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Stanley F. Mires,

Chief Counsel, Legislative.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301014; FRL–6594–6]

RIN 2070–AB78

Trifloxystrobin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for trifloxystrobin regulated as trifloxystrobin and the free form of its acid metabolite CGA–321113 in or on almond nutmeat, almond hulls, dried hops cones, sugar beet roots, sugar beet tops, sugar beet dried pulp, sugar beet molasses, potato tubers, wheat grain, wheat forage, wheat hay, wheat straw, wheat bran, and aspirated grain fractions. Novartis Crop Protection, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective July 18, 2000. Objections and requests for hearings, identified by docket control number OPP–301014, must be received by EPA on or before September 18, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION** section. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301014 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305–7740 and e-mail address: giles-parker.cynthia@epa.gov

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301014. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of August 17, 1998 (63 FR 43937) (FRL–6018–2), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide petition (PP) 8F4955 for tolerances by Novartis Crop Protection, Inc. This notice included a summary of the petition prepared by Novartis Crop Protection, Inc., the registrant. An amendment to the notice of filing was published in the **Federal Register** of August 26, 1999 (64 FR 46680) (FRL–6099–8) which revised proposed tolerance levels and added the metabolite CGA–321113. No comments were received in response to the amendment.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for combined residues of the fungicide trifloxystrobin and the free form of its acid metabolite CGA–321113, in or on almond nutmeat at 0.04 parts per million (ppm), almond hulls at 3.0 ppm, dried hops cones at 11.0 ppm, sugar beet roots at 0.1 ppm, sugar beet tops at 4.0 ppm, sugar beet dried pulp at 0.4 ppm, sugar beet molasses at 0.2 ppm, potato tubers at 0.04 ppm, fruiting vegetables at 0.5 ppm, wheat grain at 0.05 ppm, wheat forage at 0.3 ppm, wheat hay at 0.2, wheat straw at 5.0 ppm, and aspirated grain fractions at 5.0 ppm.

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

to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

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

III. 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 trifloxystrobin and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for combined residues of trifloxystrobin and the free form of its acid metabolite CGA–321113 on almond nutmeat at 0.04 ppm, almond hulls at 3.0 ppm, dried hops cones at 11.0 ppm, sugar beet roots at 0.1 ppm, sugar beet tops at 4.0 ppm, sugar beet dried pulp at 0.4 ppm, sugar beet molasses at 0.2 ppm, potato tubers at 0.04 ppm, fruiting vegetables at 0.5 ppm, wheat grain at 0.05 ppm, wheat forage at 0.3 ppm, wheat hay at 0.2, wheat bran at 0.15 ppm, and aspirated grain fractions at 5.0 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 results of toxicity studies for trifloxystrobin are listed below:

1. *Subchronic-Feeding Study— Rat.* The No Observed Adverse Effects Level (NOAEL) was 500 ppm (30.6–32.8 milligrams/kilogram/day (mg/kg/day). Decreased body weight, hypertrophy of hepatocytes in males and pancreatic atrophy were observed at the Lowest Observed Adverse Effects Level (LOAEL) of 2,000 ppm (127–133 mg/kg/day).

2. *Subchronic-Feeding Study— Mouse.* The NOAEL was 500 ppm (76.9–110 mg/kg/day). Increased liver weights and necrosis of hepatocytes were observed at the LOAEL of 2,000 ppm (315–425 mg/kg/day).

3. *Subchronic-Feeding Study— Dog.* The NOAEL was 30 mg/kg/day. Increased liver weight and hepatocyte hypertrophy in males were observed at the LOAEL of 150 mg/kg/day.

4. *28–Day Dermal Toxicity Study— Rat.* The NOAEL was 100 mg/kg/day. Increased liver and kidney weight were observed at the LOAEL of 1,000 mg/kg/day.

5. *Developmental Toxicity Study— Rat.* The maternal NOAEL was 10 mg/kg/day. Decreased body weight gain and food consumption were observed at the maternal LOAEL of 100 mg/kg/day. The developmental NOAEL was 1,000 mg/kg/day. No developmental effects were observed. The developmental LOAEL was equal to or greater than 1,000 mg/kg/day.

6. *Developmental Toxicity Study— Rabbit.* The maternal NOAEL was 10 mg/kg/day. Decreased mean body weights and decreased mean body weight gain (compared to control), food consumption and efficiency were observed at the maternal LOAEL of 50 mg/kg/day. The developmental NOAEL was 250 mg/kg/day. Skeletal anomolies were observed at the Developmental LOAEL of 500 mg/kg/day.

7. *Reproductive Toxicity Study— Rat.* The parental NOAEL was 50 ppm (3.8 mg/kg/day). Decreased mean body weight and decreased mean weight gain (compared to control), decreased food consumption, and increased incidence of liver, kidney and spleen effects were observed at the parental LOAEL of 750 ppm (55.3 mg/kg/day). The reproductive NOAEL was 1,500 ppm (110.6 mg/kg/day). The reproductive LOAEL was greater than 1,500 ppm (110.6 mg/kg/day).

8. *Chronic-Feeding Study— Dog.* The NOAEL was 5 mg/kg/day. Increased clinical signs, increased liver weight and hepatocellular hypertrophy were observed at the LOAEL of 50 mg/kg/day.

9. *Carcinogenicity Study— Mouse.* The NOAEL was 300 ppm (39.4 mg/kg/day). Liver effects were observed at the LOAEL of 1,000 ppm (131.1 mg/kg/day).

10. *Chronic Toxicity/Carcinogenicity Study— Rat.* The NOAEL was 250 ppm (9.81–11.37 mg/kg/day). Decreased mean body weight and decreased mean body weight gain (compared to control) were observed at the LOAEL of 750 ppm (29.7–34.5 mg/kg/day).

11. *Gene Mutation Study— Salmonella.* Negative.

12. *Gene Mutation study— Chinese Hamster Cultured V–79.* Positive.

13. *Structural Chromosome Aberration-Micronucleus study— Mouse.* Negative.

14. *Structural Chromosome Aberration-Cytogenetics study— Chinese Hamster.* Negative.

15. *DNA Repair study-hepatocytes— Rat.* Negative.

16. *Acute Oral Neurotoxicity study— Rat.* The NOAEL and LOAEL could not be determined.

17. *Metabolism study—Rat.* The tissue half-lives ranged from 13 to 42 hours. The highest residues were found in liver, kidneys, spleen and blood. The parent compound was extensively metabolized to approximately 35 metabolites.

B. Toxicological Endpoints

The following endpoints were used in the the risk assessments for trifloxystrobin.

1. *Acute toxicity—Dietary Developmental Toxicity Study— Rabbits.* The developmental NOAEL was 250 mg/kg/day. The endpoint was an increase in fetal incidence of fused sternebrae 1#3 and 1#4 at a LOAEL of 500 mg/kg/day. The uncertainty factor (UF) was 100 based on intraspecies and interspecies variation. The acute reference dose (RfD) was 2.5 mg/kg/day; the acute population adjusted dose (aPAD) was 2.5 mg/kg/day. In the study selected, the developmental effects were presumed to occur after a single exposure. Since this is an *in utero* effect it is applicable only to the population subgroup, females 13+ years.

2. *Short- and intermediate-term toxicity— 28–Day Dermal Toxicity Study— Rats.* The systemic NOAEL was 100 mg/kg/day. The endpoint was an increase in liver and kidney weights at a LOAEL of 1,000 mg/kg/day.

3. *Long-term toxicity.* Long-term dermal exposure is not expected based on the proposed use pattern. Therefore, a long term dermal risk assessment was not performed.

4. *Chronic toxicity—Chronic Toxicity Study— Dogs.* The NOAEL was 5 mg/kg/day. The endpoint was an increased incidence of clinical signs, increased mean liver weight and hepatocellular hypertrophy at a LOAEL of 50 mg/kg/day. The UF was 100 for intraspecies and intraspecies variation. The chronic RfD was 0.05 mg/kg/day; the chronic PAD was 0.05 mg/kg/day. The chronic toxicity study in dogs was chosen for the chronic dietary risk assessment because the study is chronic and the systemic NOAEL is lower than that in the chronic rat study. Also, the toxic effects observed were seen in the chronic rat study and the multi-generation reproduction study in rats.

5. *Carcinogenicity.* Trifloxystrobin has been classified as a ''not likely human carcinogen''.

C. Exposures and Risks

1. *From food and feed uses.* Tolerances are being established for the combined residues of trifloxystrobin and the free form of its acid metabolite CGA–321113 on the following commodities: almond nutmeat at 0.04 ppm, almond hulls at 3.0 ppm, dried hops cones at 11.0 ppm, sugar beet roots at 0.1 ppm, sugar beet tops at 4.0 ppm, sugar beet dried pulp at 0.4 ppm, sugar beet molasses at 0.2 ppm, potato tubers at 0.04 ppm, fruiting vegetables at 0.5 ppm, wheat grain at 0.05 ppm, wheat forage at 0.3 ppm, wheat hay at 0.2, wheat straw at 5.0 ppm, wheat bran 0.15 ppm, and aspirated grain fractions at 5.0 ppm. Risk assessments were conducted by EPA to assess dietary exposures 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 Dietary Exposure Evaluation Model (DEEM) detailed acute analysis estimates the distribution of single exposures for the overall U.S. population and certain subgroups. For this assessment, the only population subgroup of concern for acute dietary risk is Females 13 years and older. The analysis evaluates individual food consumption as reported by respondents in the USDA 1989–1992 Continuing Survey of Food Intake by Individuals (CSFII) and accumulates exposure to the chemical for each commodity. Each analysis assumes uniform distribution of trifloxystrobin in the commodity supply. In conducting the acute dietary risk assessment, the Agency made highly conservative assumptions. One hundred percent of proposed crops are assumed to be treated with trifloxystrobin, and this is expected to result in an overestimate of dietary risk. Therefore, this acute dietary (food only) risk assessment should be viewed as a highly conservative risk estimate. Further refinement using anticipated residues or percent of crop treated data in conjunction with a Monte Carlo analysis would result in a lower dietary exposure estimate. In the DEEM acute analysis the proposed tolerances for combined residues of trifloxystrobin and CGA–321113 utilized < 1% of the aPAD for females 13–50 years.

ii. *Chronic exposure and risk.* In conducting the chronic dietary (food only) risk assessment, the Agency made highly conservative assumptions which resulted in an overestimate of human dietary exposure. One hundred percent of proposed crops are assumed to be treated with trifloxystrobin, and this is expected to result in an overestimate of dietary risk. Therefore, this chronic dietary (food only) risk assessment should be viewed as a highly conservative risk estimate. Further refinement using anticipated residues or percent of crop treated data would result in a lower dietary exposure estimate. Thus, in making a safety determination for these tolerances, EPA takes into account this highly conservative exposure assessment. The Agency is generally concerned with chronic exposures that exceed 100% of the chronic PAD (cPAD) or chronic RfD. The proposed trifloxystrobin tolerances were used to calculate the the exposure and risk estimate. The percentages cPAD utilized were 15% for all infants (< 1 year), 18% for children 1–6 years old, and 7.5% or lower for other population subgroups.

iii. *Cancer dietary risk from food sources.* Trifloxystrobin was classified as a ''not likely human carcinogen.'' Therefore, a cancer risk assessment was not conducted.

2. *From drinking water.* EPA does not have monitoring data available to perform a quantitative dietary (drinking water) risk assessment for trifloxystrobin and the free form of its acid metabolite. In the absence of reliable, available monitoring data, EPA uses models to estimate concentrations of pesticides in ground-water and surface water. Drinking water estimates for the parent, trifloxystrobin, plus the free form of its acid metabolite CGA–321113, were generated by the Screening Concentration in Ground Water (SCI-GROW) model. Conservative assumptions were built into the ground water scenario used by the SCI-GROW model, such as assuming shallow ground water, coarse soils and high levels of irrigation. The estimate from SCI-GROW represents an upper bound on the concentration of trifloxystrobin in ground waters as a result of agricultural use.

The estimate for the parent, trifloxystrobin, using the SCI-GROW model is 0.006 part per billion (ppb). For the primary metabolite CGA–321113, the estimated value is 4.9 ppb. For risk assessment purposes, EPA used the estimates for the primary metabolite (and not a sum of parent plus metabolite) because the SCI-GROW model assumes 100% conversion from parent to CGA–321113.

Estimates of concentrations of trifloxystrobin and its metabolite in surface water were made using the generic expected environmental concentration (GENEEC) model. The peak estimate for the parent, trifloxystrobin, using the GENEEC model, ranges from 5.29 to 5.56 ppb. The 56–day average for the parent ranges from 0.64 to 2.97. For the primary metabolite, the peak estimate is 47.98 ppb, and the 56–day average estimate is 47.31 ppb. For risk assessment purposes, EPA used the estimates for the primary metabolite (and not a sum of parent plus metabolite) because the GENEEC model assumes 100% conversion from parent to CGA–321113.

A Drinking Water Level of Comparison (DWLOC) is a theoretical upper limit of a pesticide's concentration in drinking water in light of total aggregate exposure to that pesticide in food and through residential uses. A DWLOC will vary depending on the toxic endpoint, consumption and body weight. Different populations will have different DWLOCs. EPA uses DWLOCs internally in the risk assessment process as a surrogate measure of potential exposure associated with pesticide exposure through drinking water. In the absence of monitoring data for pesticides, the DWLOC is used as a point of comparison against conservative model estimates of potential pesticide concentration in water. DWLOC values are not regulatory standards for drinking water. EPA has calculated DWLOCs for acute and chronic (non-cancer) exposure to trifloxystrobin and the primary metabolite CGA–321113 for the U.S. population and selected subgroups.

The DWLOC for acute risk is 75,000 µg/l for females 13–50 years. The DWLOCs for chronic exposure are 1,600 µg/l for the U.S. population, 430 µg/l for all infants, 1,400 µg/l for females 13–50 years, and 615 µg/l for children 1–6 years. The estimated concentrations of trifloxystrobin in ground water, 4.9 µg/l and surface water, 47 µg/l, are less than the DWLOCs as a contribution to acute and chronic exposure. The estimated concentrations of trifloxystrobin and its primary metabolite in ground and surface water are considered conservative estimates. Therefore, EPA concludes with reasonable certainty that residues of trifloxystrobin in food and drinking water would not result in an unacceptable estimate of acute or chronic (non-cancer) aggregate human health risk.

3. *From non-dietary exposure.* Trifloxystrobin, is proposed for use on the following residential non-food sites: turfgrass and ornamentals. There are no homeowner uses of trifloxystrobin

proposed, but residential lawns are listed on the label as sites which may be treated by a professional pesticide applicator. Therefore, risk assessments (dermal and oral) were conducted for adults and children who may be exposed to trifloxystrobin after application by a professional pesticide applicator. Short and intermediate-term post-application residential risk estimates do not exceed EPA's level of concern, Margins Of Exposure (MOE) range from 760 to 300,000. Acute and chronic aggregate risk (food plus water) estimates do not exceed EPA's level of concern. Short- and intermediate-term aggregate risk estimates also do not exceed EPA's level of concern.

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.'' Trifloxystrobin belongs to a new class of fungicides, the MAEs (beta-methoxyacryl esters), which are synthetic analogs of strobilurin A, an antifungal secondary metabolite of the fungus *Strobilurus tenacellus*. Trifloxystrobin works by interfering with respiration in plant pathogenic fungi. The site of action of strobilurin compounds is located in the mitochondrial respiration pathway between cytochromes b and c1 at the level of the hydroquinone binding site. As a result of this mode of action, trifloxystrobin is a potent inhibitor of fungal spore germination and mycelial growth. Trifloxystrobin can be referred to more specifically as an oximinoacetate.

EPA does not have, at this time, available data to determine whether trifloxystrobin 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, trifloxystrobin 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 trifloxystrobin has a common mechanism of toxicity with other substances. For information regarding EPA efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL. start

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

1. *Acute risk.* To calculate acute aggregate dietary risk, high-end exposures from food and drinking water sources are compared to the acute PAD. Exposure to trifloxystrobin residues and the free form of its acid metabolite, CGA–321113 in food will occupy no more than < 1% of the acute PAD for females 13–50 years. Acute dietary risk from food was calculated for females 13–50 years because the endpoint upon which the acute PAD is based is on developmental effects. Residue levels used for food-source dietary risk assessments were very conservative: proposed tolerance levels were used, and 100% crop treated was assumed, with no refinements. Acute dietary exposure estimates were calculated for the 95th percentile. Estimated drinking water levels were calculated using drinking water models (SCI-GROW and GENEEC)). Estimated concentrations of trifloxystrobin residues in surface and ground water are lower than EPA's DWLOCs. Therefore, EPA does not expect acute aggregate risk to trifloxystrobin residues from acute food and drinking water sources to exceed EPA's level of concern for acute aggregate risk.

2. *Chronic risk.* Exposure to trifloxystrobin and the free form of its acid metabolite, CGA–321113 residues in food will occupy no more than 3.5% of the chronic PAD for adult population subgroups (females 13–50 years) and no more than 18% of the chronic PAD for infant/children subgroups (highest subgroup: children 1–6 years). Residue levels used for food-source dietary risk assessments were not refined and did not incorporate percent of crop treated. Estimated concentrations of trifloxystrobin residues in surface and ground water are lower than EPA's DWLOCs. Estimated drinking water levels were calculated using drinking water models. Chronic residential exposure of trifloxystrobin is not expected. EPA does not expect chronic aggregate risk to trifloxystrobin residues from food, water and residential sources to exceed EPA's level of concern for chronic aggregate risk.

3. *Short-term risk.* To calculate short-term aggregate risk, high-end residential risk (oral) is combined with chronic food and drinking water risks. Since trifloxystrobin causes the same toxic effects but different NOAELs were found across different routes, risks for food, drinking water and residential exposure paths are combined to estimate short-term risk. Based on EPA's short-term aggregate risk calculation, EPA does not expect short-term aggregate risk to trifloxystrobin residues from food, water and residential sources to exceed EPA's level of concern for short-term aggregate risk.

4. *Intermediate-term risk.* To calculate intermediate-term aggregate risk, high-end residential risk (oral) are combined with chronic food and drinking water risks. Since trifloxystrobin causes the same toxic effects but different NOAELs were found across different routes, risks for food, drinking water and residential exposure paths are combined to estimate intermediate-term risk. Based on EPA's intermediate term aggregate risk calculation, EPA does not expect intermediate-term aggregate risk to trifloxystrobin residues from food, water and residential sources to exceed the EPA's level of concern for intermediate-term aggregate risk.

5. *Aggregate cancer risk for U.S. population*. Not applicable. There is no evidence of carcinogenicity.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues.

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

EPA determined the 10x safety factor for the protection of infants and children should be removed. Based on the following:

1. The toxicology database is complete for FQPA assessment.

2. There is no indication of increased susceptibility of rat or rabbits to trifloxystrobin. In the developmental and reproductive toxicity studies, effects in the fetuses/offspring were observed only at or above treatment levels which resulted in evidence of parental toxicity.

3. It was determined that a developmental neurotoxicity study in rats is not required.

4. The exposure assessments will not underestimate the potential dietary (food and drinking water) or nondietary exposures for infants and children from the use of trifloxystrobin.

IV. Other Considerations

A. Metabolism in Plants and Animals

1. *For plants*. EPA determined that the qualitative nature of the residue in plants is adequately understood for almonds, hops, fruiting vegetables, tuberous and corm vegetables, and sugar beets based on acceptable studies conducted on apples, cucumbers, peanuts and a supplementary study on

wheat and that these plant commodities are of concern for both regulatory and risk assessment purposes. EPA concluded that additional metabolism studies would be needed to support registration of trifloxystrobin and the free form of its acid metabolite CGA–321113 on wheat.

2. *For animals.* The EPA determined that the qualitative nature of the residue in animals is adequately understood based on acceptable studies conducted in goats and laying hens. It was determined that the total toxic residues for animals, both for regulatory and risk assessment purposes, is trifloxystrobin and the free form of its acid metabolite CGA–321113. Additionally, the liver contribution for metabolite L7a (taurine conjugate of trifloxystrobin) is to be included for risk assessment purposes, assuming equal toxicity as trifloxystrobin.

B. Analytical Enforcement Methodology

EPA has completed a method validation of AG–659A on apples, wet apple pomace, grapes, summer squash, peanut hay, peanuts, cow liver, cow milk and raisins, and concluded that AG–659A is suitable for enforcement of trifloxystrobin and the free form of its acid metabolite in plant and animal commodities. Method AG–659A is the proposed analytical method for the enforcement of trifloxystrobin in plant and animal commodities. It supersedes Method AG–659. Compared to AG–659, AG–659A also includes extractability and accountability of ^{14}C-CGA–279202 in animal matrices, minor changes, and suggestions resulting from the independent laboratory validation (ILV) to improve the ruggedness of the method. Method AG–659A has been validated by the petitioner for both trifloxystrobin and its acid metabolite CGA–321113. This method adequately recovers residues of trifloxystrobin and CGA–321113, usually with a limit of quantitation (LOQ) of 0.02 ppm.

C. Magnitude of Residue

1. *Crop field trials.* The field trials were adequate in number, geographically representative, and reasonably reflected the proposed use patterns. In all cases, the tolerances EPA recommended were for combined residues of trifloxystrobin and the free form of its acid metabolite CGA–321113.

i. *Almond.* EPA recommended for a 0.04 ppm tolerance in/on almond nutmeats and 3.0 ppm in/on almond hulls.

ii. *Fruiting vegetables.* Additional residue data would be needed to support future registrations for fruiting vegetables. In the interim, EPA recommended for a 0.5 ppm tolerance.

iii. *Hops.* EPA recommended for a 11.0 ppm tolerance in/on hops, dried cones.

iv. *Potato.* EPA recommended for a tolerance of 0.04 ppm (based on LOQs).

v. *Sugar beet.* EPA recommended for a 0.1 ppm tolerance on sugar beet roots and 4.0 ppm on sugar beet tops.

vi. *Wheat.* EPA recommended at 0.05 ppm on wheat grain, 0.3 ppm on wheat forage, 0.2 ppm on wheat hay, 5.0 ppm on wheat straw.

vii. *Aspirated grain fractions.* EPA recommended for a 5.0 ppm tolerance.

2. *Processed commodities.* In all cases, the tolerances EPA recommended were for combined residues of trifloxystrobin and the free form of its acid metabolite CGA–321113.

i. *Sugar beet.* No concentration of residues occurred in refined sugar; no tolerance is required. EPA recommended a 0.2 ppm in molasses and 0.4 ppm in dried beet pulp.

ii. *Potato.* No concentration of residues occured in flakes and chips, and no tolerances are required. Residues for wet peel were lower than the tolerance level recommended for potato, hence, no tolerance for wet peel is required.

iii. *Tomato.* No concentration of residues occurred in puree; no tolerance is required. No tolerance on tomato paste is required, pending residue data reflecting the maximum application rate.

iv. *Wheat.* No concentration of residues occurred in germ, middlings, shorts, and flour. EPA recommended tolerance of 0.15 ppm on bran and 5.0 ppm on aspirated grain fractions.

3. *Residues in poultry and eggs.* Based on the poultry metabolism study, EPA concluded that finite residues of trifloxystrobin are not expected in poultry commodities. Thus, poultry feeding data and tolerances for poultry commodities are not required at this time.

4. *Residues in meat and milk.* A dairy cattle feeding study was conducted at levels equivalent to 2, 6, and 20 ppm in the diet (mg/kg diet on a dry weight basis). Because the highest feeding level was only 3–4x the calculated maximum theoretical dietary burden (6.2 ppm, beef cattle; 4.9 ppm, dairy cattle) and because residues of trifloxystrobin and the acid metabolite CGA–321113 were detected in fat at this feeding level, EPA concluded that animal commodity tolerances were needed. Based on LOQs each for parent and CGA–321113 of 0.01 ppm for milk and 0.02 ppm for other animal commodities, EPA has established a 0.02 ppm LOQ tolerance for combined residues of trifloxystrobin and the free form of its acid metabolite CGA–321113 in milk and a 0.05 ppm combined residue tolerance for the meat, fat and meat byproducts of cattle, goats, hogs, horses and sheep. For risk assessment purposes only, 0.1 ppm trifloxystrobin-equivalent residue is used for liver. This value is based on the sum of the liver contribution of metabolite L7a (estimated at ca 0.05 ppm trifloxystrobin equivalent, adjusted to a 1x feeding level from the goat metabolism study, TFMP–^{14}C label) plus that of the recommended 0.05 ppm tolerance for the combined residues of trifloxystrobin and CGA–321113 in meat byproducts.

D. International Residue Limits

There are no Codex, Canadian, or Mexican maximum residue limits (MRLs) established for trifloxystrobin. Harmonization is thus not an issue at this time.

E. Rotational Crop Restrictions

An acceptable confined rotational crop study was submitted. The predominant metabolite, trifluoroacetic acid, is not of concern at the (≤ 0.2 ppm) levels reported. Quantifiable residues (≥ 0.02 ppm) of trifloxystrobin and CGA–321113 are not expected in/on crops rotated at a 30–day plantback interval. Nonetheless, the petitioner did submit new data on field accumulation in rotational crops. Trifloxystrobin (as CGA–279202 50 WG) was applied to squash or cucumbers as a post-foliar spray four times at 7–day intervals at 0.25 lb active ingredient/acre (ai/A/) application for a maximum rate of 1.0 lb ai/A/season. The last application occurred on the day of primary crop harvest. Rotational crops were planted 30–31, and 120 days after the last application. The following rotational crops were planted: leaf lettuce, turnips, and wheat. Crops were grown under normal agricultural conditions. Samples of the appropriate RACs were collected at normal harvest maturity, frozen, and maintained frozen (approximately -20° C) until analysis using method AG–659A. The LOQ for both analytes were 0.02 ppm. Residues of trifloxystrobin and its acid metabolite CGA–321113 were all less than the LOQ in all crops planted at 30–31 days after the last application. The revised draft Flint® label (EPA Reg. 100–919) proposes a 30–day plantback restriction for crops not listed on the label and would permit treated areas to be replanted immediately following harvest with any crop listed on the label (pome fruits, grapes, cucurbit vegetables, almonds, fruiting vegetables, hops, potatoes, sugar

beets, and wheat). For the Stratego® labels, celery, cereals, corn, pineapple, and sugarcane may be replanted 30 days after the last application; for all other crops, a 105–day plantback interval must be observed. The proposed plantback restrictions for Flint® and Stratego® are adequate and no rotational crop tolerances need to be proposed, provided that rotational crop restrictions of the Stratego® labels are compatible with those of the propiconazole labels.

V. Conclusion

Therefore, tolerances are established for combined residues of trifloxystrobin and the free form of its acid metabolite CGA–321113 in/on almond nutmeat at 0.04 ppm, almond hulls at 3.0 ppm, dried hops cones at 11.0 ppm, sugar beet roots at 0.1 ppm, sugar beet tops at 4.0 ppm, sugar beet dried pulp at 0.4 ppm, sugar beet molasses at 0.2 ppm, potato tubers at 0.04 ppm, fruiting vegetables at 0.5 ppm, wheat grain at 0.05 ppm, wheat forage at 0.3 ppm, wheat hay at 0.2, wheat straw at 5.0 ppm, wheat bran 0.15 ppm, and aspirated grain fractions at 5.0 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301014 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before September 18, 2000.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Room M3708, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A. of this preamble, you should also send a copy of your request to the PIRB for its inclusion in the official record that is described in Unit I.B.2. of this preamble. Mail your copies, identified by docket number OPP–301014, 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 or by courier, bring a copy to the location of the PRIB described in Unit I.B.2. of this preamble. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid 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. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established EPA, 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(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 et seq., or impose any enforceable duty or contain any

unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); 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 or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), 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. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4).

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this 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 29, 2000.

James Jones,

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. 321(q), (346a), and 371.

2. Section 180.555 is amended by alphabetically adding the following entries to the table in paragraph (a) to read as follows:

§ 180.555 Trifloxystrobin; tolerances for residues.

(a) * * *

Commodity	Parts per million
Almond, hulls	3.0
Almond, nutmeat	0.04
* * * * *	
Aspirated grain fractions	5.0
* * * * *	
Fruiting vegetables	0.5
* * * * *	
Hops, dried cones	11.0
* * * * *	
Potato, tubers	0.04
* * * * *	
Sugar beet, dried pulp	0.4
Sugar beet, molasses	0.2
Sugar beet, roots	0.1
Sugar beet, tops	4.0
Wheat, bran	0.15
Wheat, forage	0.3
Wheat, grain	0.05
Wheat, hay	0.2
Wheat, straw	5.0

* * * * *

[FR Doc. 00–18100 Filed 7–17–00; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301015; FRL–6594–8]

RIN 2070–AB78

Vinclozolin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of vinclozolin, 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione and its metabolites containing the 3,5-dichloroaniline moiety in or on the raw agricultural commodities: succulent beans at 2.0 parts per million (ppm); canola at 1.0 ppm; eggs, milk, and the meat, fat, and meat byproducts of cattle, goats, hogs, horses, and sheep at 0.05 ppm; and in the meat, fat, and meat byproducts of poultry at 0.1 ppm. These tolerances will expire and are revoked on September 30, 2003. BASF Corporation requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective July 18, 2000. Objections and requests for hearings, identified by docket control number OPP–301015, must be received by EPA on or before September 18, 2000.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301015 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection