Dated: August 13, 2004.

Vanessa T. Vu,

Director, EPA Science Advisory Board Staff Office.

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ENVIROMENTAL PROTECTION AGENCY

[OPP–2004–0245; FRL–7372–4]

Quizalofop-Ethyl; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket identification (ID) number OPP–2004–0245, must be received on or before September 24, 2004.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you an agricultural producer, food manufacturer, or pesticide manufacturer Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established an official public docket for this action under docket ID number OPP–2004–0245. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do

not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2004–0245. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to *opp-docket@epa.gov*, Attention: Docket ID number OPP–2004–0245. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2004–0245.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA, Attention: Docket ID number OPP–2004–0245. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 16, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by E.I. du Pont de Nemours and Company and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

E.I. du Pont de Nemours and Company

PP 3F4268

EPA has received additional residue studies required by the Agency in support of a pesticide petition PP 3F4268 from E. I. du Pont de Nemours and Company, DuPont Crop Protection,

Laurel Run, Wilmington, DE 19880–0038 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR 180.441(a)(1) by establishing tolerances for residues of quizalofop (2-[4-(6-chloroquinoxalin-2yl)oxy)phenoxy])-propanoic acid], and quizalofop ethyl [ethyl-2-[4-(6-chloroquinoaxalin-2yl)oxy)phenoxy)propanoate), all expressed as quizalofop ethyl (DUPONT ASSURE II) in or on the raw agricultural commodities, dry beans at 0.4 parts per million (ppm), dry bean straw at 3.0 ppm, succulent beans at 0.25 ppm, succulent bean forage at 3.0 ppm, dry peas at 0.25 ppm, dry pea straw at 3.0 ppm, succulent peas at 0.3 ppm, succulent pea forage at 3.0 ppm, sugar beet root at 0.1 ppm, sugar beet top at 0.5 ppm; and paragraph (a) (3) by establishing a permanent tolerance for quizalofop p-ethyl for sugar beet molasses at 0.2 ppm. These proposed permanent tolerances will replace the time-limited tolerances listed in paragraph (a) (4). This summary was prepared by the petitioner. EPA has determined that the petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting the petition. Additional data may be needed before EPA rules in the petition. The additional residue studies were required by the Agency upon issuance of the time-limited tolerances, which published in the **Federal Register** of June 14, 1996 (61 FR 30171) (FRL–5375–6).

A. Residue Chemistry

1. *Plant metabolism.* The registrant has provided plant metabolism studies for cotton, potatoes, soybeans, sugar beets, and tomatoes. These studies have been previously reviewed in PP 3F4268. In summary, quizalofop-p ethyl ester is metabolized by cleavage at three sites as follows:

i. Primary pathway is hydrolysis of the ethyl ester to form the quizalofop-p acid.

ii. Cleavage of the enol ether linkage in the acid, between the phenyl and quinoxalinyl rings, to form phenols.

iii. Cleavage of the ether linkage between the isopropanic group and the phenyl ring to form a phenol.

The plant metabolism data show that quizalofop-p ethyl ester does not translocate, but is rapidly hydrolyzed to the corresponding acid; then the phenols conjugate with the plant sugars. Metabolism studies in soybeans using the racemic mixture quizalofop ethyl ester and the resolved D+ isomer show nearly identical pathways.

The nature of the quizalofop-p ethyl ester residue in cottonseed, potatoes, tomatoes, soybeans, and sugar beets is adequately understood. The residues of concern are quizalofop-p ethyl ester and its acid metabolite, quizalofop-p, and the S enantiomers of both the ester and the acid, all expressed as quizalofop-p ethyl ester.

2. *Analytical method.* An adequate analytical methodology (high-pressure liquid chromatography using either ultraviolet or fluorescence detection) is available for enforcement purposes in Vol. II of the Food and Drug Administration Pesticide Analytical Method (PAM II, Method I). There are currently no actions pending against the registration of this chemical. Any secondary residues expected to occur in eggs; meat, fat, and meat byproducts of cattle, goats, hogs, horses, sheep, and poultry; and milk from this use will be covered by existing tolerances.

Adequately validated residue analytical method, DuPont 2829 (Xenos Method XAM-38A, Determination of Quizalofop-P-Ethyl and its Metabolites in Canola, Flax, Lentils, Peas, Dry and Succulent Beans and Sugar Beet Tops and Roots, by Liquid Chromatography). This method determines residues of quizalofop-P-ethyl and its metabolites in oilseed and other crops. It measures levels of quizalofop-P-ethyl, quizalofop-P acid and conjugates as total residues in the form of 2methoxy-6-chloroquinoxaline (MeCHQ). Quantitation was carried out using normal phase high pressure liquid chromatography with fluorescence detection. The residues were expressed as equivalents of quizalofop-P-ethyl.

A successful tolerance method validation (TMV) on DuPont 2829 (Xenos Method XAM-38A) is not a prerequisite for a tolerance on beans (succulent and dried) as well as sugar beets and sugar beet molasses as there is already an enforcement method in PAM II.

3. *Magnitude of residues*—a. *Magnitude of the residue in plants.* The studies submitted include field trials in three regions for succulent beans, six additional sites for dry beans in four regions, and five additional sites in three regions for sugar beets.

In conjunction with previously submitted data an adequate amount of geographically representative crop field trial residue data were presented which show that the proposed tolerances should not be exceeded when quizalofop ethyl is formulated into DUPONT ASSURE II and used as directed.

b. *Magnitude of the residue in animals.* A ruminant feeding study has been submitted and reviewed in PP 5F3252 and PP 1F3951. In summary, three groups of three lactating dairy cows plus a control group were fed 0.1, 0.5, and 5.0 ppm quizalofop ethyl ester (encapsulated) for 28-consecutive days. Milk was collected daily and a sub-sample was divided into skim milk and cream. Two cows were sacrificed after 28 days with samples of fat, skeletal muscle, liver, and kidney being collected and analyzed. The remaining cow in each test group was fed a regular diet without encapsulated quizalofop ethyl ester for an additional 7 days before sacrifice. Whole milk, skim milk, and cream from the control, and the 0.1 and 0.5 ppm dose groups showed no quizalofop to <0.02 ppm (0.05 ppm in cream). From the 5 ppm dose, quizalofop residues ranged from 0.01 to 0.02 ppm in whole, and when these samples were separated into cream and skim milk, the quizalofop partitioned into the cream with residues plateauing at 0.26 to 0.31 ppm. No quizalofop to <0.02 ppm was detected in skeletal muscle, and to <0.05 ppm was detected in any liver or fat sample from any of the three doses. Quizalofop was detected in one kidney sample as 0.05 ppm from the 5 ppm dose.

From the feed items in this petition, all of the feed items in cattle diets can be treated with quizalofop ethyl ester. A theoretical beef cattle diet consisting of bean and pea forage, canola meal, pea hay, and sugar beet tops which none-the-less maximizes the potential quizalofop exposure of 2.1 ppm. A theoretical dairy cattle diet consisting of pea and bean forage would none-the-less maximize the potential quizalofop exposure at 2.4 ppm. Substitutions of other feed items and varying their percentages in the diets would give a lower-dietary quizalofop burden.

The results of the quizalofop ethyl ester bovine feeding study show that finite residues will actually occur in milk and tissues from the feeding of quizalofop ethyl ester treated raw agricultural commodities (RACs) or their processed feed items when DUPONT ASSURE II is used as directed. The established quizalofop and quizalofop ethyl ester tolerance in milk, and in fat, meat, and meat by-products of cattle, goats, hogs, horse, and sheep are adequate and need not be increased from these additional uses.

