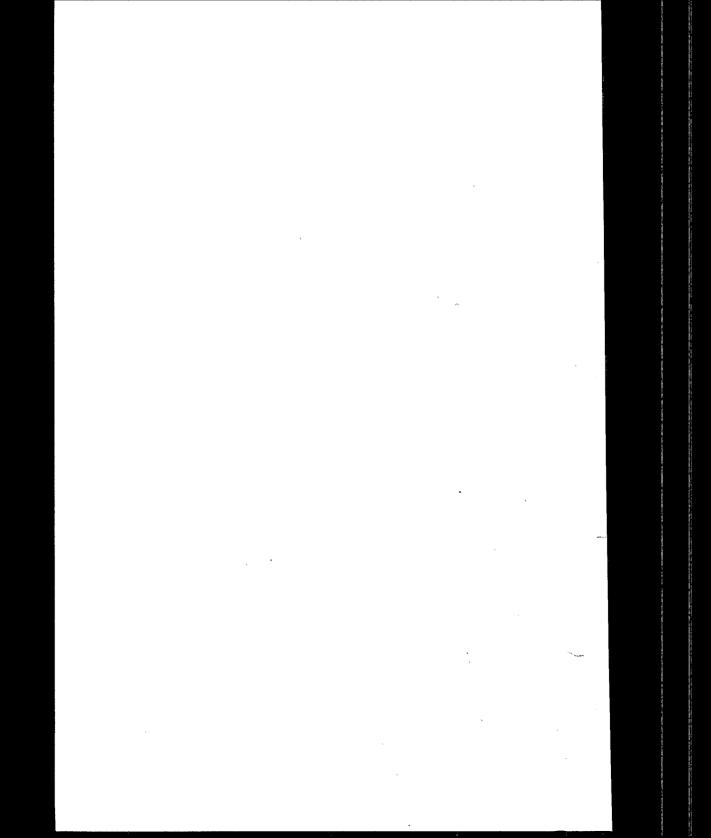
ŞEPA

Office of Pesticide Programs

The Federal Insecticide, Fungicide, and Rodenticide Act as Amended



FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

(THROUGH P.L. 100-460, 100-464 to 100-526, & 100-532)

(References [] in brackets are to title 7, United States Code)

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Bracketed material and footnotes did not appear in Acts.

Prepared by the Senate Legislative Counsel's Office.

Act of June 25, 1947 Chapter 125

AN ACT

To regulate the marketing of economic poisons and devices, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. [prec. 121] SHORT TITLE AND TABLE OF CONTENTS.

(a) Short Title.—This Act may be cited as the "Federal Insecticide, Fungicide, and Rodenticide Act".

(b) TABLE OF CONTENTS.—

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SEC. 2. [136] DEFINITIONS.

For purposes of this Act-

(a) ACTIVE INGREDIENT.—The term "active ingredient" means—

(1) in the case of a pesticide other than a plant regulator, defoliant, or desiccant, an ingredient which will prevent, destroy,

repel, or mitigate any pest;

(2) in the case of a plant regulator, an ingredient which, through physiological action, will accelerate or retard the rate of growth or rate of maturation or otherwise alter the behavior of ornamental or crop plants or the product thereof;

(3) in the case of a defoliant, an ingredient which will cause

the leaves or foliage to drop from a plant; and

(4) in the case of a desiccant, an ingredient which will artificially accelerate the drying of plant tissue.

(b) ADMINISTRATOR.—The term "Administrator" means the Administrator of the Environmental Protection Agency.

(c) ADULTERATED.—The term "adulterated" applies to any pesticide if—

(1) its strength or purity falls below the professed standard of quality as expressed on its labeling under which it is sold;

(2) any substance has been substituted wholly or in part for the pesticide; or

(3) any valuable constituent of the pesticide has been wholly or in part abstracted.

(d) Animal.—The term "animal" means all vertebrate and invertebrate species, including but not limited to man and other mammals, birds, fish, and shellfish.

(e) CERTIFIED APPLICATOR, ETC.—

(1) Certified applicator.—The term "certified applicator" means any individual who is certified under section 4 2 1 as authorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or use dilutions of registered pesticides consistent with section 2(ee) of this Act, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served is not deemed to be a seller or distributor of pesticides under this Act.

(2) PRIVATE APPLICATOR.—The term "private applicator" means a certified applicator who uses or supervises the use of any pesticide which is classified for restricted use for purposes of producing any agricultural commodity on property owned or rented by him or his employer or (if applied without compensation other than trading of personal services between producers of agricultural commodities) on the property of another person.

(3) COMMERCIAL APPLICATOR.—The term "commercial applicator" means an applicator (whether or not he is a private applicator with respect to some uses) who uses or supervises the use of any pesticide which is classified for restricted use for any purpose or on any property other than as provided by para-

graph (2).

(4) Under the direct supervision of a certified applicator.—Unless otherwise prescribed by its labeling, a pesticide shall be considered to be applied under the direct supervision of a certified applicator if it is applied by a competent person acting under the instructions and control of a certified applicator who is available if and when needed, even though such certified applicator is not physically present at the time and place the pesticide is applied.

(f) Defoliant.—The term "defoliant" means any substance or mixture of substances intended for causing the leaves or foliage to

drop from a plant, with or without causing abscission.

(g) Desiccant.—The term "desiccant" means any substance or mixture of substances intended for artificially accelerating the

drying of plant tissue.

(h) Device.—The term "device" means any instrument or contrivance (other than a firearm) which is intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life (other than man and other than bacteria, virus, or other microorganism on or in living man or other living animals); but not including equipment used for the application of pesticides when sold separately therefrom.

²¹So in original. Probably should be "section 11".

(i) DISTRICT COURT.—The term "district court" means a United States district court, the District Court of Guam, the District Court of the Virgin Islands, and the highest court of American Samoa.

(j) Environment.—The term "environment" includes water, air, land, and all plants and man and other animals living therein, and

the interrelationships which exist among these.

(k) Fungus.—The term "fungus" means any non-chlorophyll-bearing thallophyte (that is, any non-chlorophyll-bearing plant of a lower order than mosses and liverworts), as for example, rust, smut, mildew, mold, yeast, and bacteria, except those on or in living man or other animals and those on or in processed food, beverages, or pharmaceuticals.

(I) IMMINENT HAZARD.—The term "imminent hazard" means a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered by the Secretary of the Interior under Public Law 91-135.

35.
(m) INERT INGREDIENT.—The term "inert ingredient" means an

ingredient which is not active.
(n) INGREDIENT STATEMENT.—The term "ingredient statement"

means a statement which contains—

(1) the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticide;

(2) if the pesticide contains arsenic in any form, a statement of the percentages of total and water soluble arsenic, calculat-

ed as elementary arsenic.

(o) INSECT.—The term "insect" means any of the numerous small invertebrate animals generally having the body more or less obviously segmented, for the most part belonging to the class insecta, comprising six-legged, usually winged forms, as for example, beetles, bugs, bees, flies, and to other allied classes of arthropods whose members are wingless and usually have more than six legs, as for example, spiders, mites, ticks, centipedes, and wood lice.

(p) LABEL AND LABELING.—

(1) Label.—The term "label" means the written, printed, or graphic matter on, or attached to, the pesticide or device or any of its containers or wrappers.

(2) LABELING.—The term "labeling" means all labels and all

other written, printed, or graphic matter-

- (A) accompanying the pesticide or device at any time; or (B) to which reference is made on the label or in literature accompanying the pesticide or device, except to current official publications of the Environmental Protection Agency, the United States Departments of Agriculture and Interior, the Department of Health and Human Services, State experiment stations, State agricultural colleges, and other similar Federal or State institutions or agencies authorized by law to conduct research in the field of pesticides.
- (q) MISBRANDED.—

(1) A pesticide is misbranded if—

(A) its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular;

(B) it is contained in a package or other container or wrapping which does not conform to the standards established by the Administrator pursuant to section 25(c)(3);

(C) it is an imitation of, or is offered for sale under the

name of, another pesticide;

(D) its label does not bear the registration number assigned under section 7 to each establishment in which it

was produced;

(E) any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(F) the labeling accompanying it does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any requirements imposed under section 3(d) of this Act, are adequate to protect health and the environ-

ment;

(G) the label does not contain a warning or caution statement which may be necessary and if complied with, together with any requirements imposed under section 3(d) of this Act, is adequate to protect health and the environ-

ment; or

(H) in the case of a pesticide not registered in accordance with section 3 of this Act and intended for export, the label does not contain, in words prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or graphic matter in the labeling) as to render it likely to be noted by the ordinary individual under customary conditions of purchase and use, the following: "Not Registered for Use in the United States of America".

