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ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 180**

[OPP-300677; FRL-5797-7]

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 raspberries. 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 raspberries. This regulation establishes maximum permissible levels 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, 1999.

DATES: This regulation is effective July 10, 1998. Objections and requests for hearings must be received by EPA on or before September 8, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP-300677], 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-300677], 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, 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-300677]. 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 raspberries at 3.0 parts per million (ppm). This tolerance will expire and is revoked on December 31, 1999. 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 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 Bifenthrin on Raspberries and FFDCA Tolerances

The Applicants state that an emergency situation is present due to these pests developing resistance to available alternatives, and the low tolerance for weevil contamination in raspberries. Rejection by the processors of contaminated raspberries can lead to significant losses in revenue for the growers. EPA has authorized under FIFRA section 18 the use of bifenthrin on raspberries for control of weevils in Washington and Oregon. After having reviewed the 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 bifenthrin in or on raspberries. In doing so, EPA considered the new safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance 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 this tolerance without notice and opportunity for public comment under section 408(e), as provided in section 408(l)(6). Although this tolerance will expire and is revoked on December 31, 1999, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on raspberries 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 this tolerance earlier if any experience with scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this tolerance is being approved under emergency conditions EPA has not made any decisions about whether bifenthrin meets EPA's registration requirements for use on raspberries or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this tolerance serves as a basis for registration of bifenthrin by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for any State other than Washington and Oregon 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 bifenthrin, 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 enactment 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/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 the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (non-nursing infants, less than 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 bifenthrin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of bifenthrin on raspberries at 3.0 ppm. 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 bifenthrin are discussed below.

1. *Acute toxicity.* The maternal NOEL of 1 milligram/kilogram/day (mg/kg/day) from the oral developmental toxicity study in rats is used for acute dietary risk assessments. The maternal lowest observable effect level (LOEL) of this study of 2 mg/kg/day was based on tremors from day 7-17 of dosing. This acute dietary endpoint is used to estimate dietary risks to all population subgroups.

2. *Short- and intermediate-term toxicity.* The maternal NOEL of 1 mg/kg/day from the oral developmental toxicity study in rats is also used for short- and intermediate-term MOE calculations (as well as acute, discussed in (1) above).

3. *Chronic toxicity.* EPA has established the RfD for bifenthrin at 0.015 mg/kg/day. This RfD is based on a 1-year oral feeding study in dogs with a NOEL of 1.5 mg/kg/day, based on

intermittent tremors at the LOEL of 3 mg/kg/day; an uncertainty factor of 100 is used.

4. *Carcinogenicity.* OPP has classified bifenthrin as a Group C chemical (possible human carcinogen) based upon urinary bladder tumors in mice, but did not recommend assignment of a Q*.

B. Exposures and Risks

1. From food and feed uses.

Tolerances have been established (40 CFR 180.442) for the residues of bifenthrin, in or on a variety of raw agricultural commodities. Tolerances, in support of registrations, currently exist for residues of bifenthrin on hops; strawberries; corn grain, forage, and fodder; cotton seed; and livestock commodities of cattle, goats, hogs, horses, sheep, and poultry. Additionally, time-limited tolerances associated with emergency exemptions have been established for broccoli, cauliflower, raspberries, cucurbits, and canola. Risk assessments were conducted by Novigen Sciences, Inc., and reviewed by EPA, to assess dietary exposures and risks from bifenthrin 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 1 day or single exposure. The acute risk assessment used Monte Carlo methodology. This methodology incorporates distributions of residues and refined percent of crop treated estimates, and thus results in highly refined risk estimates. For the most highly exposed population subgroup, children 1-6 years old, the resulting high-end exposure (at the 99.9th percentile) results in a dietary (food only) MOE of 193; at the 99th percentile the MOE is 1018. For non-nursing infants <1 Year Old, the high-end exposure (at the 99.9th percentile) MOE is 590; at the 99th percentile it is 880. For the Overall U.S. population, the high-end exposure (99.9th percentile) MOE is 466; at the 99th percentile it is 1768. The MOE estimates are all well within acceptable limits (>100) for all population subgroups.

ii. Short- and intermediate-term risk.

The short- and intermediate-term risk assessment used maximum anticipated residue levels for cotton, extrapolated residue levels for meat/milk/poultry/eggs, and air monitoring data collected from 15 homes in four states. Based on this data, the MOEs for children are calculated to be 280 for the average consumer and 250 for the high-end consumer. The MOEs for adults are

calculated to be 450 for the average consumer and 390 for the high-end consumer. EPA generally has no concern for MOEs greater than 100, and thus these do not exceed EPA's level of concern.

iii. *Chronic exposure and risk.* The chronic dietary (food only) risk assessment for bifenthrin was conducted using Monte Carlo methodology, and thus these risk estimates are highly refined. This risk assessment estimated that dietary exposure to bifenthrin will utilize 0.1% of the RfD for the overall U.S. population. The major identifiable subgroup with the highest exposure is non-nursing infants <1 year old, at 0.3% of the RfD. This is further discussed below in the section on infants and children. EPA generally has no concern for exposure below 100 percent 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.

2. *From drinking water.* A Tier II drinking water assessment of bifenthrin was conducted, using computer models which simulate the fate in a surface water body. The estimated environmental concentrations (EECs) are generated for high exposure agricultural scenarios and represent one in ten years EECs in a stagnant pond with no outlet that receives pesticide loading from an adjacent 100% cropped, 100% treated field. As such, these computer generated EECs represent conservative screening levels for ponds and lakes and are used only for screening. The EECs for surface water ranged from a peak of 0.260 part per billion (ppb), to a 90-days average of 0.018 ppb. In conducting both the acute and chronic risk assessments, Monte Carlo methodology was again used, and thus these risk estimates are considered to be highly refined.

i. *Acute exposure and risk.* The MOEs for the acute risk estimate from drinking water for bifenthrin ranged from 29,035 for the most highly exposed population subgroup, non-nursing infants (<1 yr old), to 131,980 for the overall U.S. population. EPA generally has no concern for MOEs greater than 100, and thus these risk estimates are well within acceptable limits.

ii. *Chronic exposure and risk.* For the chronic risk estimates, the percentage of RfD utilized by contribution through drinking water was estimated to be well below 0.0% for all population subgroups.

3. *Non-dietary exposure.* Bifenthrin is currently only registered for residential non-food use as a termiticide. Based on information

referred to above regarding short- and intermediate-term exposure, this use is not expected to result in risks that exceed levels of concern. Therefore, reasonable certainty of no harm is expected from exposure through non-dietary, non-occupational routes.

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 bifenthrin 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, bifenthrin 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 bifenthrin 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 overall U.S. population, the calculated MOE value (for food only) is 466; for food plus drinking water, this estimate is 464. For the most highly exposed subgroup, children 1 - 6 years old, the MOE for food is 193; from food plus drinking water, this estimate is 192. As stated above, EPA generally has no concern for MOEs greater than 100, and thus these are within acceptable limits. Therefore, EPA concludes that there is reasonable certainty that no harm will result from acute exposure to bifenthrin.

2. *Chronic risk.* Using the Monte Carlo methodology described above, EPA has concluded that aggregate exposure to bifenthrin from food will utilize 0.1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is non-nursing infants <1 year old, with 0.3% of the RfD utilized, further discussed below. 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. The risk estimates from drinking water exposure are calculated to be well below 0.0% of the RfD for all population subgroups, and thus do not add appreciably to the estimates for food alone. Therefore, EPA concludes that there is a reasonable certainty that no harm will result from chronic aggregate exposure to bifenthrin 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. Based on bifenthrin not being registered for indoor residential or pet uses, EPA concludes that the aggregate short- and intermediate-term risks do

not exceed levels of concern, and that there is reasonable certainty that no harm will result.

D. 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 bifenthrin, 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 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 MOE/safety factor.

ii. *Developmental toxicity studies.* In the rabbit developmental study, there were no developmental effects observed in the fetuses exposed to bifenthrin. The maternal NOEL was 2.67 mg/kg/day based on head and forelimb twitching at the LOEL of 4 mg/kg/day.

In the rat developmental study, the maternal NOEL was 1 mg/kg/day, based on tremors at the LOEL of 2 mg/kg/day. The developmental (pup) NOEL was also 1 mg/kg/day, based upon increased incidence of hydroureter at the LOEL of 2 mg/kg/day. There were 5/23 (22%) of the litters affected (5/141 fetuses since each litter only had one affected fetus) in the 2 mg/kg/day group, compared with zero in the control, 1, and 0.5 mg/kg/day groups. According to recent historical data (1992-1994) for this

strain of rat, background incidence of distended ureter averaged 11% with a maximum incidence of 90%.

iii. *Reproductive toxicity study.* In the rat reproduction study, parental toxicity occurred as decreased body weight and tremors at 5.0 mg/kg/day with a NOEL of 3.0 mg/kg/day. There were no developmental (pup) or reproductive effects up to 5.0 mg/kg/day (highest dose tested).

iv. *Pre- and post-natal sensitivity— a. Pre-natal.* Since there was not a dose-related finding of hydroureter in the rat developmental study and in the presence of similar incidences in the recent historical control data, the marginal finding of hydroureter in rat fetuses at 2 mg/kg/day (in the presence of maternal toxicity) is not considered a significant developmental finding. Nor does it provide sufficient evidence of a special dietary risk (either acute or chronic) for infants and children which would require an additional safety factor.

b. *Post-natal.* Based on the absence of pup toxicity up to dose levels which produced toxicity in the parental animals, there is no evidence of special post-natal sensitivity to infants and children in the rat reproduction study.

v. *Conclusion.* Based on the above, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children.

2. *Acute risk.* EPA believes that residential exposures are more appropriately included in the short-term exposure scenario, and thus estimates acute risk from dietary exposure only. EPA concluded that aggregate dietary acute risk (food plus water) would not exceed levels of concern. This is discussed in greater detail above.

3. *Chronic risk.* Using the Monte Carlo methodology described above, EPA has concluded that aggregate exposure estimates to bifenthrin from food will utilize from 0.1 to 0.3% of the RfD for infants and children. 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 to infants and children from aggregate exposure to bifenthrin residues.

4. *Short- or intermediate-term risk.* The estimated short- and intermediate-term risks do not exceed EPA's levels of concern for children. MOEs for children are calculated to be 280 for the average

consumer and 250 for the high-end consumer, discussed in greater detail above. There is generally no concern for MOEs which are greater than 100.

V. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of bifenthrin in raspberries is adequately understood for the purposes of this tolerance. The residue of concern is the parent compound only.

B. Analytical Enforcement Methodology

There is a practical analytical method for detecting and measuring levels of bifenthrin in or on food with a limit of detection that allows monitoring of food with residues at or above the levels set in this tolerance document (Gas chromatography with Electron Capture Detection, analytical method P-2132M, PP# 0E3921; MRID#41658601). EPA has provided information on this method to FDA. The method is available to anyone who is interested from OPP's Health Effects Division (7509C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

C. Magnitude of Residues

Residues of bifenthrin are not likely to exceed 3.0 ppm in or on raspberries as a result of the proposed use. Secondary residues are not expected to occur in animal commodities.

D. International Residue Limits

There are no Codex, Canadian, or Mexican residue limits for residues of bifenthrin in or on raspberries.

E. Rotational Crop Restrictions

The confined rotational crop data requirements for bifenthrin have been satisfied. The following rotation instructions are required: (1) Leafy vegetables and root crops may be rotated 30 days following the final application of bifenthrin; (2) Crops for which bifenthrin tolerances exist may be rotated at any time; and (3) All other crops may be rotated seven months following the final application of bifenthrin. There are no rotational crop considerations associated with raspberries.

VI. Conclusion

Therefore, the tolerance is established for residues of bifenthrin in or on raspberries at 3.0 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 September 8, 1998, 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 and Electronic Submissions

EPA has established a record for this rulemaking under docket control number [OPP-300677] (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 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, 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 a time-limited tolerance 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 tolerance 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.

X. 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 recordkeeping requirements.

Dated: June 24, 1998.

Peter Caulkins,

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. In § 180.442, by amending the table under paragraph (b) by revising the entry for "Raspberries" to read as follows:

§ 180.442 Bifenthrin; tolerances for residues.

* * * * *
(b) * * *

Commodity	Parts per million	Expiration/Revocation Date
* * * Raspberries	* * 3.0	* * 12/31/99
* * *	* *	* *

* * * * *

[FR Doc. 98-18279 Filed 7-9-98; 8:45 am]
BILLING CODE 6560-50-F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-300665; FRL-5794-3]

RIN 2070-AB78

Gliocladium Catenulatum Strain J1446; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This rule establishes an exemption from the requirement of a tolerance for residues of the biological pesticide *Gliocladium catenulatum* strain J1446 in or on all agricultural commodities. Kemira Agro Oy submitted a petition to EPA under the Federal Food, Drug and Cosmetic Act as amended by the Food Quality Protection Act of 1996 requesting the tolerance exemption. This regulation eliminates the need to establish a maximum permissible level for residues of *Gliocladium catenulatum* strain J1446.
DATES: This regulation is effective July 10, 1998. Objections and requests for hearings must be received by EPA on or before September 8, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP-300665],

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 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-300665], 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, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of electronic 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 electronic objections and hearing requests must be identified by the docket number [OPP-300665]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Susanne Cerrelli, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, Office location and telephone number, and e-mail address: CM #2 Rm. 902 W48, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-8077, e-mail address: cerrelli.susanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 25, 1997 (62 FR 34271)(FRL-5721-7), EPA issued a notice pursuant to section 408(d), of the Federal Food, Drug and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), announcing the filing of a pesticide tolerance

petition by Kemira Agro Oy (PP 7F4137). The notice contained a summary of the petition prepared by the petitioner and this summary contained conclusions and arguments to support its conclusion that the petition complied with the Food Quality Protection Act (FQPA) of 1996. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of the biological pest control agent *Gliocladium catenulatum* strain J1446. There were no comments received in response to the notice of filing.

The data submitted in the petition and other material have been evaluated. The toxicology data requirements in support of this exemption from the requirement of a tolerance were satisfied via submitted data.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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 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..." Additionally, section 408(b)(2)(D)(v) requires that 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 performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

II. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the