

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: August 25, 2004.

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 180.565 is amended by alphabetically adding the commodity to the table in paragraph (b) to read as follows:

§ 180.565 Thiamethoxam; tolerances for residues.

| Commodity | Parts per million | Expiration/revocation date |
|-----------|-------------------|----------------------------|
| Cranberry | 0.02 ppm | 12/31/07 |

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CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

40 CFR Part 1620

Administrative Claims Arising Under the Federal Tort Claims Act

AGENCY: Chemical Safety and Hazard Investigation Board.

ACTION: Final rule.

SUMMARY: The Chemical Safety and Hazard Investigation Board (CSB) adopts the following rule to aid the processing of administrative claims for monetary damages filed under the Federal Tort Claims Act (FTCA). This rule provides information to members of the public who suffer loss or damage of property, personal injury, death, or other damages allegedly caused by the negligence or other wrongful act or omission of CSB officers or employees while acting in the scope of their office

or employment. The rule also governs the procedures by which such claims are administratively processed.

DATES: This rule is effective November 15, 2004.

FOR FURTHER INFORMATION CONTACT: Christopher M. Lyon, CSB Office of General Counsel, (202) 261-7600.

SUPPLEMENTARY INFORMATION: The Federal Tort Claims Act (FTCA), 28 U.S.C. 1346(b), 2401(b), 2671-2680, waives the federal government’s sovereign immunity to civil suits for damages in certain instances arising out of the negligent or otherwise wrongful acts or omissions committed by federal employees while acting within the scope of their employment. General regulations issued by the U.S. Department of Justice for processing FTCA claims, found at 28 CFR 14.11, authorize federal agencies to issue supplementing regulations. Accordingly, the CSB is adopting this rule to inform the public about the CSB’s method of accepting and processing claims arising under the FTCA filed against the agency. This rule provides the public with guidance in presenting a tort claim against the CSB, while also ensuring that the agency has established procedures to receive, investigate and adjudicate such claims. The CSB published a proposed rule on administrative claims arising under the FTCA, and invited public comments on the rule, in the **Federal Register** of June 17, 2004 (69 FR 33879). No comments were received. This final rule is being published unchanged from the proposed version.

Regulatory Impact

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires that a rule that has a significant economic impact on a substantial number of small entities, small businesses, or small organizations must include an initial regulatory flexibility analysis describing the regulation’s impact on such small entities. This analysis need not be undertaken if the agency has certified that the regulation will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). The CSB has considered the impact of this rule under the Regulatory Flexibility Act. The CSB’s General Counsel hereby certifies that this rule will not have a significant economic impact on a substantial number of small business entities.

Paperwork Reduction Act

This rule does not contain any information collection requirements that

require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Unfunded Mandates Reform Act of 1995

This rule does not require the preparation of an assessment statement in accordance with the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531. This rule does not include a Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year.

List of Subjects in 40 CFR Part 1620

Claims, Administrative practice and procedure.

Dated: September 9, 2004.

Christopher W. Warner,
General Counsel.

■ Accordingly, for the reasons set forth in the preamble, the Chemical Safety and Hazard Investigation Board adds a new 40 CFR Part 1620 to read as follows:

PART 1620—ADMINISTRATIVE CLAIMS ARISING UNDER THE FEDERAL TORT CLAIMS ACT

Sec.

- 1620.1 Purpose and scope of regulations.
- 1620.2 Administrative claim; when presented.
- 1620.3 Administrative claim; who may file.
- 1620.4 Investigations.
- 1620.5 Administrative claim; evidence and information to be submitted.
- 1620.6 Authority to adjust, determine, compromise, and settle.
- 1620.7 Limitations on authority.
- 1620.8 Referral to Department of Justice.
- 1620.9 Final denial of claim.
- 1620.10 Action on approved claim.

Authority: 28 U.S.C. 2672; 42 U.S.C. 7412(r)(6)(N); 28 CFR 14.11.

§ 1620.1 Purpose and scope of regulations.

The regulations in this part apply only to administrative claims presented or filed with the Chemical Safety and Hazard Investigation Board (CSB), under the Federal Tort Claims Act (FTCA), 28 U.S.C. 1346(b), 2401(b), 2671–2680, as amended, for money damages against the United States for damage to or loss of property, personal injury, death, or other damages caused by the negligent or wrongful act or omission of an officer or employee of CSB while acting within the scope of his or her office or employment, but only under circumstances where the United States, if a private person, would be liable to the claimant in accordance with the law

of the place where the act or omission occurred.

§ 1620.2 Administrative claim; when presented.

(a) For purposes of the provisions of 28 U.S.C. 2401(b), 2672, and 2675, a claim is deemed to have been presented when the CSB receives from a claimant, and/or his or her authorized agent, attorney, or other legal representative, an executed Standard Form 95 (Claim for Damage, Injury or Death), or other written notification of an incident, accompanied by a claim for money damages stating a sum certain (a specific dollar amount) for specified damage to or loss of property, personal injury, death, or other compensable damages alleged to have occurred as a result of the incident. A claimant must present a claim within 2 years of the date of accrual of the claim. The date of accrual generally is determined to be the time of death, injury, or other alleged damages, or if the alleged damages are not immediately apparent, when the claimant discovered (or reasonably should have discovered) the alleged damages and its cause, though the actual date of accrual will always depend on the facts of each case. Claimants should be advised that mailing a claim by the 2-year time limit is not sufficient if the CSB does not receive the claim through the mail by that date. Additionally, claimants should be advised that a claim is not considered presented by the CSB until the CSB receives all information requested in this paragraph. Incomplete claims will be returned to the claimant.

(b) All claims filed under the FTCA as a result of the alleged negligence or wrongful act or omission of the CSB or its employees must be mailed or delivered to the Office of the General Counsel, 2175 K Street NW., Suite 650, Washington, DC 20037.

(c) The FTCA requires that a claim must be presented to the Federal agency whose activities gave rise to the claim. A claim that should have been presented to CSB, but was mistakenly addressed to or filed with another Federal agency, is presented to the CSB, as required by 28 U.S.C. 2401(b), as of the date the claim is received by the CSB. When a claim is mistakenly presented to the CSB, the CSB will transfer the claim to the appropriate Federal agency, if ascertainable, and advise the claimant of the transfer, or return the claim to the claimant if the appropriate Federal agency cannot be determined.

(d) A claimant whose claim arises from an incident involving the CSB and one or more other Federal agencies will

identify each agency to which the claim has been submitted at the time the claim is presented to the CSB. The CSB will contact all other affected Federal agencies in order to designate a single agency that will investigate and decide the merits of the claim. In the event a designation cannot be agreed upon by the affected agencies, the Department of Justice will be consulted and that agency will designate a specific agency to investigate and determine the merits of the claim. The designated agency will then notify the claimant that all future correspondence concerning the claim must be directed to the designated Federal agency. All involved Federal agencies may agree to conduct their own administrative reviews and to coordinate the results, or to have the investigation conducted solely by the designated Federal agency. However, in any event, the designated agency will be responsible for the final determination of the claim.

(e) A claim presented in compliance with paragraph (a) of this section may be amended by the claimant at any time prior to final agency action or prior to the exercise of the claimant's option under 28 U.S.C. 2675(a). Amendments must be in writing and signed by the claimant or his or her authorized agent, attorney, or other legal representative. Upon the timely filing of an amendment to a pending claim, the CSB will have an additional 6 months in which to investigate the claim and to make a final disposition of the claim as amended. A claimant's option under 28 U.S.C. 2675(a) will not accrue until 6 months after the filing of an amendment.

§ 1620.3 Administrative claim; who may file.

(a) A claim for damage to or loss of property may be presented by the owner of the property, or his or her authorized agent, attorney, or other legal representative.

(b) A claim for personal injury may be presented by the injured person, or his or her authorized agent, attorney or other legal representative.

(c) A claim based on death may be presented by the executor or administrator of the decedent's estate, or by any other person legally entitled to assert a claim under the applicable State law, provided that the basis for the representation is documented in writing.

(d) A claim for loss totally compensated by an insurer with the rights to subrogate may be presented by the insurer. A claim for loss partially compensated by an insurer with the rights to subrogate may be presented by the insurer or the insured individually

as their respective interests appear, or jointly. When an insurer presents a claim asserting the rights to subrogate the insurer must present appropriate evidence that it has the rights to subrogate.

(e) A claim presented by an agent or legal representative must be presented in the name of the claimant, be signed by the agent, attorney, or other legal representative, show the title or legal capacity of the person signing, and be accompanied by evidence of his or her authority to present a claim on behalf of the claimant as agent, attorney, executor, administrator, parent, guardian, conservator, or other legal representative.

§ 1620.4 Investigations.

CSB may investigate, or may request any other Federal agency to investigate, a claim filed under this part.

§ 1620.5 Administrative claim; evidence and information to be submitted.

(a) *Death.* In support of a claim based on death, the claimant may be required to submit the following evidence or information:

(1) An authenticated death certificate or other competent evidence showing cause of death, date of death, and age of the decedent.

(2) Decedent's employment or occupation at time of death, including his or her monthly or yearly salary or earnings (if any), and the duration of his or her last employment or occupation.

(3) Full names, addresses, birth date, kinship and marital status of the decedent's survivors, including identification of those survivors who were dependent on support provided by the decedent at the time of death.

(4) Degree of support afforded by the decedent to each survivor dependent on him or her for support at the time of death.

(5) Decedent's general physical and mental condition before death.

(6) Itemized bills for medical and burial expenses incurred by reason of the incident causing death, or itemized receipts of payment for such expenses.

(7) If damages for pain and suffering before death are claimed, a physician's detailed statement specifying the injuries suffered, duration of pain and suffering, any drugs administered for pain, and the decedent's physical condition in the interval between injuries and death.

(8) True and correct copies of relevant medical treatment records, laboratory and other tests, including X-Rays, MRI, CT scans and other objective evidence of medical evaluation and diagnosis, treatment of injury/illness, and prognosis, if any had been made.

(9) Any other evidence or information that may have a bearing on either the responsibility of the United States for the death or the amount of damages claimed.

(b) *Personal injury.* In support of a claim for personal injury, including pain and suffering, the claimant may be required to submit the following evidence or information:

(1) A written report by the attending physician or dentist setting forth the nature and extent of the injury, nature and extent of treatment, any degree of temporary or permanent disability, the prognosis, period of hospitalization, and any diminished earning capacity. If damages for pain and suffering are claimed, a physician's detailed statement specifying the duration of pain and suffering, a listing of drugs administered for pain, and the claimant's general physical condition.

(2) True and correct copies of relevant medical treatment records, laboratory and other tests including X-Rays, MRI, CT scans and other objective evidence of medical evaluation and diagnosis, treatment injury/illness and prognosis.

(3) The claimant may be required to submit to a physical or mental examination by a physician employed by CSB or another Federal agency. On written request, CSB will make available to the claimant a copy of the report of the examining physician employed by the United States, provided the claimant has furnished CSB with the information noted in paragraphs (b)(1) and (b)(2) of this section. In addition, the claimant must have made or agrees to make available to CSB all other physicians' reports previously or thereafter made of the physical or mental condition that is subject matter of his or her claim.

(4) Itemized bills for medical, dental, and hospital expenses incurred, and/or itemized receipts of payment for such expenses.

(5) If the prognosis reveals the necessity for future treatment, a statement of the expected treatment and the expected expense for such treatment.

(6) If a claim is made for loss of time from employment, a written statement from his or her employer showing actual time lost from employment, whether he or she is a full-time or part-time employee, and wages or salary actually lost.

(7) If a claim is made for loss of income and the claimant is self-employed, documentary evidence showing the amount of earnings actually lost.

(8) Any other evidence or information that may have a bearing on either the responsibility of the United States for

the personal injury or the damages claimed.

(c) *Property damage.* In support of a claim for damage to or loss of property, real or personal, the claimant may be required to submit the following evidence or information:

(1) Proof of ownership of the property.

(2) A detailed statement of the amount claimed with respect to each item of property.

(3) An itemized receipt of payment for necessary repairs or itemized written estimates of the cost of such repairs.

(4) A statement listing date of purchase, purchase price, and salvage value.

(5) Photographs or video footage documenting the damage, including photographs showing the condition of the property at issue both before and after the alleged negligence or wrongful act or omission.

(6) Any other evidence or information that may have a bearing on either the responsibility of the United States for the damage to or loss of property or the damages claimed.

§ 1620.6 Authority to adjust, determine, compromise, and settle.

The General Counsel of CSB, or his or her designee, is delegated authority to consider, ascertain, adjust, determine, compromise and settle claims under the provision of 28 U.S.C. 2672, and this part. The General Counsel, in his or her discretion, has the authority to further delegate the responsibility for adjudicating, considering, adjusting, compromising and settling any claim submitted under the provision of 28 U.S.C. 2672, and this part, that is based on the alleged negligence or wrongful act or omission of a CSB employee acting in the scope of his or her employment. However, in any case, any offer of compromise or settlement in excess of \$5,000 exercised by the CSB Chairperson or any other lawful designee can only be made after a legal review is conducted by an attorney within the CSB Office of General Counsel.

§ 1620.7 Limitations on authority.

(a) An award, compromise, or settlement of a claim under 28 U.S.C. 2672, and this part, in excess of \$25,000 can be made only with the prior written approval of the CSB General Counsel and Chairperson, after consultation and approval by the Department of Justice. For purposes of this paragraph a principal claim and any derivative or subrogated claim will be treated as a single claim.

(b) An administrative claim may be adjusted, determined, compromised or

settled under this part only after consultation with the Department of Justice when, in the opinion of the General Counsel of CSB, or his or her designee:

(1) A new precedent or a new point of law is involved; or

(2) A question of policy is or may be involved; or

(3) The United States is or may be entitled to indemnity or contribution from a third party and CSB is unable to adjust the third party claim; or

(4) The compromise of a particular claim, as a practical matter, will or may control the disposition of a related claim in which the amount to be paid may exceed \$25,000.