(2) A pesticide is misbranded if—

(Â) the label does not bear an ingredient statement on that part of the immediate container (and on the outside container or wrapper of the retail package, if there be one, through which the ingredient statement on the immediate container cannot be clearly read) which is presented or displayed under customary conditions of purchase, except that a pesticide is not misbranded under this subparagraph if—

(i) the size of form of the immediate container, or the outside container or wrapper of the retail package, makes it impracticable to place the ingredient statement on the part which is presented or displayed under customary conditions of purchase; and

(ii) the ingredient statement appears prominently on another part of the immediate container, or outside container or wrapper, permitted by the Administrator;

(B) the labeling does not contain a statement of the use classification under which the product is registered;

(C) there is not affixed to its container, and to the outside container or wrapper of the retail package, if there be one, through which the required information on the immediate container cannot be clearly read, a label bearing—

(i) the name and address of the producer, registrant,

or person for whom produced;

(ii) the name, brand, or trademark under which the

pesticide is sold;

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(iii) the net weight or measure of the content, except that the Administrator may permit reasonable variations; and

(iv) when required by regulation of the Administrator to effectuate the purposes of this Act, the registration number assigned to the pesticide under this Act, and the use classification; and

(D) the pesticide contains any substance or substances in quantities highly toxic to man, unless the label shall bear, in addition to any other matter required by this Act—

(i) the skull and crossbones;

(ii) the word "poison" prominently in red on a background of distinctly contrasting color; and

(iii) a statement of a practical treatment (first aid or

otherwise) in case of poisoning by the pesticide.

(r) NEMATORE.—The term "nematode" means invertebrate animals of the phylum nemathelminthes and class nematoda, that is, unsegmented round worms with elongated, fusiform, or saclike bodies covered with cuticle, and inhabiting soil, water, plants, or plant parts; may also be called nemas or eelworms.

(s) Person.—The term "person" means any individual, partnership, association, corporation, or any organized group of persons

whether incorporated or not.

(t) Pest.—The term "pest" means (1) any insect, rodent, nematode, fungus, weed, or (2) any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under section 25(c)(1).

(u) Pesticide.—The term "pesticide" means (1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant, except that the term "pesticide" shall not include any article that is a "new animal drug" within the meaning of section 201(w) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(w)), that has been determined by the Secretary of Health and Human

Services not to be a new animal drug by a regulation establishing

conditions of use for the article, or that is an animal feed within the meaning of section 201(x) of such Act (21 U.S.C. 321(x)) bearing

or containing a new animal drug.

(v) Plant Regulator.—The term "plant regulator" means any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term "plant regulator" shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products, intended for improvement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, nonpoisonous in the undiluted packaged concentration.

(w) Producer and Produce.—The term "producer" means the person who manufacturers, prepares, compounds, propagates, or processes any pesticide or device or active ingredient used in producing a pesticide. The term "produce" means to manufacture, prepare, compound, propagate, or process any pesticide or device or active ingredient used in producing a pesticide. The dilution by individuals of formulated pesticides for their own use and according to the directions on registered labels shall not of itself result in such individuals being included in the definition of "producer" for

the purposes of this Act.

(x) PROTECT HEALTH AND THE ENVIRONMENT.—The terms "protect health and the environment" and "protection of health and the environment" mean protection against any unreasonable adverse effects on the environment.

(y) REGISTRANT.—The term "registrant" means a person who has registered any pesticide pursuant to the provisions of this Act.

(z) REGISTRATION.—The term "registration" includes reregistration.

(aa) STATE.—The term "State" means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Trust Territory of the Pacific Islands, and American Samoa.

(bb) Unreasonable Adverse Effects on the Environment.— The term "unreasonable adverse effects on the environment" means any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.

benefits of the use of any pesticide.

(cc) Weed.—The term "weed" means any plant which grows

where not wanted.

(dd) ESTABLISHMENT.—The term "establishment" means any place where a pesticide or device or active ingredient used in producing a pesticide is produced, or held, for distribution or sale.

(ee) To Use Any Registered Pesticide in a Manner Inconsistent With Its Labeling.—The term "to use any registered pesticide in a manner inconsistent with its labeling" means to use any registered pesticide in a manner not permitted by the labeling, except that the term shall not include (1) applying a pesticide at any

dosage, concentration, or frequency less than that specified on the labeling unless the labeling specifically prohibits deviation from the specified dosage, concentration, or frequency, (2) applying a pesticide against any target pest not specified on the labeling if the application is to the crop, animal, or site specified on the labeling, unless the Administrator has required that the labeling specifically state that the pesticide may be used only for the pests specified on the labeling after the Administrator has determined that the use of the pesticide against other pests would cause an unreasonable adverse effect on the environment, (3) employing any method of application not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods specified on the labeling, (4) mixing a pesticide or pesticides with a fertilizer when such mixture is not prohibited by the labeling, (5) any use of a pesticide in conformance with section 5, 18, or 24 of this Act, or (6) any use of a pesticide in a manner that the Administrator determines to be consistent with the purposes of this Act. After March 31, 1979, the term shall not include the use of a pesticide for agricultural or forestry purposes at a dilution less than label dosage unless before or after that date the Administrator issues a regulation or advisory opinion consistent with the study provided for in section 27(b) of the Federal Pesticide Act of 1978, which regulation or advisory opinion specifically requires the use of definite amounts of dilution.

(ff) Outstanding Data Requirement.—

(1) In GENERAL.—The term "outstanding data requirement" means a requirement for any study, information, or data that is necessary to make a determination under section 3(c)(5) and which study, information, or data—

(A) has not been submitted to the Administrator; or

(B) if submitted to the Administrator, the Administrator has determined must be resubmitted because it is not valid, complete, or adequate to make a determination under section 3(c)(5) and the regulations and guidelines issued under such section.

(2) Factors.—In making a determination under paragraph (1)(B) respecting a study, the Administrator shall examine, at a minimum, relevant protocols, documentation of the conduct and analysis of the study, and the results of the study to determine whether the study and the results of the study fulfill the data requirement for which the study was submitted to the Administrator.

(gg) To Distribute or Sell.—The term "to distribute or sell" means to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, release for shipment, or receive and (having so received) deliver or offer to deliver. The term does not include the holding or application of registered pesticides or use dilutions thereof by any applicator who provides a service of controlling pests without delivering any unapplied pesticide to any person so served.

SEC. 3. [136a] REGISTRATION OF PESTICIDES.

(a) REQUIREMENT OF REGISTRATION.—Except as provided by this Act, no person in any State may distribute or sell to any person

any pesticide that is not registered under this Act. To the extent necessary to prevent unreasonable adverse effects on the environment, the Administrator may by regulation limit the distribution, sale, or use in any State of any pesticide that is not registered under this Act and that is not the subject of an experimental use permit under section 5 or an emergency exemption under section 18.

(b) Exemptions.—A pesticide which is not registered with the Ad-

ministrator may be transferred if-

(1) the transfer is from one registered establishment to another registered establishment operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment; or

(2) the transfer is pursuant to and in accordance with the re-

quirements of an experimental use permit.

