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MEMORANDUM

SUBJECT: PP# 0F3834 Quizalofop Ethyl (Assure®, DPX-Y6202) in or on Lentils, Dry Beans and Dry Peas. Evaluation of Analytical Methods and Residue Data.

MRID No. 413208-00, 01 DEB No. 6206, 6207
HED# 0-0475

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and

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Health Effects Division (H7509C)

THRU: Richard D. Schmitt, Ph.D., Chief
Dietary Exposure Branch
Health Effects Division (H7509C)

The petitioner, E. I. du Pont de Nemours & Co. (Inc.), proposes the establishment of tolerances for the residues of quizalofop ethyl (ethyl 2-[4-(6-chloroquinoxaline-2-yl-oxy)phenoxy]propanoate) and its metabolite, 2-[4-(6-chloroquinoxaline-2-yl-oxy)phenoxy]propanoic acid, expressed as quizalofop ethyl in or on the raw agricultural commodities, lentils, dried beans and dried peas, at 0.05 parts per million (ppm).

Residues of quizalofop ethyl are currently regulated under 40 CFR 180.441(a) at 0.05 ppm in or on soybeans and 180.441(b) at 0.01 to 0.05 ppm on milk, meat, poultry, eggs and their by-products.

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CONCLUSIONS

1. The nature of the residue in plants is adequately understood for the purposes of this petition only. The residues of concern are the parent and its metabolite, 2-[4-(6-chloroquinoxaline-2-yl-oxy)phenoxy]propanoic acid, expressed as parent.

2.(a) DEB concludes that there is adequate analytical methodology to enforce the proposed tolerance on lentils (a minor crop) only. There is an adequate method in the Pesticides Analytical Manual II.

2.(b) No raw data and/or chromatograms were submitted with this petition. Due to the complexity of the methodology, representative copies of the raw data and/or chromatograms are required to be submitted for review.

2.(c) The analytical method in PAM II has been found to be adequate for soybeans. However, DEB has previously concluded that the method requires simplification or documented attempts at simplification prior to the registration of additional RAC's. The current method is considered to be inadequate for dried beans and peas without a revised, simplified method or resulting documentation of unsuccessful attempts at revising the method. A second method validation trial would be required for the revised method or the old method on the new commodity.

3.(a) The submitted residue data are adequate for lentils only for a PHI of 60 days. The proposed 30 day PHI is inadequate. A revised Section B is required increasing the proposed PHI for lentils.

3.(b) The submitted lentil residue data are inadequate to support the establishment of a tolerance on dried beans. Residue data for dried beans with at least two field trials each from different locations in California, Colorado, Idaho, Michigan and North Dakota would be required. This would encompass both the major growing and climatic regions for dried beans. Residue data generated must reflect the use pattern, i.e. must include aerial application data as well as ground application data.

3.(c) The submitted lentil residue data are inadequate to support the establishment of a tolerance on dried peas. A minimum of four additional field trials are needed for dried peas (to give a total of twelve when combined with the lentil data) from Idaho and Washington. This would encompass the major growing and climatic region and give adequate representation for dried peas. Additional residue data generated must reflect the use pattern, i.e. must include aerial application data as well as ground application data.

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4.(a) No residue data were submitted for lentil vines and hay. Lentil vines and hay are considered minor feed items. Unless the petitioner submits residue data for lentil vines and hay, a revised Section B is required with a feeding restriction for lentil vines and hay.

4.(b) Bean vines and hay are considered feed items. No residue data for these items were submitted with this petition. Residue data are required for bean vines and hay from the representative growing and climatic regions. Alternatively, label feeding restrictions could be imposed.

4.(c) Pea vines and hay are considered feed items. No residue data were submitted with this petition. Residue data are required for bean vines and hay from the representative growing region. Note that although a minimum of four field trials are required for dried peas, additional trials would be required for vines and hay since there are no translatable residue data from lentil vines and hay. Alternatively, label feeding restrictions could be imposed.

5. An "International Residue Limit Status" sheet is attached. There are no Canadian, Mexican, or Codex tolerances for quizalofop ethyl (Assure®, DPX-Y6202) on lentils, dried bean and dried peas. There are no compatibility problems associated with this petition.

RECOMMENDATIONS

DEB recommends against the establishment of the proposed tolerances because of conclusions 2b, 2c, 3a, 3b, 3c, 4a, 4b and 4c.

Subject to a favorable review of the raw data and/or chromatograms and if the petitioner withdraws the proposed dried bean and pea tolerances, DEB would recommend for the proposed tolerance on lentils providing the petitioner submitted a revised Section B increasing the PHI to 60 days and adding a feeding restriction on lentil vines and hay to the label.

DETAILED CONSIDERATIONS

MANUFACTURE AND FORMULATION

The manufacturing process and product chemistry has been previously adequately reviewed (PP#5F3252/FAP#6H5479,7/29/87 and previous memos, G.Otakie). DEB does not anticipate any residue problems from impurities in the technical product.

Assure® (EPA Reg. No. 352-441) is a 10% liquid formulation (0.8 lb a.i./gal) of quizalofop ethyl (DPX-Y6202).

PROPOSED USE (MRID# 413208-00)

Assure® is to be applied for postemergence control of actively growing grasses in dry beans, dry peas and lentils. Application can be by either ground or aerial sprays.

For ground spraying, always include a non-phytotoxic petroleum oil concentrate at 1% v/v (4 qts/100 gal) or a non-ionic surfactant at 0.25% v/v (1 qt/100 gal). Use a minimum of 10 gallons of water per acre in humid areas or a minimum of 15 gallons per acre in arid areas. Do not exceed 40 gallons per acre in either humid or arid areas.

For aerial applications, always include a non-phytotoxic petroleum oil concentrate at 0.5% v/v (2 qts/100 gal) or a non-ionic surfactant at 0.25% v/v (1 qt/100 gal). Use a minimum of 3 gallons of water per acre in Humid Areas or a minimum of 5 gallons per acre in Arid Areas.

Application rates vary according to the annual grass to be controlled and whether the area to be treated is considered to be arid or humid. Recommended rates vary from a minimum of 10 to a maximum of 24 oz of Assure® per acre. This corresponds to 0.063 to 0.15 lbs a.i./A.

Do not apply within 30 days of harvest. Do not apply after pod set. Do not apply through any type of irrigation equipment.

NATURE OF THE RESIDUE

No new metabolism data were submitted with this petition. There are available adequate plant metabolism data for soybeans (PP#5F3252/FAP#6H5479, 9/25/85, M. Firestone) and these are adequate to be able to be translated for the purpose of this petition. DEB considers the residues of concern in plants to be the parent and its metabolite, 2-[4-(6-chloroquinoxaline-2-yl-oxy)phenoxy]propanoic acid, expressed as parent.

ANALYTICAL METHOD (MRID 413208-01)

The analytical method used was Dupont AMR-153-83, "Determination of Residues of DPX-Y6202 and DPX-Y6202 Acid in Soybeans."; Revisions B; April 14, 1986, by L.W. Hershberger, S.S. Goldberg, and A.W. Babicki, Jr. A successful method verification (PP#5F3252/FAP#6H5479, 5/25/88, R. Sarmiento) was conducted on soybeans. However, significant reservations were expressed at

the complexity of the methodology (PP#5F3252/FAP#6H5479, 6/27/88, G. Otakie). The petitioner was advised that any additional uses or change in uses of quizalofop ethyl (Assure®, DPX-Y6202) would require either a simplified method or proof that extensive efforts were made unsuccessfully to simplify the method.

Briefly, a 4 g sample was homogenized in acetone/acetic acid/water (750/2/250 v/v/v) and the solids removed by centrifugation. The pellet was extracted twice more and the liquid fractions filtered and combined. The sample was concentrated at 35°C. The sample was extracted with 100 ml of chloroform the organic layer filtered through anhydrous sodium sulfate. This process was repeated and both extracts combined. The sample was evaporated to dryness at 35°C, dissolved in hexane/acetic acid (980/20) and evaporated to dryness.

The sample was then dissolved in 4 ml of hexane/acetone/acetic acid (580/400/20), centrifuged to remove undissolved solids and filtered prior to medium pressure chromatography on a silica column. Using a flow rate of 5 ml/min with a mobile phase of hexane/acetone/acetic acid (580/400/20) the correct fractions (based on a previous calibration run) for DPX-Y6202 and DPX-Y6202 acid were collected and concentrated to dryness. The column was washed for 20 minutes prior to injection with the next sample. The DPX-Y6202 acid was derivatized to Me-DPX-Y6202 by adding Methyl-8® reagent at 105°C for 1 hour. The sample was evaporated to dryness.

For the hplc analysis, each fraction was dissolved in 1 ml of hexane/acetic acid (980/20) and filtered. This chromatography procedure uses two columns, C_1, a Sepralyte® OH column, and C_2, a Partisil 5 Silica RAC II column and multiple changes in flow rate and mobile phase composition.

For DPX-Y6202, the sample was injected onto C_1 and as the peak was eluted, the eluant was directed into C_2. When the DPX-Y6202 had been loaded onto C_2, the eluant of C_1 was directed to waste. After C_1 was washed and re-equilibrated, the flow from C_1 was switched back to C_2 and DPX-Y6202 was eluted and quantitated by uv detection at 335 nm. A similar approach was used for Me-DPX-Y-6202 only using different mobile phase compositions and switching timing patterns.

No raw data and/or chromatograms were submitted with this petition. Due to the complexity of the methodology, representative copies of the raw data and/or chromatograms are required to be submitted for review.

For the purposes of use on lentils only (a minor crop), DEB considers the current methodology adequate. For the purpose of

use on dried beans or peas the method is considered inadequate. Documented attempts at simplification of the method would be required.

RESIDUE DATA **(MRID 413208-01)**

The method was validated by fortification at 0.1 and 0.2 ppm with both parent and the acid metabolite. Recoveries ranged from 66 to 89% for parent with an average of 80% from four samples and from 46 to 90% with an average of 75% from three samples for the acid metabolite.

TABLE I.

Location	Treatment (oz a.i./A)	GPA	PHI	Acid (ppm)	Ester (ppm)
WASHINGTON					
Fairfield	4	33	35	<0.05	<0.05
Fairfield	4	23	61	<0.05	<0.05
Fairfield	4	23	61	<0.05	<0.05
Fairfield	check	--	--	<0.05	<0.05
Fairfield	check	--	--	<0.05	<0.05
Latah	4	33	35	<0.05	<0.05
Latah	check	--	--	<0.05	<0.05
Latah	check	--	--	<0.05	<0.05
Tekoa	4	33	45	<0.05	<0.05
Tekoa	4	23	61	<0.05	<0.05
Tekoa	4	23	61	<0.05	<0.05
Tekoa	check	--	--	<0.05	<0.05
IDAHO					
Kendrick	4	23	62	<0.05	<0.05
Kendrick	check	--	--	<0.05	<0.05

Residue trials were held in Washington and Idaho on lentils only in 1984 and 1985. This is adequate representation for lentils, which are a minor crop and are primarily produced in these two states. This is not, however, adequate geographical representation to support translation of these data to dried beans (Washington and Idaho produce only 3.2% and 9.0% of total US production, respectively [Agricultural Statistics 1986].). Additionally, lentils are considered to be in the pea family in the crop definitions (40 CFR 180.1). The number of field trials

is also insufficient to support a non-minor crop use. Residue data for dried beans with at least two field trials each from different locations in California, Colorado, Idaho, Michigan and North Dakota would be required. This would encompass both the major growing and climatic regions for dried beans. Residue data generated must reflect the use pattern, i.e. must include aerial application data as well as ground application data.

A total of eight lentil samples and six controls were analyzed (Table I). Residue values for all samples including controls, were less than the limit of detection of 0.05 ppm. A PHI of 30 days was recommended, but samples were all taken a minimum of 35 days after treatment. No sample data match the recommended PHI. Therefore, a PHI of 30 days cannot be supported. The data would, however, support a PHI of 60 days for lentils. The application rate of 4 oz a.i./A corresponds to 1.7 times the maximal recommended rate.

Samples were analyzed anywhere from 373 to 723 days after sampling. Storage stability data from soybeans are adequate to translate for lentils (PP#5F3252/FAP#6H5479). DEB considers the residues of concern to be stable in lentils for a period up to 24 months.

The only data submitted to support a tolerance on dried peas were the eight lentil residue values. This is not sufficient to translate for a non-minor crop such as dried peas. A minimum of four additional trials are needed (to give a total of twelve) from Idaho and Washington. Additional residue data generated must reflect the use pattern, i.e. must include aerial application data as well as ground application data.

The available residue data are not adequate to support the proposed tolerances on dried beans and peas. Because lentils are a minor crop, the data are adequate to recommend for the proposed tolerance on lentils, providing a revised Section B extending the PHI to 60 days is submitted.

In order to recommend for a tolerance on dried beans and peas, additional residue data need to be submitted.

MEAT, MILK, POULTRY AND EGGS

Feeding studies for livestock and poultry were previously submitted and found to be adequate (PP#5F3252, 5/9/88, G. Otakie).

No residue data were submitted for lentil forage and hay. Lentil forage and hay are considered minor livestock feed items. No

tolerance was proposed for lentil forage and hay.

DEB has concluded (Overview of Residue Chemistry Guidelines, 10/10/89) that, in lieu of a tolerance proposal, a label restriction against the feeding and foraging of lentil vines and hay would be acceptable.

The residue data that are available allow DEB to recommend for the proposed tolerance on lentils, providing a revised Section B proposing a restriction on the feeding and foraging of lentil vines and hay is submitted.

No residue data are available for bean or pea seed, vine and hay, all of which are considered feed items. In the absence of such data for a non-minor feed item, DEB cannot recommend for a tolerance on dried beans or peas. The petitioner would need to either provide residue data and tolerance proposals for bean forage and hay or impose label feeding restrictions on these commodities.

OTHER CONSIDERATIONS

There are no Canadian, Codex or Mexican tolerances on lentils, dried beans or dried peas for quizalofop ethyl (Assure®, DPX-Y6202).

Attachment: International Residue Limit Status Sheet.

CC: S. Koepke (DEB),PP0F3834, PIB/FOB (C. Furlow), Circulation(7),RF, R. Schmitt

H7509C:DEB:Reviewer(SK):CM#2:Rm810:557-7888:Typist(SK):5/18/90. RDI:Section Head: R.S. Quick:5/18/90: Br.Sr.Scientist:R.A. Loranger:5/18/90.