scene Coast Guard patrol personnel include commissioned, warrant and petty officers of the Coast Guard on board Coast Guard, Coast Guard Auxiliary, local, state, and federal law enforcement vessels.

(3) No person may enter the waters within the boundaries of the security zone unless previously authorized by the Captain of the Port, Portland, Maine or his authorized patrol representative.

Dated: December 7, 2001.

M. P. O'Malley,

Commander, U.S. Coast Guard Captain of the Port, Portland, Maine.

[FR Doc. 01–32119 Filed 12–28–01; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301202; FRL–6817–1]

RIN 2070–AB78

Clethodim; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for combined residues of clethodim and its metabolites and their sulphoxides and sulphones in or on tall fescue forage and tall fescue hay. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on tall fescue. This regulation establishes a maximum permissible level for residues of clethodim in these food commodities. The tolerances will expire and are revoked on June 30, 2004.

DATES: This regulation is effective December 31, 2001. Objections and requests for hearings, identified by docket control number OPP–301202, must be received by EPA on or before March 1, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VII. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301202 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Barbara Madden, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–6463]; and e-mail address: Madden.Barbara@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 categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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

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

1. *Electronically.*You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2.*In person.* The Agency has established an official record for this action under docket control number OPP–301202. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Mall # 2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

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 herbicide clethodim, [(*E*)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, expressed as clethodim, in or on tall fescue forage at 10 parts per million (ppm) and tall fescue hay at 20 ppm. These tolerances will expire and are revoked on June 30, 2004. EPA will publish a document in the **Federal Register** to remove the revoked tolerance from the Code of Federal Regulations.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on section 18 related tolerances to set binding precedents for the application of section 408 and the new safety standard to other tolerances and exemptions. Section 408(e) of the

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 the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act (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 (FQPA). EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemption for Clethodim on Tall Fescue and FFDCA Tolerances

Missouri is the second leading State in beef cows and grass hay production. These cows are predominantly raised on tall fescue (*Festuca arundinacea*) forage and hay because of its adaptation to the environmental conditions in Missouri. Tall fescue is susceptible to an endopyte-fungus *Acremonium coenophialum* which produces peptide ergot alkaloids that are toxic to cattle. Over the last decade a great deal of information has been developed about the causal relationship of the fungal endophyte-fescue relationship and the true nature of the toxic interactions. This increased awareness was aided by the identification of the primary toxic compound of *A. coenophialum* called ergovaline which is found in the highest concentration in the seedhead and seed of tall fescue. Therefore control of these reproductive structures will help reduce the overall concentration of ergovaline.

The toxic effects of ergovaline include: reproductive problems, summer syndrome (weight loss), staggers, reduced milk production, and fescue foot (poor circulation leading to loss of hind feet). The reproductive problems include reduction in pregnancy rates from 86 to 91% in endophyte-free pastures down to 67 to 72% in endophyte-infected pastures (a 22% reduction). Decreased milk production has been demonstrated with beef cattle showing a 25% reduction in milk production and Polled Hereford cows showing a 40% reduction in milk production. This reduced milk production will directly reduce calf survival. Another related syndrome is a hyperthermia response. This is believed to be a peripheral vasoconstriction associated with the endophyte. This leads to a reduced temperature in the legs and tail, an increase temperature in the core body, increased respiration, open mouthed breathing, and reduced average daily weight gain.