(c) An administrative claim may be adjusted, determined, compromised or settled under 28 U.S.C. 2672 and this part only after consultation with the Department of Justice when CSB is informed or is otherwise aware that the United States or an employee, agent or contractor of the United States is involved in litigation based on a claim arising out of the same incident or transaction.

§ 1620.8 Referral to Department of Justice.

When Department of Justice approval or consultation is required, or the advice of the Department of Justice is otherwise to be requested, under this regulation, the written referral or request will be transmitted to the Department of Justice by the General Counsel of CSB, or his or her designee.

§ 1620.9 Final denial of claim.

Final denial of an administrative claim must be in writing and sent to the claimant, his or her agent, attorney, or other legal representative by certified or registered mail. The notification of final denial may include a statement of the reasons for the denial. However, it must include a statement that, if the claimant is dissatisfied with the CSB action, he or she may file suit in an appropriate United States District Court not later than 6 months after the date of mailing of the notifications, along with the admonition that failure to file within this 6 month timeframe could result in the suit being time-barred by the controlling statute of limitations. In the event that a claimant does not hear from the CSB after 6 months have passed from the date that the claim was presented, a claimant should consider the claim denied and, if desired, should proceed with filing a civil action in the appropriate U.S. District Court.

§ 1620.10 Action on approved claim.

(a) Payment of a claim approved under this part is contingent on

claimant's execution of a Standard Form 95 (Claim for Damage, Injury or Death); a claims settlement agreement; and a Standard Form 1145 (Voucher for Payment), as well as any other forms as may be required. When a claimant is represented by an attorney, the Voucher for Payment will designate both the claimant and his or her attorney as payees, and the check will be delivered to the attorney, whose address is to appear on the Voucher for payment.

(b) Acceptance by the claimant, his or her agent, attorney, or legal representative, of an award, compromise or settlement made under 28 U.S.C. 2672 or 28 U.S.C. 2677 is final and conclusive on the claimant, his or her agent, attorney, or legal representative, and any other person on whose behalf or for whose benefit the claim has been presented, and constitutes a complete release of any and all claims against the United States and against any employee of the Federal Government whose act(s) or omission(s) gave rise to the claim, by reason of the same subject matter. To that end, as noted above, the claimant, as well as any agent, attorney or other legal representative that represented the claimant during any phase of the process (if applicable) must execute a settlement agreement with the CSB prior to payment of any funds.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

45 CFR Part 160

[CMS-0010-IFC]

RIN 0938-AM63

Civil Money Penalties: Procedures for Investigations, Imposition of Penalties, and Hearings—Extension of Expiration Date

AGENCY: Office of the Secretary, HHS.

ACTION: Final rule.

SUMMARY: An interim final rule establishing procedures for the imposition, by the Secretary of Health and Human Services, of civil money penalties on entities that violate standards adopted by the Secretary under the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) was published on April 17, 2003. The interim final rule expires on September 16, 2004. This regulatory action extends the expiration date one

year to avoid the disruption of ongoing enforcement actions while HHS proceeds with rulemaking to develop a more comprehensive enforcement rule.

DATES: Effective September 15, 2004, the expiration date of 45 CFR part 160, subpart E is extended from September 16, 2004, to September 16, 2005.

FOR FURTHER INFORMATION CONTACT:

Karen Shaw, (202) 205-0154.

SUPPLEMENTARY INFORMATION:

I. Background

On April 17, 2003, the Secretary of Health and Human Services published an interim final rule with request for comments. 68 FR 18895. The interim final rule adopted rules of procedure for the imposition by the Department of Health and Human Services (HHS) of civil money penalties on entities that violate standards and requirements adopted by HHS under the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191. These rules are codified at 45 CFR part 160, subpart E (subpart E).

As corrected at 68 FR 22453 (April 28, 2003), subpart E expires on September 16, 2004. HHS intends to propose in the near future a rule to establish complete procedural and substantive provisions for the enforcement of the HIPAA rules through the imposition of civil money penalties. The final rule that will result from this forthcoming rulemaking will supersede subpart E. However, as additional time is needed to complete the rulemaking, HHS has decided to extend the expiration date of subpart E from September 16, 2004 to September 16, 2005.

II. Comments on Subpart E

The April 17, 2003 interim final rule requested comment, and HHS received 19 public comments during the public comment period. We will describe and respond to those comments in the preamble to the forthcoming proposed rule.

III. Procedural Requirements

A. Determination To Issue Final Rule Extending Expiration Date Without Notice and Comment, To Be Effective in Less Than 30 Days

As noted, HHS expects to propose a rule to amend subpart E in the near future. However, this forthcoming rulemaking will not be completed by September 16, 2004, when the interim final rule that adopted subpart E is scheduled to expire. The resulting hiatus in the procedures for civil money penalty enforcement actions could