(c) Procedure for Registration.—

(1) STATEMENT REQUIRED.—Each applicant for registration of a pesticide shall file with the Administrator a statement which includes—

(A) the name and address of the applicant and of any other person whose name will appear on the labeling;

(B) the name of the pesticide;

(C) a complete copy of the labeling of the pesticide, a statement of all claims to be made for it, and any directions for its use:

(D) except as otherwise provided in paragraph (2)(D), if requested by the Administrator, a full description of the tests made and the results thereof upon which the claims are based, or alternatively a citation to data that appear in the public literature or that previously had been submitted to the Administrator and that the Administrator may consider in accordance with the following provisions:

(i) with respect to pesticides containing active ingredients that are initially registered under this Act after the date of enactment of the Federal Pesticide Act of 1978 [September 30, 1978], data submitted to support the application for the original registration of the pesticide, or an application for an amendment adding any new use to the registration and that pertains solely to such new use, shall not, without the written permission of the original data submitter, be considered by the Administrator to support an application by another person during a period of ten years following the date the Administrator first registers the pesticide, except that such permission shall not be required in the case of defensive data;

(ii) except as otherwise provided in clause (i), with respect to data submitted after December 31, 1969, by an applicant or registrant to support an application for registration, experimental use permit, or amendment adding a new use to an existing registration, to support or maintain in effect an existing registration,

or for reregistration, the Administrator may, without the permission of the original data submitter, consider any such item of data in support of an application by any other person (hereinafter in this subparagraph referred to as the "applicant") within the fifteen-year period following the date the data were originally submitted only if the applicant has made an offer to compensate the original data submitter and submitted such offer to the Administrator accompanied by evidence of delivery to the original data submitter of the offer. The terms and amount of compensation may be fixed by agreement between the original data submitter and the applicant, or, failing such agreement, binding arbitration under this subparagraph. If, at the end of ninety days after the date of delivery to the original data submitter of the offer to compensate, the original data submitter and the applicant have neither agreed on the amount and terms of compensation nor on a procedure for reaching an agreement on the amount and terms of compensation, either person may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. The parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator determines that an original data submitter has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Notwithstanding any other provision of this Act, if the Administrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this subparagraph, or failed to comply with the terms of an agreement or arbitration decision concerning compensation under this subparagraph, the Administrator shall deny the application or cancel the registration of the pesticide in support of which the data were used without further hearing. Before the Administrator takes action under either of the preceding two sentences, the Administrator shall furnish to the affected person, by certified mail, notice of intent to take action and allow fifteen days from the date of delivery of the notice for the affected person to respond. If a registration is denied or canceled under this subparagraph, the Administrator may make such order as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registration action by the Administrator shall not be delayed pending the fixing of compensation;

(iii) after expiration of any period of exclusive use and any period for which compensation is required for the use of an item of data under clauses (i) and (ii), the Administrator may consider such item of data in support of an application by any other applicant without the permission of the original data submitter and without an offer having been received to compensate the original data submitter for the use of such item of

(E) the complete formula of the pesticide; and

(F) a request that the pesticide be classified for general use for restricted use, or for both.

(2) DATA IN SUPPORT OF REGISTRATION.—

(A) The Administrator shall publish guidelines specifying the kinds of information which will be required to support the registration of a pesticide and shall revise such guidelines from time to time. If thereafter he requires any additional kind of information under subparagraph (B) of this paragraph, he shall permit sufficient time for applicants to obtain such additional information. The Administrator, in establishing standards for data requirements for the registration of pesticides with respect to minor uses, shall make such standards commensurate with the anticipated extent of use, pattern of use, and the level and degree of potential exposure of man and the environment to the pesticide. In the development of these standards, the Administrator shall consider the economic factors of potential national volume of use, extent of distribution, and the impact of the cost of meeting the requirements on the incentives for any potential registrant to undertake the development of the required data. Except as provided by section 10, within 30 days after the Administrator registers a pesticide under this Act he shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision.

(B)(i) If the Administrator determines that additional data are required to maintain in effect an existing registration of a pesticide, the Administrator shall notify all existing registrants of the pesticide to which the determina-

tion relates and provide a list of such registrants to any

interested person.

(ii) Each registrant of such pesticide shall provide evidence within ninety days after receipt of notification that it is taking appropriate steps to secure the additional data that are required. Two or more registrants may agree to develop jointly, or to share in the cost of developing, such data if they agree and advise the Administrator of their intent within ninety days after notification. Any registrant who agrees to share in the cost of producing the data shall be entitled to examine and rely upon such data in support of maintenance of such registration. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iii) If, at the end of sixty days after advising the Administrator of their agreement to develop jointly, or share in the cost of developing data, the registrants have not further agreed on the terms of the data development arrangement or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration proceedings by requesting the Federal Mediation and Conciliation Service to appoint an arbitrator from the roster of arbitrators maintained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbitrator and to such arbitration proceedings, and the findings and determination of the arbitrator shall be final and conclusive, and no official or court of the United States shall have power or jurisdiction to review any such findings and determination, except for fraud, misrepresentation, or other misconduct by one of the parties to the arbitration or the arbitrator where there is a verified complaint with supporting affidavits attesting to specific instances of such fraud, misrepresentation, or other misconduct. All parties to the arbitration shall share equally in the payment of the fee and expenses of the arbitrator. The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by clause (iv) if a registrant fails to comply with this clause.

(iv) Notwithstanding any other provision of this Act, if the Administrator determines that a registrant, within the time required by the Administrator, has failed to take appropriate steps to secure the data required under this subparagraph, to participate in a procedure for reaching agreement concerning a joint data development arrangement under this subparagraph or in an arbitration proceeding as required by this subparagraph, or to comply with the terms of an agreement or arbitration decision concerning a joint data development arrangement under this subparagraph, the Administrator may issue a notice of intent to suspend such registrant's registration of the

pesticide for which additional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Administrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any suspension proposed under this subparagraph shall become final and effective at the end of thirty days from receipt by the registrant of the notice of intent to suspend, unless during that time a request for hearing is made by a person adversely affected by the notice or the registrant has satisfied the Administrator that the registrant has complied fully with the requirements that served as a basis for the notice of intent to suspend. If a hearing is requested, a hearing shall be conducted under section 6(d) of this Act. The only matters for resolution at that hearing shall be whether the registrant has failed to take the action that served as the basis for the notice of intent to suspend the registration of the pesticide for which additional data is required, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with this Act. If a hearing is held, a decision after completion of such hearing shall be final. Notwithstanding any other provision of this Act, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing. Any registration suspended under this subparagraph shall be reinstated by the Administrator if the Administrator determines that the registrant has complied fully with the requirements that served as a basis for the suspension of the registration.

(v) Any data submitted under this subparagraph shall be subject to the provisions of paragraph (1)(D). Whenever such data are submitted jointly by two or more registrants, an agent shall be agreed on at the time of the joint submission to handle any subsequent data compensation mat-

ters for the joint submitters of such data.

(C) Within nine months after the date of enactment of this subparagraph [September 30, 1978], the Administrator shall, by regulation, prescribe simplified procedures for the registration of pesticides, which shall include the provisions of subparagraph (D) of this paragraph.

(D) Exemption.—No applicant for registration of a pesticide who proposes to purchase a registered pesticide from another producer in order to formulate such purchased pesticide into the pesticide that is the subject of the appli-

cation 3-1 shall be required to-

(i) submit or cite data pertaining to such purchased product; or

⁵¹ Section 102(b)(2)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act Amendments of 1988 (P.L. 100-532) amended this subparagraph by striking out "an end use product" and inserting in lieu thereof "the pesticide that is the subject of the application". Before the amendment, the text of this subparagraph contained the phrase "an end-use product", with a hyphen. The amendment was executed to this subparagraph to effectuate the probable intent of Con-OTRES.

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(ii) offer to pay reasonable compensation otherwise required by paragraph (1)(D) of this subsection for the use of any such data.

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- (3) TIME FOR ACTING WITH RESPECT TO APPLICATION.—
 - (A) The Administrator shall review the data after receipt of the application and shall, as expeditiously as possible, either register the pesticide in accordance with paragraph (5), or notify the applicant of his determination that it does not comply with the provisions of the Act in accordance with paragraph (6).

(B)(i) The Administrator shall, as expeditiously as possible, review and act on any application received by the Administrator that—

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or

(II) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.

(ii) In expediting the review of an application for an action described in clause (i), the Administrator shall—

(I) within 45 days after receiving the application, notify the registrant whether or not the application is complete and, if the application is found to be incomplete, reject the application;

(II) within 90 days after receiving a complete application, notify the registrant if the application has been granted or denied; and

(III) if the application is denied, notify the registrant in writing of the specific reasons for the denial of the application.

- (4) NOTICE OF APPLICATION.—The Administrator shall publish in the Federal Register, promptly after receipt of the statement and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide if it contains any new active ingredient or if it would entail a changed use pattern. The notice shall provide for a period of 30 days in which any Federal agency or any other interested person may comment.
- (5) APPROVAL OF REGISTRATION.—The Administrator shall register a pesticide if he determines that, when considered with any restrictions imposed under subsection (d)—

(A) its composition is such as to warrant the proposed

claims for it;
(B) its labeling and other material required to be submitted comply with the requirements of this Act;

(C) it will perform its intended function without unreasonable adverse effects on the environment; and

(D) when used in accordance with widespread and commonly recognized practice it will not generally cause un-

reasonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a criterion for denying registration of any pesticide. Where two pesticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an application for the registration of a pesticide, the Administrator may waive data requirements pertaining to efficacy, in which event the Administrator may register the pesticide without determining that the pesticide's composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be efficacious by any State under section 24(c) of this Act, a presumption is established that the Administrator shall waive data requirements pertaining to efficacy for use of the pesticide in such State.

(6) Denial of registration.—If the Administrator determines that the requirements of paragraph (5) for registration are not satisfied, he shall notify the applicant for registration of his determination and of his reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and notifies the Administrator thereof during the 30day period beginning with the day after the date on which the applicant receives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, he shall notify the applicant of his decision and of his reasons (including the factual basis) therefor. The Administrator shall promptly publish in the Federal Register notice of such denial of registration and the reasons therefor. Upon such notification, the applicant for registration or other interested person with the concurrence of the applicant shall have the same remedies as provided for in section 6.

(7) REGISTRATION UNDER SPECIAL CIRCUMSTANCES.—Notwith-

standing the provisions of paragraph (5)-

(A) The Administrator may conditionally register or amend the registration of a pesticide if the Administrator determines that (i) the pesticide and proposed use are identical or substantially similar to any currently registered pesticide and use thereof, or differ only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment, and (ii) approving the registration or amendment in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. An applicant seeking conditional registration or amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data because it has not yet been generated, the Administrator may register or amend the registration of the pesticide under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to

similar pesticides already registered under this Act.

(B) The Administrator may conditionally amend the registration of a pesticide to permit additional uses of such pesticide notwithstanding that data concerning the pesticide may be insufficient to support an unconditional amendment, if the Administrator determines that (i) the applicant has submitted satisfactory data pertaining to the proposed additional use, and (ii) amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provisions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pesticide if the Administrator has issued a notice stating that such pesticide, or any ingredient thereof, meets or exceeds risk criteria associated in whole or in part with human dietary exposure enumerated in regulations issued under this Act, and during the pendency of any risk-benefit evaluation initiated by such notice, if (I) the additional use of such pesticide involves a major food or feed crop, or (II) the additional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concurrence of the Secretary of Agriculture, there is available an effective alternative pesticide that does not meet or exceed such risk criteria. An applicant seeking amended registration under this subparagraph shall submit such data as would be required to obtain registration of a similar pesticide under paragraph (5). If the applicant is unable to submit an item of data (other than data pertaining to the proposed additional use) because it has not yet been generated, the Administrator may amend the registration under such conditions as will require the submission of such data not later than the time such data are required to be submitted with respect to similar pesticides already registered under this Act.

(C) The Administrator may conditionally register a pesticide containing an active ingredient not contained in any currently registered pesticide for a period reasonably sufficient for the generation and submission of required data (which are lacking because a period reasonably sufficient for generation of the data has not elapsed since the Administrator first imposed the data requirement) on the condition that by the end of such period the Administrator receives such data and the data do not meet or exceed risk criteria enumerated in regulations issued under this Act, and on such other conditions as the Administrator may prescribe. A conditional registration under this subparagraph shall be granted only if the Administrator determines that use of the pesticide during such period will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is in the public interest.

(8) Interim administrative review.—Notwithstanding any other provision of this Act, the Administrator may not initiate a public interim administrative review process to develop a risk-benefit evaluation of the ingredients of a pesticide or any of its uses prior to initiating a formal action to cancel, suspend, or deny registration of such pesticide, required under this Act, unless such interim administrative process is based on a validated test or other significant evidence raising prudent concerns of unreasonable adverse risk to man or to the environment. Notice of the definition of the terms "validated test" and "other significant evidence" as used herein shall be published by the Administrator in the Federal Register.

(d) Classification of Pesticides.—

(1) CLASSIFICATION FOR GENERAL USE, RESTRICTED USE, OR BOTH.—

(A) As a part of the registration of a pesticide the Administrator shall classify it as being for general use or for restricted use. If the Administrator determines that some of the uses for which the pesticide is registered should be for general use and that other uses for which it is registered should be for restricted use, he shall classify it for both general use and restricted use. Pesticide uses may be classified by regulation on the initial classification and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are classified for general use and other uses are classified for restricted use, the directions relating to its general uses shall be clearly separated and distinguished from those directions relating to its restricted uses. The Administrator may require that its packaging and labeling for restricted uses shall be clearly distinguishable from its packaging and labeling for general uses.

(B) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, will not generally cause unreasonable adverse effects on the environment, he will classify the pesticide, or the particular use or uses of the pesticide to which the determination

applies, for general use.

(C) If the Administrator determines that the pesticide, when applied in accordance with its directions for use, warnings and cautions and for the uses for which it is registered, or for one or more of such uses, or in accordance with a widespread and commonly recognized practice, may generally cause, without additional regulatory restrictions, unreasonable adverse effects on the environment, including injury to the applicator, he shall classify the pesticide, or the particular use or uses to which the determination applies, for restricted use:

(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use be-

cause of a determination that the acute dermal or inhalation toxicity of the pesticide presents a hazard to the applicator or other persons, the pesticide shall be applied for any use to which the restricted classification applies only by or under the direct supervision of a certified applicator.

(ii) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because of a determination that its use without additional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination applies only by or under the direct supervision of a certified applicator, or subject to such other restrictions as the Administrator may provide by regulation. Any such regulation shall be reviewable in the appropriate court of appeals upon petition of a person adversely affected filed within 60 days of the publication of the regulation in final form.

(2) CHANGE IN CLASSIFICATION.—If the Administrator determines that a change in the classification of any use of a pesticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, he shall notify the registrant of such pesticide of such determination at least forty-five days before making the change and shall publish the proposed change in the Federal Register. The registrant, or other interested person with the concurrence of the registrant, may seek relief from such determination under sec-

tion 6(b).

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(3) CHANGE IN CLASSIFICATION FROM RESTRICTED USE TO GENERAL USE.—The registrant of any pesticide with one or more uses classified for restricted use may petition the Administrator to change any such classification from restricted to general use. Such petition shall set out the basis for the registrant's position that restricted use classification is unnecessary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environment. The Administrator, within sixty days after receiving such petition, shall notify the registrant whether the petition has been granted or denied. Any denial shall contain an explanation therefor and any such denial shall be subject to judicial review under section 16 of this Act.

(e) Products With Same Formulation and Claims.—Products which have the same formulation, are manufactured by the same person, the labeling of which contains the same claims, and the labels of which bear a designation identifying the product as the same pesticide may be registered as a single pesticide; and additional names and labels shall be added to the registration by supplemental statements.

(f) MISCELLANEOUS.—

(1) EFFECT OF CHANGE OF LABELING OR FORMULATION.—If the labeling or formulation for a pesticide is changed, the registration shall be amended to reflect such change if the Administra-

tor determines that the change will not violate any provision of this Act.

(2) REGISTRATION NOT A DEFENSE.—In no event shall registration of an article be construed as a defense for the commission of any offense under this Act. As long as no cancellation proceedings are in effect registration of a pesticide shall be prima facie evidence that the pesticide, its labeling and packaging comply with the registration provisions of the Act.

(3) AUTHORITY TO CONSULT OTHER FEDERAL AGENCIES.—In connection with consideration of any registration or application for registration under this section, the Administrator may consult with any other Federal agency.

SEC. 4. [136b] REREGISTRATION OF REGISTERED PESTICIDES.

- (a) GENERAL RULE.—The Administrator shall reregister, in accordance with this section, each registered pesticide containing any active ingredient contained in any pesticide first registered before November 1, 1984, except for any pesticide as to which the Administrator has determined, after November 1, 1984, and before the effective date of this section [December 24, 1988], that—
 - (1) there are no outstanding data requirements; and(2) the requirements of section 3(c)(5) have been satisfied.
- (b) REREGISTRATION PHASES.—Reregistrations of pesticides under this section shall be carried out in the following phases:

(1) The first phase shall include the listing under subsection (c) of the active ingredients of the pesticides that will be reregistered.

(2) The second phase shall include the submission to the Administrator under subsection (d) of notices by registrants respecting their intention to seek reregistration, identification by registrants of missing and inadequate data for such pesticides, and commitments by registrants to replace such missing or inadequate data within the applicable time period.

(3) The third phase shall include submission to the Administrator by registrants of the information required under subsection (e).

(4) The fourth phase shall include an independent, initial review by the Administrator under subsection (f) of submissions under phases two and three, identification of outstanding data requirements, and the issuance, as necessary, of requests for additional data.

(5) The fifth phase shall include the review by the Administrator under subsection (g) of data submitted for reregistration and appropriate regulatory action by the Administrator.

(c) Phase One.—

(1) Priority for reregistration.—For purposes of the reregistration of the pesticides described in subsection (a), the Administrator shall list the active ingredients of pesticides and shall give priority to, among others, active ingredients (other than active ingredients for which registration standards have been issued before the effective date of this section [December 24, 1988]) that—

(A) are in use on or in food or feed and may result in postharvest residues;

(B) may result in residues of potential toxicological concern in potable ground water, edible fish, or shellfish;

(C) have been determined by the Administrator before the effective date of this section [December 24, 1988] to have significant outstanding data requirements; or

(D) are used on crops, including in greenhouses and nurseries, where worker exposure is most likely to occur.
 (2) Referentation lists.—For purposes of reregistration

under this section, the Administrator shall by order-

(A) not later than 70 days after the effective date of this section [December 24, 1988], list pesticide active ingredients for which registration standards have been issued before such effective date;

(B) not later than 4 months after such effective date, list the first 150 pesticide active ingredients, as determined

under paragraph (1);

(C) not later than 7 months after such effective date, list the second 150 pesticide active ingredients, as determined under paragraph (1); and

(D) not later than 10 months after such effective date, list the remainder of the pesticide active ingredients, as

determined under paragraph (1).

Each list shall be published in the Federal Register.

(3) JUDICIAL REVIEW.—The content of a list issued by the Administrator under paragraph (2) shall not be subject to judicial review.

(4) Notice to registrants.—On the publication of a list of pesticide active ingredients under paragraph (2), the Administrator shall send by certified mail to the registrants of the pesticides containing such active ingredients a notice of the time by which the registrants are to notify the Administrator under subsection (d) whether the registrants intend to seek or not to seek reregistration of such pesticides.

(d) Phase Two.—

- (1) IN GENERAL.—The registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) shall submit to the Administrator, within the time period prescribed by paragraph (4), the notice described in paragraph (2) and any information, commitment, or offer described in paragraph (3).
- (2) NOTICE OF INTENT TO SEEK OR NOT TO SEEK REREGISTRATION.—
 - (A) The registrant of a pesticide containing an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) shall notify the Administrator by certified mail whether the registrant intends to seek or does not intend to seek reregistration of the pesticide.

(B) If a registrant submits a notice under subparagraph (A) of an intention not to seek reregistration of a pesticide, the Administrator shall publish a notice in the Federal Register stating that such a notice has been submitted.

(3) Missing or inadequate data.—Each registrant of a pesticide that contains an active ingredient listed under subpara-

graph (B), (C), or (D) of subsection (c)(2) and for which the registrant submitted a notice under paragraph (2) of an intention to seek reregistration of such pesticide shall submit to the Administrator—

(A) in accordance with regulations issued by the Admin-

istrator under section 3, an identification of—

(i) all data that are required by regulation to support the registration of the pesticide with respect to such active ingredient;

(ii) data that were submitted by the registrant previously in support of the registration of the pesticide that are inadequate to meet such regulations; and

(iii) data identified under clause (i) that have not

been submitted to the Administrator; and

(B) either—

(i) a commitment to replace the data identified under subparagraph (A)(ii) and submit the data identified under subparagraph (A)(iii) within the applicable time period prescribed by paragraph (4)(B); or

(ii) an offer to share in the cost to be incurred by a person who has made a commitment under clause (i) to replace or submit the data and an offer to submit to arbitration as described by section 3(c)(2)(B) with

regard to such cost sharing.

For purposes of a submission by a registrant under subparagraph (A)(ii), data are inadequate if the data are derived from a study with respect to which the registrant is unable to make the certification prescribed by subsection (e)(1)(G) that the registrant possesses or has access to the raw data used in or generated by such study. For purposes of a submission by a registrant under such subparagraph, data shall be considered to be inadequate if the data are derived from a study submitted before January 1, 1970, unless it is demonstrated to the satisfaction of the Administrator that such data should be considered to support the registration of the pesticide that is to be reregistered.

(4) Time periods.—

(A) A submission under paragraph (2) or (3) shall be made—

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 3 months after the date of publication of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 3 months after the date of publication of the list-

ing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 3 months after the date of publication of the listing of such active ingredient.

On application, the Administrator may extend a time period prescribed by this subparagraph if the Administra-

tor determines that factors beyond the control of the registrant prevent the registrant from complying with such

period.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (3)(B) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

(5) CANCELLATION AND REMOVAL.—

(A) If the registrant of a pesticide does not submit a notice under paragraph (2) or (3) within the time prescribed by paragraph (4)(A), the Administrator shall issue a notice of intent to cancel the registration of such registrant for such pesticide and shall publish the notice in the Federal Register and allow 60 days for the submission of comments on the notice. On expiration of such 60 days, the Administrator, by order and without a hearing, may cancel the registration or take such other action, including extension of applicable time periods, as may be necessary to enable reregistration of such pesticide by another person.

(B)(i) If—

(I) no registrant of a pesticide containing an active ingredient listed under subsection (c)(2) notifies the Administrator under paragraph (2) that the registrant intends to seek reregistration of any pesticide containing that active ingredient;

(II) no such registrant complies with paragraph

(3)(A); or

(III) no such registrant makes a commitment under paragraph (3)(B) to replace or submit all data described in clauses (ii) and (iii) of paragraph (3)(A);

the Administrator shall publish in the Federal Register a notice of intent to remove the active ingredient from the list established under subsection (c)(2) and a notice of intent to cancel the registrations of all pesticides containing such active ingredient and shall provide 60 days for comment on such notice.

(ii) After the 60-day period has expired, the Administrator, by order, may cancel any such registration without hearing, except that the Administrator shall not cancel a

registration under this subparagraph if—

(I) during the comment period a person acquires the

rights of the registrant in that registration;

(II) during the comment period that person furnishes a notice of intent to reregister the pesticide in accordance with paragraph (2); and

(III) not later than 120 days after the publication of the notice under this subparagraph, that person has complied with paragraph (3) and the fee prescribed by

subsection (i)(1) has been paid.

(6) Suspensions and penalties.—The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 3(c)(2)(B)(iv) if the Administrator determines that (A) progress is insufficient to ensure the submission of the data required for such pesticide under a commitment made under paragraph (3)(B) within the time period prescribed by paragraph (4)(B) or (B) the registrant has not submitted such data to the Administrator within such time period.

(e) Phase Three.—

(1) Information about studies.—Each registrant of a pesticide that contains an active ingredient listed under subparagraph (B), (C), or (D) of subsection (c)(2) who has submitted a notice under subsection (d)(2) of an intent to seek the reregistration of such pesticide shall submit, in accordance with the guidelines issued under paragraph (4), to the Administrator—

(A) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient and considered by the registrant to be adequate to meet the requirements of section 3 and the regulations

issued under such section;

(B) a summary of each study concerning the active ingredient previously submitted by the registrant in support of the registration of a pesticide containing such active ingredient that may not comply with the requirements of section 3 and the regulations issued under such section but which the registrant asserts should be deemed to comply with such requirements and regulations;

(C) a reformat of the data from each study summarized under subparagraph (A) or (B) by the registrant concerning chronic dosing, oncogenicity, reproductive effects, mutagenicity, neurotoxicity, teratogenicity, or residue chemistry of the active ingredient that were submitted to the Ad-

ministrator before January 1, 1982;

(D) where data described in subparagraph (C) are not required for the active ingredient by regulations issued under section 3, a reformat of acute and subchronic dosing data submitted by the registrant to the Administrator before January 1, 1982, that the registrant considers to be adequate to meet the requirements of section 3 and the regulations issued under such section;

(E) an identification of data that are required to be submitted to the Administrator under section 6(a)(2) indicat-

ing an adverse effect of the pesticide;

(F) an identification of any other information available that in the view of the registrant supports the registration; (G) a certification that the registrant or the Administrator possesses or has access to the raw data used in or gen-

erated by the studies that the registrant summarized under subparagraph (A) or (B);

(H) either—

(i) a commitment to submit data to fill each outstanding data requirement identified by the registrant; or

(ii) an offer to share in the cost of developing such data to be incurred by a person who has made a commitment under clause (i) to submit such data, and an offer to submit to arbitration as described by section 3(c)(2)(B) with regard to such cost sharing; and

(I) evidence of compliance with section 3(c)(1)(D)(ii) and regulations issued thereunder with regard to previously submitted data as if the registrant were now seeking the

original registration of the pesticide. A registrant who submits a certification under subparagraph (G) that is false shall be considered to have violated this Act and shall be subject to the penalties prescribed by section 14.

(2) TIME PERIODS.—

(A) The information required by paragraph (1) shall be

submitted to the Administrator-

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 12 months after the date of publication of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 12 months after the date of publication of the

listing of such active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 12 months after the date of publication of the

listing of such active ingredient.

(B) A registrant shall submit data in accordance with a commitment entered into under paragraph (1)(H) within a reasonable period of time, as determined by the Administrator, but not more than 48 months after the date the registrant submitted the commitment under such paragraph. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

(3) CANCELLATION.—

(A) If the registrant of a pesticide fails to submit the information required by paragraph (1) within the time prescribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pesticide.

(B)(i) If the registrant of a pesticide submits the information required by paragraph (1) within the time prescribed by paragraph (2) and such information does not conform to

the guidelines for submissions established by the Administrator, the Administrator shall determine whether the registrant made a good faith attempt to conform its submis-

sion to such guidelines.

(ii) If the Administrator determines that the registrant made a good faith attempt to conform its submission to such guidelines, the Administrator shall provide the registrant a reasonable period of time to make any necessary changes or corrections.

(iii)(I) If the Administrator determines that the registrant did not make a good faith attempt to conform its submission to such guidelines, the Administrator may issue a notice of intent to cancel the registration. Such a notice shall be sent to the registrant by certified mail.

(II) The registration shall be canceled without a hearing or further notice at the end of 30 days after receipt by the registrant of the notice unless during that time a request

for a hearing is made by the registrant.

(III) If a hearing is requested, a hearing shall be conducted under section 6(d), except that the only matter for resolution at the hearing shall be whether the registrant made a good faith attempt to conform its submission to such guidelines. The hearing shall be held and a determination made within 75 days after receipt of a request for hearing.

(4) GUIDELINES.—

- (A) Not later than 1 year after the effective date of this section [December 24, 1988], the Administrator, by order, shall issue guidelines to be followed by registrants in—
 - (i) summarizing studies;(ii) reformatting studies;

(iii) identifying adverse information; and

(iv) identifying studies that have been submitted previously that may not meet the requirements of section 3 or regulations issued under such section, under paragraph (1).

(B) Guidelines issued under subparagraph (A) shall not

be subject to judicial review.

(5) Monitoring.—The Administrator shall monitor the progress of registrants in acquiring and submitting the data required under paragraph (1).

(f) Phase Four.—

(1) Independent review and identification of outstanding data requirements.—

(A) The Administrator shall review the submissions of all registrants of pesticides containing a particular active ingredient under subsections (d)(3) and (e)(1) to determine if such submissions identified all the data that are missing or inadequate for such active ingredient. To assist the review of the Administrator under this subparagraph, the Administrator may require a registrant seeking reregistration to submit complete copies of studies summarized under subsection (e)(1).

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tion. The Administrator, at the same time, shall issue a notice under section 3(c)(2)(B) for the submission of the additional data that are required to meet such requirements. (2) TIME PERIODS.—

(A) The Administrator shall take the action required by

paragraph (1)—

(i) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(B), not later than 18 months after the date of the listing of such active ingredient;

(ii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(C), not later than 24 months after the date of the listing of such

active ingredient; and

(iii) in the case of a pesticide containing an active ingredient listed under subsection (c)(2)(D), not later than 33 months after the date of the listing of such

active ingredient.

(B) If the Administrator issues a notice to a registrant under paragraph (1)(B) for the submission of additional data, the registrant shall submit such data within a reasonable period of time, as determined by the Administrator, but not to exceed 48 months after the issuance of such notice. The Administrator, on application of a registrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary circumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period.

(3) 4-1 Suspensions and penalties.—The Administrator shall issue a notice of intent to suspend the registration of a pesticide in accordance with the procedures prescribed by section 3(c)(2)(B)(iv) if the Administrator determines that (A) tests necessary to fill an outstanding data requirement for such pesticide have not been initiated within 1 year after the issuance of a notice under paragraph (1)(B), or (B) progress is insufficient to ensure submission of the data referred to in clause (A) within the time period prescribed by paragraph (2)(B) or the required data have not been submitted to the Administrator within such time period.

(g) Phase Five.—

(1) Data review.—The Administrator shall conduct a thorough examination of all data submitted under this section concerning an active ingredient listed under subsection (c)(2) and

⁺¹So in original. Margin of paragraph (3) should be aligned with margin of preceding paragraph (2).

of all other available data found by the Administrator to be relevant.

(2) Reregistration and other actions.—

(A) Within 1 year after the submission of all data concerning an active ingredient of a pesticide under subsection (f), the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration. For extraordinary circumstances, the Administrator may extend such period for not more than 1 addi-

tional year.

(B) Before reregistering a pesticide, the Administrator shall obtain any needed product-specific data regarding the pesticide by use of section 3(c)(2)(B) and shall review such data within 90 days after its submission. The Administrator shall require that data under this subparagraph be submitted to the Administrator not later than 8 months after a determination of eligibility under subparagraph (A) has been made for each active ingredient of the pesticide, unless the Administrator determines that a longer period is required for the generation of the data.

(C) After conducting the review required by paragraph (1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Administrator shall determine whether to reregister a pesticide by determining whether such pesticide meets the requirements of section 3(c)(5). If the Administrator determines that a pesticide is eligible to be reregistered, the Administrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide

under subparagraph (B).

(D) If after conducting a review under paragraph (1) or subparagraph (B) of this paragraph the Administrator determines that a pesticide should not be reregistered, the Administrator shall take appropriate regulatory action.

(h) Compensation of Data Submitter.—If data that are submitted by a registrant under subsection (d), (e), (f), or (g) are used to support the application of another person under section 3, the registrant who submitted such data shall be entitled to compensation for the use of such data as prescribed by section 3(c)(1)(D). In determining the amount of such compensation, the fees paid by the registrant under this section shall be taken into account.

(i) FEES.—

(1) Initial fee for food or feed use pesticide active ingre-DIENTS.—The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (c)(2) and that is an active ingredient of any pesticide registered for a major food or feed use shall collectively pay a fee of \$50,000 on submission of information under paragraphs (2) and (3) of subsection (d) for such ingredient.

(2) Final fee for food or feed use pesticide active

INGREDIENTS.-

(A) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) 33

of subsection (c)(2) and that is an active ingredient of any pesticide registered for a major food or feed use shall collectively pay a fee of \$100,000—

(i) on submission of information for such ingredient under subsection (e)(1) if data are reformatted under

subsection (e)(1)(C); or

(ii) on submission of data for such ingredient under subsection (e)(2)(B) if data are not reformatted under

subsection (e)(1)(C).

(B) The registrants of pesticides that contain an active ingredient that is listed under subsection (c)(2)(A) and that is an active ingredient of any pesticide registered for a major food or feed use shall collectively pay a fee of \$150,000 at such time as the Administrator shall prescribe.

(3) FEES FOR OTHER PESTICIDE ACTIVE INGREDIENTS.—

(A) The registrants of pesticides that contain an active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (c)(2) and that is not an active ingredient of any pesticide registered for a major food or feed use shall collectively pay fees in amounts determined by the Administrator. Such fees may not be less than one-half of, nor greater than, the fees required by paragraphs (1) and (2). A registrant shall pay such fees at the times corresponding to the times fees prescribed by paragraphs (1) and (2) are to be paid.

(B) The registrants of pesticides that contain an active ingredient that is listed under subsection (c)(2)(A) and that is not an active ingredient of any pesticide that is registered for a major food or feed use shall collectively pay a fee of not more than \$100,000 and not less than \$50,000 at

such time as the Administrator shall prescribe.