Currently, there are no pesticides registered for control of tall fescue seedheads in pasture or hay fields. Tests of vaccines and use of anthelmintics (anti-parasitoids) have provided only short-term relief (days) to cattle from the problem. Non-chemical control methods include pasture renovation and reseeding to non-endophytic fescue, rotation to non-fescue pastures, dilution with legumes, supplementing the feed with grain to reduce the amount of toxin ingested, controlled grazing (heavy foraging reduces seedhead formation), ammoniate hay to neutralize the toxic effects of ergovaline, and mechanically removing the seedheads with mowing. Taken singly or together these cultural methods do not provide an effective, economic long-term relief from the problem. Pasture renovation or dilution with legumes does not stop the reintroduction of endophyte-fescue. Rotation to non-fescue pastures is difficult because other pasture grasses do not grow as well therefore, there are very few non-fescue pastures. Supplementing grazing with other grains is expensive due to the cost of the grain, and the equipment to feed it. Controlled heavy grazing to remove seedheads is difficult because of the heavy flush of vegetative growth coincides with seedhead formation in the spring. Ammoniating hay is not effective in a pasture situation. Mechanical mowing to remove seedheads requires mowing the fields two to four times during the season and is costly in terms of time and money. EPA has authorized under FIFRA section 18 the use of clethodim on tall fescue to suppress stem and seedhead formation in tall fescue pasture or hay to reduce toxin producing endophyte-fungus in Missouri. After having reviewed the submission, EPA concurs that emergency conditions exist for this State.

As part of its assessment of this emergency exemption, EPA assessed the potential risks presented by residues of clethodim in or on tall fescue forage and tall fescue hay. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in section 408(l)(6). Although these tolerances will expire and are revoked on June 30, 2004, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerance remaining in or on tall fescue forage and tall fescue hay 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 this tolerance 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 clethodim meets EPA's registration requirements for use on tall fescue 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 clethodim by a State for special local needs under FIFRA section 24(c). Nor do these tolerances serve as the basis for any State other than Missouri to use this pesticide on this crop under section 18 of FIFRA without following all provisions of EPA's regulations implementing section 18 as identified in 40 CFR part 166. For additional information regarding the emergency exemption for clethodim, 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 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), 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 clethodim and to make a determination on aggregate exposure, consistent with section 408(b)(2), for time-limited tolerances for combined residues of clethodim in or on tall fescue forage at 10 ppm and tall fescue hay at 20 ppm.

No fescue residue data were submitted for this specific emergency exemption request. The proposed use rate of clethodim for tall fescue is approximately one-eighth of the rate registered for use on alfalfa and clover. Therefore, the use of alfalfa and clover was translated to tall fescue for this section 18 use. The established tolerances for meat and milk are adequate to cover this section 18 use. According to Table 1 of OPPTS 860.1000 and the recommended and established tolerances for clethodim, the maximum theoretical dietary burdens were determined for beef and dairy cattle. Based on previous feeding studies, the secondary residues in meat and milk will not exceed the established tolerances as a result of this section 18 use.

Residues of clethodim in or on tall fescue are not expected to increase dietary exposure. Since tall fescue is not consumed by humans, any exposure to residues of clethodim from this emergency exeption will result from the consumption of meat or milk. The use of clethodim on tall fescue is not expected to result in exceedances of the tolerances that already exist for meat and milk. Therefore, establishing the tall fescue tolerance will not increase the most recent estimated aggregate risks resulting from use of clethodim, as discussed in the September 17, 2001 **Federal Register** (66 FR 47971, FRL–6800–9) final rule establishing tolerances for combined residues of clethodim in or on green onion, leaf lettuce, the Brassica head and stem subgroup, flax seed, flax meal, mustard seed, canola seed and canola meal, because in that prior action, risk was estimated assuming all meat and milk products contained tolerance level residues. Refer to the September 17, 2001 **Federal Register** document for a detailed discussion of the aggregate risk assessments and determination of safety. EPA relies upon that risk assessment and the findings made in the **Federal Register** document in support of this action. Below is a brief summary of the aggregate risk assessment.

An endpoint for acute dietary exposure was not identified since no effects were observed in oral toxicity studies that could be attributable to a single dose. Short-term and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Clethodim is not registered for use on any sites that would result in residential exposure. Therefore, short-term and intermediate-term aggregate risks were not assessed. Clethodim has been classified as a group E carcinogen. Therefore, clethodim is not expected to pose a cancer risk to humans. Therefore, the only exposure scenario the Agency assessed is for chronic (non-cancer) exposures to clethodim.

Using the Dietary Exposure Evaluation Model (DEEM™), an analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to clethodim for each commodity. The following assumptions were made for the chronic exposure assessments: The 3–day average of consumption for each sub-population is combined with residues to determine average exposure as milligram/kilogram/day (mg/kg/day). The chronic analysis was performed using tolerance level residues for all crops and livestock commodities. The projected percent crop treated (PCT) data (2% for lettuce, broccoli and cauliflower, 15% for cabbage, 25% for onion, and 1% for brussels sprouts), weighted average PCT treated data for existing registrations, and 100% crop treated (CT) data for all other uses.

Using the exposure assumptions described above, EPA has concluded that exposure to clethodim from food will utilize less than 1% of the chronic population adjusted dose (cPAD) for the U.S. population, less than 1% of the cPAD for females (13-50 years) and less than 1% of the cPAD for children 1-6 years old. There are no residential uses for clethodim that result in chronic residential exposure to clethodim. In addition, there is potential for chronic dietary exposure to clethodim in drinking water. After calculating drinking water levels of comparision (DWLOCs) and comparing them to the estimated environmental concentration (EECs) for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 1:

TABLE 1.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO CLETHODIM

Population Subgroup	cPAD (mg/kg)	% cPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. population (total)	0.01	0.0030	6.1	0.08	250
Children 1-6 years	0.01	0.0061	6.1	0.08	40
Females 13-50 years	0.01	0.0023	6.1	0.08	230

Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to clethodim residues.

V. Other Considerations

A. Analytical Enforcement Methodology

As discuseed in the September 17, 2001 **Federal Register** document (66 FR 47971), an adequate enforcement methodology is available to enforce the tolerance expression. The methods may be requested from: Francis Griffith, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Fort George G. Mead, Maryland, 20755–5350; telephone

number: (410) 305–2905; e-mail address: griffith.francis@epa.gov.

B. International Residue Limits

There are no established Codex maximum residue limits for residues of clethodim in or on tall fescue forage or hay. Therefore, there are no questions with respect to Codex/U.S. tolerance compatibility.

C. Conditions

One application may be made. A maximum of 0.031 pound active ingredient may be applied per acre. Clethodim is not to be applied within 15 days of grazing, feeding, or harvesting (cutting) forage or hay.

VI. Conclusion

Therefore, the tolerance is established for combined residues of clethodim, [(*E*)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, expressed as clethodim, in or on tall fescue forage at 10 ppm and tall fescue hay at 20 ppm.

VII. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301202 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 March 1, 2002.

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

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

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

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3.*Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit 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 Unit I.B.2. Mail your copies, identified by the docket control number OPP–301202, 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 Unit I.B.2. 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 178.32).

VIII. Regulatory Assessment Requirements

This final rule establishes time-limited tolerances under FFDCA section 408. 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 FFDCA section 408, such as the tolerances 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.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this 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: December 19, 2001.

Peter Caulkins,

Acting 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), 346(a) and 371.

2. Section 180.458 is amended by adding paragraph (b) to read as follows:

§ 180.458 Clethodim; tolerances for residues.

* * * * *

(b)*Section 18 emergency exemptions.* Time-limited tolerances are established for the combined residues of clethodim, [(*E*)-(±)-2-[1-[[(3-chloro-2-propenyl)oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one] and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, expressed as clethodim in connection with use of the pesticide under section 18 emergency exemptions granted by EPA. These tolerances will expire and are revoked on the date specified in the following table:

Commodity	Parts per million	Expiration/revocation date
Fescue, tall, forage	10	6/30/04
Fescue, tall, hay	20	6/30/04

* * * * *

[FR Doc. 01–32105 Filed 12–28–01; 8:45 am]
BILLING CODE 6560–50–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 413, 419, and 489

[CMS–1159–F3]

RIN 0938–AL35

Medicare Program; Prospective Payment System for Hospital Outpatient Services; Delay in Effective Date of Calendar Year 2002 Payment Rates and the Pro Rata Reduction on Transitional Pass-Through Payments

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

ACTION: Final rule; delay of effective date.