A poultry feeding study has been submitted and reviewed (ibid). In summary, three groups of 20 hens (plus one control group) were dosed with

encapsulated quizalofop ethyl ester at 0.1, 0.5, and 5 ppm daily for 28-consecutive days. Eggs were collected daily, and after 28 days ¾ of the hens in each test group were sacrificed, and samples of fat, liver, kidney, breast and thigh muscles were collected and analyzed. Tissues from each test group were pooled prior to analysis. The remaining five hens were fed a regular poultry diet without quizalofop ethyl ester for an additional 7 days before sacrifice. No quizalofop residues were detected in the liver to <0.05 ppm, and in breast and thigh muscles to <0.02 ppm for any dose administered. From the 5 ppm dose, one kidney sample showed 0.09 ppm quizalofop, two fat samples were 0.05 and 0.06 ppm quizalofop, and one egg sample was 0.02 ppm quizalofop.

The results of the quizalofop ethyl ester poultry feeding study show that while it is not possible to establish with certainty whether finite residues will actually occur in eggs and tissues from the feeding of quizalofop ethyl ester treated RACS or their processed feed items when DUPONT ASSURE II is used as directed, there is a reasonable expectation for such residues to occur. The established tolerance of quizalofop and quizalofop ethyl ester in eggs, and in fat, meat, and meat by-products of poultry are adequate and need not be changed from these additional uses.

B. Toxicological Profile

1. *Acute toxicity.* Several acute toxicology studies were conducted and the overall results placed technical grade quizalofop ethyl in toxicity Category III. These include the following studies in Category III: acute oral toxicity (LD_{50s} 1,480 and 1,670 for female and male rats, respectively)and eye irritation (mild effects; reversible within 4 days). Dermal toxicity (LD_{50} > 5,000 milligram/kilogram (mg/kg); rabbit), inhalation toxicity LC_{50} >5.8 (mg/Liter (L)); rat) and dermal irritation were classified within Category IV. Technical quizalofop ethyl was not a dermal sensitizer.

2. *Genotoxicty.* Technical quizalofop ethyl was negative in the following genotoxicity tests: Bacterial gene mutation assays with *E. coli* and *S. typhimurium*; gene mutation assays in Chinese hamster ovary (CHO) cells; *in vitro* DNA damage assays with *B. subtillis* and in rat hepatocytes; and an *in vitro* chromosomal aberration test in CHO cells.

3. *Reproductive and developmental toxicity.* Studies supporting the registration include: A developmental toxicity study in rats administered dosage levels of 0, 30, 100, and 300 mg/kg/day on days 6 to 15 of gestation. The maternal toxicity no observed effect level (NOEL) was 30 mg/kg/day and a developmental toxicity NOEL was greater than 300 mg/kg/day. The maternal NOEL was based on reduced food consumption and increased liver weights at 100 and 300 mg/kg/day and reduced maternal weight gain at 300 mg/kg/day. There was an equivocal effect on maternal weight gain in the 100 mg/kg/day group (body weight in this group was lower before the outset of dosing, so unclear if subsequent effects were compound related).

A developmental toxicity study in rabbits administered dosage levels of 0, 7, 20, and 60 mg/kg/day on days 7–19 of gestation with no developmental effects noted at 60 mg/kg/day. The maternal toxicity NOEL was 20 mg/kg/day based on decreases in food consumption at 60/mg/kg/day.

A 2-generation reproduction study in rats fed diets containing 0, 25, 100, or 400 ppm (or approximately 1, 1.25, 5, and 20 mg/kg/day, respectively) with a developmental (systemic effects) NOEL of 1.25 mg/kg/day for F2B weanlings based on increased liver weights and increased incidence of eosinophilic changes in the livers at 5.0 mg/kg/day. These liver changes were considered to be physiological or adaptive changes to compound exposure among weanlings. When access to the mother's feed is available, it is a common observation that young rats will begin consuming chow prior to complete weaning at 21 days of age. Consumption could not be quantified; therefore, the maternal consumption was assumed as the NOEL (if normalized on a body weight basis, exposures to the weanling rats were likely higher). The parental NOEL of 5.0 mg/kg/day was based on decreased body weight and premating weight gain in males at 20 mg/kg/day, highest dose level (HDT).

4. *Subchronic toxicity.* A 90–day study was conducted in rats fed diets containing 0, 40, 128, and 1,280 ppm (or approximately 0, 2, 6.4, and 64 mg/kg/day, respectively). The NOEL was 2 mg/kg/day. This was based on increased liver weights at 6.4 mg/kg.

A 90–day feeding study in mice was conducted with diets that contained 0, 100, 316, or 1,000 ppm (or approximately 0, 15, 47.4, and 150 mg/kg/day, respectively). The NOEL was <15 mg/kg/day, lowest dose level (LDT) based on increased liver weights and reversible histopathological effects in the liver at the LDT.

A 6–month feeding study in dogs was conducted with diets that contained 0, 25, 100, or 400 ppm (or approximately 0, 0.625, 2.5, and 10 mg/kg/day, respectively). The NOEL was 2.5 mg/kg/day based on increased blood urea nitrogen at 10 mg/kg/day.

A 21–day dermal study was conducted in rabbits at doses of 0, 125, 500, or 2,000 mg/kg/day. The NOEL was 2,000 mg/kg/day HDT.

5. *Chronic toxicity.* An 18–month carcinogenicity study was conducted in CD–1 mice fed diets containing 0, 2, 10, 80 or 320 ppm (or approximately 0, 0.3, 1.5, 12, and 48 mg/kg/day, respectively). There were no carcinogenic effects observed under the conditions of the study at levels up to and including 12 mg/kg/day. A marginal increase in the incidence of hepatocellular tumors was observed at 48 mg/kg/day HDT, which exceeded the maximum tolerated dose (MTD). (Please see the discussion by the EPA HED Carcinogenicity Peer Review Committee.)

A 2–year chronic toxicity/carcinogenicity study was conducted in rats fed diets containing 0, 25, 100, or 400 ppm (or 0, 0.9, 3.7, and 15.5 mg/kg/day for males and 0, 1.1, 4.6, and 18.6 mg/kg/day for females, respectively). There were no carcinogenic effects observed under the conditions of the study at levels up to and including 18.6 gram (g)/kg/day HDT. The systemic NOEL was 0.9 mg/kg/day based on altered red cell parameters and slight/minimal centrilobuler enlargement of the liver at 3.7 mg/kg/day.

A 1–year feeding study was conducted in dogs fed diets containing 0, 25, 100, or 400 ppm (or approximately 0, 0.625, 2.5, and 10 mg/kg/day, respectively). The NOEL was 10 mg/kg/day HDT. EPA has classified quizalofop ethyl as carcinogenicity Category D (not classifiable as to human cancer potential).

6. *Animal metabolism.* The metabolism of quizalofop ethyl in animals (goat, poultry, and rat) is well understood. 14_C-phenyl and 14_C-quinoxaline quizalofop ethyl ester metabolism studies have been conducted in each species. There are similarities among these species with respect to metabolism. Quizalofop ethyl is rapidly and extensively metabolized and rapidly excreted by rats. The principal metabolites were the quizalofop-p acid and two dechlorinated hydroxylated forms of the acid. Tissue residues were minimal and there was no evidence of accumulation of quizalofop ethyl or its metabolites in the rat.

The primary pathway in ruminants is hydrolysis of the ethyl ester to form the quizalofop-p methyl ester. In poultry, the primary metabolic pathway is also the hydrolysis of the ethyl ester to form the quizalofop-p acid, then the methyl

esterification to form the quizalofop methyl ester becomes a minor pathway.

The nature of the quizalofop ethyl ester residue in livestock is adequately understood. The residues of concern are quizalofop ethyl, quizalofop methyl, and quizalofop, all expressed as quizalofop ethyl.

7. *Metabolite toxicology.* There is no evidence that the metabolites of quizalofop ethyl as identified as either the plant or animal metabolism studies are of any toxicological significance.

