

established on the basis of a petition under FFDCA section 408(d), such as the exemptions 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). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175.

Thus, Executive Order 13175 does not apply to this rule.

XI. Congressional Review Act

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 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: October 28, 2005.
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. In § 180.910 the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

Inert Ingredient	Limits	Uses
* * *	* *	* *
2-Bromo-2-nitro-1,3-propanediol (CAS Reg. No. 52-51-7)	0.04% or less by weight of the total pesticide formulation	In-can preservative
* * *	* *	* *
* * *	* *	

■ 3. In § 180.930 the table is amended by adding alphabetically the following inert ingredient to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

Inert Ingredient	Limits	Uses
* * *	* *	* *
2-Bromo-2-nitro-1,3-propanediol (CAS Reg. No. 52-51-7)	0.04% or less by weight of the total pesticide formulation	In-can preservative
* * *	* *	* *
* * *	* *	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180
[OPP-2005-0254; FRL-7740-8]

Flucarbazon-sodium; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).
ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of flucarbazon-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-N-[2(trifluoromethoxy)phenyl] sulfonyl-1H-1,2,4-triazole 1-carboxamide, sodium salt and its N-desmethyl metabolite in or on wheat, forage at 0.30 parts per million (ppm); wheat, grain at 0.01 ppm; wheat, hay at 0.10 ppm; and wheat, straw at 0.05 ppm; and combined residues of flucarbazon-sodium and its metabolites converted to 2-(trifluoromethoxy) benzene sulfonamide and calculated as flucarbazon-sodium in or on milk at 0.005 ppm; meat and meat byproducts (excluding liver) of cattle, goats, hogs, horses, and sheep at 0.01 ppm; and liver of cattle, goats, hogs, horses, and sheep at 1.5 ppm. Arysta LifeScience North America Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA). The tolerance will expire on November 30, 2006.

DATES: This regulation is effective November 9, 2005. Objections and requests for hearings must be received on or before January 9, 2006.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in

Unit VI. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under Docket identification (ID) number OPP-2005-0254. All documents in the docket are listed in the EDOCKET index at <http://www.epa.gov/edocket>. Although listed in the index, some information is not publicly available, i.e., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Jim Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5697; e-mail address: Tompkins.Jim@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. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in <http://docket.epa.gov/edkpub/index.jsp>. 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 and Other Related Information?

In addition to using EDOCKET (<http://www.epa.gov/edocket/>), you may access this **Federal Register** document electronically through the EPA Internet under the “**Federal Register**” listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at E-CFR Beta Site Two at <http://www.gpoaccess.gov/ecfr/>. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at <http://www.epa.gov/opptsfrs/home/guidelin.html>.

II. Background and Statutory Findings

In the **Federal Register** of September 29, 2000 (65 FR 58364) (FRL-6745-9), EPA issued a time-limited tolerance for combined residues of the herbicide, flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-N-[2(trifluoromethoxy)phenyl] sulfonyl-1H-1,2,4-triazole 1-carboxamide, sodium salt and its N-desmethyl metabolite in or on wheat, forage at 0.30 ppm; wheat, grain at 0.01 ppm; wheat, hay at 0.10 ppm; and wheat, straw at 0.05 ppm; and combined residues of flucarbazone-sodium and its metabolites converted to 2-(trifluoromethoxy) benzene sulfonamide and calculated as flucarbazone-sodium in or on milk at 0.005 ppm; meat and meat byproducts (excluding liver) of cattle, goats, hogs, horses, and sheep at 0.01 ppm; and liver of cattle, goats, hogs, horses, and sheep at 1.5 ppm. The tolerance will expire on November 1, 2005.

In the **Federal Register** of July 27, 2005 (70 FR 43412) (FRL-7727-2), EPA issued a notice pursuant to section 408(d)(3) of the FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 5F6949) by Arysta LifeScience North America Corporation, 100 First Street, Suite 1700, San Francisco, CA 94105. The petition requested that 40 CFR 180.562 be amended by establishing a tolerance for combined residues of the herbicide, flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-N-[2(trifluoromethoxy)phenyl] sulfonyl-1H-1,2,4-triazole 1-carboxamide, sodium salt and its N-desmethyl metabolite in or on wheat, forage at 0.30 ppm; wheat, grain at 0.01 ppm; wheat, hay at 0.10 ppm; and wheat, straw at 0.05 ppm; and combined residues of flucarbazone-sodium and its metabolites converted to 2-(trifluoromethoxy) benzene sulfonamide and calculated as

flucarbazone-sodium in or on milk at 0.005 ppm; meat and meat byproducts (excluding liver) of cattle, goats, hogs, horses, and sheep at 0.01 ppm; and liver of cattle, goats, hogs, horses, and sheep at 1.5 ppm. This notice included a summary of the petition prepared by Arysta LifeScience North America Corporation, the registrant. Comments were received on the notice of filing. EPA response to those comments is discussed in Unit IV.D.

The time limited-tolerance previously issued September 29, 2000 (65 FR 58364) (FRL-6745-9), will be extended for 13 months and will expire on November 30, 2006. A time-limited tolerance will be issued due to outstanding studies (independent laboratory validations of: Analytical Method for the Determination O-Desmethyl MKH 6562 (Metabolite of MKH 6562 in Soil by High Performance Liquid Chromatography Tandem Mass Spectrometry), Analytical Method for the Determination of MKH 6562 and Metabolites NODT (N,O-dimethyltriazolinone), Sulfonic Acid and Sulfonamide in Soil by High Performance Liquid Chromatography Tandem Mass Spectrometry, and Analytical Method for the Determination of MKH 6562 and Three Metabolites in Groundwater by High Performance Liquid Chromatography Tandem Mass Spectrometry) will be submitted to the Agency by the registrant in January 2006.

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) of the 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 the 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. . . .”

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 of the FFDCA and a complete description of

the risk assessment process, see <http://docket.epa.gov/edkpub/index.jsp>.

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D) of the FFDCA, 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, consistent with section 408(b)(2) of the FFDCA, for a tolerance for combined residues of flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-N-[2(trifluoromethoxy)phenyl] sulfonyl-1H-1,2,4-triazole 1-carboxamide, sodium salt and its N-desmethyl metabolite in or on wheat, forage at 0.30 ppm; wheat, grain at 0.01 ppm; wheat, hay at 0.10 ppm; and wheat, straw at 0.05 ppm; and combined residues of flucarbazone-sodium and its metabolites converted to 2-(trifluoromethoxy) benzene sulfonamide and calculated as flucarbazone-sodium in or on milk at 0.005 ppm; meat and meat byproducts (excluding liver) of cattle, goats, hogs, horses, and sheep at 0.01 ppm; and liver of cattle, goats, hogs, horses, and sheep at 1.5 ppm. EPA's assessment of 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. Specific information on the studies received and the nature of the toxic effects caused by flucarbazone-sodium as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies can be found at <http://docket.epa.gov/edkpub/index.jsp>.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is

applied to reflect 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.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify non-threshold hazards such as cancer. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk, estimates risk in terms of the probability of occurrence of additional cancer cases. More information can be found on the general principles EPA uses in risk characterization at <http://docket.epa.gov/edkpub/index.jsp>.

A summary of the toxicological endpoints for flucarbazone-sodium used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of September 29, 2000 (65 FR 58363) (FRL-6745-9).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established 40 CFR 180.562 for the combined residues of flucarbazone-sodium, in or on wheat, forage at 0.30 ppm; wheat, grain at 0.01 ppm; wheat, hay at 0.10 ppm; and wheat, straw at 0.05 ppm; and combined residues of flucarbazone-sodium and its metabolites converted to 2-(trifluoromethoxy) benzene sulfonamide and calculated as flucarbazone-sodium in or on milk at 0.005 ppm; meat and meat byproducts (excluding liver) of cattle, goats, hogs, horses, and sheep at 0.01 ppm; and liver of cattle, goats, hogs, horses, and sheep at 1.5 ppm. Risk assessments were conducted by EPA to assess dietary exposures from flucarbazone-sodium in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a one day or single exposure. The Dietary Exposure Evaluation Model (DEEM™) analysis evaluated the individual food consumption as reported by respondents in the United States Department of Agriculture (USDA) 1989–1992 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity.

A summary of the acute dietary exposure assessment is discussed in Unit III.C. of the final rule published in the **Federal Register** of September 29, 2000 (65 FR 58363).

ii. *Chronic exposure.* In conducting this chronic dietary exposure and risk assessment the DEEM™ analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 Nationwide CSFII and accumulated exposure to the chemical for each commodity.

A summary of the chronic dietary exposure assessment is discussed in Unit III.C. of the final rule published in the **Federal Register** of September 29, 2000 (65 FR 58363).

iii. *Cancer.* A summary of the dietary exposure assessment is discussed in Unit III.C. of the final rule published in the **Federal Register** of September 29, 2000 (65 FR 58363).

Section 408(b)(2)(E) of the FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E) of the FFDCA, EPA will issue a Data Call-In for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of this tolerance.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for flucarbazone-sodium in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of flucarbazone-sodium. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://docket.epa.gov/edkpub/index.jsp>.

A summary of the dietary exposure from drinking water assessment is discussed in Unit III. C. of the final rule published in the **Federal Register** of September 29, 2000 (65 FR 58363).

Based on the generic expected environmental concentration (GENEEC) and screening concentration in ground water (SCI-GROW) models, the estimated environmental concentrations (EECs) of flucarbazone-sodium for acute exposures are estimated to be 1.42 parts per billion (ppb) for surface water and

0.2 ppb for ground water. The EECs for chronic exposures are estimated to be 1.25 ppb for surface water and 0.2 ppb for ground water.

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).

Flucarbazone-sodium is not registered for use on any sites that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of the 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to flucarbazone-sodium and any other substances and flucarbazone-sodium 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 flucarbazone-sodium has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the 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/>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408 of the FFDCA provides that EPA shall apply an additional tenfold 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 data base on toxicity and exposure 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors in

calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity.* A summary of the prenatal and postnatal sensitivity assessment is discussed in Unit III.D. of the final rule published in the **Federal Register** of September 29, 2000 (65 FR 58363).

3. *Conclusion.* There is a complete toxicity data base for flucarbazone-sodium and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. A summary of the safety factor is discussed in Unit III.D. of the final rule published in the **Federal Register** of September 29, 2000 (65 FR 58363).

E. Aggregate Risks and Determination of Safety

1. *Acute risk.* A summary of the acute risk assessment is discussed in Unit III.E. of the final rule published in the **Federal Register** of September 29, 2000 (65 FR 58363).

2. *Chronic risk.* A summary of the chronic risk assessment is discussed in Unit III.E. of the final rule published in the **Federal Register** of September 29, 2000 (65 FR 58363).

3. *Short-term risk.* A summary of the short-term risk assessment is discussed in Unit III.E. of the final rule published in the **Federal Register** of September 29, 2000 (65 FR 58363).

4. *Intermediate-term risk.* A summary of the intermediate-term risk assessment is discussed in Unit III.E. of the final rule published in the **Federal Register** of September 29, 2000 (65 FR 58363).

5. *Aggregate cancer risk for U.S. population.* A summary of the aggregate cancer risk for U.S. population assessment is discussed in Unit III.E. of the final rule published in the **Federal Register** of September 29, 2000 (65 FR 58363).

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, and to infants and children from aggregate exposure to flucarbazone-sodium residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

The petitioner has proposed residue analytical methods for tolerance enforcement in wheat and livestock commodities. The analytical enforcement method for wheat employs accelerated solvent extraction, clean-up using solid phase extraction columns followed by detection and quantitation by liquid chromatography/tandem mass spectroscopy (LC/MS/MS). The

analytical method for livestock commodities is a common moiety method which measures residues of flucarbazone-sodium (MKH6562) in animal tissues and milk by extracting and hydrolyzing MKH 6562 and MKH 6562-related residues to MKH 6562 sulfonamide. Detection is achieved using negative ion electrospray mass spectrometry using deuterated MKH 6562 sulfonamide as an internal standard. Both methods have undergone successful validations by independent laboratories and have been accepted by the Agency. The analytical standards for these methods are available 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.

B. International Residue Limits

A default Maximum Residue Limit (MRL) of 0.01 ppm has been established in Canada for residues of flucarbazone-sodium and its N-desmethyl metabolite on wheat grain. This value is consistent with the tolerance being established in the United States on wheat grain. There are no Codex MRLs for this compound on wheat. Therefore, no compatibility issues exist with Codex in regard to the U.S. tolerances discussed in this review.

C. Conditions

None.

D. Comments

Public comments were received from B. Sachau who objected to the proposed tolerances because of the supposed harmful effects to the human genes. B. Sachau's comments contained no scientific data or evidence to rebut the Agency's conclusion that there is a reasonable certainty that no harm will result from aggregate exposure to flucarbazone-sodium including all anticipated dietary exposures and all other exposures for which there is reliable information. EPA has responded to B. Sachau's generalized comments on numerous previous occasions. 70 FR 1349, 1354 (January 7, 2005); 69 FR 63083, 63096 (October 29, 2004).

V. Conclusion

Therefore, the time-limited tolerance (expires November 30, 2006) is established for combined residues of flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-N-[2(trifluoromethoxy)phenyl] sulfonyl-1H-1,2,4-triazole 1-carboxamide, sodium salt and its N-desmethyl metabolite, in or on wheat, forage at 0.30 ppm; wheat, grain at 0.01 ppm; wheat, hay at 0.10 ppm; and wheat,

straw at 0.05 ppm; and combined residues of flucarbazone-sodium and its metabolites converted to 2-(trifluoromethoxy) benzene sulfonamide and calculated as flucarbazone-sodium in or on milk at 0.005 ppm; meat and meat byproducts (excluding liver) of cattle, goats, hogs, horses, and sheep at 0.01 ppm; and liver of cattle, goats, hogs, horses, and sheep at 1.5ppm.

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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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 sections 408 and 409 of the FFDCA. 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 ID number OPP-2005-0254 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 January 9, 2006.

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 issue(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 (1900L), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Suite 350, 1099 14th St., NW., Washington, DC 20005. 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) 564-6255.

2. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in **ADDRESSES**. Mail your copies, identified by docket ID number OPP-2005-0254, to: Public Information and Records Integrity Branch, Information Technology and Resources Management Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in **ADDRESSES**. 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 6.1/8.0 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 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 issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of the 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 due to its lack of significance, 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). 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 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); or 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 section 408(d) of the 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. The Agency hereby certifies that this rule will not have significant negative economic impact on a substantial number of small entities. 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 section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Congressional Review Act

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 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: October 28, 2005.

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 180.562 is revised to read as follows:

§ 180.562 Flucarbazone-sodium; tolerances for residues.

(a) *General.* (1) Time-limited tolerances are established for combined residues of the herbicide flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-N-[[2(trifluoromethoxy)phenyl]sulfonyl]-1H-1,2,4-triazole 1-carboxamide, sodium salt) and its N-desmethyl metabolite in or on the following food commodities:

Commodity	Parts per million	Expiration/Revocation Date
Wheat, forage	0.30	11/30/06
Wheat, grain	0.01	11/30/06
Wheat, hay	0.10	11/30/06
Wheat, straw	0.05	11/30/06

(2) Time-limited tolerances are established for combined residues of the herbicide flucarbazone-sodium, 4,5-dihydro-3-methoxy-4-methyl-5-oxo-N-[[2(trifluoromethoxy)phenyl]sulfonyl]-1H-1,2,4-triazole 1-carboxamide, sodium salt) and its metabolites converted to 2-(trifluoromethoxy)benzene sulfonamide and calculated as flucarbazone-sodium in or on the following food commodities:

Commodity	Parts per million	Expiration/Revocation Date
Cattle, liver	1.50	11/30/06
Cattle, meat	0.01	11/30/06
Cattle, meat by-products except liver.	0.01	11/30/06
Goat, liver	1.50	11/30/06
Goat, meat	0.01	11/30/06
Goat, meat by-products except liver.	0.01	11/30/06
Hog, liver	1.50	11/30/06

Commodity	Parts per million	Expiration/Revocation Date
Hog, meat	0.01	11/30/06
Hog, meat by-products except liver.	0.01	11/30/06
Horse, liver	1.50	11/30/06
Horse, meat	0.01	11/30/06
Horse, meat by-products except liver.	0.01	11/30/06
Milk	0.005	11/30/06
Sheep, liver	1.50	11/30/06
Sheep, meat	0.01	11/30/06
Sheep, meat by-products except liver.	0.01	11/30/06

(b) *Section 18 emergency exemptions.*

[Reserved]

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

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

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 20 and 68

[WT Docket 01-309, FCC 05-166]

Hearing Aid Compatibility Requirements for Wireless Carriers Offering Dual-Band GSM Handsets; Request for Waiver of Hearing Aid Compatibility Requirements for Cingular Wireless LLC

AGENCY: Federal Communications Commission.

ACTION: Final rule; petitions for waiver.

SUMMARY: The Federal Communications Commission (FCC or Commission) ruled that, until August 1, 2006, it will base the hearing aid compatibility compliance rating of dual-band GSM handsets on their operation in the 1900 MHz band only. Given its broad applicability, the Commission clarified that its action applies to all handset manufacturers, carriers and service providers that offer dual-band GSM wireless handsets that operate in both the 850 MHz and 1900 MHz bands. Consistent with this action, the Commission granted in part a request from Cingular Wireless LLC (Cingular). Finally, the Commission imposed conditions on Cingular and all other entities that elect to avail themselves of the temporary relief granted by the Memorandum Opinion and Order (MO&O).

DATES: Effective September 8, 2005.