

INSECT CONTROL PRODUCT UPDATE – OLDER OP'S AND NEW PRODUCTS

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Abstract

Cotton products have been under review at EPA under FQPA requirements and FIFRA reregistration of older products. To date, the focus has been on the 44 organophosphates (OP's), many are registered for use in cotton. Cotton OP products will be maintained for cotton with relatively minor modifications in usage restrictions. The 12 OP's to be maintained include Lorsban, Orthene, Curacron, Bidrin, Di-Syston, Thimet and Def/Folex (defoliant), malathion, methyl parathion, Cygon, Imidan and Supracide. Guthion and Monitor will be phased out over the next few years. Registrants are not supporting continued registration for Bolstar and Diazinon on cotton. In the next few months, EPA is expected to complete review of malathion, methyl parathion, and endosulfan and then the Cumulative Risk Assessment of the OP's as a group. In the meantime, EPA will continue with the FQPA/FIFRA review process on remaining products. Two groups of cotton products to be reviewed include the carbamates and the synthetic pyrethroids. There are nine new products for cotton that have been registered within the past 5 years and there are seven products in the advanced developmental stage. Also, the pipeline for future developmental products looks good at this time.

Introduction

A major portion of this presentation is a status report on the progress of EPA's FQPA and FIFRA reviews of cotton insect control products. This report will summarize the status of older products (those originally registered prior to 1984), review the newer products already on the market, and provide an overview of products in the research and development pipeline. A brief summary of products are expected to be reviewed in the immediate future will be presented.

The Review Process

There are actually two review processes being conducted in parallel. First, The Food Quality Protection Act (FQPA) enacted on August 3, 1996, involves all existing tolerances under the FQPA standards. Then, an already underway reregistration of older products will be conducted along with FQPA tolerance reassessments. A summary of each process is described in the following section.

FQPA

FQPA directs EPA, in regulating pesticides used in or on food crops, to apply a new, more rigorous safety standard -- "reasonable certainty of no harm" -- instead of the previous, no "unreasonable adverse effects" standard. FQPA gives authority for EPA to consider an aggregate of all other means of exposure to residues of a particular pesticide, rather than just from residues on foods. EPA now must also consider residues in drinking water, from pest control in homes, in schools, on golf courses, and other means of non-occupational exposure. It allows for special protection infants and children, and it requires that active ingredients be evaluated for possible endocrine disruptor effects. This activity will complete the review of the 10,000 tolerances the EPA has on the books for registered pesticides. Within 10 years, EPA must reassess all existing tolerances to be sure they meet the new standard. This process is known as tolerance reassessment. We are now six and one half years into FQPA implementation.

In the FQPA tolerance review, these different exposures are added together to fit into a "risk cup" or that level of exposure that EPA has determined, through various toxicological studies, usage estimates, and exposure probability studies, to have a reasonable certainty of no harm.

Another worrisome aspect of FQPA is that it requires EPA to do a cumulative risk assessment. That is, if a class of pesticides can be shown to work through a common mechanism of toxicity, the organophosphates for example, then, those pesticides can be lumped together as if they were all one compound. EPA would then estimate the risk of exposure for all of them combined. That process, although nearing completion, is not final at this time.

FIFRA

Prior to FQPA, EPA was already in the process of re-registering all of the older products; those originally registered prior to 1984. The FIFRA re-registration process is now being conducted on a parallel path with FQPA tolerance reassessment.

Important issues deal with assessment of health, ecological and occupational risks. Occupational risks are those of mixers, loaders and applicators. As a part of FIFRA, EPA must weigh the benefits of a product against the risks of its use. EPA is re-

viewing older pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to ensure that they meet current scientific and regulatory standards. This process is called reregistration. It considers the human health and ecological effects of pesticides and results in actions to reduce risks that are of concern. As previously mentioned, EPA also is reassessing tolerances (pesticide residue limits in food) to ensure that they met the safety standard established by the Food Quality Protection Act (FQPA) of 1996. EPA has integrated FIFRA reregistration of older products and FQPA tolerance reassessment to accomplish the goals of both programs.

The Organophosphates

Organophosphate Reviews

One group of older products important to cotton are the organophosphates (OP's). Of the 44 OP's, about 22 of these have existing registration for use on cotton. During reviews, reassessments of each of the organophosphate products has been conducted in an open process involving six review phases covering from 4 months up to 24 months. At this point, all of the OP's have been taken through the six phases. Some OP's, malathion and methyl parathion for example, are the last to go through the 6-phase process. While these tolerance reassessment reviews are complete, they are only interim, since the final will come only after the cumulative assessment has been conducted. Since this is an ongoing process with events and decisions being made every day, this summary report is a status report at this time.

To date, the FQPA reassessment has resulted in only minor impact on cotton products. However; the FIFRA mandated reregistration has had significant impact on cotton products. In most cases, there have been risks to occupational workers (pesticide mixers, loaders and applicators) that have caused compromises in product usage in order to mitigate risks associated with each product. In some cases, ecological risks (water and wildlife) had to be mitigated through usage restrictions of the product(s) in question. Some of those restrictions will be reviewed in the next section.

Status of Organophosphate Cotton Products

To date, FQPA has not presented major problems for cotton. However, for products used on fresh fruits and vegetables used in kid's foods, residential products, and lawn and garden products, FQPA has resulted in major problems. For the cotton industry, the FIFRA re-registration process has actually presented far more challenges than FQPA because FIFRA addresses ecological risks and risks to mixers, loaders, and applicators.

However, since this is a FIFRA process, the Agency must weigh benefits vs risks. Cotton OP products for the most part come through the FIFRA reregistration review process with relatively minor modifications in usage restrictions. Some products will be lost because of phase out over a period of time or the company simply did not want to incur the expense involved with maintaining registration for little-used products.

Registration for cotton uses will be maintained for 12 of the OP's. Included are Lorsban, Orthene, Curacron, Bidrin, Di-Syston, Thimet and Def/Folex (defoliant), malathion, methyl parathion, Cygon, Imidan and Supracide. Risk mitigation process for malathion and methyl parathion is incomplete but should be completed in the near future. Guthion and Monitor will be phased out over the next few years. Registrants are not supporting continued registration for Bolstar and Diazinon on cotton.

When will Changes Take Effect?

It should be noted that these changes become final only upon completion of the cumulative risk assessment of the OP's as a group. EPA will then prepare and issue a Registration Eligibility Document (RED) for each product. Within one to three years, when all of this is completed and new product is manufactured, the new labels at that time will contain the changes. There will be, in most cases, provisions for existing stocks to be used according to the existing label on the products. In most cases, there will likely be both old product and new product with new revised labels in the marketplace at the same time. At this point, it is always best to follow the label instructions and to seek the advice of extension, consultants, and company reps.

Review of Changes for Selected OP's

Because of restrictions that came about during risk mitigation negotiations, there will be some fairly significant changes on cotton OP products. Some of the changes for selected products will be reviewed. Risk mitigation for cotton products has followed a trend. Usually, maximum label rates are reduced, and often the total allowable applications per acre per season are reduced as well as seasonal maximum allowable pounds per acre. There is a rapid move to "closed systems" and other engineering controls like enclosed cabs and cockpits. Also, longer REI's and more personal protective equipment (PPE) have been established as well. Some of the changes for selected products are described below.

Orthene. The seasonal per acre maximum will be reduced from 6 to 4 lbs active per acre and the maximum application rate will be 0.75 lbs in all states except CA and AZ where it will be at 1.0 lbs per acre. A minimum interval between applications will be 3 days for rates up to 0.5 lbs and 7 days for all higher rates. Orthene formulations will move to a water-soluble pellet and/or water-soluble packaging system. Enclosed cockpits for aerial applications will become a requirement as well as more personal protective equipment (PPE) for handlers (mixers and loaders).

Malathion. FIFRA risk mitigation will be completed during the spring. Only minor changes in REI's and possibly buffers are anticipated.

Methyl Parathion. FIFRA risk mitigation of methyl parathion will be completed during the spring of this year. However, in August of 1999, EPA made decisions on methyl parathion that went into effect immediately. Closed systems and enclosed cabs and cockpits were new requirements, along with interim Restricted Reentry Intervals (REI's) set at 4 to 5 days. As the FIFRA mitigation is completed, there may be other changes regarding per acre, season maximum per use, PPE requirements and REI's.

Curacron. The maximum per acre rate of Curacron will become 0.75 pounds active and 1 pound ai/A for use on Lepidoptera with a maximum 2 applications per season at the 1.0 lb rate. The seasonal maximum is reduced to a total of 5 pounds active per acre. Closed mixing and loading, along with enclosed cabs and cockpits will be required. Additionally, pilots cannot mix and load on the same day as the application. There will be a warning to consultants about the need to provide PPE.

Bidrin. Bidrin is only used on cotton. In today's cotton system, it has become important for control of aphids, plant bugs and especially stink bugs. For brown stink bug, it is the standard. EPA has completed its reassessment of dicofol (Bidrin). While finding acceptable levels of risk for dietary and drinking water exposure, EPA is establishing risk mitigation measures based on its determination that exposure risks are high for applicators and the bird population. NCC staff has worked closely with EPA and AMVAC on the 18-month reassessment, developing a comprehensive benefits document in support of Bidrin's continued use. To mitigate these risks there will be changes. Seasonal maximum for Bidrin will be reduced to 0.83 pounds of which 0.5 pounds can be used before August 1 to mitigate risk to nesting birds. The product will be containerized to allow handling the product in a closed system to reduce worker dermal exposure. A six-day re-entry interval (REI) will be required. EPA will place a cap on production of Bidrin at the average level of the past 3 years (1999-2001). Unfortunately, aerial application of Bidrin will be phased out by January 1, 2005. There is a possibility that the registrant can provide new data that will allow us to revisit this phase out timeline.

Di-Syston and Thimet. Will be maintained for soil applications only as a safener to Command herbicide applications.

DEF/Folex. DEF/Folex is a cotton defoliant, and a very important one at that. It also happens to be an organophosphate and therefore was subjected to the same rigorous review as the insecticide OP's endured. EPA originally informally asked the registrant to voluntarily cancel the product. The company, Bayer, wanted to keep its registration and obviously the cotton industry wanted very much to keep it. Scientists at Bayer, NCC staff, and cotton defoliation specialists across the belt worked for a period of 24 months to help EPA understand the harvesting process and the role of DEF in harvesting preparation. A challenge was to convincingly explain the difference between a defoliant, a desiccant, and a boll opener. NCC and Arizona Cotton Growers Association even sponsored a trip for five EPA staff to Arizona to help them understand the harvesting process. EPA estimated that exposure risk to mixers, loaders and applicators were unacceptable.

A provision under FIFRA allows EPA to weigh the risks and the benefits of a product. If the benefits are significant, EPA can balance the risks vs the benefits. The NCC and defoliation specialists developed an extensive benefits statement. The estimated impact of DEF to the cotton industry was in the neighborhood of \$200 million a year. In mitigating risks, the label rates for DEF/Folex will be reduced to a maximum of 1.125 pounds active per acre with 1.85 pounds per acre rate reserved for use in California and Arizona where higher rates are required. The company agreed to a closed system beginning in the year 2002. A bio-monitoring study will be conducted to provide a better estimate of the exposure level. The ULV application was cancelled by the company, as was the use of cottonseed oil as an additive.

Guthion. Guthion will be phased out over a four-year period. Its use will be limited to grower use in Texas where eradication programs have not been initiated. It will continue to be an option for use in weevil eradication programs. The maximum application rate will be reduced from 0.75 pound to 0.5 pound active per acre. The seasonal use will be reduced from 3 pounds per acre to 2 pounds. REI's will go from 2 days to 7 days and closed packaging and mixing/loading systems will be required.

Monitor. Monitor will continue to be available until the phase out is completed by 2007.

Selected Non-Organophosphates

Vydate. Vydate is a carbamate insecticide and nematicide. During risk mitigation, the maximum per acre use rate was reduced to 0.5 pounds except for California and Arizona where the rate will remain retain a 1.0 pound active per acre rate. The seasonal maximum will be 3 pounds active per acre. The soil broadcasts in cotton will be cancelled. Soil applications must be incorporated by water or mechanical means.

Endosulfan. The active ingredient endosulfan is an organochlorine. EPA completed an interim re-registration eligibility document (IRED) on July 31, 2002. A 60-day comment period ended January 6, 2003. Endosulfan will be continued only for use in California, Arizona, Texas, New Mexico and Oklahoma. A maximum per rate of 1.5 pounds will be allowed by ground

application while only 0.75 pounds active per acre by air will be allowed. The rate for aerial application had to be reduced in order to get the risks within acceptable range. The season maximum is 2 pounds by ground and 1.5 pounds by air. Closed systems mixing and loading are required for aerial applications of emulsifiable concentrate. The aerial application capped rate of 0.75 lbs. per acre is not efficacious and ground application in irrigated production is not practical. Therefore, comments were prepared to propose to EPA that the 1.0 lb. rate by air could be used in a manner that would be fully protective of workers, monitored for compliance and allow an efficacious rate of 1.0 lb. to be used. The NCC filed comments in support of those submitted by Dr Peter Ellsworth of University of Arizona. Dr. Ellsworth filed extensive comments to show why the use of 1.0 rate by air could be regulated in such a manner to insure safety of mixers, loaders and applicators. EPA will consider Dr. Ellsworth's data before making a final decision on endosulfan.

What's Next??

This section will provide an overview of products coming up for FQPA and/or FIFRA review in the next two years. First, EPA is expected to complete review of malathion, methyl parathion, and endosulfan. The Cumulative Risk Assessment of the OP's as a group must be completed before the reregistration of individual OP products can become final.

Meanwhile, EPA will follow with FQPA/FIFRA review process on remaining products. One group of cotton products to be reviewed includes the carbamates, such as aldicarb (Temik), methomyl (Lannate), thiodicarb (Larvin), and carbofuran (Furadan). The group of synthetic pyrethroids will also be up for reregistration in November of this year.

Remaining individual cotton products, include Cacodylic acid harvest aid product, etridiazole (Terrazole fungicide), Ethion, MSMA herbicide, propargite (Omite miticide), diuron herbicide, oxyflurafen (Goal herbicide), and sodium acifluorfen (Blazer herbicide).

New Products on the Market

Drs. Ralph Bagwell and Roger Leonard, Louisiana State University and Dr. Scott Stewart, University of Tennessee are acknowledged for their assistance in providing information for the remaining sections of the presentation. There are nine new products for cotton that have been registered within the past 5 years. Many of which have qualified for EPA's reduced risk initiative, which provides for a fast track registration review. The newer cotton products are:

Trimax 4F

Imidacloprid is an insecticide from Bayer. This product was originally labeled as Provado in 1995. Target pests are aphids and plant bugs. Imidacloprid is sold as Gaucho seed treatment and Admire as soil applied product.

Tracer

Spinosad insecticide is from Dow AgroSciences. Tracer received a label in 1997 for control of tobacco budworm, bollworm, loopers and armyworms.

Confirm

Tebufenozide IGR is from Dow AgroSciences. Confirm was obtained upon acquisition of Rohm and Haas. Confirm received a label in 2000 and the target pests are beet armyworm, fall armyworm and cabbage looper.

Intrepid

Methoxyfenozide is from Dow AgroSciences. Intrepid was also obtained upon acquisition of Rohm and Haas. Intrepid received a label in 2001. The IGR is used for control of beet armyworm, fall armyworm, loopers and budworm/bollworms.

Steward

Indoxacarb is an insecticide from DuPont. Steward received a label in 2001 for control of budworm/bollworm, loopers and plant bugs.

Centric

Thiamethoxam is an insecticide from Syngenta. Centric, a neonicotinoid, received a label in 2001 for control of thrips, aphids, plant bugs and whiteflies in cotton. It will be known as Cruiser when used as a seed treatment.

Intruder

Acetamiprid is an insecticide originally known as Assail during development by Aventis/Nippon Soda. Recently, as result of the Aventis/Bayer merger, the DuPont Company obtained marketing and distribution rights to acetamiprid. Intruder, its new trade name, received a label in 2002 for control of aphids, plant bugs and whiteflies.

Knack

Pyriproxifen is an IGR from Valent, USA. Knack received a label in 2000 for control of whitefly.

Courier

Is based on buprofezin from Nichino. It was formally known as Applaud and was originally developed by AgrEvo/Aventis as a whitefly IGR. It received a label in 2002 for control of whitefly.

Products in the Pipeline

This section will give a overview of seven new products that could come on the market in the next 1 to 3 years. They are described below.

Denim is from Syngenta and is based on the active ingredient, emamectin benzoate. It has been available on Section 18 Emergency Exemption from 1999 to 2002 for control of resistant tobacco budworm and beet armyworm. Full registration of Denim could come this year.

S-1812 is an insecticide being developed by Valent, USA. It is thought to be an IGR for control of beet armyworm, fall armyworm, budworm/bollworm and loopers. Registration could come in 2004.

Prolex (DE 225) is from Dow AgroSciences. A fourth generation synthetic pyrethroid, gamma cyhalothrin, controls pests similar to other pyrethroids. It is highly active at rates one tenth of those for Karate (lambda cyhalothrin). Registration is expected in 2003 with product launch in cotton in 2004.

Novaluran is a new insecticide from Uniroyal. It will be marketed as Diamond and it is chitin inhibitor, related to Dimilin. Target pests are plant bugs. Registration is anticipated in 2004.

Fulfil is based on pymetrozine from Sygenta. Registration status is uncertain. Target pests are aphids and possibly whitefly.

Regent is based on fipronil from BASF. It has been developed by Aventis, and was obtained by BASF as result of the Aventis/Bayer merger. Regent target pests are plant bugs and thrips. Label status is uncertain.

Flonicamid is a new product under development by FMC. It is developed as F1785 and target pests include the sucking insects.

There are a number of products under research and development in field trials under secrecy agreements at this time. These products are 3 to 5 years from registration. Limited information is that new products are promising with most of the activity targeted toward the bug complex.

Summary

Cotton products have been in review at EPA according to FQPA requirements and FIFRA reregistration. To date, the focus has been on the 44 organophosphates (OP's), many are currently registered for use in cotton. Cotton OP products for the most part survived the FIFRA reregistration review process with relatively minor modifications in usage restrictions. Registration for cotton uses will be maintained for 12 of the OP's. Included are Lorsban, Orthene, Curacron, Bidrin, Di-Syston, Thimet and Def/Folex (defoliant), malathion, methyl parathion, Cygon, Imidan and Supracide. Risk mitigation process for malathion and methyl parathion is incomplete but should be completed in the near future. Guthion and Monitor will be phased out over the next few years. Registrants are not supporting continued registration for Bolstar and Diazinon on cotton.

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