51735, October 4, 1993), this action is not a ''significant regulatory action'' and is, therefore, not subject to review by the Office of Management and Budget (''OMB''). This action is not a ''major rule'' as defined by 5 U.S.C. 804(2). The technical correction does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Because EPA has made a ''good cause'' finding that this action is not subject to notice and comment requirements under the APA or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), or to sections 202 and 205 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). In addition, this action does not significantly or uniquely affect small governments or impose a significant intergovernmental mandate, as described in sections 203 and 204 of the UMRA.

The correction does not have substantial direct effects on the States, or 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, Federalism (64 FR 43255, August 10, 1999).

Today's action also does not significantly or uniquely affect the communities of tribal governments, as specified by Executive Order 13175, Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 9, 2000). The technical correction also is not subject to Executive Order 13045, Protection of Children from Environmental Health and Safety Risks (62 FR 19885, April 23, 1997) because it is not economically significant.

The correction is not subject to Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

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 rule without providing notice and an opportunity for public comment. We have determined that there is good cause for making today's action final without prior proposal and opportunity for comment because the change to the rule corrects an error, is noncontroversial, and is consistent with the technical basis of the rule. Thus, notice and public procedure are unnecessary. We find that this constitutes good cause under 5 U.S.C. 553(b)(B) (*see also* the final sentence of section 307(d)(1) of the CAA, 42 U.S.C. 7607(d)(1), indicating that the good cause provisions of the APA continue to apply to rulemaking under section 307(d) of the Clean Air Act (CAA).

Section 553(d)(3) allows an agency, upon a finding of good cause, to make a rule effective immediately. Because today's changes relieve an unintended restriction, we find good cause to make these technical corrections effective immediately.

The correction action does not involve changes to the technical standards related to test methods or monitoring methods; thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272) do not apply.

The correction also does not involve special consideration of environmental justice-related issues as required by Executive Order 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by SBREFA 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 U.S. The EPA will submit a report containing this final action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the U.S. prior to publication of today's action in the **Federal Register**. Today's action is not a ''major rule'' as defined by 5 U.S.C. 804(2). The final rule will be effective on June 24, 2005.

List of Subjects in 40 CFR Part 63

Environmental protection, Administrative practice and procedure, Air pollution control, Hazardous substances, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: June 16, 2005.

Jeffrey R. Holmstead,

Assistant Administrator for Air and Radiation.

■ For the reasons set out in the preamble, title 40, chapter I, part 63 of the Code of Federal Regulations is amended as follows:

PART 63—[AMENDED]

■ 1. The authority citation for part 63 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart UUUU—[Amended]

■ 2. Section 63.5610 is amended by revising the following definitions in paragraph (g) to read as follows:

§ 63.5610 What definitions apply to this subpart?

* * * * *

(g) * * *

Cellulose ether process change means a change to the cellulose ether process that occurred no earlier than January 1991 that allows the recovery of organic HAP, reduction in organic HAP usage, or reduction in organic HAP leaving the reactor. Includes extended cookout.

* * * * *

Viscose process change means a change to the viscose process that occurred no earlier than January 1991 that allows either the recovery of carbon disulfide or a reduction in carbon disulfide usage in the process.

* * * * *

[FR Doc. 05–12576 Filed 6–23–05; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0155; FRL–7720–2]

Trifloxystrobin; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for combined residues of trifloxystrobin in or on soybean, forage; soybean, hay; and soybean, seed. 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 soybeans. This regulation establishes a maximum permissible level for residues of trifloxystrobin in this food commodity. The tolerances will expire and are revoked on December 31, 2009.

DATES: This regulation is effective June 24, 2005. Objections and requests for hearings must be received on or before August 23, 2005.

ADDRESSES: To submit a written objection or hearing request follow the

detailed instructions as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION**. EPA has established a docket for this action under docket identification (ID) number OPP–2005–0155. 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., 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 electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Room 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: Carmen Rodia, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 306–0327; fax number: (703) 308–5433; e-mail address: *rodia.carmen@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 on E-CFR Beta Site Two at *http://www.gpoaccess.gov/ecfr/*.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with sections 408(e) and 408(l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, is establishing a tolerance for combined residues of the fungicide trifloxystrobin, (benzeneacetic acid, (E,E)-[alpha]-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl)phenyl]ethylidene] amino]oxy]methyl]-,methylester) and the free form of its acid metabolite CGA–321113 ((E,E)-methoxyimino-[2-[1-(3-trifluoromethylphenyl) ethylideneaminooxymethyl]-phenyl] acetic acid) in or on soybean, forage at 4.0 parts per million (ppm); soybean, hay at 6.5 ppm; and soybean, seed at 0.04 ppm. These tolerances will expire and are revoked on December 31, 2009. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations (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 FIFRA section 18 related 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.'' This provision was not amended by the Food Quality Protection Act of 1996 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Trifloxystrobin on Soybeans and FFDCA Tolerances

Multiple States throughout the United States have petitioned the Agency requesting an emergency exemption for use of trifloxystrobin to control soybean rust under the provisions of section 18 of FIFRA. The soybean rust pathogen (*Phakopsora pachyrhizi*) was recently identified in the continental United States. Soybean rust has been designated as a biosecurity threat by action of the U.S. Congress and; therefore, it is important that control measures be available to soybean growers in the United States. Accordingly, EPA has expedited review under section 18 of FIFRA to authorize the use of trifloxystrobin on soybeans for control of soybean rust for requesting states in the United States, having concluded that emergency conditions exist regarding this chemical use.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of trifloxystrobin in or on soybeans. 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 section 18 of FIFRA. 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 these tolerances will expire and are revoked on December 13, 2009, under section 408(l)(5) of FFDCA, residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on poultry, soybeans, or swine after that date will not be unlawful, provided the pesticide is applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these tolerances at the time of that application. EPA will take action to revoke these tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these tolerances are being approved under emergency conditions, EPA has not made any decisions about whether trifloxystrobin meets EPA's registration requirements for use on soybeans or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that these tolerances serve as a basis for registration of trifloxystrobin by a State for special local needs under section 24(c) of FIFRA. Nor do these tolerances serve as the basis for any State that has not been specifically authorized by EPA to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 of FIFRA as identified in 40 CFR part 166. For additional information regarding the emergency exemption for trifloxystrobin, contact the Agency's Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

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 FFDCA and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

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. EPA has sufficient data to assess the hazards of trifloxystrobin and to make a determination on aggregate exposure, consistent with section 408(b)(2) of FFDCA, for a time-limited tolerance for combined residues of trifloxystrobin in or on soybean, forage at 4.0 ppm; soybean, hay at 6.5 ppm; and soybean, seed at 0.04 ppm. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Endpoints

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 endpoint. 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. An UF of 100 is routinely used, 10x to account for interspecies differences and 10x for intra species differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns over risk to children's health, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic population adjusted dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor (SF).

For non-dietary risk assessments (other than cancer) the UF is used to determine the level of concern (LOC). For example, when 100 is the appropriate UF (10x to account for interspecies differences and 10x for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer} = point of departure/exposures) is calculated. A summary of the toxicological endpoints for trifloxystrobin used for human risk assessment is shown in Table 1 of this unit:

TABLE 1.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR TRIFLOXYSTROBIN FOR USE IN HUMAN RISK ASSESSMENT

Exposure/scenario	Dose used in risk assessment, UF	FQPA SF* and level of concern for risk assessment	Study and toxicological effects
Acute dietary (Females 13–49 years of age)	NOAEL = 250 milligram/kilogram/day (mg/kg/day) UF = 100 Acute RfD = 2.5 mg/kg/day	FQPA SF = 1x aPAD = acute RfD/FQPA SF = 2.5 mg/kg/day	Developmental toxicity—rat LOAEL = 500 mg/kg/day based on increased fetal skeletal anomalies.
Acute Dietary (General U.S. population, including infants and children).	There were no appropriate toxicological effects attributable to a single exposure (dose) observed in oral toxicity studies including maternal effects in developmental studies in rats and rabbits. Therefore, a dose and endpoint were not identified for this risk assessment.		
Chronic dietary (All populations)	Parental NOAEL = 3.8 mg/kg/day UF = 100 Chronic RfD = 0.038 mg/kg/day	FQPA SF = 1x cPAD = chronic RfD/FQPA SF = 0.038 mg/kg/day	2-Generation reproduction study—rat LOAEL = 55.3 mg/kg/day based on decreases in body weight, body weight gains, reduced food consumption, and histopathological lesions in the liver, kidneys, and spleen.
Short- (1 to 30 days) and intermediate-term (1–6 months) Oral	Offspring NOAEL = 3.8 mg/kg/day	LOC for MOE = 100 (residential, includes FQPA SF)	2-Generation reproduction study—rat LOAEL = 55.3 mg/kg/day based on reduced pup body weights during lactation.
Short- (1 to 30 days) and intermediate-term (1–6 months) Dermal	Dermal study NOAEL = 100 mg/kg/day	LOC for MOE = 100 (occupational) LOC for MOE = 100 (residential, includes FQPA SF)	28-Day dermal toxicity study—rat LOAEL = 1,000 mg/kg/day based on increases in mean absolute and relative liver and kidney weights.
Long-term (> 6 months) Dermal	Oral study NOAEL = 3.8 mg/kg/day (dermal absorption rate = 33%)	LOC for MOE = 100 (occupational) LOC for MOE = 100 (residential, includes FQPA SF)	2-Generation reproduction study—rat LOAEL = 55.3 mg/kg/day based on decreases in body weight, body weight gains, reduced food consumption, and histopathological lesions in the liver, kidneys, and spleen.
Short- (1 to 30 days), intermediate- (1–6 months), and long-term (> 6 months) Inhalation	Oral study NOAEL = 3.8 mg/kg/day (inhalation absorption rate = 100%)	LOC for MOE = 100 (occupational) LOC for MOE = 100 (residential, includes FQPA SF)	2-Generation reproduction study—rat LOAEL = 55.3 mg/kg/day based on decreases in body weight, body weight gains, reduced food consumption, and histopathological lesions in the liver, kidneys, and spleen.
Cancer (Oral, dermal, and inhalation)	Classification: "Not Likely Human Carcinogen," based on the lack of evidence of carcinogenicity in mouse and rat cancer studies.		

*The reference to the FQPA SF refers to any additional SF retained due to concerns unique to FQPA.

B. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.555) for the combined residues of trifloxystrobin, in or on a variety of raw agricultural commodities (RACs). Specifically, tolerances for almonds, barley, carrots, celery, citrus, field corn, fruiting vegetables, hops, pecans, potatoes, rice, stone fruits, sugar beets, and wheat. Risk assessments were conducted by EPA to assess dietary exposures from trifloxystrobin in food as follows:

i. *Acute exposure.* Acute dietary (food only) exposure assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID™), Version 1.3, which incorporates the individual food consumption data as reported by respondents in the United States Department of Agriculture (USDA) 1994–1996 and 1998 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The acute dietary (food only) exposure analysis for trifloxystrobin is unrefined, assuming 100% crop treated and tolerance level residues. No additional data were used to refine the analysis. The acute dietary endpoint is applicable to the population subgroup females, 13–49 years only. An acute dietary endpoint for the general U.S. population, including infants and children, was not identified. The estimated dietary (food only) exposure for females, 13–49 years old occupies less than 1% of the aPAD and does not exceed EPA's level of concern.

ii. *Chronic exposure.* In conducting this chronic dietary (food only) exposure assessment, EPA used the DEEM-FCID™ software, incorporating the individual food consumption data as reported by respondents in the USDA 1994–1996 and 1998 CSFII and accumulated exposure to the chemical for each commodity. The chronic dietary (food only) exposure analysis for trifloxystrobin is unrefined, assuming 100% crop treated and tolerance level residues. The chronic dietary endpoint applies to all population subgroups, including infants and children. Risk

estimates for all population subgroups are below EPA's level of concern (100% of the cPAD).

iii. *Cancer*. EPA's previous reviews of data (May 1999) related to trifloxystrobin have determined that trifloxystrobin should be classified as a ''Not Likely Human Carcinogen.'' Accordingly, no additional cancer risk assessment was performed for trifloxystrobin.

iv. *Anticipated residue and percent crop treated (PCT) information*. Established and recommended tolerances were used in the acute and chronic dietary (food only) exposure assessments for trifloxystrobin. The metabolite L7a (taurine conjugate of trifloxystrobin) was also included in the exposure assessment for liver, based on the amount found in the ruminant metabolism study. EPA did not apply PCT data for this assessment. DEEM-FCID™ default concentration factors were used except for tomato juice, puree, paste, and catsup. Processing data show no concentration in these fractions.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for trifloxystrobin 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 trifloxystrobin.

The Agency uses the First Index Reservoir Screening Tool (FIRST) or the Pesticide Root Zone/Exposure Analysis modeling system (PRZM/EXAMS) to produce estimates of pesticide concentrations in an index reservoir. The Screening Concentration in Ground Water modeling system (SCI-GROW) is used to predict pesticide concentrations in shallow ground water. For a screening-level assessment for surface water, EPA will generally use FIRST (a tier 2 model) before using PRZM/EXAMS (a tier 2 model). The FIRST model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. While both FIRST and PRZM/EXAMS incorporate an index reservoir environment, the PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to trifloxystrobin, they are further discussed in Unit IV.D., aggregate risk.

Based on the PRZM/EXAMS and SCI-GROW models, the EECs of trifloxystrobin for acute exposures are estimated to be 48 parts per billion (ppb) for surface water and 3.4 ppb for ground water. The EECs for chronic exposures are estimated to be 140 ppb for surface water and 3.4 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).

Trifloxystrobin is currently registered for use in turf grass and ornamentals. No new residential uses are proposed in this action. Because FQPA requires consideration of aggregate exposure to all likely non-occupational uses, this assessment uses non-occupational post-application contact with trifloxystrobin following potential use on turf grass as the most common and worst case contributor to such exposures. The current registered use of trifloxystrobin on turf grass and ornamentals may only be applied by a Certified Pest Control Operator (PCO); therefore, an assessment of dermal or inhalation exposure for residential handlers is not required and was not performed.

EPA calculated MOEs for exposure scenarios involving potential residential exposure resulting from the currently registered uses of the chemical. The lowest MOE was 800 for children resulting from direct dermal contact with treated lawns (this represents the exposure scenario with the highest exposure; conversely, the adult dermal MOE was 1,300). The highest MOE for children was 220,000 from ingestion of soil from treated lawns. All calculated non-occupational post-application MOEs are greater than 100 on the day of application and; therefore, did not exceed EPA's level of concern.

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.''

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 trifloxystrobin and any other substances and trifloxystrobin does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action; therefore, EPA has not assumed that trifloxystrobin has a common mechanism of toxicity with other substances. For information regarding EPA'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 OPP 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 of FFDCA provides that EPA shall apply an additional ten-fold margin of safety for infants and children in the case of threshold effects to account for prenatal and post-natal 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 an MOE analysis or through using UFs in calculating a dose level that poses no appreciable risk to humans.

2. *Discussion*. There is no indication of an increased susceptibility of rat or rabbit fetuses/pups to pre- and/or post-natal exposure to trifloxystrobin. In the developmental and reproduction

toxicity studies, effects in the fetuses/pups were observed only at or above treatment levels, which resulted in evidence of parental toxicity. As a result, the Agency determined that a developmental neurotoxicity (DNT) study in rats is not required.

The acute and chronic dietary (food only) exposure assessments utilize existing and proposed tolerance level residues and 100% crop treated information for all commodities. By using these screening-level assessments, actual exposures/risks will not be underestimated. Additionally, the exposure assessments will not underestimate the potential dietary (food and drinking water) or non-dietary exposures for infants and children from the use of trifloxystrobin.

The dietary drinking water assessment utilizes water concentration values generated by model and associated modeling parameters, which are designed to provide conservative, health protective, high-end estimates of water concentrations, which are not likely to be exceeded. The residential post-application assessment is based upon the residential standard operating procedures (SOPs) and is based upon surrogate study data. These data are reliable and are not expected to underestimate risk to adults or children. The residential SOPs are based upon reasonable ''worst-case'' assumptions and are not expected to underestimate risk.

3. *Conclusion*. EPA has evaluated the potential for increased susceptibility of infants and children from exposure to trifloxystrobin. There is a complete toxicity data base for trifloxystrobin and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. The Agency has concluded that there are no residual uncertainties for pre- and/or post-natal toxicity. Further, based on existing hazard data and the quality of exposure data for trifloxystrobin, EPA has determined that traditional 10x safety factors are adequately protective for all populations, and the special FQPA SF need not be applied (e.g., it has been reduced from 10x to 1x).

D. Aggregate Risks and Determination of Safety

1. *General discussion*. To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water [e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + chronic non-dietary, non-occupational exposure)]. This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the EPA's Office of Water are used to calculate DWLOCs: 2 liter (L)/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to trifloxystrobin in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of trifloxystrobin on drinking water as a part of the aggregate risk assessment process.

2. *Summary of aggregate risk analysis*. Acute and chronic aggregate risk estimates were calculated in this risk assessment. Acute aggregate risk was calculated by comparing acute DWLOCs to potential drinking water exposure to trifloxystrobin. Similarly, chronic aggregate risk was calculated by comparing chronic DWLOCs to potential drinking water exposure. The surface and ground water EECs were used to compare against back-calculated DWLOCs for aggregate risk assessments.

Short-term risk is based on exposures occurring over 1 to 30 days. Short-term aggregate risk was calculated by combining risk estimates for high-end residential oral and/or dermal exposures with chronic food and drinking water risks. Intermediate-term exposure (1 to 6 months) to the parent trifloxystrobin is not expected to occur in residential settings due to its short half-life (about 2 days based on soil and aquatic metabolism studies). Therefore, an intermediate-term aggregate risk assessment was not performed. Chronic non-dietary aggregate risk was not calculated as chronic dermal and oral exposures (from residential treatment) are not expected. Cancer aggregate risk was not calculated because trifloxystrobin has been classified as a ''not likely human carcinogen.''

Acute, short-term and chronic aggregate risk estimates resulting from aggregate exposure to trifloxystrobin in food and drinking water were assessed, and are below EPA's level of concern.

3. *Acute risk*. The acute aggregate risk assessment takes into account exposure estimates from dietary consumption of trifloxystrobin from food and drinking water sources. Acute aggregate risk was not calculated for the general U.S. population (including infants and children or other population subgroups) as hazard endpoints have not been identified for those groups.

The acute risk estimate for females, 13–49 years, resulting from aggregate exposure to trifloxystrobin in food and drinking water, is below EPA's level of concern. DWLOCs were calculated for females 13–49 years, the only subgroup to which the acute dietary endpoint applies. Surface and ground water EECs were used to compare against back-calculated DWLOCs for aggregate risk assessments. To calculate the DWLOC for acute exposure relative to an acute toxicity endpoint, the acute dietary food exposure (from DEEM-FCID™) was subtracted from the aPAD to obtain the acceptable acute exposure to trifloxystrobin in drinking water.

The DWLOC was 75,000 ppb for females, 13–49 years, a value that is well above the EECs for drinking water. Therefore, acute aggregate risk is below EPA's level of concern. EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in Table 2 of this unit:

TABLE 2.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO TRIFLOXYSTROBIN

Population subgroup	aPAD (mg/kg/day)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
Females 13–49 years	2.5	< 1	92 (turf) 48 (rice)	3.4	75,000

4. *Chronic risk*. For the chronic aggregate risk scenario, potential food and drinking water exposures were analyzed. Chronic exposure in residential settings is not expected. The surface and ground water EECs were used to compare against back-calculated DWLOCs for aggregate risk assessments. To calculate DWLOCs for chronic exposure relative to an chronic toxicity endpoint, the chronic dietary food exposure (from DEEM-FCID™) was subtracted from the cPAD to obtain the acceptable chronic exposure to trifloxystrobin in drinking water.

DWLOCs were calculated for the general U.S. population, children aged 1–2 years, females aged 13–49 years and adults aged 50 years and older. DWLOCs ranged from 170 ppb for children to 1,200 ppb for adults aged 50 years and older. These values are above the EECs for drinking water. Therefore, chronic aggregate risk is below EPA's level of concern. EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in Table 3 of this unit:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO TRIFLOXYSTROBIN

Population subgroup	cPAD (mg/kg/day)	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
General U.S. population	0.038	15	140 (rice) 50 (turf)	3.4	1,100
Children 1–2 years		54			170

5. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Though residential exposure could occur with the use of trifloxystrobin, the potential short-term exposures were not aggregated with chronic dietary food and water exposures because the toxic effects are different. Different endpoints have been identified for short-term incidental oral and dermal risk assessment (the basis for the oral endpoint is reduced pup body weights and the dermal endpoint is based on increases in liver and kidney weights). Therefore, based on the best available data and current policies, potential risks do not exceed EPA's level of concern.

A short-term risk assessment was not required for adults, because no incidental oral exposure is expected for adults. A short-term risk assessment was performed for infants and children because of residential post-application oral exposure scenarios. Incidental oral exposure for toddlers is assumed to include hand-to-mouth exposure, object-to-mouth exposure and exposure through incidental ingestion of soil.

DWLOCs were calculated for the general U.S. population, children aged 1–2 years, females aged 13–49 years and adults 50 years and older. DWLOCs ranged from 130 ppb for children to 1,200 ppb for adults aged 50 years and older. Although the surface water EEC for rice (140 ppb) exceeds the DWLOC for children (130 ppb), EPA does not believe this is a cause for concern, because the surface water estimate for rice is considered to be a gross overestimate of the true value found in the environment. EPA's careful analysis indicates that the turf grass estimate (50 ppb) is a more realistic estimate of drinking water residues. Thus, EPA does not consider short-term aggregate risk for children to exceed the Agency's level of concern, as shown in Table 4 of this unit:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR SHORT-TERM EXPOSURE TO TRIFLOXYSTROBIN

Population subgroup	Aggregate MOE (Food + Residential)	Aggregate Level of Concern (LOC)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Short-Term DWLOC (ppb)
General U.S. population	690	100	140 (rice) 50 (turf)	3.4	1,100
All infants < 1 year	190				180
Children 1–2 years	150				130
Females 13–49 years	970				1,000
Adults > 50 years	950				1,200

6. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account non-dietary, non-occupational exposure plus chronic exposure to food and water (considered to be a background exposure level). An intermediate-term aggregate risk assessment (1 to 6 months of exposure to trifloxystrobin residues from food, drinking water, and residential pesticide uses) is not expected to occur based on the short soil half-life of trifloxystrobin (about 2 days). Therefore, EPA did not perform an intermediate-term aggregate risk assessment.

