

97% of applied 1-MCP was bound rapidly and tightly to the surfaces of four different soil types, and that no 1-MCP was detected in the soil leachates. This study indicates that 1-MCP has extremely low mobility in the soil and that it is highly unlikely that it will move into ground water. Modeling of potential runoff into surface waters using the generic expected environmental concentration (GENEEC) 2, shows that the maximum potential concentration of 1-MCP in surface waters following runoff would not exceed approximately 25 ppb.

With regard to the potential exposure and effects on human health as a result of the newly approved usage of 1-MCP in pre-harvest treatments, the applicant submitted extensive guideline animal studies. These studies were conducted using doses much greater than any measured or estimated environmental concentration of 1-MCP following applications at the maximum allowable label rate. EPA reviews of these studies concluded that 1-MCP has no adverse effects on any animal organism tested. These reviews are discussed in detail in the April 9, 2008 **Federal Register** document (73 FR 19147).

Furthermore, based on the nature of residue studies (D339988, MRIDs 47088611-12 & 47108203, field residue studies demonstrate that environmental concentrations of 1-MCP will be extremely low following applications at the maximum allowable product label use rate. When the product was applied to apple trees at the maximum product label use rate 0.28 lbs (121.4 g) 1-MCP/acre, 1-MCP residues ranged from 3 to 4 parts per billion (ppb) on apple fruits, at 3 to 7 days post-treatment; 212 to 379 ppb on apple leaves at 3 to 30 days post-treatment; and 17 ppb in the upper 2 centimeter of soil below the tree at 1 day post-treatment.

The Agency does not expect any human health concerns or negative effect on non-target organisms including endangered species, from exposure to residues of 1-MCP when applied or used as directed on the label and in accordance with good agricultural practices.

### III. Why is this Correction Issued as a Final Rule?

Section 553 of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an Agency for good cause finds that notice and public procedure are impracticable, unnecessary or contrary to the public interest, the Agency may issue a final rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause

for making today's technical correction final without prior proposal and opportunity for comment, because EPA is merely responding to comments that were not addressed in the previously published final rule. The comments received and reviewed do not affect EPA's decision for establishing an amendment to the tolerance exemption for the use 1-MCP for pre-harvest treatment. EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

### IV. Do Any of the Statutory and Executive Order Reviews Apply to this Action?

No. The applicable statutory and Executive order reviews were included in the April 8, 2008 **Federal Register** document. This document is a technical correction and as such no new reviews are applicable.

### V. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the Agency promulgating the rule must submit a rule report 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 final rule in the **Federal Register**. This final 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: July 23, 2008.

Janet L. Andersen,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. E8-17478 Filed 7-29-08; 8:45 am]

BILLING CODE 6560-50-S

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2006-0234; FRL-8370-8]

### Gentamicin; Pesticide Tolerance for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a time-limited tolerance for residues of gentamicin in or on apples. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on apples. This regulation establishes a maximum permissible level for residues of gentamicin in this food commodity. The time-limited tolerance expires and is revoked on December 31, 2010.

**DATES:** This regulation is effective July 30, 2008. Objections and requests for hearings must be received on or before September 29, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0234. To access the electronic docket, go to <http://www.regulations.gov>, select "Advanced Search," then "Docket Search." Insert the docket ID number where indicated and select the "Submit" button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in [www.regulations.gov](http://www.regulations.gov). Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Andrew Ertman, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9367; e-mail address: [ertman.andrew@epa.gov](mailto:ertman.andrew@epa.gov).

**SUPPLEMENTARY INFORMATION:**

## I. General Information

### A. Does this Action Apply to Me?

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

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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 this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

### B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

### C. Can I File an Objection or Hearing Request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (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. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0234 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 29, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit your copies, identified by docket ID number EPA-HQ-OPP-2006-0234, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket’s normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

## II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of FFDCA, 21 U.S.C. 346a(e) and 346a(l)(6), is establishing a time-limited tolerance for residues of the agricultural antibiotic gentamicin, in or on apples at 0.10 parts per million (ppm). This time-limited tolerance expires and is revoked on December 31, 2010. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the CFR.

Section 408(l)(6) of 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. EPA does not intend for its actions on section 18 related time-limited tolerances to set binding precedents for the application of section 408 of FFDCA and the new safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a

tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

## III. Emergency Exemption for Gentamicin on Apples and FFDCA Tolerances

The State of Michigan requested the use of gentamicin on apples due to the development of resistance of fire blight to the pesticide streptomycin and the lack of viable control options. After having reviewed the submission, EPA determined that emergency conditions exist for this State, and that the criteria for an emergency exemption are met. EPA has authorized under FIFRA section 18 the use of gentamicin on apples for control of fire blight in Michigan.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of gentamicin in or on apples. In doing so, EPA considered the safety standard in section 408(b)(2) of FFDCA, and EPA decided that the necessary tolerance under section 408(l)(6) of FFDCA would be consistent with the 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 as provided in section 408(l)(6) of FFDCA. Although this time-limited tolerance expires and is revoked on December 31, 2010, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amount specified in the tolerance remaining in or on apples after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke this time-limited 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 time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether gentamicin meets FIFRA's registration requirements for use on apples or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of gentamicin by a State for special local needs under FIFRA section 24(c). Nor does this tolerance serve as the basis for persons in any State other than Michigan to use this pesticide on this crop under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for gentamicin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

#### **IV. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of 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) of FFDCA 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) of FFDCA 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. . . ."

Consistent with the factors specified in FFDCA 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 and to make a determination on aggregate exposure expected as a result of this emergency exemption request and the time-limited tolerance for residues of gentamicin on apples at 0.10 ppm. EPA's assessment of exposures and risks associated with establishing time-limited tolerances follows.

##### **A. Toxicological Endpoints**

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effect are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects are observed of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term, and chronic-term risks are evaluated by comparing food, water, and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect greater than that expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment

process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for gentamicin used for human risk assessment can be found at <http://www.regulations.gov> in the document registration #06MI01. "Section 18 Emergency Exemption for the application of Gentamicin Sulfate to Apples. Human-Health Risk Assessment" pages 25–26 in docket ID number EPA–HQ–OPP–2006–0234.

##### **B. Exposure Assessment**

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to gentamicin, EPA considered exposure under the time-limited tolerance established by this action. EPA assessed dietary exposures from gentamicin in food as follows:

i. *Acute exposure.* No such effects were identified in the toxicological studies for gentamicin; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* A Tier 1 chronic dietary-exposure assessment was conducted using the established/recommended tolerances for all food commodities, 100% crop treated information for all proposed and existing uses, and DEEM™ Version 7.81 default processing factors for some processed commodities. Drinking water was incorporated directly into the dietary assessment using the EDWC generated by GENEEC2.

iii. *Cancer.* A cancer dietary exposure assessment was not performed for gentamicin because gentamicin is not likely to be carcinogenic to humans.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for gentamicin. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for gentamicin in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of gentamicin. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

A Tier I Generic Expected Environmental Concentration (GENEEC2) screening model was used to determine estimated surface water concentrations of gentamicin following 3 applications to apples.

Based on the GENECC2 model described above, the highest estimated drinking water concentration (EDWC) of gentamicin for chronic exposure is estimated to be 45.08 ppb for ground water and surface water. Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model (DEEM Version 7.81). The modeled exposure scenario was conservative, as compared to the section 18 use pattern.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Gentamicin is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found gentamicin to share a common mechanism of toxicity with any other substances, and gentamicin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that gentamicin does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA's Office of Pesticide Programs concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at <http://www.epa.gov/pesticides/cumulative>.

#### C. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the

FQPA safety factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Based on data reviewed by the Agency, there is no evidence of increased susceptibility in the developmental studies in rats, rabbits, mice, and guinea pigs. Furthermore, there is no evidence in increased susceptibility in the 2-generation reproduction study in rats. In all studies, gentamicin was tested parentally, which is very conservative since about 1% of the oral dose is absorbed. The doses tested in these studies are 100-fold higher than the hypothetical oral dose. Therefore, there is no residual uncertainty for prenatal and/or postnatal susceptibility.

3. *Conclusion.* EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for gentamicin is complete.

ii. There is no indication that gentamicin is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that gentamicin results in increased susceptibility in the developmental studies in rats, rabbits, mice, and guinea pigs. There is no evidence of increased susceptibility in the 2-generation reproduction study in rats.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground water and surface water modeling used to assess exposure to gentamicin in drinking water. These assessments will not underestimate the exposure and risks posed by gentamicin.

#### D. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term, and chronic-

term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* An acute aggregate risk assessment takes into account exposure estimates from acute dietary consumption of food and drinking water. No adverse effect resulting from a single-oral exposure was identified, therefore, no acute dietary endpoint was selected. Therefore, gentamicin is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to gentamicin from food and water will utilize 1% of the cPAD for the U.S. population, 4% of the cPAD for all infants less than 1 year old, and 3% of the cPAD for children 1-2 years old. All other population subgroups utilize 2% or less of the cPAD. There are no residential uses for gentamicin that result in chronic residential exposure to gentamicin.

3. *Short-term and intermediate-term risk.* Short-term and intermediate-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Gentamicin is not registered for any use patterns that would result in residential exposure. Therefore, the short-term aggregate risk is the sum of the risk from exposure to gentamicin through food and water and will not be greater than the chronic aggregate risk.

4. *Aggregate cancer risk for U.S. population.* Gentamicin is not likely to be carcinogenic to humans and is therefore not expected to pose a cancer risk.

5. *Pharmaceutical aggregate risk.* Section 408 of the FFDCA requires EPA to consider potential sources of exposure to a pesticide and related substances in addition to the dietary sources expected to result from a pesticide use subject to the tolerance. In order to determine whether to maintain a pesticide tolerance, EPA must "determine that there is a reasonable certainty of no harm." Under FFDCA section 505, the Food and Drug Administration (FDA) reviews human drugs for safety and effectiveness and may approve a drug notwithstanding the possibility that some users may experience adverse side effects. EPA does not believe that, for purposes of the section 408 dietary risk assessment, it is compelled to treat a pharmaceutical user the same as a non-user, or to assume that combined exposures to

pesticide and pharmaceutical residues that lead to a physiological effect in the user constitutes "harm" under the meaning of section 408 of the FFDCA. Rather, EPA believes the appropriate way to consider the pharmaceutical use of gentamicin in its risk assessment is to examine the impact that the additional nonoccupational pesticide exposures would have to a pharmaceutical user exposed to a related (or, in some cases, the same) compound. Where the additional pesticide exposure has no more than a minimal impact on the pharmaceutical user, EPA could make a reasonable certainty of no harm finding for the pesticide tolerances of that compound under section 408 of the FFDCA. If the potential impact on the pharmaceutical user as a result of co-exposure from pesticide use is more than minimal, then EPA would not be able to conclude that dietary residues were safe, and would need to discuss with FDA appropriate measures to reduce exposure from one or both sources.

The pesticidal exposure estimates reflect the dietary dose from pesticidal uses of gentamicin that a user treated with a pharmaceutical gentamicin product would receive in a reasonable worst-case scenario. EPA's pesticide exposure assessment has taken into consideration the appropriate population, exposure route, and exposure duration for comparison with exposure to the pharmaceutical use of gentamicin.

EPA estimates that the pharmaceutical gentamicin exposure a user is expected to receive from a typical therapeutic dose (3–7.5 milligrams/kilogram/day (mg/kg/day)) is 2,400 to 6,000 times greater than the estimated dietary exposure from the pesticidal sources of gentamicin (0.001229 mg/kg/day). Therefore, because the pesticide exposure has no more than a minimal impact on the total dose to a pharmaceutical user, EPA believes that there is a reasonable certainty that the potential dietary pesticide exposure will result in no harm to a user being treated therapeutically with gentamicin. FDA has been made aware of EPA's conclusions regarding pesticide exposure in users receiving treatment with a pharmaceutical gentamicin drug product.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to gentamicin residues.

## V. Other Considerations

### A. Analytical Enforcement Methodology

Adequate enforcement methodology is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; e-mail address: [residuemethods@epa.gov](mailto:residuemethods@epa.gov).

### B. International Residue Limits

There are no Codex maximum residue limits (MRLs) for residues of gentamicin on apples.

## VI. Conclusion

Therefore, a time-limited tolerance is established for residues of gentamicin *per se*, in or on apple at 0.10 ppm. The tolerance expires and is revoked on December 31, 2010.

## VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under sections 408(e) and 408(l)(6) of FFDCA 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). Because this rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with sections 408(e) and 408(l)(6) of FFDCA, 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes,

nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this rule. In addition, This rule does not 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).

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).

## VIII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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 final rule in the **Federal Register**. This final 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: July 17, 2008.

**Lois Rossi,**

*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 180.642 is added to read as follows:

**§ 180.642 Gentamicin; tolerances for residues.**

(a) *General.* [Reserved].

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of gentamicin in or on the

specified agricultural commodities, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. The tolerances expire and are revoked on the date specified in the following table.

| Commodity | Parts per million | Expiration/revocation date |
|-----------|-------------------|----------------------------|
| Apple     | 0.10              | December 31, 2010          |

(c) *Tolerance with regional restrictions.* [Reserved]

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

[FR Doc. E8-17337 Filed 7-29-08; 8:45 am]

BILLING CODE 6560-50-S

**ENVIRONMENTAL PROTECTION AGENCY****40 CFR Part 180**

[EPA-HQ-OPP-2006-0857; FRL-8370-7]

**Cyfluthrin; Pesticide Tolerances**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes a tolerance for residues of cyfluthrin in or on alfalfa, forage and revises the existing tolerance for residues of cyfluthrin in or on alfalfa, hay. Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective July 30, 2008. Objections and requests for hearings must be received on or before September 29, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2006-0857. To access the electronic docket, go to <http://www.regulations.gov>, select “Advanced Search,” then “Docket Search.” Insert the docket ID number where indicated and select the “Submit” button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:**

Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5218; e-mail address: [stanton.susan@epa.gov](mailto:stanton.susan@epa.gov).

**SUPPLEMENTARY INFORMATION:****I. General Information****A. Does this Action Apply to Me?**

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

the person listed under **FOR FURTHER INFORMATION CONTACT**.

**B. How Can I Access Electronic Copies of this Document?**

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA’s tolerance regulations at 40 CFR part 180 through the Government Printing Office’s pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

**C. Can I File an Objection or Hearing Request?**

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2006-0857 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 as required by 40 CFR part 178 on or before September 29, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2006-0857, by one of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.
- **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P),