this pesticide indicate that the tolerance is not safe.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300535; FRL–5738–8]

RIN 2070–AB78

Triclopyr; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of triclopyr and its 3,5,6-trichloro-2-pyridinol metabolite in or on fish at 0.2 ppm and shellfish at 5.0 ppm. 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 on aquatic sites. This regulation establishes a maximum permissible level for residues of triclopyr in these commodities pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and are revoked on December 31, 1998.

DATES: This regulation is effective September 5, 1997. Objections and requests for hearings must be received by EPA on or before November 4, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300535], 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–300535], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services 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 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 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–300535]. 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: Olga Odiott, 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) 308-308-9363, e-mail: odiott.olga@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, 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 time-limited tolerances for residues of the herbicide triclopyr and its metabolite 3,5,6-trichloro-2-pyridinol, in or on fish at 0.2 part per million (ppm) and shellfish at 5.0 ppm. These tolerances will expire and are revoked on December 31, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerances 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 tolerance to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions.

II. Emergency Exemption for Triclopyr on Aquatic Sites and FFDCA Tolerances

The Applicants stated that the Purple loosestrife (*Lythrum salicaria*), an exotic herbaceous perennial, if not controlled, will have significant deleterious effects on the States' wetlands and wildlife. The Purple loosestrife rapidly replaces native vegetation and once established

is very difficult to control. As plant diversity diminishes, wildlife species are displaced from the wetlands due to the loss of food sources and nesting areas. The Purple loosestrife could render the wildlife areas useless for the intended purposes, and the millions of dollars that have been invested by the state and federal goverments would be lost. Use of triclopyr will allow the States to selectively remove the Purple loosestrife without harming desirable species. EPA has authorized under FIFRA section 18 the use of triclopyr on aquatic sites for control of the Purple loosestrife in North Dakota and Minnesota. After having reviewed their submission, EPA concurs that emergency conditions exist for these States.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of triclopyr in or on fish and shellfish. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the new safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although these tolerances will expire and are revoked on December 31, 1998, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on fish and shellfish after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions EPA has not made any decisions about whether triclopyr meets EPA's registration requirements for use on aquatic sites or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of triclopyr by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than North Dakota and Minnesota to use this pesticide on this crop under section 18 of FIFRA without following all provisions of section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for triclopyr, contact the Agency's Registration Division at the address provided above.

III. Risk Assessment and Statutory Findings

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

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 effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL 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 NOEL 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 NOEL) 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 3 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/NOEL 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 this pesticide, the most highly exposed population subgroup (non-nursing infants < 1 year old) was not regionally based.

IV. 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 triclopyr and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerances for residues of triclopyr and its metabolite 3,5,6-trichloro-2-pyridinol in or on fish at 0.2 ppm and shellfish at 5.0 ppm. EPA's assessment of the dietary exposures and risks associated with establishing these tolerances 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 triclopyr are discussed below.

1. *Acute toxicity*. The developmental NOEL of 30 mg/kg/day from a rabbit developmental study was recommended for the acute dietary risk assessment. At the lowest effect level (LEL) of 100 mg/kg/day, there were decreased number of live fetuses, increased fetal deaths, reduced ossification of sternebrae and digital bones, and increased percentage of fetuses with 13 ribs. This risk assessment will evaluate acute dietary risk to pregnant females age 13 and older.

2. *Short - and intermediate - term toxicity*. Based on the available data, the Agency has determined that short- and intermediate-term dermal and inhalation risk assessments are not required. A systemic NOEL of 1,000 mg/kg/day, the highest dose tested, (HDT) was determined in a 21-day dermal toxicity study in rabbits. The LC50 from the acute inhalation study was determined to be ≤ 2.6 mg/L (Toxicity Category IV).

3. *Chronic toxicity*. EPA has established the RfD for triclopyr at 0.05 milligrams/kilogram/day (mg/kg/day). This RfD is based on a reproductive toxicity study in rats with a NOEL of 5 mg/kg/day using an Uncertainty Factor of 100. At the next higher dose level (HDL) of 25 mg/kg/day, an increased incidence of degeneration of the proximal tubules of the kidney was observed in P1 and P2 parents of both sexes. On this basis, the RfD was calculated to be 0.05 mg/kg/day.

4. *Carcinogenicity*. The Agency's Cancer Peer Review Committee (CPRC) concluded that triclopyr should be classified as ''Group D chemical'' - not classifiable as to human carcinogenicity. A cancer risk assessment is not required.

B. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.417) for the residues of triclopyr in or on a variety of raw agricultural commodities. and its metabolites 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine, expressed as triclopyr, in or on rice grain (0.3 ppm), rice straw (10.0 ppm), grass forage (500 ppm), and grass hay (500 ppm). Tolerances for triclopyr and the two metabolites have been established for poultry meat, fat, and meat byproducts (except kidney) at 0.1 ppm and eggs at 0.05 ppm. Tolerances for triclopyr and the metabolite 3,5,6-trichloro-2-pyridinol have been established for meat, fat, and meat byproducts (except liver and kidney) of cattle, goats, hogs, horses, and sheep at 0.05 ppm; liver and kidney of cattle, goats, hogs, horses, and sheep at 0.5 ppm; and milk at 0.01 ppm. Risk assessments were conducted by EPA to assess dietary exposures and risks from triclopyr 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. The acute dietary (food only) risk assessment assumed tolerance level residues and 100% crop treated values. For pregnant females age 13 years and older, the dietary (food only) MOE was estimated as 2500. This estimate should be viewed as a conservative risk estimate. Refinement of the risk assessment using anticipated residue values and percent crop-treated data would result in a lower acute dietary exposure estimate.

ii. *Chronic exposure and risk.* The chronic dietary risk assessment assumed that 100% of fish and shellfish and all other commodities having triclopyr tolerances will contain triclopyr residues and those residues would be at the level of the tolerance, which result in an overestimate of human dietary exposure. Thus, in making a safety determination for these tolerances, EPA is taking into account this conservative exposure assessment. The existing triclopyr tolerances (published, pending, and including the necessary Section 18 tolerances) result in a TMRC that is equivalent to percentages of the RfD that range from 0. 9% for nursing infants < 1 year old, to 2.6% for non-nursing infants < 1 year old.

2. *From drinking water.* Based on available data used in EPA's assessment of environmental risk, triclopyr is not persistent in water. The degradation product 3,5,6-trichloro-2-pyridinol (TCP) is mobile. There are no established Maximum Contaminant Levels for residues of triclopyr in drinking water. No health advisory levels for triclopyr in drinking water have been established. Triclopyr has been detected in 5 wells out of 379 wells tested in four states. The concentrations ranged from 0.006 to 0.58 ppb. For surface water, at the maximum application rate of 12.12 lbs. a.i./A, the maximum concentration was 364 ppb and the 56-day concentration was 233 ppb.

The drinking water risk assessment was based on surface water exposure, which is considered to represent the worst case scenario in comparison to ground water. The maximum concentration of triclopyr residues (364 ppb) was used to calculate the acute exposures for adult females and children. The 56-day concentration (233 ppb) was used to calculate the chronic exposures for adult females and children. It was assumed that adult females consume 2 liters of water a day and children consume 1 liter of water a day.

i. *Acute exposure and risk.* The exposure for adult females was estimated as 1.2×10^{-2} mg/kg/day. The exposure for children was estimated as 3.6×10^{-2} mg/kg/day. The corresponding MOE values were 2500 for pregnant females and 825 for children. These values do not exceed the Agency's level of concern.

ii. *Chronic exposure and risk.* The chronic exposure was estimated as 7.7×10^{-3} mg/kg/day for adult females and 2.3×10^{-2} mg/kg/day for children. These chronic exposures to triclopyr from drinking water will utilize 15% of the RfD for adult females and 46% of the RfD for children. The Agency concludes that that there is a reasonable certainty that no harm will result from drinking water exposures to triclopyr.

3. *From non-dietary exposure.* Triclopyr is currently registered for use on outdoor non-food sites such as turf and ornamentals. These uses may result in non-occupational exposures. However, the available data indicate no evidence of significant toxicity and a reasonable certainty that no harm will result from non-occupational exposures to triclopyr residues.

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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex 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 increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether triclopyr has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, triclopyr does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that triclopyr has a common mechanism of toxicity with other substances.

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

1. *Acute risk.* For the population subgroup of concern, pregnant females age 13 and older, the Agency estimated an MOE of 1250 for the acute aggregate dietary risk (food + water) from exposures to triclopyr residues. Residential exposure was considered to be negligible. Therefore, the aggregate exposure is not expected to exceed the Agency's level of concern.

2. *Chronic risk.* Using the TMRC exposure assumptions described above, EPA has concluded that the percentage of the RfD that will be utilized by aggregate exposures [food + water] to residues of triclopyr ranges from 16% [1% for food and 15% for water] to 48% [46% for water and 2% for food] for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants <1 year old (discussed below). There are no chronic exposure scenarios for non-dietary uses of triclopyr which would

contribute to the aggregate risk. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to triclopyr residues.

3. *Short- and intermediate-term risk.* Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure. Although there is potential for outdoor residential exposures, the Agency has determined that short- and intermediate-term risk assessments are not required. The available data indicate no evidence of significant toxicity and a reasonable certainty that no harm will result from these exposures to triclopyr residues.

D. Aggregate Cancer Risk for U.S. Population

The Agency's CPRC concluded that triclopyr should be classified as ''Group D chemical'' - not classifiable as to human carcinogenicity.

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

1. *Safety factor for infants and children*— i. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of triclopyr, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-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 during 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. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. EPA believes that reliable data support using the standard 100-fold safety factor (usually 100 for combined inter- and intra-species variability) and not the additional tenfold safety factor when EPA has a complete data base under existing guidelines 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 standard safety factor.

ii. *Developmental toxicity studies*— a. *Rats*: The maternal (systemic) NOEL was 100 mg/kg/day, based on increased salivation and mortality at the lowest observed effect level (LOEL) of 300 mg/kg/day. The developmental (fetal) NOEL was 100 mg/kg/day, based on skeletal anomalies at the LOEL of 300 mg/kg/day.

b. *Rabbits.* The maternal (systemic) NOEL was 30 mg/kg/day, based on increased mortality and cesearean section observations at the LOEL of 100 mg/kg/day. The developmental (fetal) NOEL was 30 mg/kg/day, based on skeletal anomalies and variants at the LOEL of 100 mg/kg/day.

iii. *Reproductive toxicity study— Rats.* In the 2-generation reproductive toxicity study in rats, the parental (systemic) NOEL was 2.5 mg/kg/day, based on an increased incidence of degeneration of the proximal tubules of the kidney, observed in P1 and P2 parents of both sexes at the LOEL of 25 mg/kg/day. The developmental (pup) NOEL was 25 mg/kg/day based on decreased litter size, decreased body weight, and decreased survival at the LOEL of 250 mg/kg/day.

iv. *Pre- and post-natal sensitivity.* The toxicological data base for evaluating pre- and post-natal toxicity for triclopyr is complete with respect to current data requirements. There are no pre- or post-natal toxicity concerns for infants and children, based on the results of the rat and rabbit developmental toxicity studies and the 2-generation rat reproductive toxicity study. The developmental studies in rats and rabbits both have the maternal NOELs and LOELs at the same doses as the developmental NOELs and LOELs, respectively, and demonstrate that no pre-natal extra sensitivity is present. However, based on the developmental effects observed in rabbits, an acute dietary risk assessment was performed for women age 13 and older. The MOE was estimated as 2500.

The 2-generation rat reproduction study did not demonstrate any pre- or post natal extra sensivity for infants and children, since the developmental/reproductive (pup) findings occurred at 250 mg/kg/day in the presence of severe maternal toxicity.

v. *Conclusion.* The EPA concludes that reliable data support use of the standard 100-fold margin of exposure/uncertainty factor and that an additional margin/factor is not needed to protect infants and children.

2. *Acute risk.* The acute aggregate dietary MOE (food + water) was calculated to be 1250 for females age 13 and older (accounts for both maternal and fetal exposure), the population subgroup of concern. The MOE calculations were based on the developmental NOEL in rabbits of 30 mg/kg/day. This risk assessment assumed 100% crop-treated with tolerance level residues on all treated crops consumed, resulting in a significant over-estimate of dietary exposure. The large acute dietary MOE calculated for females age 13 and older provides assurance that there is a reasonable certainty of no harm for infants and children from exposures to triclopyr.

3. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that the chronic aggregate (food + water) exposure to triclopyr for infants and children occupies 48% of the RfD. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. There are no chronic exposure scenarios for non-dietary uses of triclopyr which would contribute to the aggregate risk. Taking into account the completeness and reliability of the toxicity data and this conservative exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to triclopyr residues.

V. Other Considerations

A. Metabolism In Plants and Animals

The nature of the residue in fish and shellfish is adequately understood. The residues of concern in fish and shellfish are the parent triclopyr and its metabolite 3,5,6-trichloro-2-pyridinol. The residues specified in 40 CFR 180.417 for fish and shellfish are the parent compound triclopyr and its two metabolites 3,5,6-trichloro-2-pyridinol and 2-methoxy-3,5,6-trichloropyridine. However, the Agency's Metabolism Committee determined that the residue to be regulated in plants, milk, poultry, and eggs is parent triclopyr only. The residues to be regulated in meat and meat byproducts are triclopyr and 3,5,6-trichloro-2-pyridinol .

B. Analytical Enforcement Methodology

Adequate enforcement methodologies (gas chromatography with ECD) are available in PAM, Vol. II, Methods I and II for plant and animal commodities to enforce the tolerance expression.

C. Magnitude of Residues

Residues of triclopyr and its regulated metabolites are not expected to exceed 0.2 ppm in fish and 5.0 ppm in shellfish as a result of this Section 18 use. Provided irrigation with treated water is restricted for two weeks (product label restriction), measurable residues in irrigated crops are unlikely. Secondary residues in animal commodities are not expected to exceed existing tolerances as a result of this Section 18 use.

D. International Residue Limits

There are no Codex proposals (step 6 or above), Canadian limits, or Mexican limits for triclopyr on fish and shellfish.

E. Rotational Crop Restrictions.

Residues in rotational crops are not a concern for this use of triclopyr on aquatic sites since crops will not be rotated into the treated aquatic sites.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of triclopyr and its metabolite 3,5,6-trichloro-2-pyridinol in /on fish at 0.2 ppm and shellfish at 5.0 ppm.

VII. 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 November 4, 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 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). 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 Confidential Business Information (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.

VIII. Public Record

EPA has established a record for this rulemaking under docket control number [OPP–300535] (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 Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

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 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.

IX. Regulatory Assessment Requirements

This final rule establishes time-limited tolerances under FFDCA section 408(l)(6). 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 prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or 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 these tolerances and exemptions that are established under FFDCA section 408 (l)(6), 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 acations published on May 4, 1981 (46 FR 24950), and was provided to the

Chief Counsel for Advocacy of the Small Business Administration.

X. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has 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 this rule in today's **Federal Register**. This 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 recordkeeping requirements.

Dated: August 22, 1997.

James Jones,

Acting Director, Registration Division, 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. Section 180.417 is amended as follows:

a. By adding a heading to paragraph (a) and redesignating the text of paragraph (a) as paragraph (a)(1).

b. By redesignating paragraph (b) as paragraph (a)(2).

c. By adding a new paragraph (b).

d. By adding headings and reserving paragraphs (c) and (d).

Section 180.417, as amended, reads as follows:

§ 180.417 Triclopyr; tolerances for residues.

(a) *General.* * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of the herbicide triclopyr ((3,5,6-trichloro-2-pyridinyl)oxy)acetic acid and its metabolite 3,5,6-trichloro-2-pyridinol in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. The tolerance is specified in the following table. The tolerances will expire and are revoked on the dates specified in the following table:

Commodity	Parts per million	Expiration/ revocation date
Fish	0.2	12/31/98
Shellfish	5.0	12/31/98

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

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

[FR Doc. 97–23683 Filed 9–4–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300543; FRL–5740–6]

RIN 2070–AB78

Bifenthrin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of bifenthrin in or on canola seed. 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 on canola in Idaho, Oregon, and Washington. 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 September 30, 1998.

DATES: This regulation is effective September 5, 1997. Objections and requests for hearings must be received by EPA on or before November 4, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300543], 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–300543], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services 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 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 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–300543]. 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: Andrea Beard, 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) 308-9356, e-mail: beard.andrea@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, 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 bifenthrin, in or on canola seed at 0.5 part per million (ppm). This tolerance will expire and is revoked on September 30, 1998. 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