Dated: December 8, 1998.

Herbert Barrack,

Acting Regional Administrator, Region 2.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300764; FRL–6048–4]

RIN 2070–AB78

Tralkoxydim; Time-Limited Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of the herbicide tralkoxydim in or on certain raw agricultural commodities. Zeneca Ag Products requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (Pub. L. 104–170). These tolerances will expire on February 28, 2003.

DATES: This regulation is effective December 16, 1998. Objections and requests for hearings must be received by EPA on or before February 16, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300764], 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–300764], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), 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. 119, Crystal Mall 2 (CM #2), 1921 Jefferson Davis Hwy., 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 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300764]. 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: James A. Tompkins, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the Federal Register of July 2, 1997 (62 FR 35804)(FRL–5722–9), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a announcing the filing of a pesticide petition (PP 6F4631) for tolerance by Zeneca Ag Products, 1800 Concord Pike, P.O. Box 15458, Wilmington, DE 19850–5458. This notice included a summary of the petition prepared by Zeneca Ag Products, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing time-limited tolerances for residues of the herbicide, tralkoxydim, 2-(Cyclohexen-1-one, 2-[1-(ethoxyimino)propyl]-3-hydroxy-5-(2,4,6-trimethylphenyl)-(9Cl), in or on the raw agricultural commodities barley grain, barley straw, barley hay, wheat grain, wheat forage, wheat straw, and wheat hay at 0.1 parts per million (ppm). Zeneca Ag Products subsequently amended the proposed tolerances to lower the residue levels, as follows; barley grain, barley hay, wheat grain and wheat hay at 0.02 ppm, and barley straw, wheat forage and wheat straw at 0.05 ppm. These tolerances will expire on February 28, 2003.

I. Risk Assessment and Statutory Findings

Section 408(b)(2)(A)(i) of the FFDCA 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 and in residential settings, 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. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the Final Rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed adverse effect level'' or ''NOAEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOAEL from the study with the lowest NOAEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the Rfd (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses

the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOAEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOAEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute'', ''short-term'', ''intermediate term'', and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1–day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1–7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOAEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup children 1-6 years was not regionally based.

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of tralkoxydim and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of tralkoxydim in certain raw agricultural commodities. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows:

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the

toxic effects caused by tralkoxydim are discussed below.

1. A rat acute oral study with a LD_{50} of 1,258 milligrams (mg)/kilogram (kg) for males and 934 mg/kg for females.

2. A mouse acute oral study with a LD_{50} of 1,231 mg/kg for males and 1,100 mg/kg for females.

3. A 90-day rat feeding study with a NOAEL of 250 ppm [20.5 mg/kg/day] and a Lowest Observed Adverse Effect Level (LOAEL) of 2,500 ppm [204.8 mg/kg/day] based on decreased food efficacy and minor hematologic changes.

4. A 90-day dog dietary study with a NOAEL of 0.5 mg/kg/day and a LOAEL of 5 mg/kg/day based on increased liver weights in males and increases in APDM in males and females, indicating minimal hepatotoxicity.

5. A 90-day hamster feeding study with a NOAEL of 5,000 ppm [328 mg/kg/day] and a LOAEL of 10,000 ppm [650 mg/kg/day] based on decreased body weight gains and increased liver weights in both sexes.

6. A 21-day rat dermal study with a NOAEL of 1,000 mg/kg/day, the highest dose tested [HDT].

7. A 1-year dog chronic feeding study with a NOAEL of 0.5 mg/kg/day and a LOAEL of 5 mg/kg/day based on changes in liver function and morphology in males.

8. A rat chronic feeding / carcinogenicity study with a NOAEL for systemic toxicity of 500 ppm [23.1 mg/kg/day in males and 30.1 mg/kg/day in females] and a LOAEL for systemic toxicity of 2,500 ppm [117.9 mg/kg/day in males and 162.8 mg/kg/day in females] based on decreased body weight gain, decreased food consumption, increased liver weights, and increased hepatic clear cell areas and increased ALT levels in females. Based on the incidence of Leydig cell tumors of the testes in males, tralkoxydim was considered to have a positive carcinogenic response.

9. A 3-generation rat reproduction study with a parental systemic NOAEL of 200 ppm [20 mg/kg/day] and a systemic LOAEL of 1,000 ppm [100 mg/kg/day] based on reduced body weights and body weight gains in females. No reproductive toxicity was observed. The developmental NOAEL of 200 ppm and a LOAEL of 1,000 ppm based on decreased mean pup weights (F_{1a} and F_{3a}) and pup weight gains (F_{2a}) .