8. *Endocrine disruption* No special studies investigating potential estrogenic or other endocrine effects of quizalofop p-ethyl have been conducted. However, the standard battery of required toxicology studies has been completed. These include an evaluation of the potential effects on reproduction and development, and an evaluation of the pathology of the endocrine organs following repeated or long-term exposure to doses that far exceed likely human exposures. Based on these studies there is no evidence to suggest that quizalofop p-ethyl has an adverse effect on the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure.* An analysis of chronic dietary risk was conducted to determine the total exposure from current and proposed final tolerances for quizalofop-P-ethyl. A chronic reference dose (CRfD) of 0.009 mg/kg/day was used in the analyses based on a NOEL of 0.9 mg/kg/day from the chronic rat dietary study and a 100x uncertainty factor. Using very conservative criteria, an acute reference dose (ARfD) of 0.3 mg/kg/day based on a maternal NOEL of 30 mg/kg/day (and a 100x uncertainty factor) from rat developmental toxicity study in which an effect on maternal body weight may have occurred at the outset of dosing. Although, there was a NOEL of 20 mg/kg/day in a rabbit developmental toxicity study, this was based only on lower overall food consumption in the absence of body weight effects during dosing and may not represent acute toxicity since all groups including vehicle-dosed controls had lower food consumption at the outset of dosing.

i. *Food.* The chronic dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model (DEEM™) Version 7.76 based on the current published tolerances and the proposed tolerances. The estimated exposure was 0.000343 mg/kg body weight/day for the U.S. population (total) and 0.000892 mg/kg body weight/day for the population subgroup with the highest estimated exposure (children age 1–6 years). For the U.S. population subgroup this exposure represents approximately 3.8% of the CRfD while for the population with the highest estimated exposure, this represents approximately 9.9% of the CRfD. Based on the risk estimates arrived at in this analysis, chronic dietary risk from the current and proposed uses of DUPONT ASSURE II is minimal.

The acute dietary exposure assessment was conducted using the DEEM™ Version 7.76 based on the current published tolerances and the proposed tolerances. The estimated exposure was 0.004189 mg/kg body weight/day (99.9th percentile) for the U.S. population (total) and 0.006847 mg/kg body weight/day (99.9thpercentile) for the population subgroup with the highest estimated exposure (non-nursing infants <1 year old). For the U.S. population subgroup this exposure represents approximately 1.4% of the ARfD while for the population with the highest estimated exposure, this represents approximately 2.28% of the ARfD. Based on the risk estimates arrived at in this analysis, acute dietary risk from the current and proposed uses of DUPONT ASSURE II is minimal.

ii. *Drinking water.* Acute and chronic surface water exposures were estimated using the FQPA Index Reservoir Screening Tool (FIRST) and the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) models. Ground water exposures were estimated using Screening Concentration in Ground Water (SCI-GROW).

The EPA uses drinking water levels of comparisons (DWLOCs) as a surrogate measure to capture risk associated with exposure to pesticides in drinking water. A DWLOC is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses. Since there are no residential uses for quizalofop ethyl, the aggregate exposure is due to food and water only. A DWLOC will vary depending on the residue level in foods, the toxicity endpoint, and with drinking water consumption patterns and body weights for specific subpopulations.

The acute and chronic DWLOC concentrations are likely to be many orders of magnitude higher than those estimated by the models listed in this unit. Therefore, one can conclude with reasonable certainty that residues of quizalofop ethyl in drinking water do not contribute significantly to the aggregate acute or chronic human health risk.

2. *Non-dietary exposure.* Quizalofop ethyl is not registered for any use that could result in non-occupational, non-dietary exposure to the general population.

D. Cumulative Effects

There is no evidence to indicate or suggest that quizalofop p-ethyl has any toxic effects on mammals that would be cumulative with those of any other chemicals.

E. Safety Determination

1. *U.S. population.* Using the conservative exposure assumptions described in Unit C.1. and based on the most sensitive species chronic NOEL of 0.9 mg/kg and a CRfD of 0.009 mg/kg/day, the existing tolerances and proposed uses of quizalofop ethyl on beans, peas, and sugar beet are estimated to utilize 3.8% of the CRfD for the general U.S. population. Using the conservative exposure assumptions described in Unit C.1. and based on the most sensitive species acute NOEL of 30 mg/kg and a ARfD of 0.3 mg/kg/day, the existing tolerances and proposed use of quizalofop ethyl on beans, peas, and sugar beet are estimated to utilize 1.4% of the ARfD for the general U.S. population.

These results fall below HED's level of concern (>100% RfD) and indicate that there is reasonable certainty that no chronic or acute effects would result from exposure to quizalofop p-ethyl with the recommended agricultural uses.

2. *Infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of quizalofop ethyl, data were considered from developmental toxicity studies in the rat and rabbit, and a multi-generation reproduction study in rats. There were no developmental effects observed in the absence of maternal toxicity in the rat and rabbit developmental studies. Minimal adaptive or physiological effects were observed in livers of weanlings in the 2-generation rat reproduction study described in Unit B.3. However, this effect was only observed at a dose that far exceeds any expected human exposure. Further, the NOEL of 0.9 mg/kg/day from the 2–year rat study with quizalofop ethyl which was used to calculate the RfD (discussed in Unit C.1.), is already lower than any of the NOELs defined in the developmental and reproductive toxicity studies with quizalofop ethyl.

As indicated in Unit C.1.i., infants and children have a low potential for quizalofop ethyl exposure. The toxicology profile of quizalofop ethyl

demonstrates low mammalian toxicity. Because there was no evidence that offspring were uniquely susceptible to the toxic effects of quizalofop ethyl, an additional 10–fold uncertainty factor should not be required to protect infants and children. Therefore, the RfD of 0.009 mg/kg/day, which utilizes a 100–fold safety factor, is appropriate to assure a reasonable certainty of no harm to infants and children from aggregate exposure to quizalofop ethyl.

F. International Tolerances

Since there are no Mexican or Codex MRLs tolerances, compatibility is not a problem at this time. Compatibility cannot be achieved with the Canadian negligible residue type limit at 0.1 ppm at the United States use pattern, which had findings of real residues above 0.1 ppm.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0162; FRL–7370–9]

Napropamide; Notice of Receipt of Requests to Voluntarily Cancel a Certain Pesticide Registration

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, EPA is issuing a notice of receipt of request by United Phosphorous, Inc., to voluntarily cancel one pesticide registration.

DATES: Unless a request is withdrawn by September 24, 2004 for EPA Registration Number: 70506–30, orders will be issued canceling this registration. The Agency will consider withdrawal requests postmarked no later than September 24, 2004.

FOR FURTHER INFORMATION CONTACT: Demson Fuller, Special Review and Reregistration Division (7508C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8062; e-mail address: *fuller.demson@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to persons who produce or use pesticides, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the information in this notice, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2004–0162. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

II. What Action is the Agency Taking?

This notice announces receipt by the Agency of an application from the registrant to cancel 70506–30, a pesticide product registered under section 3 of FIFRA. This registration is listed by registration number in Table 1 of this unit:

TABLE 1.—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Product Name	Chemical Name
70506–30	DEVRINOL 10-G Ornamental	Napropamide

Under section 6(f)(1)(A) of FIFRA, registrants may request, at any time, that their pesticide registrations be canceled or amended to terminate one or more pesticide uses. Section 6(f)(1)(B) of FIFRA requires that before acting on a request for voluntary cancellation, EPA must provide a 30–day public comment period on the request for voluntary cancellation. In addition, section 6(f)(1)(C) of FIFRA requires that EPA provide a 180–day comment period on a request for voluntary termination of any minor agricultural use before granting the request, unless (1) the registrants request a waiver of the comment period, or (2) the Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment. The registrants have requested that EPA waive the 180–day comment period. EPA is granting the registrants' request to waive the 180–day comment period. Therefore, EPA will provide a 30–day comment period on the proposed requests. EPA anticipates granting the cancellation request shortly after the end of the 30–day comment period for this notice. The registration for which a cancellation was requested is identified (above) in Table 1.

Unless a request is withdrawn by the registrant within 30 days of publication of this notice, orders will be issued canceling all of this registration. Users of these pesticides or anyone else desiring the retention of a registration should contact the applicable registrant directly during this 30–day period.

Table 2 of this unit includes the name and address of record for the registrant of the product in Table 1 of this unit, by EPA company number: