Correction of Publication

■ Accordingly, 26 CFR Part 1 is corrected by making the following correcting amendment:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

§ 1.951–1 [Corrected]

■ 1. In § 1.951–1(a), the undesignated paragraph is designated as paragraph (a)(3).
■ 2. Section 1.951–1(e)(6), paragraph (ii) of *Example 5,* sixth sentence, the language ''common shareholders by reference to the'' is removed and the language ''common shares by reference to the'' is added in its place.
■ 3. Section 1.951–1(e)(6), paragraph (i) of *Example 7,* sixth sentence, the language ''income of United States shareholder under'' is removed and the language ''income of a United States shareholder under'' is added in its place.
■ 4. Section 1.951–1(e)(6), paragraph (i) of *Example 8,* third sentence, the language ''Foreign Individual N, a foreign individual.'' is removed and the language ''Individual N, a foreign individual.'' is added in its place.

Cynthia E. Grigsby,

Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 05–22260 Filed 11–8–05; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0280; FRL–7743–5]

2-Bromo-2-Nitro-1,3-Propanediol (Bronopol); Exemptions from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of 2-bromo-2-nitro-1,3-propanediol, which is also known as bronopol (Chemical Abstracts Service (CAS) Registry Number (Reg. No.) 52–51–7; 1,3-propanediol, 2-bromo-2-nitro- (9CI)), when used as an inert ingredient in-can preservative at 0.04% or less by weight of the total pesticide formulation when applied to growing crops or to raw agricultural commodities after harvest under 40 CFR 180.910, and when applied to animals under 40 CFR 180.930. BASF Corporation submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting the exemptions from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of 2-bromo-2-nitro-1,3-propanediol.

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 IX. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2005–0280. 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: Karen Angulo, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 306–0404; e-mail address: *angulo.karen@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 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/*.

II. Background and Statutory Findings

In the **Federal Register** of December 24, 2002 (67 FR 78459) (FRL–7277–5), 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 tolerance petition (PP 2E6475) by BASF Corporation, 3000 Continental Drive - North, Mount Olive, NJ 07828–1234. The petition requested that exemptions from the requirement of a tolerance be established for residues of 2-bromo-2-nitro-1,3-propanediol under 40 CFR 180.910 (growing crops or to raw agricultural commodities after harvest) and under 40 CFR 180.930 (animals) when it is used as an inert ingredient in-can preservative at 0.04% or less by weight of the total pesticide formulation. This notice included a summary of the petition prepared by the petitioner BASF.

For ease of reading in this document, 2-bromo-2-nitro-1,3-propanediol will be referred to as bronopol. The CAS Reg. No. of bronopol is 52–51–7 and the CAS name is 1,3-propanediol, 2-bromo-2-nitro- (9CI).

Comments were received from the United States Food and Drug Administration (FDA) in response to the notice of filing. FDA's comments pertained to the possible formation of n-

nitrosoamines, which are potentially carcinogenic compounds, when pesticide formulations containing bronopol also contain a nitrosatable amine. Rebuttals to FDA's comments were submitted from two companies. EPA acknowledges the concerns of FDA. The Agency evaluated the carcinogenic potential of bronopol and found there to be evidence of non-carcinogenicity for humans based on a lack of cancer effects in acceptable studies with two animal species, the rat and mouse. It should be noted that n-nitrosamines are also possibly formed by the action of bronopol with naturally occurring nitrosatable amines that are present in the diet of humans or are present as bodily constituents. In addition, Agency policy requires that pesticidal formulations be analyzed for nitrosamine content, and limits the allowable amount to 1 part per million (ppm). Pesticide formulations containing bronopol will be subject to this requirement.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(c)(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. Pursuant to section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C), which 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. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by bronopol are discussed in this unit.

A Reregistration Eligibility Decision (RED) was completed in 1995 for bronopol. The RED is available on the Agency's website at *www.epa.gov/pesticides/reregistration/status.htm*. The Agency is not aware of any more recent information that changes the risk findings of the RED, therefore, the toxicity findings of the RED are being used here for the evaluation of the petition. The following briefly summarizes the toxicity findings of the RED.

Bronopol is moderately toxic in acute oral toxicity studies with rats, with a lethal dose $(LD)_{50}$ of 307 milligrams/kilogram (mg/kg) for males and 342 mg/kg for females (Toxicity Category II) (Toxicity Category I has the highest toxicity and Category IV the lowest). In an acute inhalation study on the rat, bronopol was found to be slightly toxic with an lethal concentration $(LC)_{50}$ of > 5 mg/liter (L) (Toxicity Category III).

Results from an acute dermal toxicity study (rat) suggest that bronopol is highly toxic by the dermal route (Toxicity Category I), with an LC_{50} of 64 to 160 mg/kg. Slight to moderate erythema and slight to severe edema was noted, and the results of this study determined that bronopol was a slight to severe irritant (Toxicity Category II). In a study to determine dermal sensitization potential (ai >98.8%, guinea pigs), bronopol was determined not to be a skin sensitizer. In addition, bronopol has been shown to be a corrosive eye irritation (Toxicity Category I).

A 90-day oral toxicity study using rats indicated that bronopol is a severe gastrointestinal irritant. The no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) for systemic toxicity, for both sexes, are 20 mg/kg/day and 80 mg/kg/day, respectively. A similar study in beagle dogs indicated only treatment-related effects of increased liver and spleen weights in the high dose group. In a 90–day dermal toxicity study in rabbits, a NOAEL of 2 mg/kg/day and a LOAEL of 5 mg/kg/day were determined based on dermal irritation.

A chronic feeding/carcinogenicity study with rats resulted in high mortality, stomach lesions, and severe reduction in body weight gain. The unpalatability of bronopol reduced the water intake and urine output in a dose-related manner in all treated groups, which may have affected the results of the study. Based on the above findings, the systemic NOAEL and LOAEL for both sexes are 10 mg/kg/day and 40 mg/kg/day, respectively. In a chronic dermal/carcinogenicity study, male mice exhibited moderate reduction in body weight gain in the high dose group. Bronopol was not determined to be carcinogenic in either study. The EPA Office of Pesticide Program's Reference Dose (RfD)/Peer Review Committee evaluated the carcinogenic potential of bronopol and found there to be evidence of non-carcinogenicity for humans based on a lack of evidence of cancer effects in acceptable studies. In addition, bronopol was not mutagenic in four mutagenicity studies.

Developmental toxicity studies were conducted using rats and rabbits. The results showed marginal to no effects in the rat study and effects only at the high dose level in the rabbit study. In the study on rats, no developmental effects could be attributed to the administration of bronopol, and the highest dose of >80 mg/kg/day is considered to be the NOAEL for both maternal and developmental toxicity. In the study on rabbits, the maternal and developmental NOAEL and LOAEL are 40 mg/kg/day and 80 mg/kg/day (the highest dose group), respectively. The effects observed only in the 80 mg/kg/day group include decreased fetal body weight in both sexes (10%), and an increase in fetuses with major external/visceral and skeletal abnormalities (6.9% – 29.5%).

A reproductive toxicity study using rats reported effects at the mid- to high-dose levels, including increases in kidney, thyroid, and adrenal weights, decreases in liver and body weights. The NOAEL and LOAEL for systemic toxicity are 25 mg/kg/day and 70 mg/kg/day, respectively. Reproductive toxicity was observed only in the high-dose group as evidenced by a slight decrease in the female fertility index during the F^1 mating. The NOAEL and LOAEL for reproductive toxicity are 70 mg/kg/day and 200 mg/kg/day, respectively.

For metabolism, the results from four studies show that bronopol administered orally was rapidly absorbed and rapidly excreted by the rats of both sexes, with urine being the major route of excretion.

For ecological risks, bronopol is practically nontoxic to slightly toxic to birds; slightly to moderately toxic to freshwater fish and terrestrial invertebrates; moderately to highly toxic to estuarine/marine invertebrates; and slightly toxic to estuarine/marine fish. Based on bronopol's low octanol/water ratio and high solubility in water, it is not expected to bioaccumulate. Accumulation reportedly does not occur in tested mammals and metabolism is also reported to be rapid and complete.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food.* A dietary exposure analysis for the inert ingredient use of bronopol was conducted using the generic screening model for estimating inert ingredient dietary exposure. The dietary assessment is unrefined and extremely conservative in nature because the screening model assumes that the inert ingredient is used on all commodities, and that 100 percent of crops are treated with the inert ingredient. Further, the screening model assumes residues will be present for every consumed commodity (including meat, milk, poultry and eggs) that is included in the Dietary Exposure Evaluation Model (DEEM™). The screening model does not specifically include an application rate input, rather it is based on tolerances for pesticide active ingredients that are typically found in agricultural food use products at concentrations greater than 50%. Therefore, to more accurately estimate residues resulting from bronopol's lower application rate limitation of 0.04% (the tolerance exemption limitation proposed by the petitioner), the results from the screening model were adjusted by a factor of 1250 (50% ÷ 0.04%).

The results for acute and chronic dietary exposure for all population subgroups are considered to be not of concern. The highest dietary exposure estimate was for children (1–2 years), where the acute dietary risk was estimated to be 0.0007512 mg/kg/day and 0.19% of the acute Population Adjusted Dose (aPAD), and where the chronic dietary risk was estimated to be 0.0003376 mg/kg/day and 0.34% of the chronic Population Adjusted Dose (cPAD). These are well-below any dose level at which an adverse effect is expected from exposure to bronopol when it is used as an inert ingredient in-can preservative at 0.04% or less by weight of the total pesticide formulation.

2. *Drinking water exposure.* Bronopol is expected to have a relatively short half-life upon release into the environment. Bronopol is not anticipated to be present in drinking waterwhen used as an inert ingredient in-can preservative at 0.04% or less by weight of the total pesticide formulation.

B. Other Non-Occupational Exposure

Pesticide products containing bronopol as an in-can preservative may be used in residential settings. Considering the small amount of bronopol that will be used in pesticide formulations (no more than 0.04% by weight), inhalation and dermal exposures of concern are not anticipated from residential uses.

V. Cumulative Effects

Section 408 (b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance or tolerance exemption, the Agency consider ''available information'' concerning the cumulative effects of a particular chemical's residues and ''other substances that have a common mechanism of toxicity.'' Unlike other pesticide chemicals 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 bronopol. For the purposes of this tolerance action, therefore, EPA has not assumed that bronopol 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/*.

VI. Determination of Safety for U.S. Population, Infants and Children

Based on the information in this preamble and on the modeled exposure levels that are well-below any dose level where adverse effects are expected, EPA concludes that there is a reasonable certainty of no harm to any population subgroup from aggregate exposure to residues of bronopol. Accordingly, EPA finds that exempting bronopol from the requirement of a tolerance will be safe for the general population including infants and children.

VII. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), ''may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect . . . .'' EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing bronopol for endocrine effects may be required.

B. Analytical Method(s)

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Existing Tolerances

There are no existing tolerances or tolerance exemptions for bronopol.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for bronopol, nor have any CODEX maximum residue levels been established for any food crops at this time.

VIII. Conclusions

There is sufficient information on bronopol to conduct this assessment. Bronopol has been shown to have significant dermal acute toxicity, and eye and gastrointestinal irritation, but it is not a skin sensitizer. Study results indicate that bronopol has moderate acute and chronic oral toxicity, and slight acute inhalation toxicity. It is not considered to be carcinogenic. For developmental effects, marginal to no effects were reported in the rat study and effects were observed only at the high dose level in the rabbit study. Reproductive toxicity was observed only in the high-dose group as evidenced by a slight decrease in the female fertility index during the F^1 mating.

Although, bronopol does have toxicity, the small amount that will be permitted for use in pesticide

formulations (0.04% or less by weight) is expected to result in no effects of concern for all endpoints, including residential exposures. The results from a conservative dietary screening model show that acute and chronic dietary exposure for all population subgroups are considered to be not of concern. The highest dietary exposure estimates from the conservative screening model are well-below any dose level at which an adverse effect is expected. Bronopol is expected to have a relatively short half-life upon release into the environment, therefore, its contribution to drinking water is not expected.

Considering the information above, there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to the pesticide chemical (bronopol) residue, including all anticipated dietary exposures and all other exposures for which there is reliable information. Exemptions from the requirement of a tolerance are established for 2-bromo-2-nitro-1,3-propanediol; (CAS Reg. No. 52–51–7;) when used as an inert ingredient in-can preservative at 0.04% or less by weight of the total pesticide formulation when applied to growing crops or to raw agricultural commodities after harvest under 40 CFR 180.910, and when applied to animals under 40 CFR 180.930.

IX. 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 ID number OPP–2005–0280 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 VIII.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–2005–0280, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. 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).

X. Statutory and Executive Order Reviews

This final rule establishes an exemption from the tolerance requirement 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). 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 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
* * *	* *	* *

* * * * *

[FR Doc. 05–22255 Filed 11–8–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0254; FRL–7740–8]

Flucarbazone-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 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 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 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. 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