SUMMARY: This document delays the effective date of the payment rates announced for Medicare hospital outpatient services paid under the prospective payment system for calendar year 2002. These rates were announced in a November 30, 2001 final rule (66 FR 59856). In addition, this document delays the effective date of the uniform reduction to be applied to each of the transitional pass-through payments for CY 2002. Certain provisions of the November 30, 2001 rule, as discussed in the **SUPPLEMENTARY INFORMATION** section, are not delayed.

DATES: The effective date of the amendments to 42 CFR published at 66 FR 59856 (November 30, 2001) remains January 1, 2002, except that the effective date for § 419.32(b)(1)(iii) is delayed indefinitely. Also, the effective date for § 419.62(d), added at 66 FR 55865, published on November 2, 2001, is delayed indefinitely. The effective date of the payment rates announced for Medicare hospital outpatient services paid under the prospective payment system for calendar year 2002, published in the preamble and addenda of the November 30, 2001 final rule, and the uniform reduction to be applied to each of the transitional pass-through payments for CY 2002, published in the preamble and addenda of the November 30, 2001 final rule, is delayed until no later than April 1, 2002. These rates were announced in a November 30, 2001 final rule (66 FR 59856). We will publish a document in the **Federal Register** announcing the new effective date for the rates and for § 419.32(b)(1)(iii) and § 419.62(d).

FOR FURTHER INFORMATION CONTACT: James L. Hart, (410) 786–0378.

SUPPLEMENTARY INFORMATION:

Availability of Copies and Electronic Access

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $9. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through GPO Access, a service of the U.S. Government Printing Office. The Website address is: *http://www.access.gpo.gov/nara/index.html.*

I. Background

On November 30, 2001, we published a final rule announcing the final ambulatory payment classification (APC) groups, relative weights, and payment rates under the hospital outpatient prospective payment system (OPPS) for calendar year 2002 (66 FR 59856). As discussed in detail in that document, in setting the APC relative weights, we incorporated 75 percent of the estimated costs for devices eligible for transitional pass-through payments in 2002 into the costs of the APC groups associated with the use of the devices (66 FR 59906).

After the publication of the November 30 final rule, we discovered that the final rule reflects several inadvertent technical errors in which we incorrectly associated specific devices approved for transitional pass-through payments with particular procedures. The effects of the errors we have identified are of a magnitude significant enough to affect not only the estimate of total transitional pass-through payments and the uniform reduction percentage to be applied to transitional pass-through payments in 2002, but also the payment rates for all APCs. Using rates that reflect these errors would result in inappropriate, uneven effects on payments to hospitals. Thus, we believe it would be inappropriate to proceed to make the payment rates published on November 30 effective without further changes.

In order to thoroughly assess the accuracy of the data files containing these errors and to assure that they do not contain further errors that might also have significant implications, an intensive review of the data will be necessary. Because of the time needed for this review, we cannot complete this review and recalculate the rates before the previously published effective date of January 1, 2002. We will, therefore, continue to pay for services covered under the OPPS after January 1 and until no later than April 1, 2002 under the rates in effect on December 31, 2001. We will also continue until no later than April 1, 2002 to make transitional pass-through payments for drugs and devices without applying the uniform reduction announced on November 30, 2001.

Once our review has been completed and the rates corrected, we will publish a final rule with revised rates and a revised calculation of the uniform reduction in transitional pass-through payments. We will announce the effective date of these changes in that rule.

II. List of OPPS Provisions That Are Not Delayed

This document does not delay the following provisions:

- Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 coinsurance limit.
- Limitation of coinsurance amount to inpatient hospital deductible amount.
- Changes in services covered within the scope of OPPS.
- Categories of hospitals subject to, and excluded from, the OPPS.
- Criteria for new technology APCs.
- Provider-based issues.
- Change to the definition of ''single-use devices'' for transitional pass-through payments.

III. Waiver of Notice of Proposed Rulemaking and the 30-Day Delay in the Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment