

(b), before “finds” in subsec. (e), and before “may” in subsec. (f).

1988—Subsec. (f). Pub. L. 100-532, § 801(q)(1)(D), substituted “136i” for “136b”.

Subsec. (g). Pub. L. 100-532, § 801(d), substituted “require. Such pesticide” for “require: *Provided*, That such pesticide”.

1978—Subsec. (a). Pub. L. 95-396, § 10(1), provided for review of application, issuance or nonissuance of experimental use permit within prescribed period including reasons for denial, correction of application, and waiver of conditions and substituted provision for filing an application for experimental use permit at any time for prior provision for filing at the time of or before or after an application for registration is filed.

Subsec. (f). Pub. L. 95-396, § 10(2), substituted in first sentence “shall” for “may” where first appearing.

1975—Subsec. (g). Pub. L. 94-140 added subsec. (g).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

§ 136d. Administrative review; suspension

(a) Existing stocks and information

(1) Existing stocks

The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under this section, or section 136a or 136a-1 of this title, to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter.

(2) Information

If at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator.

(b) Cancellation and change in classification

If it appears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provisions of this subchapter or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment, the Administrator may issue a notice of the Administrator's intent either—

(1) to cancel its registration or to change its classification together with the reasons (including the factual basis) for the Administrator's action, or

(2) to hold a hearing to determine whether or not its registration should be canceled or its classification changed.

Such notice shall be sent to the registrant and made public. In determining whether to issue any such notice, the Administrator shall include among those factors to be taken into account the impact of the action proposed in such notice

on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy. At least 60 days prior to sending such notice to the registrant or making public such notice, whichever occurs first, the Administrator shall provide the Secretary of Agriculture with a copy of such notice and an analysis of such impact on the agricultural economy. If the Secretary comments in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator shall publish in the Federal Register (with the notice) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the notice and analysis within 30 days after receiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period notwithstanding the foregoing 60-day time requirement. The time requirements imposed by the preceding 3 sentences may be waived or modified to the extent agreed upon by the Administrator and the Secretary. Notwithstanding any other provision of this subsection and section 136w(d) of this title, in the event that the Administrator determines that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health, then upon such a finding the Administrator may waive the requirement of notice to and consultation with the Secretary of Agriculture pursuant to this subsection and of submission to the Scientific Advisory Panel pursuant to section 136w(d) of this title and proceed in accordance with subsection (c). When a public health use is affected, the Secretary of Health and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides. The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a request for a hearing is made by a person adversely affected by the notice. In the event a hearing is held pursuant to such a request or to the Administrator's determination under paragraph (2), a decision pertaining to registration or classification issued after completion of such hearing shall be final. In taking any final action under this subsection, the Administrator shall consider restricting a pesticide's use or uses as an alternative to cancellation and shall fully explain the reasons for these restrictions, and shall include among those factors to be taken into account the impact of such final action on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Administrator shall publish in the Federal Register an analysis of such impact.

(c) Suspension

(1) Order

If the Administrator determines that action is necessary to prevent an imminent hazard

during the time required for cancellation or change in classification proceedings, the Administrator may, by order, suspend the registration of the pesticide immediately. Except as provided in paragraph (3), no order of suspension may be issued under this subsection unless the Administrator has issued, or at the same time issues, a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b). Except as provided in paragraph (3), the Administrator shall notify the registrant prior to issuing any suspension order. Such notice shall include findings pertaining to the question of "imminent hazard". The registrant shall then have an opportunity, in accordance with the provisions of paragraph (2), for an expedited hearing before the Administrator on the question of whether an imminent hazard exists.

(2) Expedite hearing

If no request for a hearing is submitted to the Administrator within five days of the registrant's receipt of the notification provided for by paragraph (1), the suspension order may be issued and shall take effect and shall not be reviewable by a court. If a hearing is requested, it shall commence within five days of the receipt of the request for such hearing unless the registrant and the Administrator agree that it shall commence at a later time. The hearing shall be held in accordance with the provisions of subchapter II of chapter 5 of title 5, except that the presiding officer need not be a certified administrative law judge. The presiding officer shall have ten days from the conclusion of the presentation of evidence to submit recommended findings and conclusions to the Administrator, who shall then have seven days to render a final order on the issue of suspension.

(3) Emergency order

Whenever the Administrator determines that an emergency exists that does not permit the Administrator to hold a hearing before suspending, the Administrator may issue a suspension order in advance of notification to the registrant. The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) and the Administrator shall proceed to issue the notice under subsection (b) within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) within 90 days of issuing an emergency order, the emergency order shall expire. In the case of an emergency order, paragraph (2) shall apply except that (A) the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of a final order on suspension, and (B) no party other than the registrant and the Administrator shall participate except that any person adversely affected may file briefs within the time allotted by the Agency's rules. Any person so filing briefs shall be considered a party to such proceeding for the purposes of section 136n(b) of this title.

(4) Judicial review

A final order on the question of suspension following a hearing shall be reviewable in accordance with section 136n of this title, notwithstanding the fact that any related cancellation proceedings have not been completed. Any order of suspension entered prior to a hearing before the Administrator shall be subject to immediate review in an action by the registrant or other interested person with the concurrence of the registrant in an appropriate district court, solely to determine whether the order of suspension was arbitrary, capricious or an abuse of discretion, or whether the order was issued in accordance with the procedures established by law. The effect of any order of the court will be only to stay the effectiveness of the suspension order, pending the Administrator's final decision with respect to cancellation or change in classification. This action may be maintained simultaneously with any administrative review proceedings under this section. The commencement of proceedings under this paragraph shall not operate as a stay of order, unless ordered by the court.

(d) Public hearings and scientific review

In the event a hearing is requested pursuant to subsection (b) or determined upon by the Administrator pursuant to subsection (b), such hearing shall be held after due notice for the purpose of receiving evidence relevant and material to the issues raised by the objections filed by the applicant or other interested parties, or to the issues stated by the Administrator, if the hearing is called by the Administrator rather than by the filing of objections. Upon a showing of relevance and reasonable scope of evidence sought by any party to a public hearing, the Hearing Examiner shall issue a subpoena to compel testimony or production of documents from any person. The Hearing Examiner shall be guided by the principles of the Federal Rules of Civil Procedure in making any order for the protection of the witness or the content of documents produced and shall order the payment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, the subpoena may be enforced by an appropriate United States district court in accordance with the principles stated herein. Upon the request of any party to a public hearing and when in the Hearing Examiner's judgment it is necessary or desirable, the Hearing Examiner shall at any time before the hearing record is closed refer to a Committee of the National Academy of Sciences the relevant questions of scientific fact involved in the public hearing. No member of any committee of the National Academy of Sciences established to carry out the functions of this section shall have a financial or other conflict of interest with respect to any matter considered by such committee. The Committee of the National Academy of Sciences shall report in writing to the Hearing Examiner within 60 days after such referral on these questions of scientific fact. The report shall be made public and shall be considered as part of the hearing record. The Administrator shall enter into appropriate arrangements with the National Acad-

emy of Sciences to assure an objective and competent scientific review of the questions presented to Committees of the Academy and to provide such other scientific advisory services as may be required by the Administrator for carrying out the purposes of this subchapter. As soon as practicable after completion of the hearing (including the report of the Academy) but not later than 90 days thereafter, the Administrator shall evaluate the data and reports before the Administrator and issue an order either revoking the Administrator's notice of intention issued pursuant to this section, or shall issue an order either canceling the registration, changing the classification, denying the registration, or requiring modification of the labeling or packaging of the article. Such order shall be based only on substantial evidence of record of such hearing and shall set forth detailed findings of fact upon which the order is based.

(e) Conditional registration

(1) The Administrator shall issue a notice of intent to cancel a registration issued under section 136a(c)(7) of this title if (A) the Administrator, at any time during the period provided for satisfaction of any condition imposed, determines that the registrant has failed to initiate and pursue appropriate action toward fulfilling any condition imposed, or (B) at the end of the period provided for satisfaction of any condition imposed, that condition has not been met. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose conditional registration has been canceled under this subsection to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment.

(2) A cancellation proposed under this subsection shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to cancel unless during that time a request for hearing is made by a person adversely affected by the notice. If a hearing is requested, a hearing shall be conducted under subsection (d) of this section. The only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this subchapter. A decision after completion of such hearing shall be final. Notwithstanding any other provision of this section, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing.

(f) General provisions

(1) Voluntary cancellation

(A) A registrant may, at any time, request that a pesticide registration of the registrant be canceled or amended to terminate one or more pesticide uses.

(B) Before acting on a request under subparagraph (A), the Administrator shall publish in the Federal Register a notice of the receipt of the request and provide for a 30-day period in which the public may comment.

(C) In the case of a pesticide that is registered for a minor agricultural use, if the Administrator determines that the cancellation or termination of uses would adversely affect the availability of the pesticide for use, the Administrator—

(i) shall publish in the Federal Register a notice of the receipt of the request and make reasonable efforts to inform persons who so use the pesticide of the request; and

(ii) may not approve or reject the request until the termination of the 180-day period beginning on the date of publication of the notice in the Federal Register, except that the Administrator may waive the 180-day period upon the request of the registrant or if the Administrator determines that the continued use of the pesticide would pose an unreasonable adverse effect on the environment.

(D) Subject to paragraph (3)(B), after complying with this paragraph, the Administrator may approve or deny the request.

(2) Publication of notice

A notice of denial of registration, intent to cancel, suspension, or intent to suspend issued under this subchapter or a notice issued under subsection (c)(4) or (d)(5)(A) of section 136a-1 of this title shall be published in the Federal Register and shall be sent by certified mail, return receipt requested, to the registrant's or applicant's address of record on file with the Administrator. If the mailed notice is returned to the Administrator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish delivery of the notice to the registrant or applicant after making reasonable efforts to do so, the notice shall be deemed to have been received by the registrant or applicant on the date the notice was published in the Federal Register.

(3) Transfer of registration of pesticides registered for minor agricultural uses

In the case of a pesticide that is registered for a minor agricultural use:

(A) During the 180-day period referred to in paragraph (1)(C)(ii), the registrant of the pesticide may notify the Administrator of an agreement between the registrant and a person or persons (including persons who so use the pesticide) to transfer the registration of the pesticide, in lieu of canceling or amending the registration to terminate the use.

(B) An application for transfer of registration, in conformance with any regulations the Administrator may adopt with respect to the transfer of the pesticide registrations, must be submitted to the Administrator within 30 days of the date of notification provided pursuant to subparagraph (A). If such an application is submitted, the Administrator shall approve the transfer and

shall not approve the request for voluntary cancellation or amendment to terminate use unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.

(C) If the Administrator approves the transfer and the registrant transfers the registration of the pesticide, the Administrator shall not cancel or amend the registration to delete the use or rescind the transfer of the registration, during the 180-day period beginning on the date of the approval of the transfer unless the Administrator determines that the continued use of the pesticide would cause an unreasonable adverse effect on the environment.

(D) The new registrant of the pesticide shall assume the outstanding data and other requirements for the pesticide that are pending at the time of the transfer.

(4) Utilization of data for voluntarily canceled pesticide

When an application is filed with the Administrator for the registration of a pesticide for a minor use and another registrant subsequently voluntarily cancels its registration for an identical or substantially similar pesticide for an identical or substantially similar use, the Administrator shall process, review, and evaluate the pending application as if the voluntary cancellation had not yet taken place except that the Administrator shall not take such action if the Administrator determines that such minor use may cause an unreasonable adverse effect on the environment. In order to rely on this subsection, the applicant must certify that it agrees to satisfy any outstanding data requirements necessary to support the reregistration of the pesticide in accordance with the data submission schedule established by the Administrator.

(g) Notice for stored pesticides with canceled or suspended registrations

(1) In general

Any producer or exporter of pesticides, registrant of a pesticide, applicant for registration of a pesticide, applicant for or holder of an experimental use permit, commercial applicator, or any person who distributes or sells any pesticide, who possesses any pesticide which has had its registration canceled or suspended under this section shall notify the Administrator and appropriate State and local officials of—

- (A) such possession,
- (B) the quantity of such pesticide such person possesses, and
- (C) the place at which such pesticide is stored.

(2) Copies

The Administrator shall transmit a copy of each notice submitted under this subsection to the regional office of the Environmental Protection Agency which has jurisdiction over the place of pesticide storage identified in the notice.

(h) Judicial review

Final orders of the Administrator under this section shall be subject to judicial review pursuant to section 136n of this title.

(June 25, 1947, ch. 125, § 6, as added Pub. L. 92-516, § 2, Oct. 21, 1972, 86 Stat. 984; amended Pub. L. 94-140, § 1, Nov. 28, 1975, 89 Stat. 751; Pub. L. 95-251, § 2(a)(2), Mar. 27, 1978, 92 Stat. 183; Pub. L. 95-396, §§ 11, 12, Sept. 30, 1978, 92 Stat. 828; Pub. L. 98-620, title IV, § 402(4)(A), Nov. 8, 1984, 98 Stat. 3357; Pub. L. 100-532, title II, § 201, title IV, § 404, title VIII, § 801(e), (q)(2)(B), Oct. 25, 1988, 102 Stat. 2668, 2673, 2681, 2683; Pub. L. 101-624, title XIV, § 1494, Nov. 28, 1990, 104 Stat. 3628; Pub. L. 102-237, title X, § 1006(a)(5), (b)(1), (2), (3)(C)-(E), Dec. 13, 1991, 105 Stat. 1895, 1896; Pub. L. 104-170, title I, §§ 102, 106(a), title II, §§ 210(g), (h), 233, Aug. 3, 1996, 110 Stat. 1489, 1491, 1500, 1509.)

Editorial Notes

CODIFICATION

“Subchapter II of chapter 5 of title 5”, referred to in subsec. (c)(2), was in the original “subchapter II of Title 5”, and was editorially changed to reflect the probable intent of Congress.

PRIOR PROVISIONS

A prior section 6 of act June 25, 1947, was classified to section 135d of this title prior to amendment of act June 25, 1947, by Pub. L. 92-516.

AMENDMENTS

1996—Subsec. (a). Pub. L. 104-170, § 106(a)(1), substituted “Existing stocks and information” for “Cancellation after five years” in heading.

Subsec. (a)(1). Pub. L. 104-170, § 106(a)(2), amended heading and text generally. Prior to amendment, text read as follows: “The Administrator shall cancel the registration of any pesticide at the end of the five-year period which begins on the date of its registration (or at the end of any five year period thereafter) unless the registrant, or other interested person with the concurrence of the registrant, before the end of such period, requests in accordance with regulations prescribed by the Administrator that the registration be continued in effect. The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is canceled under this subsection or subsection (b) of this section to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator determines that such sale or use is not inconsistent with the purposes of this subchapter and will not have unreasonable adverse effects on the environment. The Administrator shall publish in the Federal Register, at least 30 days prior to the expiration of such five-year period, notice that the registration will be canceled if the registrant or other interested person with the concurrence of the registrant does not request that the registration be continued in effect.”

Subsec. (b). Pub. L. 104-170, § 233, inserted “When a public health use is affected, the Secretary of Health and Human Services should provide available benefits and use information, or an analysis thereof, in accordance with the procedures followed and subject to the same conditions as the Secretary of Agriculture in the case of agricultural pesticides.” before “The proposed action shall become final”.

Subsec. (c)(1). Pub. L. 104-170, § 102(a), amended second sentence generally. Prior to amendment, second sentence read as follows: “No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of the Administrator’s intention to cancel the registration or change the classification of the pesticide.”

Subsec. (c)(3). Pub. L. 104-170, §102(b), inserted after first sentence "The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b) of this section and the Administrator shall proceed to issue the notice under subsection (b) of this section within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) of this section within 90 days of issuing an emergency order, the emergency order shall expire." and substituted "In the case of an emergency order" for "In that case".

Subsec. (f)(1)(C)(ii). Pub. L. 104-170, §210(g)(1), substituted "180-day" for "90-day" in two places.

Subsec. (f)(3)(A). Pub. L. 104-170, §210(g)(2), substituted "180-day" for "90-day".

Subsec. (f)(4). Pub. L. 104-170, §210(h), added par. (4). 1991—Subsec. (a)(1). Pub. L. 102-237, §1006(b)(1), substituted "the Administrator" for "he" before "may specify" and before "determines".

Subsec. (a)(2). Pub. L. 102-237, §1006(b)(3)(C), substituted "the registrant" for "he" before "shall".

Subsec. (b). Pub. L. 102-237, §1006(b)(1), (2), substituted "the Administrator's" for "his" in introductory provisions and par. (1), and "the Administrator" for "he" before "shall publish" in last sentence.

Subsec. (c)(1). Pub. L. 102-237, §1006(b)(1), (2), substituted "the Administrator" for "he" before "may" and "the Administrator's" for "his" before "intention".

Subsec. (c)(3). Pub. L. 102-237, §1006(b)(1), (3)(D), substituted "the Administrator" for "he" before "may" and "the Administrator" for "him" after "permit".

Subsec. (d). Pub. L. 102-237, §1006(b)(2), (3)(E), in penultimate sentence substituted "the Administrator's" for "his" and "the Administrator" for "him" before "and issue".

Subsec. (f)(3)(B). Pub. L. 102-237, §1006(a)(5), substituted "adverse effect" for "adverse affect".

1990—Subsec. (f)(1). Pub. L. 101-624, §1494(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "A registrant at any time may request that any of its pesticide registrations be canceled or be amended to delete one or more uses. Before acting on such request, the Administrator shall publish in the Federal Register a notice of the receipt of the request. Thereafter, the Administrator may approve such a request."

Subsec. (f)(3). Pub. L. 101-624, §1494(2), added par. (3). 1988—Subsec. (a)(1). Pub. L. 100-532, §801(e)(1), substituted "effect. The Administrator" for "effect: *Provided*, That the Administrator".

Subsec. (c). Pub. L. 100-532, §801(e)(2)-(4), in par. (1) directed that undesignated paragraph beginning "Except as provided" be run into sentence ending "of the pesticide." and substituted "before the Administrator" for "before the Agency", in par. (2) substituted "submitted to the Administrator" for "submitted to the Agency" and "and the Administrator" for "and the Agency", and in par. (3) substituted "(A)" for "(i)", "and the Administrator" for "and the Agency", and "(B)" for "(ii)".

Subsec. (e). Pub. L. 100-532, §801(e)(5), (6), in par. (1), substituted "met. The Administrator" for "met: *Provided*, That the Administrator", and in par. (2), substituted "section. The only" for "section: *Provided*, That the only".

Subsec. (f). Pub. L. 100-532, §201, added subsec. (f). Former subsec. (f) redesignated (h).

Subsec. (f)(2). Pub. L. 100-532, §801(q)(2)(B), made a technical amendment to the reference to section 136a-1 of this title to reflect the renumbering of the corresponding section of the original act.

Subsec. (g). Pub. L. 100-532, §404, added subsec. (g).

Subsec. (h). Pub. L. 100-532, §201, redesignated former subsec. (f) as (h).

1984—Subsec. (c)(4). Pub. L. 98-620 struck out provisions requiring petitions to review orders on the issue of suspension to be advanced on the docket of the court of appeals.

1978—Subsec. (b). Pub. L. 95-396, §11, required the Administrator, in taking any final action under subsec. (b), to consider restricting a pesticide's use or uses as an alternative to cancellation and to fully explain the reasons for the restrictions.

Subsec. (c)(2). Pub. L. 95-251 substituted "administrative law judge" for "hearing examiner".

Subsecs. (e), (f). Pub. L. 95-396, §12, added subsec. (e) and redesignated former subsec. (e) as (f).

1975—Subsec. (b). Pub. L. 94-140 established criteria which Administrator must use in determining the issuance of a suspension of registration notice and the time periods relating to such notice, set forth required procedures to be followed by Administrator prior to publication of such notice, required procedures when the Secretary elects to comment or fails to comment on suspension notice, waiver or modification of time periods in specified required procedures, required procedures for waiver of notice and consent by Secretary for suspension of registration, and established criteria for Secretary taking any final action.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-532 effective on expiration of 60 days after Oct. 25, 1988, see section 901 of Pub. L. 100-532, set out as a note under section 136 of this title.

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by Pub. L. 98-620 not applicable to cases pending on Nov. 8, 1984, see section 403 of Pub. L. 98-620, set out as an Effective Date note under section 1657 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE

For effective date of section, see section 4 of Pub. L. 92-516, set out as a note under section 136 of this title.

§ 136e. Registration of establishments

(a) Requirement

No person shall produce any pesticide subject to this subchapter or active ingredient used in producing a pesticide subject to this subchapter in any State unless the establishment in which it is produced is registered with the Administrator. The application for registration of any establishment shall include the name and address of the establishment and of the producer who operates such establishment.

(b) Registration

Whenever the Administrator receives an application under subsection (a), the Administrator shall register the establishment and assign it an establishment number.

(c) Information required

(1) Any producer operating an establishment registered under this section shall inform the Administrator within 30 days after it is registered of the types and amounts of pesticides and, if applicable, active ingredients used in producing pesticides—

(A) which the producer is currently producing;

(B) which the producer has produced during the past year; and

(C) which the producer has sold or distributed during the past year.

The information required by this paragraph shall be kept current and submitted to the Administrator annually as required under such regulations as the Administrator may prescribe.