Spirotetramat is not subject to the cancellation process because it was never lawfully registered. 2009 WL 5033959, at *7. EPA therefore may not permit its continued sale and use.

In a letter to the Court dated January 20, 2010, EPA cited the Termilind revocation as an example of the agency’s authority to issue cancellation orders that permit continued use following termination of a registration. This comparison is inapt. EPA approved the use of Termilind products pursuant to a lawful registration process. When EPA later discovered that the registrant had made fraudulent claims, the agency exercised its discretion to initiate a cancellation procedure. 62 Fed. Reg. 61890 (Nov. 19, 1997). EPA lacks this discretion with respect to spirotetramat because the Court has already determined that “the cancellation process applies to lawfully registered pesticides, and spirotetramat was not lawfully registered.” 2009 WL 5033959, at *7.

The agency’s position that it can permit the continued use of spirotetramat appears to be an attempt to circumvent the Court’s conclusion that vacatur is necessary because of the serious deficiency in EPA’s unlawful registration process and the lack of sufficient evidence that vacatur would cause environmental harm or economic disruption. The Court has already ruled that spirotetramat must be removed from the market. Absent a stay of this decision, EPA has no authority to allow continued distribution, sale, or use. EPA’s attempt to circumvent the Court’s vacatur command through an administrative cancellation procedure that will permit continued use of the pesticide is contrary to the Court’s mandate and FIFRA.

EPA asserts that a cancellation procedure is necessary because the agency cannot otherwise regulate the use of unregistered pesticides. This is inconsistent with the language and purpose of FIFRA. Congress previously strengthened EPA’s authority to “safeguard[] the public interest” through amendments that “transformed FIFRA from a labeling law into a comprehensive regulatory statute” that “regulate[s] the use, as well as the sale and labeling” of pesticides. *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 991 (1984); *see also Found. on Econ. Trends v. Thomas*, 637 F. Supp. 25, 26 (D.D.C. 1986) (FIFRA “prohibits the registration, and hence the use and marketing of pesticides which cause unreasonable adverse effects on the environment.”) (internal quotation marks omitted).

EPA's interpretation of the statute would lead to absurd results. Under EPA's view, now that the spirotetramat registrations have been vacated, it would be unlawful for an end user to return pesticides to Bayer for reimbursement or disposal, but it would be perfectly lawful to apply the chemical during bloom or at five times the label rate, or otherwise use it in violation of label restrictions. This interpretation makes no sense, and is inconsistent with the fundamental canon of statutory construction that a law should not be construed to lead to absurd results. *See, e.g., EEOC v. Commercial Office Prods. Co.*, 486 U.S. 107, 120-21 (1988) (rejecting reading of statute that would lead to "absurd or futile results . . . plainly at variance with the policy of the legislation as a whole") (internal quotations omitted).

Even absent the Court's order vacating the registrations, EPA has independent authority to issue a recall to prohibit the further use of spirotetramat. Whenever the Administrator has "reason to believe . . . that [a] pesticide . . . is in violation of any of the provisions of this subchapter . . . or when the registration of the pesticide has been canceled . . . the Administrator may issue a written 'stop sale, use, or removal' order to any person who owns, controls, or has custody of such pesticide or device, and after receipt of such order no person shall sell, use, or remove the pesticide or device described in the order." 7 U.S.C. § 136k(a). The distinction between violations of "any of the provisions" of FIFRA and cancellations of registration establishes EPA authority to stop the use of a pesticide without initiating a cancellation proceeding. *Cf. Astoria Fed. Savings & Loan Ass'n v. Solimino*, 501 U.S. 104, 112 (1991) (statutes should be construed "so as to avoid rendering superfluous" any statutory language).

Even assuming that EPA's approach is lawful, the notice of cancellation fails to provide any information about what EPA in fact proposes to do with respect to existing stocks. EPA identifies six criteria that it might consider in issuing an existing stocks order, including the quantity of existing stocks at each level of the channels of trade. But EPA does not identify what, if any, factual information it has regarding spirotetramat stocks currently in the distribution chain. During a phone conversation with EPA counsel and Bayer counsel on January 22, 2010, both EPA and Bayer informed me that they did not know the answer to that question (what quantity of existing stocks are in the hands of end users or others in the distribution chain). Without this information – or information pertaining to the other criteria that EPA identifies – it is hard to see how EPA can make a reasoned decision about the appropriate treatment of existing stocks.

Finally, FIFRA section 18 provides a more appropriate mechanism for allowing targeted, specific use of spirotetramat during the remand period, on a sufficient showing of emergency. 7 U.S.C. § 136p; 40 C.F.R. Part 166. If any legitimate emergency mandates the use of spirotetramat while EPA reconsiders its registration decision, section 18 provides the appropriate method for evaluating that use. EPA's proposed existing stocks order is therefore not only unlawful but unnecessary as a means of dealing with any urgent pest problems.

Respectfully,


Aaron Colangelo

Comment

[Meredith Laws](#)

U.S. Environmental Protection Agency
Office of Pesticide Programs

Spirotetramat – Comment to EPA Notice of Cancellation Order

Dear Ms. Laws,

On behalf of the California Grape & Tree Fruit League, a public policy agricultural industry association representing California's table grape and deciduous tree fruit growers, packers and shippers; our members produce fresh fruit throughout the state and includes: Coachella Valley (table grapes), San Joaquin Valley (all commodities), Santa Clara County (cherries), Lake County (pears), as well as Mendocino, Yuba, Stanislaus, San Joaquin and Sacramento Counties (pears, plums, cherries, kiwi and apricots).

We are writing specifically to express industry concerns regarding the recent *Notice of Cancellation Order on Spirotetramat* and the subsequent impacts that may restrict availability, use and therefore agricultural production benefits stemming from an isolated procedural omission.

The industry greatly appreciates the opportunity to provide input into the decision as to how the Agency will address this situation and or further revise earlier policy into cancellation orders. Given that the Agency has determined there is no difference between an Order of Revocation and a Cancellation Order and has now provided notice that a cancellation order will be issued, we would expect that the product already within the channels of trade for Spirotetramat include distributors, wholesalers and retailers, in addition to end users, and that the Agency should provide the necessary authorization for sale and use under the intended product's label.

As noted in the request for public comment, the Agency's decision to register a product is based almost exclusively on both risk and benefit of the material's use. In this situation, the judge concluded that because the Agency failed to publish notice of receipt of the application for registration it should be vacated. We do not see this to mean there was an absence of the scientific assessment or that a new conclusion should be drawn to identify significant risk concerns to further prohibit or restrict current labeled use for product within the channels of trade. The Agency did issue other notices and has made public the scientific data and analyses supporting its conclusion that Spirotetramat does not pose unreasonable risk to human health or the environment.

An additional point that should be noted; the Codex Alimentarius Commission and numerous other countries have reached similar positive conclusions regarding the active ingredient Spirotetramat and approved its use in those countries following reviews including data on metabolism, fate in the environment and use patterns.

To provide an example to the Agency's policy statement criteria for considering existing stocks is the need to understand that growers put their own dollars in researching how or if newer chemistries can replace materials that are lost or if further benefits may be achieved on additional target insects and or diseases. During the period of time the product was registered, industry invested a material amount of dollars in research with Spirotetramat as a potential alternative to post plant treatments in vineyards to control soilborne pests and weeds. This is in part to address the loss of NemaCur. Research trials have indicated that Spirotetramat may provide some control in root feeding pests; however if the opportunity to further investigate specific timings or application methods is now lost, the industry is stripped of an opportunity which may have provided an alternative treatment and research dollars spent in vain if the Agency is unable to remedy this situation.

We can appreciate the Agency's difficulty in determining how best to address this situation and would like to thank you for providing the impacted stakeholder the opportunity to share these concerns. If we can provide any additional information please do not hesitate to contact us at (559) 226-6330 or email mmartin@cgfl.com.

Sincerely,