7. *Aggregate cancer risk for U.S. population*. EPA has concluded that trifloxystrobin should be classified as a ''Not Likely Human Carcinogen.'' Due to the classification, an aggregate cancer risk assessment was not performed.

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

V. Other Considerations

A. Analytical Enforcement Methodology

EPA has completed a method validation trial of AG–659A on apples, cow liver, cow milk, grapes, peanut hay, peanuts, raisins, summer squash, and wet apple pomace and concluded that AG–659A is suitable for enforcement of trifloxystrobin and the free form of its acid metabolite in plant and livestock commodities. The analytical methods, AG–659A or AG–659A/REM 177.04, are adequate for collecting data for residues of trifloxystrobin and its acid metabolite CGA–321113 in or on soybeans.

The regulable residue was tested in accordance with the Pesticide Analytical Manual (PAM), Volume I, Appendix II. Trifloxystrobin gave adequate responses through protocol C, and was completely recovered from fortified apple samples when analyzed through protocols D and E. Acid metabolite CGA–321113 was recoverable through protocol B and residues from apples fortified with CGA–321113 were completely recovered through Section 402 E2/C1 (extraction with methylene chloride). The enforcement method has been forwarded to the Food and Drug Administration (FDA) for inclusion in the PAM II.

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

B. International Residue Limits

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

C. Conditions

There are no conditions for registration placed on these time-limited tolerances.

VI. Conclusion

Therefore, tolerances are established for combined residues of trifloxystrobin, (benzeneacetic acid, (E,E)-[alpha]-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl) phenyl]ethylidene]amino]oxy]methyl]-,methylester) and the free form of its acid metabolite CGA–321113 ((E,E)-methoxyimino-[2-[1-(3-trifluoromethylphenyl) ethylideneaminooxymethyl]-phenyl]acetic acid) in or on soybean, forage at 4.0 ppm, soybean, hay at 6.5 ppm; and soybean, seed at 0.04 ppm.

VII. Objections and Hearing Requests

Under section 408(g) of FFDCA, as amended by 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 FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of 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) of FFDCA, as was provided in the old sections 408 and 409 of 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–2005–0155 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 August 23, 2005.

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 part 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR part 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 VII.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 the docket ID number OPP–2005–0155, 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 20460–0001. 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 issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR part 178.32).

VIII. Statutory and Executive Order Reviews

This final rule establishes a time-limited tolerance under section 408 of FFDCA. 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 FIFRA section 18 exemption under section 408 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. 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.

IX. 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: June 17, 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 180.555 is amended by adding text to paragraph (b) to read as follows:

§ 180.555 Trifloxystrobin; tolerances for residues.

* * * * *

(b) * * * Time-limited tolerances are established for combined residues of the fungicide trifloxystrobin, (benzeneacetic acid, (E,E)-[alpha]-(methoxyimino)-2-[[[[1-[3-(trifluoromethyl)phenyl] ethylidene]amino]oxy]methyl]-,methylester) and the free form of its acid metabolite CGA–321113 ((E,E)-methoxyimino-[2-[1-(3-trifluoromethylphenyl) ethylideneaminooxymethyl]-phenyl]acetic acid) in connection with the use of the pesticide under FIFRA section 18 emergency exemptions granted by EPA. The tolerances will expire and are revoked on the date specified in the table in this unit.

Commodity	Parts per million	Expiration/ revocation date
Soybean, forage	4.0	12/31/09
Soybean, hay	6.5	12/31/09
Soybean, seed ..	0.04	12/31/09

* * * * *

[FR Doc. 05–12447 Filed 6–23–05; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 416

[CMS–1478–CN]

RIN 0938–AN23

Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Correction of interim final rule with comment period.

SUMMARY: This document corrects technical errors that appeared in the interim final rule with comment period published in the **Federal Register** on May 4, 2005 entitled ''Medicare Program; Update of Ambulatory Surgical Center List of Covered Procedures.''

DATES: Effective July 1, 2005.

FOR FURTHER INFORMATION CONTACT: Dana Burley, (410) 786–0378.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc. 05–8875 of May 4, 2005 (70 FR 23690), there were several technical errors that are identified and corrected in the Correction of Errors section below. The provisions in this correction notice are effective as if they had been included in the document published May 4, 2005. Accordingly, the corrections are effective July 1, 2005.

II. Correction of Errors

In FR Doc. 05–8875 of May 4, 2005 (70 FR 23690), make the following corrections:

On page 23690, in the first column, in the ''Effective Date'' section, the effective date of July 5, 2005 is an error. Remove ''July 5, 2005'' and add in its place ''July 1, 2005.''

On page 23710, in section IV, Waiver of Proposed Rulemaking, in column 2, in lines 1 and 8, remove ''July 5, 2005'' and add in its place ''July 1, 2005.''

On page 23752, there are three CPT codes erroneously included in the list of ASC covered procedures. These CPT codes are not on the ASC list because they were discontinued for 2005. Therefore on page 23752, remove CPT codes 50559, Renal endoscopy/ radiotracer, 50959, Ureter endoscopy and tracer, and 50978, Ureter endoscopy and tracer.

The final error is one of omission. One public comment and the response were not included in the May 4, 2005 interim final rule. That comment and response are as follows:

Comment: We received one comment requesting that we add CPT code 55873, Cryosurgical ablation of the prostate, to the ASC list. The commenter also asked that we assign the procedure to a newly created payment group with a higher rate than current payment group 9. The commenter believes that the procedure meets the criteria for inclusion on the ASC list and that adding it to the list will permit reasonable site-of-service flexibility for physicians.

Response: We agree with the commenter that the procedure meets the criteria for inclusion on the ASC list. Utilization data show that the service is performed most of the time in the hospital outpatient setting and our medical staff agreed that it is appropriate for the ASC setting. We cannot however, create a new, higher payment level for this procedure because we do not have data upon which to base new payment rates and because the Congress has relieved us of performing a new survey and has, instead, mandated development of a new payment system. Therefore, we assigned the procedure to Group 9, the highest paying of the existing payment groups under which payments for ASC facility services are currently made.

III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of a notice take effect. We can waive this procedure, however, if we find good cause that notice and comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporate a statement of the finding and the reasons for it into the notice issued.

We find it unnecessary to undertake notice and comment rulemaking because this notice merely provides technical corrections to the regulations. Therefore, we find good cause to waive notice and comment procedures.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 20, 2005.

Ann C. Agnew,

Executive Secretary to the Department.

[FR Doc. 05–12522 Filed 6–23–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 050125016–5097–02; I.D. 061605B]

Pacific Halibut Fisheries; Oregon Sport Fisheries

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; inseason adjustment; request for comments.

SUMMARY: NMFS announces changes to the regulations for the Area 2A sport halibut fisheries off the central coast of Oregon. This action would clarify the halibut regulations for the central Oregon coast sport fishery sub-area to specify that halibut may be onboard recreational fishing vessels trolling for salmon within the Oregon yelloweye rockfish conservation area (YRCA). The purpose of this action is to allow recreational salmon vessels to retain halibut caught legally outside of the YRCA while those vessels are legally fishing for salmon within the YRCA.

DATES: Effective June 24, 2005, through the 2006 annual management measures which will publish in a later **Federal Register** document. Comments must be received no later than 5 p.m., local time, on July 11, 2005.

ADDRESSES: You may submit comments, identified by I.D. 061605B by any of the following methods:

- E-mail: *Halibut2005inseason.nwr@noaa.gov*: Include 061605B in the subject line of the message.
- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Fax: 206–526–6736, Attn: Yvonne deReynier
- Mail: D. Robert Lohn, Administrator, Northwest Region, NMFS, 7600 Sand Point Way NE, Seattle, WA 98115–0070, Attn: Yvonne deReynier.