10. A rat developmental study with a maternal NOAEL of 30 mg/kg/day and with a maternal LOAEL of 200 mg/kg/day based on maternal mortality, reduced body weights, and reduced food consumption and a developmental NOAEL of 30 mg/kg/day and a developmental LOAEL of 200 mg/kg/day based on reduced ossification of the centrum and hemicentrum, centrum bipartite, misshapen centra and fused centra.

11. A rabbit developmental study with a maternal NOAEL of 20 mg/kg/day and a maternal LOAEL of 100 mg/kg/day based on reduced food consumption and a developmental NOAEL of 20 mg/kg/day and a developmental LOAEL of 100 mg/kg/day based on abortions and increases in late resorptions.

12. Tralkoxydim was negative for mutagenic/genotoxic effects in a Gene mutation Ames Assay in bacteria, a forward gene mutation in mouse lymphoma cells in culture, chromosome damage/*In vitro* assay in human lymphocyte cells, DNA damage repair *in vivo* assay in rat hepatocytes, and chromosome damage *in vivo* mouse micronuclei.

13. Based on the results of the hamster and rat metabolism studies, tralkoxydim was readily absorbed and excreted within 24 and 48 hours after dosing, respectively. In hamsters, the metabolic profile in urine was similar for males and females; no unchanged tralkoxydim was detected and two major metabolites were identified: tralkoxydim acid and tralkoxydim acid oxazole. The metabolic profile in the urine of rats included two additional metabolites, tralkoxydim alcohol and tralkoxydim diol.

14. Several mechanistic studies and subchronic feeding studies were submitted to support the selection of hamster in preference to the mouse in assessing the carcinogenic potential of tralkoxydim. The submitted data indicate that of all the species tested only the mouse is susceptible to porphydrin accumulation in the liver following treatment with tralkoxydim. The mouse was considered an inappropriate species to use for carcinogenicity testing of tralkoxydim because of its distinctive method of metabolism. However, the submitted hamster cancer study was unacceptable owing to unacceptably high mortality in the females. An acceptable second species carcinogenicity study is required.

B. Toxicological Endpoints

1. *Acute dietary toxicity*. EPA has established an acute RfD for tralkoxydim of 0.3 milligrams/kilogram/day (mg/kg/day). This RfD is based on the NOAEL of 30 mg/kg/day established in the rat developmental study and using an uncertainty factor of 100 based on 10 X for inter-species extrapolation and 10X for intra-species variation.

2. *Short - and intermediate - term toxicity*. EPA could not identify any toxicological effects that could be attributable to short or intermediate-term dietary exposure .

3. *Chronic toxicity*. EPA has established the RfD for tralkoxydim at 0.005 mg/kg/day. This RfD is based on NOAEL of 0.5 mg/kg/day in the chronic toxicity study in dogs with a 100-fold uncertainty factor to account for inter-species extrapolation (10 x) and intra-species variability (10 x).

4. *Carcinogenicity*. The Health Effects Division Cancer Assessment Review Committee has classified Tralkoxydim in accordance with the Agency's Proposed Guidelines for Carcinogen Risk Assessment (April 10, 1996) as a ''likely to be human carcinogen''. This classification is based on the following factors:

i. Occurrence of benign Leydig cell tumors at all dose levels with the incidences at the high dose exceeding the concurrent and historical control range.

ii. Lack of an acceptable carcinogenicity study in a second species as required by Subdivision F Guidelines.

iii. The relevance of the testicular tumors to human exposure can not be discounted

C. Exposures and Risks

1. *From food and feed uses.* The proposed tolerances in or on the raw agricultural commodities: barley grain, barley hay, wheat grain and wheat hay at 0.02 ppm, and barley straw, wheat forage and wheat straw at 0.05 ppm are the first to be established for tralkoxydim, 2-(Cyclohexen-1-one, 2-[1-(ethoxyimino)propyl]-3-hydroxy-5-(2,4,6-trimethylphenyl)-(9Cl). There is no reasonable expectation of residues of tralkoxydim occurring in meat, milk, poultry, or eggs from its use on wheat and barley. Risk assessments were conducted by EPA to assess dietary exposures from tralkoxydim as follows:

i. Acute exposure and risk. Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. An acute dietary risk assessment was conducted for tralkoxydim based on the NOAEL of 30 mg/kg/day from the rat developmental study. The acute dietary analysis using the DEEM computer program estimates that the distribution of single-day exposures utilizes 0.02% of acute RfD.

ii. *Chronic exposure and risk*. The Reference Dose (RfD) for Tralkoxydim is 0.005 mg/kg/day. This value is based on

the systemic NOAEL of 0.5 mg/kg/day in the dog chronic feeding study with a 100-fold safety factor to account for interspecies extrapolation (10x) and intraspecies variability (10x).

A DEEM chronic exposure analysis was conducted using tolerance levels for wheat and barley and assuming that 100% of the crop is treated to estimate dietary exposure for the general population and 22 subgroups. The chronic analysis showed that exposures from the tolerance level residues in or on wheat, and barley for children 1-6 years old (the subgroup with the highest exposure) would be 1.4% of the Reference Dose (RfD). The exposure for the general U.S. population would be less than 1% of the RfD.

iii. A lifetime dietary carcinogenicity exposure analysis was conducted for tralkoxydim using the proposed tolerances along with the assumption of 100% of the crop treated and a Q* of 1.68×10^{-2} $(mg/kg/day)^{-1}$. A lifetime risk exposure analysis was also conducted using the DEEM computer analysis. The estimated cancer risk (5×10^{-7}) is less than the level that the Agency usually considers for negligible cancer risk estimates.

2. *From drinking water.* Drinking water estimated concentrations (DWECs) for surface water (parent tralkoxydim) were calculated by PRIZM computer models to be an average of 9.1 parts per billion (ppb). the DWECs for ground water based on the computer model SCI-GROW2 were calculated to be an average of .016 ppb.

3. *From non-dietary exposure.* There are no non-food uses of tralkoxydim currently registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended. No non-dietary exposures are expected for the general population.

4. *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.''

EPA does not have, at this time, available data to determine whether tralkoxydim has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Tralkoxydim is structurally a cyclohexanedione. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, tralkoxydim does not appear to produce a toxic metabolite produced by other substances. For the purposes of these tolerances action, therefore, EPA has not assumed that tralkoxydim has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the Final Rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute risk.* The acute dietary analysis based on the NOAEL of 30 mg/kg/day from the rat developmental study using the DEEM computer program estimates that the distribution of single-day exposures utilizes 0.02% of acute RfD. The drinking water level of comparisons (DWLOCs) for acute exposure to tralkoxydim in drinking water calculated for females 13+ years old was 9,000 ppb. The estimated average concentration in surface water for tralkoxydim is 9 ppb. EPA's acute drinking water level of comparison is well above the estimated exposures for tralkoxydim in water for the subgroup of concern. For groundwater, the estimated environmental concentrations (EEC's) using the SCI-GROW model were all less than 1 ppb.

2. *Chronic risk.* A DEEM chronic exposure analysis showed that exposure from tolerance level residues in or on wheat, and barley for children 1-6 years old (the subgroup with the highest exposure) would be 1.4% of the Reference Dose (RfD). The exposure for the general U.S. population would be less than 1% of the RfD. The drinking water level of comparisons (DWLOCs) for chronic exposure to tralkoxydim in drinking water calculated for U.S. population was 150 ppb and for children (1–6 years old) the DWLOC was 50 ppb. The estimated average concentration in surface water for tralkoxydim is 9 ppb. EPA's chronic drinking water level of concern is above the estimated exposures for tralkoxydim in water for the U.S. population and the subgroup of concern. Conservative model estimates (SCI-GROW) of the concentrations of tralkoxydim in groundwater indicate that exposure will be minimal.

3. *Cancer risk.* A DWLOC for cancer was calculated as 1 ppb. The estimated concentration in surface water and groundwater for tralkoxydim for chronic exposure are 0.9 ppb [2.8 ppb (the 56-day concentration)/3] and 0.1 ppb, respectively. The model exposure estimates are less than the cancer DWLOC.

EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to tralkoxydim residues.

E. Aggregate Risks and Determination of Safety for Infants and Children

Safety factor for infants and children. In assessing the potential for additional sensitivity of infants and children to residues of tralkoxydim, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. The Agency concluded that an extra safety factor to protect infants and children is not needed based on the following considerations:

- The toxicology data base is complete for the assessment of special sensitivity of infants and children
- The developmental and reproductive toxicity data do not indicate increase susceptibility of rats or rabbits to *in utero* and/or postnatal exposure
- The NOAEL used in deriving the RfD is based on changes in liver function and morphology in male adult dogs (not developmental or neurotoxic effects) after chronic exposure and thus are not relevant for enhanced sensitivity to infants and children
- Unrefined dietary exposure estimates (assuming all commodities contain tolerance level residues) overestimate dietary exposure
- Model data used for ground and surface source drinking water exposure assessments result in estimates considered to be upper-bound concentrations
- There are no registered uses for tralkoxydim that could result in residential exposures.

EPA concludes that there is a reasonable certainty that no harm will result to children from aggregate exposure to tralkoxydim residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in barley, wheat, rotational crops, and livestock is adequately understood. The residues of concern for the tolerance expression are parent per se. Based on the results of animal metabolism studies it is unlikely that secondary residues would occur in animal commodities from the use of tralkoxydim on wheat and barley.

B. Analytical Enforcement Methodology

An adequate analytical method, gas chromatography/mass spectrometry with selected ion monitoring, is available for enforcement purposes. Because of the long lead time from establishing these tolerances to publication of the enforcement methodology in the Pesticide Analytical Manual, Vol. II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm 101FF, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–305–5229).

C. Endocrine Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other effect . . . '' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

D. Magnitude of Residues

Based on the results of animal metabolism studies it is unlikely that significant residues would occur in secondary animal commodities from the use of tralkoxydim on wheat and barley.

The nature of the residue in plants is adequately understood for the purposes of these time-limited tolerances.

E. International Residue Limits

There are no Codex Alimentarius Commission (Codex) or Mexican Maximum Residue Levels (MRLs) for tralkoxydim at this time.

F. Rotational Crop Restrictions.

No tolerances for inadvertent residues of tralkoxydim are required in rotational crops.

IV. Conclusion

Due to the second species carcinogenicity study data gap: EPA believes it is inappropriate to establish permanent tolerances for the uses of tralkoxydim at this time. EPA believes that the existing data support time-limited tolerances to February 28, 2003. Therefore, time-limited tolerances are established for residues of the herbicide, tralkoxydim, 2-(Cyclohexen-1-one, 2-[1-(ethoxyimino)propyl]-3-hydroxy-5-(2,4,6-trimethylphenyl)-(9Cl), in or on the raw agricultural commodities: barley grain, barley hay, wheat grain and wheat hay at 0.02 ppm, and barley straw, wheat forage and wheat straw at 0.05 ppm. These time-limited tolerances will expire and be revoked on February 28, 2003.

V. 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 new section 408(e) and (l)(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 govern 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 February 16, 1999, 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 above (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) or a request for a fee waiver. If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (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 issues 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 CBI. Information so marked 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.

VI. Public Record and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP–300764] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, 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 Rm. 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia

address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). Nor does it require any special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

In addition, since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The proposed rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit 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 United States prior to publication of the rule in the **Federal Register**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: December 3, 1998.

Stephen L. Johnson,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I 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 § 180.548, to read as follows:

§ 180.548 Tralkoxydim; tolerances for residues.

(a) *General.* Time-limited tolerances are established for residues of the herbicide, tralkoxydim, 2-(Cyclohexen-1-one, 2-[1-(ethoxyimino)propyl]-3-hydroxy-5-(2,4,6-trimethylphenyl)-(9Cl) in or on the raw agricultural commodities:

Commodity	Parts per million	Expiration/Revocation Date
Barley, grain	0.02	2/28/03
Barley, hay	0.02	2/28/03
Barley, straw	0.05	2/28/03
Wheat, forage	0.05	2/28/03
Wheat, grain	0.02	2/28/03
Wheat, hay	0.02	2/28/03
Wheat, straw	0.05	2/28/03

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 98–33121 Filed 12–15–98; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300762; FRL–6048–1]

RIN 2070–AB78

Bifenthrin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of bifenthrin in or on citrus, whole fruit; citrus oil; and citrus dried pulp. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide bifenthrin on citrus. This regulation establishes a maximum permissible level for residues of bifenthrin in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. The tolerance will expire and is revoked on December 31, 2000.

DATES: This regulation is effective December 16, 1998. Objections and requests for hearings must be received by EPA on or before February 16, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300762], 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–300762], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), 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. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., 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 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300762]. 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: Barbara Madden, 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: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–6463, e-mail: madden.barbara@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to sections 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 bifenthrin in or on citrus, whole fruit at 0.03 parts per million (ppm); 0.3 ppm for citrus oil; and 0.3 ppm for citrus dried pulp. This tolerance will expire and is revoked on December 31, 2000. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

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 Federal Food, Drug, and Cosmetic Act (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 are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL–5572–9).

New section 408(b)(2)(A)(i) of the FFDCA 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 and in residential settings, 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) of the FFDCA 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. Such tolerances can be established without providing notice or period for public comment.

Because decisions on section 18-related tolerances must proceed before EPA reaches closure on several policy issues relating to interpretation and implementation of the FQPA, EPA does not intend for its actions on such tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Bifenthrin on Citrus and FFDCA Tolerances

Recently Diaprepes root weevil has spread into citrus areas in Florida. Much of the infested citrus acreage is exhibiting severe decline or is out of production. Registered controls only provide 75% control of Diaprepes root