40 CFR Part 180

[OPP–300457; FRL–5592–2]

RIN 2070–AB78

Clofencet; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes tolerances for the residues of the plant growth regulator (hybridizing agent) clofencet, [2-(4-chlorophenyl)-3-ethyl-2,5-dihydro-5-oxo-4-pyridazinecarboxylic acid, potassium salt] expressed as the free acid, active ingredient code 128726, CAS No. 82697–71–0 in or on the raw agricultural commodities wheat as a primary application; in or on the cereal grains group (except rice, wild rice, sweet corn and wheat) and soybeans as rotational crops; and in animal products. Monsanto Co. submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 requesting the tolerances.

EFFECTIVE DATE: This rule becomes effective March 5, 1997.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [OPP–300457], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect in 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP–300457]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries. Additional information on electronic submissions can be found below in this document.

FOR FURTHER INFORMATION CONTACT: By mail: Philip V. Errico, Product Manager (PM) 25, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number and e-mail address: Rm. 241, CM #2, 1921 Jefferson Davis Highway., Arlington, VA 22202, (703) 305–6027; e-mail: errico.philip@epamail. epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 7, 1996 (61 FR 41153), (PF–667; FRL–5388–7), EPA issued a notice announcing that Monsanto Company, 700 14th St., NW., Suite 1100, Washington, DC 20005, had submitted pesticide petition 4F4346 to EPA which requested that the Administrator, pursuant to section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), amend 40 CFR part 180 to establish tolerances for residues of clofencet, [2-(4-chlorophenyl)-3-ethyl-2,5-dihydro-5-oxo-4-pyridazinecarboxylic acid, potassium salt] expressed as the free acid, in or on the raw agricultural commodities: wheat grain at 250 parts per million (ppm), wheat hay at 40 ppm, wheat straw at 50 ppm and wheat forage at 10 ppm; in the animal product commodities of cattle, goats, hogs, horses and sheep: fat at 0.04 ppm, kidney at 10 ppm, meat at 0.15 ppm, meat by-products (except kidney) at 0.5 ppm and milk at 0.02 ppm; in animal product commodities of poultry: eggs at 1 ppm, fat at 0.04 ppm, meat at 0.15 ppm and meat by-products at 0.20 ppm; and rotational crop tolerances in the raw agricultural commodities: soybeans at 30 ppm, soybean hay at 10 ppm and soybean forage at 10 ppm; cereal grains group (except rice, wild rice, sweet corn and wheat): grain at 20 ppm, straw at 4 ppm, forage at 4 ppm, stover (fodder) at 1 ppm and hay at 15 ppm.

In the Federal Register of December 12, 1996 (61 FR 65392), (PF–678; FRL–5576–2), EPA issued a second notice to bring the Notice into conformity with the Food Quality Protection Act (FQPA) of 1996. The notice contained a summary of the petition prepared by the petitioner, Monsanto Co., including information and arguments to support its conclusion that the petition complied with FQPA. It was stated in the notice that the conclusions and arguments were not of the EPA.

There were no comments received in response to the notices of filing.

The data submitted in the petition and other relevant material have been evaluated. The toxicological data listed below were considered in support of these tolerances.

I. Toxicology Profile

1. A battery of acute toxicity studies placing technical clofencet in toxicity category II for eye irritation, category III for oral LD_{50}, category IV for inhalation LC_{50} and dermal irritation and category V for dermal LC_{50}.

2. A 90–day rat neurotoxicity study at doses of 0, 200, 2,000 or 20,000 ppm (males = 0, 12.3, 124.5 or 1,232 milligrams per kilogram per day (mg/kg/day); females = 0, 15.2, 149.8 or 1,537.2 mg/kg/day) with a No Observed Effect Level (NOEL) of 2,000 ppm in females based on decreased body weight gain in females and 20,000 ppm in males. At the 20,000 ppm (Highest Dose Tested (HDT)), no neurotoxicity was observed in either male or female rats.

3. A 21–day rat dermal toxicity study at doses of 0, 100, 300 or 1,000 mg/kg/day which showed no significant toxic effects at any dose tested with a systemic and dermal NOEL of 1,000 mg/kg/day.

4. A 90–day dog feeding study at doses of 0, 10, 50, 200 or 500 mg/kg/day with a NOEL of 50 mg/kg/day based on histological findings in the thymus and testes.

5. A 90–day rat feeding study at doses of 0, 200, 1,000, 5,000 or 20,000 ppm (males = 0, 12, 60, 311 or 1,207 mg/kg/day; females = 0, 15, 75, 373 or 1,477 mg/kg/day) with a NOEL of 5,000 ppm in the diet based on decreased cumulative weight gain and slightly increased kidney weights in females.

6. A rat developmental toxicity study at doses of 0, 100, 300 or 1,000 mg/kg/day with a maternal and developmental NOEL of 1,000 mg/kg/day HDT. There was no developmental toxicity considered to be the result of clofencet administration.

7. A rabbit developmental toxicity study at doses of 0, 50, 150 or 500 mg/kg/day) with a maternal and developmental NOEL of 150 mg/kg/day based on mortality, increased abortions and decreased body weight gain, decreased food consumption, lower fetal body weights, increased incidence of fetal hydrocephalus and an increase in

the number of fetuses/litters with unossified bones.

8. A rat two-generation reproduction study at dietary concentrations of 0, 500, 5,000 or 20,000 ppm (males = 0, 38, 393 or 1,602 mg/kg/day; females = 0, 52, 529 or 2,044 mg/kg/day) with a maternal NOEL of 5,000 ppm based on suggestive increase in mortality, decrease in body weight/weight gains and lung pathology. The reproductive NOEL is 500 ppm based on an increase in pup mortality in F1a and F1b during lactation days 1 to 4 and decreased body weights during lactation.

9. A 1–year dog chronic toxicity study at doses of 0, 5, 30 or 200 mg/kg/day. The NOEL was 5 mg/kg/day based on liver and epididymal/testicular effects.

10. An 18–month mouse carcinogenicity study at doses of 0, 70, 300, 3,000 or 7,000 ppm (males = 0, 11.45, 50.31, 501.20 or 1,228.22 mg/kg/day; females = 0, 16.92, 70.67, 710.79 or 1,608.46 mg/kg/day) with a systemic NOEL of 3,000 ppm based on decreased survival as well as bone marrow myeloid hyperplasia, lung congestion and skin fibrosis in males and an increased incidence of histiocytic sarcomas in females at 7,000 ppm (HDT).

11. A 2–year rat chronic/carcinogenicity study at dietary doses of 0, 100, 1,000, 10,000 or 20,000 ppm (males = 0, 4.7, 47, 470 or 989 milligrams per kilogram of body weight per day (mg/kg bwt/day)); females = 0, 5.9, 58, 607 or 1,288 mg/kg bwt/day) with a systemic NOEL of 1,000 ppm based on hematuria, white/gray lung foci and kidney lesions. Clofencet at 20,000 ppm (HDT) may cause an increase in the number of animals with hepatocellular carcinomas and adenomas/carcinomas in males and an increase in thyroid C-cell adenomas in males and females.

12. A metabolism study in rats indicated that clofencet was rapidly absorbed and excreted by 7 days post-dosing, with the majority of the administered ^{14}C-label (>78%) eliminated in the urine within 24 hours. Analysis of the excreta indicated that ^{14}C MON 21200 was eliminated mostly unmetabolized in the urine (87.9 to 92.1% of the administered dose) and in the feces (4.5 to 9.1% of the administered dose). Less than 1% was of the administered ^{14}C-label was eliminated as expired CO_2. Less than 1% was retained in the tissue at 7 days post-dosing, indicating low bioaccumulation. There were no apparent sex- or dose-related differences in the absorption, distribution, metabolism or elimination.

13. Acceptable studies on gene mutation and other genotoxic effects: Ames *Salmonella* Assay; CHO/HGPRT Point Mutation Assay; *In Vitro* Cytogenetics Assay in Human Lymphocytes; Mouse Micronucleus Assay; and *In Vivo/In Vitro* Hepatocyte DNA Repair Assay yielded negative results.

II. Dose Response Assessment

Reference dose (RfD). The RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The RfD is determined by using the toxicological end-point or the NOEL for the most sensitive mammalian toxicological study. To assure the adequacy of the RfD, the Agency uses an uncertainty factor in deriving it. The factor is usually 100 to acount for both interspecies extrapolation and intraspecies variability represented by the toxicological data. The EPA has determined a RfD of 0.05 mg/kg/day with an uncertainty factor of 100 for this risk assessment, based on a NOEL of 5.0 mg/kg/day from a 1–year feeding study in dogs which demonstrated the effect of epididymitis, tubular degeneration and absence of spermatozoa as endpoint effects.

Carcinogenicity classification. Using the Guidelines for Carcinogenic Risk Assessment published September 24, 1986 (51 FR 33992), the EPA has classified clofencet as Group ''C'' for carcinogenicity (possible human carcinogen) based on the increase in histiocytic sarcomas (malignant) by both pair-wise and trend analyses in female mice. The thyroid C-cell tumors in male rats (mainly benign) were considered to have occurred only at an excessive dose. There were no apparent genotoxicity concerns and little additional support for carcinogenicity based on structure-activity relationship (SAR) with a related wheat hybridizing agent, fenridazon; therefore, the EPA's Carcinogenicity Peer Review Committee recommended that for the purpose of risk characterization, the RfD approach be used for quantitation of human risk.

III. Residential Exposure Assessment

The toxicological endpoint of concern for residential exposure is systemic toxicity resulting from chronic exposure. There are no proposed residential uses for clofencet and it is not likely to be applied in or near residential areas; therefore, there are no residential risk concerns.

IV. Dietary Exposure Assessment

Use of a pesticide results or may reasonably be expected to result, directly or indirectly, in pesticide residues in food. Primary residues or indirect/inadvertent residues in agricultural commodities are determined by chemical analysis. To account for the diversity of growing conditions, cultural practices, soil types, climatic conditions, crop varieties and methods of application of the pesticide, data from studies that represent the commodities are collected and evaluated to determine an appropriate level of residue that would not be exceeded if the pesticide is used as represented in the studies.

1. *Plant/animal metabolism and magnitude of the residue*. The nature of the residue (metabolism) of clofencet in plants and animals is adequately understood for the purposes of these tolerances. There are no Codex maximum residue levels established for residues of clofencet on wheat or the rotational crops. The residue of concern to be regulated is the parent, clofencet.

2. *Residue analytical methods.* The analytical method proposed for detecting and measuring levels of clofencet in or on the commodities with a limit of detection that allows monitoring of food with residues at or above the levels set in the tolerance for primary and rotational crops includes derivatization of clofencet to its methyl ester followed by analysis via gas chromatography with electron capture detection, however, for rotational crops, it is necessary to first hydrolyze clofencet-sugar conjugates to clofencet before proceeding with derivatization. The method for animal tissues includes derivatization of clofencet to its methyl ester followed by analysis via HPLC with UV detection. For milk and eggs, analysis is achieved by extraction, concentration and direct analysis via HPLC with UV detection. EPA will provide information on this method to the Food and Drug Administration (FDA). Because of the long lead time from establishing these tolerances to publication, the enforcement methodology is being made available in the interim to anyone interested in pesticide enforcement when requested by mail from: Calvin Furlow, Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 1130A, CM #2, 1921 Jefferson-Davis Highway, Arlington, VA 22202, (703) 305–5937.

The presence of the pesticide or degradates of the pesticide in potable water may also be a source of dietary exposure that must be considered in establishing a tolerance level for an agricultural commodity.

V. Aggregate Exposures Assessment

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residue in food, including water, and all other non-occupational exposures. The aggregate sources of exposure the Agency looks at include food, drinking water or groundwater, and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Acute dietary*. There is no concern for acute effects due to dietary exposure to clofencet.

2. *Chronic dietary*. Tolerances in this petition are based on residues from field trial data. Using the Dietary Risk Evaluation System (DRES), a routine chronic exposure analysis was based on 0.1% crop treated and on tolerance values for wheat and rotational crops listed in this petition. Although percent crop treated were used, the estimate is conservative, since it is assumed that 100% of the fields treated with clofencet in the United States are rotated to cereal grains group crops (except rice, wild rice, sweet corn and wheat) and soybeans at the same time. At this time, there is no concern for chronic effects due to exposure of clofencet in the diet.

3. *Drinking water*. Because the Agency lacks specific water- related exposure data for most pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfD's or acute dietary NOEL's) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by consumption of water containing that pesticide. This analysis is included in the docket for this rulemaking. While EPA has not yet pinpointed the appropriate bounding figure for consumption of water containing pesticides, the ranges the Agency is continuing to examine are all well below the level that would cause clofencet to exceed the RfD by granting the tolerances being considered in this document. The Agency has therefore concluded that the potential exposures associated with clofencet in water, even at the higher levels the Agency is considering as a conservative upper bound, will not prevent the Agency from determining that there is a reasonable certainty of no harm.

4. *Non-occupational non-dietary*. Since the proposed use does not involve residential use and since clofencet is not likely to be used in or near residential areas, non-occupational non-dietary exposure is not expected.

5. *Cumulative exposure to substances with common mechanism of toxicity*. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also policies and methodologies for conducting cumulative risk assessments. While the Agency has some information in its files that may be helpful in determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodology to resolve the scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will enable it to develop and apply policies for evaluating the cumulative effects of chemicals having a common mechanism of toxicity. At present, however, the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments.

In making individual tolerance decisions, the Agency will determine whether: (1) It has sufficient information to determine that a pesticide does not appear to share a common mechanism of toxicity with other substances; or (2) it is unable to conclude that a pesticide does not share a common mechanism of toxicity with other substances.

For pesticides falling into the first category, the Agency will explain its determination and factor the determination into the tolerance decision. For pesticides falling into the second category, the Agency will conclude that it does not have sufficient available information concerning common mechanism of toxicity to scientifically apply that information to the tolerance decision, the tolerance decision will be reached based upon the best available and useful information for the individual chemical, and a risk assessment will be performed for the tolerance action assuming that no common mechanism of toxicity exists. However, tolerance decisions falling into the second category will be reexamined by the Agency after EPA establishes methodologies and procedures for integrating information concerning common mechanism into its risk assessments. In such circumstances, related registration actions may be conditioned upon the provision of such data as may be necessary to evaluate common mechanism of toxicity issues in a risk assessment.

In the case of clofencet, EPA has not yet determined whether or how to include this chemical in a cumulative risk assessment. This tolerance determination therefore does not take into account common mechanism issues. After EPA develops a methodology for applying common mechanism of toxicity issues to risk assessments, the Agency will develop a process (either as part of the periodic review of pesticides or otherwise) to reexamine those tolerance decisions made earlier. The registrant must submit, upon EPA's request and according to a schedule determined by the Agency, such information as the Agency directs to be submitted in order to evaluate issues related to whether clofencet share(s) a common mechanism of toxicity with any other substance and, if so, whether any tolerances for clofencet needs to be modified or revoked.

VI. Determination of Safety for the U.S. Population and Non-nursing Infants

Using the Dietary Risk Evaluation System (DRES), a routine chronic dietary exposure analysis was based on use of 0.1% of the wheat crop treated, and 0.1% of the cereal grains group crops (except rice, wild rice, sweet corn and wheat) and soybeans as rotated crops in fields previously containing wheat treated with clofencet, and tolerance levels established in this document. Percent crop treated of 0.1% is based on the petitioner's expectations that up to 33,000 acres of wheat grown for seed will be treated in the year 2000. This 33,000 acres is 0.05% of the approximate 70,000,000 acres of wheat which is grown for grain in the United States. Pursuant to section 408(b)(2)(F) of FFDCA as amended, the Agency may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated

with the pesticide chemical, and finds that the data are reliable and provides a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue, finds that the exposure estimate does not understate exposure for any significant subpopulation group, finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Agency, and provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

The Agency believes the above conditions have been met for the conditions stated above. Based on the available information and the use of this conservative risk assessment, EPA finds the exposure estimate does not understate exposure for any significant subpopulation group. Also, EPA has no data that show clofencet use on wheat grown for seed, and consumption of food in a particular area differ significantly from that used in the conservative risk assessment stated herein. Registration of end-use product(s) containing clofencet conditioned on production of no more clofencet than necessary to treat no more than 35,000 acres per year. The additional 2,000 acres was requested by the registrant, and does not significantly effect the results of this risk determination. Before the petitioner can increase production of product for treatment of greater than 35,000 acres per year, permission from the Agency must be obtained. The petitioner must also provide annual reports on production of end-use products containing clofencet, number of acres treated, and a best estimate of which crops and how many acres were planted as rotational crops on fields previously planted to wheat treated with clofencet. The registrant must also provide field residue data on wheat grain, forage, hay and straw from commercially treated crop beginning 18 months after wheat grain is first harvested. Field residue trials on the rotated crops listed in this document may also be required. The Agency will provide for periodic reevaluation of the dietary exposure, if warranted, with percent crop treated, acres of wheat treated, end-use product production information provided by the petitioner and other available sources, and submitted field residue data. The reason for using 0.1% instead of 0.05% crop treated is to allow expansion of use if other conditions of registration are satisfied. Before expansion beyond 0.1% is allowed, reevaluation of the dietary exposure may be performed using all available information as necessary.

Based on the conservative dietary assessment presented above, the proposed use of clofencet uses 0.73% of the RfD for the U.S. population and for the most highly exposed subgroups, 0.6% for non-nursing infants (<1 year old), 1.6% for children (1 to 6 years old) and 1.2% for children (7 to 12 years old). The risk estimate from combined food and water sources is expected to be below 25% of the RfD even with the addition of a reasonable bounding figure for the contribution from drinking water. EPA concluded there is a reasonable certainty that no harm will occur from aggregate exposure to clofencet for this directed use on wheat and the subsequent rotational crops [cereal grains group (except rice, wild rice, sweet corn and wheat) and soybeans].

VII. Determination of Safety for Infants and Children

Risk to infants and children was determined by the use of the two developmental toxicity studies in rats and rabbits and the two-generation reproduction study in rats noted above. The developmental toxicity studies evaluates the potential for adverse effects on the developing organism resulting from exposure during prenatal development to the female parent. The reproduction study provides information relating to effects from exposure to the chemical on the reproductive capability of both (mating) parents and on systemic toxicity.

FFDCA section 408 provides that the EPA shall apply an additional safety factor of 10 in the case of threshold effects for infants and children to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines, based on reliable data, that a different safety factor would be appropriate. EPA believes that reliable data support using a different safety factor (usually 100X (100 times)) and not the additional safety factor when EPA has a complete data base and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the traditional safety factors. The Agency believes that an additional safety factor for infants and children is not warranted here. First, a complete set of developmental and reproductive studies have been submitted and EPA has found them to be acceptable. Second, since the NOELs from the developmental and reproductive studies are 7.6X to 200X (7.6 times to 200 times) higher than the NOEL used for the RfD, the Agency does not believe the effects seen in these studies are of such concern to require an additional safety factor. Accordingly, the Agency believes the RfD has an adequate margin of protection for infants and children. The percent of the RfD that would be utilized by the aggregate exposure to clofencet will range from 0.6% for non-nursing infants to 1.6% for children 1 to 6 years old. EPA concluded that there is reasonable certainty that no harm will occur to infants and children from aggregate exposure to clofencet.

VIII. Other Considerations

Endocrine effects. No specific tests have been conducted with clofencet to determine whether the chemical may have an effect in humans that is similar to an effect produced by a naturally occuring estrogen or other endocrine effects. However, there were no significant findings in other relative toxicity studies, i.e., teratology and multi-generation reproductive studies, which would suggest that clofencet produces these kinds of effects.

IX. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under the new section 408(e) and (1)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which governs the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by May 5, 1997 file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given below (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on

which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

X. Public Docket

A record has been established for this rulemaking and all written comments for this rule under docket number [OPP–300457]. A public version of this record, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. EPA has also established a special record for post-FQPA tolerances which contains documents of general applicability. This record can be found in the same location.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above, is kept in paper form. Accordingly, in the event there are objections and hearing requests, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place paper copies in the official rulemaking record.

XI. Regulatory Assessment Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and, since this action does not impose any information collection requirements subject to approval under the Paperwork Reduction Act, 44 U.S.C. 3501 et seq., it is not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, or contain any ''unfunded mandates'' as described in Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), or require prior consultation as specified by Executive Order 12875 (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898 (59 FR 7629, February 16, 1994).

Because tolerances established on the basis of a petition under section 408(d) of FFDCA do not require issuance of a proposed rule, the regulatory flexibility analysis requirements of the Regulatory Flexibility Act (RFA), 5 U.S.C. 604(a), do not apply. Prior to the recent amendment of the FFDCA, EPA had treated such rulemakings as subject to the RFA; however, the amendments to the FFDCA clarify that no proposal is required for such rulemakings and hence that the RFA is inapplicable.

Under 5 U.S.C. 801(a)(1)(A) of the Administrative Procedure Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (Title II of Pub. L. 104–121, 110 Stat. 847), EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's Federal Register. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2) of the APA as amended.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 24, 1997.

Daniel M. Barolo,

Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority : 21 U.s.c. 346a and 371.

2. By adding § 180.497, to read as follows:

§ 180.497 Clofencet; tolerances for residues.

