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

5/2/1997

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Section 18- Specific Exemption for Use of Azoxystrobin on Rice to control Rice Blast and Sheath Blight [97-LA-01 and 97-MS-01]-- ACTION MEMORANDUM

FROM: James J. Jones, Acting Director
Registration Division

TO: Steven L. Johnson, Acting Deputy Director
Office of Pesticide Programs

I. APPLICANT'S REQUESTS

APPLICANTS: Louisiana Department of Agriculture
Mississippi Department of Agriculture

CHEMICAL: Azoxystrobin

PRODUCT: Quadris™Flowable Fungicide (22% suspension concentrate), Manufactured by Zeneca Ag. Products

SITE: Rice

PEST: Rice blast (*Pyricularia grisea*) and Sheath blight (*Rhizoctinia solani*)

USE PATTERN: Quadris fungicide shall be applied at a rate of 0.20 to 0.30 lbs a.i. of product per acre not to exceed 0.7 lbs a.i. per acre per year.

REQUIREMENTS: A pre-harvest interval of 28 days is required.

ACREAGE: Louisiana - 85,000 acres
Mississippi - 50,000 acres

USE SEASON: May 1, 1997 to September 15, 1997

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EMERGENCY SITUATION/ ALTERNATIVE CONTROLS AND PRACTICES:

II. BACKGROUND

The Louisiana and Mississippi Departments of Agriculture requested a specific exemption for this use on December 19, 1996 and January 30, 1997, respectively. This is the first year this use has been requested under §18 of FIFRA.

Time-limited tolerances in connection with the FIFRA §18 emergency exemption are expected to be established by the end of June for residues of azoxystrobin on rice, rice feed items and various animal raw agricultural commodities as listed in the table below.

Commodity	Parts per million
rice, grain	4
rice, straw	10
rice, hulls	20
liver of cattle, goat, horse, and sheep	0.03
meat and fat of cattle, goat, horse, sheep, poultry, and swine	0.01
kidney, cattle:	0.06
milk	0.006
liver , poultry	0.4
liver, hog	0.2
eggs	0.4

These tolerances will be revoked after June 30, 1998.

PROGRESS TOWARDS REGISTRATION:

Azoxystrobin was recently registered for use on golf courses and commercial turf farms. Zeneca, the manufacturer, has petitioned the Agency for section 3 registrations for several food uses which will likely be approved in the next few weeks. Zeneca has indicated through communications with PM Team 22 that it expects to submit a petition for registration of

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azoxystrobin on rice later this year. Based on these events, it appears that progress towards registration may be considered adequate.

RE-REGISTRATION AND SPECIAL REVIEW CONCERNS:

Since azoxystrobin was just recently registered it is not subject to reregistration under FIFRA.

III. EPA EVALUATION

BIOLOGICAL AND ECONOMIC ANALYSIS

The Biological and Economic Analysis Division (BEAD) reviewed this 1997 request for the use of azoxystrobin on rice in Louisiana and Mississippi and has concluded that the situation is non-routine and therefore constitutes an emergency situation. Each state contends that due to very wet conditions this year, late planting may expose the rice crop to heavy disease pressure late in the season. In addition, while resistance of the Blast pathogen (*Pyricularia grisea*) to benomyl has not been demonstrated, the State has shown reasonable evidence of reduced efficacy of benomyl, an alternate compound.

However, neither state fully explains the non-routine aspects of this situation. If either state requests this exemption next year, the following information should be submitted: 1) yield representative of the region affected for the past 5 years which demonstrates a recent, substantial increase of these diseases and/or impact from them (e.g. yield and/or quality); 2) adequate documentation of the pathogen's resistance to benomyl if applicable; and 3) information indicating that the losses rice growers incur will be economically significant (greater than the normal losses now being incurred).

AGGREGATE RISK ASSESSMENT AND DETERMINATION OF SAFETY

Consistent with § 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. Azoxystrobin is already registered by EPA for use on gulf courses and ornamental turf with no residential uses. For the purposes of this emergency exemption, EPA has sufficient data to assess the hazards of azoxystrobin and to make a determination on aggregate exposure, consistent with §408(b)(2), for a time-limited tolerance for residues of azoxystrobin on rice, rice feed items and secondary residues in animal products as listed in the table above in Section II. EPA's assessment of the dietary exposures and risks associated with establishing this tolerance is discussed in the attached tolerance document.

RISK CHARACTERIZATION FOR WORKER EXPOSURE

An assessment of the risk from occupational exposure was not conducted because of either the low toxicity of azoxystrobin or lack of exposure, depending upon the duration of exposure. For short- and intermediate- term exposure, toxicity demonstrated in tests was low. The NOEL in a 21-day dermal toxicity study was 1000 at the highest dose tested assuring an acceptable MOE of 100 or more. Acute inhalation toxicity was category III. No chronic assessment was conducted since there is no chronic occupational exposure scenario for this section 18 use. For cancer risk, azoxystrobin has been classified by the Health Effects Division Reference Dose Committee as "not likely" to be carcinogenic to humans via relevant routes of exposure, therefore, no assessment was necessary, therefore, no assessment was necessary.

RISK CHARACTERIZATION FOR ECOLOGICAL EFFECTS

The Ecological Effects Branch (EEB) reviewed the submission by Louisiana for this use and concluded that the use of azoxystrobin as proposed is not expected to present any undue adverse effects to birds and mammals. Adverse effects to aquatic organisms, especially invertebrates, are possible if an overflow event occurs (e.g. break in a levee). Estuarine invertebrates present in shallow waters adjacent to treated rice fields also might be affected from aerial drift. The extent of risk from an outflow event probably depends primarily on the amount of dilution of contaminated water with untreated water by the time aquatic organisms are exposed. Slight risk also might occur to aquatic plants and terrestrial plants along the inside banks of waterways receiving outflow water. Drift from aerial application is not likely to result in acute risk, but some risk to invertebrates, especially shrimp, is possible if they are exposed.

RISK CHARACTERIZATION AND MITIGATION FOR ENVIRONMENTAL FATE EFFECTS

The Environmental Fate and Groundwater Branch (EFGWB) reviewed the requests from Louisiana and Mississippi for use of azoxystrobin on rice. Current information in the environmental fate data base indicates that azoxystrobin, the parent compound, does not appear to be mobile, but there is some evidence for persistence and mobility of a primary degradate. For the section 3 registration, EFGWB is recommending standard language regarding the contamination for ground water from the degradate. This language is also being required for the section 18 label.

IV. RECOMMENDATION

I recommend that this specific exemption be granted to Louisiana and Mississippi Departments of Agriculture for the use of azoxystrobin on rice to control rice blast and sheath blight, for the reasons listed below. The states, regional office, and the respective Departments of Health will be informed of the findings of the evaluation of this request and advised of the time-

limited tolerance for enforcement purposes.

1. The possibility for emergency conditions exist if weather is favorable for disease later in the year, especially if susceptible areas are considered separately. Historic data demonstrates that for years in which rice blast disease pressure was high, yields from Louisiana's experimental plots were substantially reduced.

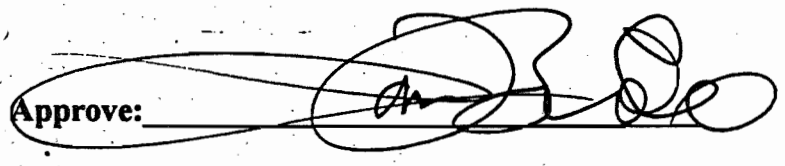
2. The available toxicology data for azoxystrobin support the proposed use. Residues of azoxystrobin and its regulated metabolite are not expected to exceed the the levels listed in the table under the heading "Background". Occupational exposure, aggregate risk and risk to infants and children do not appear to exceed the Agency's levels of concern.

3. A time-limited tolerance in connection with the FIFRA section 18 emergency exemption is expected to be established by the end of this June for residues of azoxystrobin on rice at levels listed in the table under the heading "Background". This tolerance will be revoked after June 30, 1998.

4. The proposed use should not pose undue adverse effects to birds and mammals. Label language limiting exposure to nontarget organisms is being required on the Section 18 label. Risk to endangered species present in Louisiana (pallid sturgeon, gulf sturgeon, and the Louisiana pearlshell) is not anticipated considering their distribution in relation to rice fields.

5. This is the first year that any state has requested this use under section 18 of FIFRA. The registrant has submitted petitions for several food uses. Food uses are expected to be registered within a few weeks. A submission for use on rice is expected this year. Progress toward registration is considered adequate.

6. Federal Farm Programs change this year. The subsidies will decrease beginning in 1997 and continue to decline for seven years and then end. This is the first year that the federal subsidies are decreasing. The projected yield losses are expected to be unusually high if the weather is favorable for Rice Blast and Sheath Blight. For these reasons, rice growers may incur significant economic losses if loss of federal subsidies is coupled with yield losses due to weather conditions.

Approve: 

Disapprove: _____

Date: 5/2/97

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MEMORANDUM

SUBJECT: Dietary Exposure Analysis for Azoxystrobin in/on Bananas, Peaches, Peanuts, and Tomatoes (PP# 6F4762).

FROM: Brian Steinwand
Dietary Risk Evaluation Section
Science Analysis Branch/HED (7509C)

Through: Elizabeth Doyle, Section Head
Dietary Risk Evaluation Section
SAB/Health Effects Division

TO: M. Metzger, Chief
RCAB (7509C)

Action Requested

Provide a chronic dietary exposure analysis for the use of azoxystrobin in/on bananas, peanuts, peaches and tomatoes. The petition requests and CBTS recommends establishing a permanent tolerance of 0.5 ppm on bananas (0.05 ppm for banana pulp), 0.8 ppm for peaches, 0.01 ppm and 0.03 ppm on peanuts and peanut oil respectively, 0.2 ppm on tomatoes, juice and puree, and 0.6 ppm on tomato paste and catsup. (See Memo, J. Garbus, 5/20/97).

Discussion

This analysis includes pending uses on grapes, pecans and a Section 18 request on rice, milk, meat, eggs and poultry.

Toxicological Endpoint:

The Reference Dose (RfD) used in the analysis is 0.18 mg/kg bwt/day, based on a NOEL of 18.2 mg/kg/day. Effects seen at the LOEL, 34 mg/kg/day, were reduced body weight and bile duct lesions in males. An uncertainty factor (UF) of 100 was used to account for both the interspecies extrapolation and the intra species variability (See Memo, RfD Committee, 11/7/96).

Currently, azoxystrobin is classified as a "not likely" carcinogen (See TES document, 12/10/96).

No acute endpoint was identified by the TES (Toxicology Endpoint Selection) committee 12/10/96.

Residue Information

Being a new chemical, tolerances for azoxystrobin have yet to be published in 40 CFR. Tolerance level residues and 100 percent crop treated assumptions were made for all commodities.

Results

A summary of the residue information considered in this analysis is attached as Table 1. A DRES chronic exposure analysis was performed using tolerance level residues and 100 percent crop treated information to estimate the Theoretical Maximum Residue Contribution (TMRC) for the general population and 22 subgroups. Summaries of the TMRCs and their representations as percentages of the Reference Dose (RfD) are included as Table 1 and 2.

Chronic Exposure Analysis

Exposure from Existing Tolerances for azoxystrobin:

Subgroup	Exposure (mg/kg/day)	%RfD
U.S. Population	0.000000	0
Non-Nursing Infants (<1 year old)	0.000000	0

Proposed new Tolerances on the proposed commodities:

U.S. Population	0.000604	0.335
Non-Nursing Infants (<1 year old)	0.001988	1.104

If all pending tolerances (including the new petition) are approved the TMRC will be:

U.S. Population	0.002224	1.23
Non-Nursing Infants (<1 year old)	0.008610	4.78

The chronic analysis for azoxystrobin is a worst case estimate of dietary exposure with all residues at tolerance level and 100 percent of the commodities assumed to be treated with azoxystrobin. Thus, the chronic dietary risk concern due to azoxystrobin appears to be minimal for this petition on bananas, peaches, tomatoes and peanuts and does not exceed the RfD for any of the DRES subgroups.

Attachments

cc: DRES; Caswell 123AZO; RD PM 22 C. Giles-Parker; CBTS (J. Garbus)