(a) *Tolerances--general.* Tolerances are established for the plant growth regulator (hybridizing agent) clofencet, [2-(4-chlorophenyl)-3-ethyl-2,5 dihydro-5-oxo-4-pyridazinecarboxylic acid, potassium salt] expressed as the free acid in or on the following raw agricultural commodities:

Commodities	Parts per million
Cattle, fat	0.04
Cattle, kidney	10.0
Cattle, mbyp (except kidney)	0.5
Cattle, meat	0.15
Eggs	1.0
Goats, fat	0.04
Goats, kidney	10.0
Goats, mbyp (except kidney)	0.5
Goats, meat	0.15
Hogs, fat	0.04
Hogs, kidney	10.0
Hogs, mbyp (except kidney)	0.5
Hogs, meat	0.15
Horses, fat	0.04
Horses, kidney	10.0
Horses, mbyp (except kidney)	0.5
Horses, meat	0.15
Milk	0.02
Poultry, fat	0.04
Poultry, mbyp	0.20
Poultry, meat	0.15
Sheep, fat	0.04
Sheep, kidney	10.0
Sheep, mbyp (except kidney)	0.5
Sheep, meat	0.15
Wheat, forage	10.0
Wheat, grain	250.0
Wheat, hay	40.0
Wheat, straw	50.0

(b) *Tolerances for Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent residues of the plant growth regulator (hybridizing agent) clofencet, [2-(4-chlorophenyl)-3-ethyl-2,5-dihydro-5-oxo-4-pyridazinecarboxylic acid, potassium salt] expressed as the free acid in or on the following raw agricultural commodities when present therein as a result of the application of clofencet to the growing crops in paragraph (a) of this section:

Commodities	Parts per million
Cereal grains group (except rice, wild rice, sweet corn and wheat), forage	4.0

Commodities	Parts per million
Cereal grains group (except rice, wild rice, sweet corn and wheat, grain	20.0
Cereal grains group (except rice, wild rice, sweet corn and wheat), hay	15.0
Cereal grains group (except rice, wild rice, sweet corn and wheat), stover (fodder)	1.0
Cereal grains group (except rice, wild rice, sweet corn and wheat), straw	4.0
Soybeans	30.0
Soybean, forage	10.0
Soybean, hay	10.0

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40 CFR Part 180

[OPP–300456; FRL–5591–7]

RIN 2070–AC78

Tebufenozide; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of the insecticide tebufenozide in or on the raw agricultural commodities peppers, non-brassica leafy vegetables (Crop Group 4 - celery, lettuce, spinach, swiss chard), turnips grown for foliage tops only, and brassica (cole) leafy vegetables (Crop Group 5 - broccoli, cabbage, cauliflower, collards, kale, kohlrabi, and mustard greens) in connection with EPA's granting of emergency exemptions under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of tebufenozide on peppers, leafy vegetables (except brassica), turnips grown for foliage tops only and brassica leafy vegetables in Texas; and lettuce, broccoli, cauliflower, cabbage and spinach in Arizona. This regulation establishes maximum permissible levels for residues of tebufenozide in these foods. These tolerances will expire on February 28, 1998.

DATES: This regulation becomes effective March 5, 1997. This regulation expires on February 28, 1998. Objections and requests for hearings must be received by EPA on May 5, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300456], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300456], should be submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Highway., Arlington, VA. A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov.

Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket number [OPP–300456]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Pat Cimino, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Sixth Floor, Crystal Station #1, 2800 Jefferson Davis Highway, Arlington, VA 22202. (703) 308–8328, e-mail: cimino.pat@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing a tolerance for residues of the insecticide tebufenozide (benzoic acid, 3,5-dimethyl-1-(1,1-dimethylethyl)-2-(4-ethylbenzoyl)hydrazide) in or on peppers at 0.5 part per million (ppm), leafy vegetables (except brassica) at 5.0 ppm, turnip tops at 5.0 ppm, and brassica (cole) leafy vegetables at 5.0 ppm. These tolerances will expire on February 28, 1998.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the FFDCA, 21 U.S.C. 301 et seq., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq. The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities were discussed in detail in the final rule establishing the time-limited tolerance for an emergency exemption for use of propiconazole on sorghum (61 CFR 58135, November 13, 1996)(FRL–5572–9).

New section 408(b)(2)(A)(i) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State Agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Section 408(l)(6) also requires EPA to promulgate regulations by August 3, 1997, governing the establishment of tolerances and exemptions under section 408(l)(6) and requires that the