(4) REDUCTION OR WAIVER OF FEES FOR MINOR USE AND OTHER PESTICIDES.-

(A) An active ingredient that is contained only in pesticides that are registered solely for agricultural or nonagricultural minor uses, or a pesticide the value or volume of use of which is small, shall be exempt from the fees pre-

scribed by paragraph (3).

(B) An antimicrobial active ingredient, the production level of which does not exceed 1,000,000 pounds per year, shall be exempt from the fees prescribed by paragraph (3). For purposes of this subparagraph, the term "antimicrobial active ingredient" means any active ingredient that is contained only in pesticides that are not registered for any food or feed use and that are-

(i) sanitizers intended to reduce the number of living bacteria or viable virus particles on inanimate surface

or in water or air;

(ii) bacteriostats intended to inhibit the growth of

bacteria in the presence of moisture;

(iii) disinfectants intended to destroy or irreversibly inactivate bacteria, fungi, or viruses on surfaces or inanimate objects;

(iv) sterilizers intended to destroy viruses and all living bacteria, fungi, and their spores on inanimate surfaces; or

(v) fungicides or fungistats.

(C)(i) Notwithstanding any other provision of this subsection, in the case of a small business registrant of a pesticide, the registrant shall pay a fee for the reregistration of each active ingredient of the pesticide that does not exceed an amount determined in accordance with this subparagraph.

(ii) If during the 3-year period prior to reregistration the average annual gross revenue of the registrant from pesti-

cides containing such active ingredient is-

(I) less than \$5,000,000, the registrant shall pay 0.5 percent of such revenue;

(II) \$5,000,000 or more but less than \$10,000,000, the registrant shall pay 1 percent of such revenue; or

(III) \$10,000,000 or more, the registrant shall pay 1.5 percent of such revenue, but not more than \$150,000.

(iii) For the purpose of this subparagraph, a small business registrant is a corporation, partnership, or unincorporated business that—

(I) has 150 or fewer employees; and

(II) during the 3-year period prior to reregistration, had an average annual gross revenue from chemicals that did not exceed \$40,000,000.

(5) MAINTENANCE FEE.—

(A) Subject to other provisions of this paragraph, each registrant of a pesticide shall pay an annual fee by March 1 of each year of—

(i) in the case of a registrant holding not more than 50 pesticide registrations, \$425 for each registration;

and

(ii) in the case of a registrant holding more than 50 pesticide registrations—

(I) \$425 for each registration up to 50 registra-

tions; and

(II) \$100 for each registration over 50 registrations, except that no fee shall be charged for more than 200 registrations held by any registrant.

(B) The amount of each fee prescribed under subparagraph (A) shall be adjusted by the Administrator to a level that will result in the collection under this paragraph of, to the extent practicable, an aggregate amount of \$14,000,000 each fiscal year.

(C)(i) The maximum annual fee payable by a registrant under clause (i) of subparagraph (A) (as adjusted under

subparagraph (B)) shall be \$20,000.

(ii) The maximum annual fee payable by a registrant under clause (ii) of subparagraph (A) (as adjusted under subparagraph (B)) shall be \$35,000.

(D) If any fee prescribed by this paragraph with respect to the registration of a pesticide is not paid by a registrant

by the time prescribed, the Administrator, by order and without hearing, may cancel the registration.

(E) The authority provided under this paragraph shall

terminate on September 30, 1997.

(6) OTHER FEES.—During the period beginning on the date of enactment of this section [October 25, 1988] and ending on September 30, 1997, the Administrator may not levy any other fees for the registration of a pesticide under this Act except as provided in paragraphs (1) through (5).

(7) Apportionment.—

(A) If two or more registrants are required to pay any fee prescribed by paragraph (1), (2), or (3) with respect to a particular active ingredient, the fees for such active ingredient shall be apportioned among such registrants on the basis of the market share in United States sales of the active ingredient for the 3 calendar years preceding the date of payment of such fee, except that—

(i) small business registrants that produce the active ingredient shall pay fees in accordance with paragraph (4)(C); and

(ii) registrants who have no market share but who choose to reregister a pesticide containing such active ingredient shall pay the lesser of—

(I) 15 percent of the reregistration fee; or

(II) a proportionate amount of such fee based on the lowest percentage market share held by any registrant active in the marketplace.

In no event shall registrants who have no market share but who choose to reregister a pesticide containing such active ingredient collectively pay more than 25 percent of the total active ingredient reregistration fee.

(B) The Administrator, by order, may require any registrant to submit such reports as the Administrator determines to be necessary to allow the Administrator to determine and apportion fees under this subsection or to determine the registrant's eligibility for a reduction or

waiver of a fee.

(C) If any such report is not submitted by a registrant after receiving notice of such report requirement, or if any fee prescribed by this subsection (other than paragraph (5)) for an active ingredient is not paid by a registrant to the Administrator by the time prescribed under this subsection, the Administrator, by order and without hearing, may cancel each registration held by such registrant of a pesticide containing the active ingredient with respect to which the fee is imposed. The Administrator shall reapportion the fee among the remaining registrants and notify the registrants that the registrants are required to pay to the Administrator any unpaid balance of the fee within 30 days after receipt of such notice.

(j) Exemption of Certain Registrants.—The requirements of subsections (d), (e), (f), and (i) (other than subsection (i)(5)) regarding

data concerning an active ingredient and fees for review of such data shall not apply to any person who is the registrant of a pesticide to the extent that, under section 3(c)(2)(D), the person would not be required to submit or cite such data to obtain an initial registration of such pesticide.

(k) Reregistration and Expedited Processing Fund.—

(1) ESTABLISHMENT.—There shall be established in the Treasury of the United States a reregistration and expedited processing found.

essing fund.

(2) Source and use.—All fees collected by the Administrator under subsection (i) shall be deposited into the fund and shall be available to the Administrator, without fiscal year limitation, to carry out reregistration and expedited processing of similar applications.

(3) EXPEDITED PROCESSING OF SIMILAR APPLICATIONS.—

(A) The Administrator shall use each fiscal year not more than \$2,000,000 of the amounts in the fund to obtain sufficient personnel and resources to assure the expedited

processing and review of any application that-

- (i) proposes the initial or amended registration of an end-use pesticide that, if registered as proposed, would be identical or substantially similar in composition and labeling to a currently-registered pesticide identified in the application, or that would differ in composition and labeling from any such currently-registered pesticide only in ways that would not significantly increase the risk of unreasonable adverse effects on the environment; or
- (ii) proposes an amendment to the registration of a registered pesticide that does not require scientific review of data.
- (B) Any amounts made available under subparagraph (A) shall be used to obtain sufficient personnel and resources to carry out the activities described in such subparagraph that are in addition to the personnel and resources available to carry out such activities on the date of enactment of this section [October 25, 1988].

(4) UNUSED FUNDS.—Money in the fund not currently needed

to carry out this section shall be-

(A) maintained on hand or on deposit;

(B) invested in obligations of the United States or guar-

anteed thereby; or

(C) invested in obligations, participations, or other instruments that are lawful investments for fiduciary, trust, or public funds.

(5) ACCOUNTING.—The Administrator shall—

(A) provide an annual accounting of the fees collected and disbursed from the fund; and

(B) take all steps necessary to ensure that expenditures from such fund are used only to carry out this section.

(l) JUDICIAL REVIEW.—Any failure of the Administrator to take any action required by this section shall be subject to judicial review under the procedures prescribed by section 16(b).

SEC. 5. [136c] EXPERIMENTAL USE PERMITS.

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(a) Issuance.—Any person may apply to the Administrator for an experimental use permit for a pesticide. The Administrator shall review the application. After completion of the review, but not later than one hundred and twenty days after receipt of the application and all required supporting data, the Administrator shall either issue the permit or notify the applicant of the Administrator's determination not to issue the permit and the reasons therefor. The applicant may correct the application or request a waiver of the conditions for such permit within thirty days of receipt by the applicant of such notification. The Administrator may issue an experimental use permit only if the Administrator determines that the applicant needs such permit in order to accumulate information necessary to register a pesticide under section 3 of this Act. An application for an experimental use permit may be filed at any time.

(b) TEMPORARY TOLERANCE LEVEL.—If the Administrator determines that the use of a pesticide may reasonably be expected to result in any residue on or in food or feed, he may establish a temporary tolerance level for the residue of the pesticide before issuing

the experimental use permit.

(c) USE UNDER PERMIT.—Use of a pesticide under an experimental use permit shall be under the supervision of the Administrator, and shall be subject to such terms and conditions and be for such period of time as the Administrator may prescribe in the permit.

(d) STUDIES.—When any experimental use permit is issued for a pesticide containing any chemical or combination of chemicals which has not been included in any previously registered pesticide, the Administrator may specify that studies be conducted to detect whether the use of the pesticide under the permit may cause unreasonable adverse effects on the environment. All results of such studies shall be reported to the Administrator before such pesticide may be registered under section 3.

(e) Revocation.—The Administrator may revoke any experimental use permit, at any time, if he finds that its terms or conditions are being violated, or that its terms and conditions are inadequate

to avoid unreasonable adverse effects on the environment.

(f) STATE ISSUANCE OF PERMITS.—Notwithstanding the foregoing provisions of this section, the Administrator shall, under such terms and conditions as he may by regulations prescribe, authorize any State to issue an experimental use permit for a pesticide. All provisions of section 11 relating to State plans shall apply with equal force to a State plan for the issuance of experimental use permits under this section.

(g) Exemption for Agricultural Research Agencies.—Notwithstanding the foregoing provisions of this section, the Administrator may issue an experimental use permit for a pesticide to any public or private agricultural research agency or educational institution which applies for such permit. Each permit shall not exceed more than a one-year period or such other specific time as the Administrator may prescribe. Such permit shall be issued under such terms and conditions restricting the use of the pesticide as the Administrator may require. Such pesticide may be used only by such

research agency or educational institution for purposes of experimentation.

SEC. 6. [136d] ADMINISTRATIVE REVIEW; SUSPENSION.

(a) CANCELLATION AFTER FIVE YEARS—

(1) PROCEDURE.—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 fiveyear 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) to such extent, under such conditions, and for such uses as he may specify if he determines that such sale or use is not inconsistent with the purposes of this Act 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.

(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, he 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 Act 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 his intent either—

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

(2) to hold a hearing to determine whether or not its regis-

tration 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 (b) and section 25(d), 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 subsection (b) and of submission to the Scientific Advisory Panel pursuant to section 25(d) and proceed in accordance with subsection (c). 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 he 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, he may, by order, suspend the registration of the pesticide immediately. No order of suspension may be issued unless the Administrator has issued or at the same time issues notice of his intention to cancel the registration or change the classification of the pesticide. 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 title 5 of the United States Code, except that the presiding officer need not be a certified hearing examiner. 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 him to hold a hearing before suspending, he may issue a suspension order in advance of notification to the registrant. In that case, 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 Administrator's rules. Any person so filing briefs shall be considered a party to such proceeding for the purposes of section 16(b).

(4) JUDICIAL REVIEW.—A final order on the question of suspension following a hearing shall be reviewable in accordance with Section 16 of this Act, 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 proceeding 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 subpena 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 pavment of reasonable fees and expenses as a condition to requiring testimony of the witness. On contest, the subpena 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 Academy 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 Act. 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 him and issue an order either revoking his 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 3(c)(7) of this Act 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 Act 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 Act. 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 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.

(2) Publication of notice.—A notice of denial of registration, intent to cancel, suspension, or intent to suspend issued under this Act or a notice issued under subsection (c)(4) or (d)(5)(A) of section 4 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.

(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

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SEC. 7. [136e] REGISTRATION OF ESTABLISHMENTS.

- (a) REQUIREMENT.—No person shall produce any pesticide subject to this Act or active ingredient used in producing a pesticide subject to this Act 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), he 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 he is currently producing;

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

(C) which he has sold or distributed during the past ear.

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.

(2) Any such producer shall, upon the request of the Administrator for the purpose of issuing a stop sale order pursuant to section 13, inform him of the name and address of any recipient of any pesticide produced in any registered establishment which he operates.

(d) Confidential Records and Information.—Any information submitted to the Administrator pursuant to subsection (c) other than the names of the pesticides or active ingredients used in producing pesticides produced, sold, or distributed at an establishment shall be considered confidential and shall be subject to the provisions of section 10.

SEC. 8. [136f] BOOKS AND RECORDS.

(a) REQUIREMENTS.—The Administrator may prescribe regulations requiring producers, registrants, and applicants for registration to maintain such records with respect to their operations and the pesticides and devices produced as he determines are necessary for the effective enforcement of this Act and to make the records available for inspection and copying in the same manner as provided in subsection (b). No records required under this subsection shall extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed).

(b) Inspection.—For the purposes of enforcing the provisions of this Act, any producer, distributor, carrier, dealer, or any other person who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this Act, shall, upon request of any officer or employee of the Environmental Protection Agency or of any State or political subdivision, duly designated by the Admin-

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istrator, furnish or permit such person at all reasonable times to have access to, and to copy: (1) all records showing the delivery, movement, or holding of such pesticide or device, including the quantity, the date of shipment and receipt, and the name of the consignor and consignee; or (2) in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device. Any inspection with respect to any records and information referred to in this subsection shall not extend to financial data, sales data other than shipment data, pricing data, personnel data, and research data (other than data relating to registered pesticides or to a pesticide for which an application for registration has been filed). Before undertaking an inspection under this subsection, the officer or employee must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness.

SEC. 9. [136g] INSPECTION OF ESTABLISHMENTS, ETC.

(a) In General.—(1) For purposes of enforcing the provisions of this Act, officers or employees of the Environmental Protection Agency or of any State duly designated by the Administrator are authorized to enter at reasonable times (A) any establishment or other place where pesticides or devices are held for distribution or sale for the purpose of inspecting and obtaining samples of any pesticides or devices, packaged, labeled, and released for shipment, and samples of any containers or labeling for such pesticides or devices, or (B) any place where there is being held any pesticide the registration of which has been suspended or canceled for the purpose of determining compliance with section 19.

(2) Before undertaking such inspection, the officers or employees must present to the owner, operator, or agent in charge of the establishment or other place where pesticides or devices are held for distribution or sale, appropriate credentials and a written statement as to the reason for the inspection, including a statement as to whether a violation of the law is suspected. If no violation is suspected, an alternate and sufficient reason shall be given in writing. Each such inspection shall be commenced and completed with reasonable promptness. If the officer or employee obtains any samples, prior to leaving the premises, he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained and, if requested, a portion of each such sample equal in volume or weight to the portion retained. If an analysis is made of such samples, a copy of the results of such analysis shall be furnished promptly to the owner, operator, or agent in charge.

(b) WARRANTS.—For purposes of enforcing the provisions of this Act and upon a showing to an officer or court of competent jurisdiction that there is reason to believe that the provisions of this Act have been violated, officers or employees duly designated by

the Administrator are empowered to obtain and to execute warrants authorizing—

(1) entry, inspection, and copying of records for purposes of

this section or section 8;

- (2) inspection and reproduction of all records showing the quantity, date of shipment, and the name of consignor and consignee of any pesticide or device found in the establishment which is adulterated, misbranded, not registered (in the case of a pesticide) or otherwise in violation of this Act and in the event of the inability of any person to produce records containing such information, all other records and information relating to such delivery, movement, or holding of the pesticide or device; and
- (3) the seizure of any pesticide or device which is in violation of this Act.

(c) Enforcement.—

(1) CERTIFICATION OF FACTS TO ATTORNEY GENERAL.—The examination of pesticides or devices shall be made in the Environmental Protection Agency or elsewhere as the Administrator may designate for the purpose of determining from such examinations whether they comply with the requirements of this Act. If it shall appear from any such examination that they fail to comply with the requirements of this Act, the Administrator shall cause notice to be given to the person against whom criminal or civil proceedings are contemplated. Any person so notified shall be given an opportunity to present his views, either orally or in writing, with regard to such contemplated proceedings, and if in the opinion of the Administrator it appears that the provisions of this Act have been violated by such person, then the Administrator shall certify the facts to the Attorney General, with a copy of the results of the analysis or the examination of such pesticide for the institution of a criminal proceeding pursuant to section 14(b) or a civil proceeding under section 14(a), when the Administrator determines that such action will be sufficient to effectuate the purposes of this Act.

(2) NOTICE NOT REQUIRED.—The notice of contemplated proceedings and opportunity to present views set forth in this subsection are not prerequisites to the institution of any proceed-

ing by the Attorney General.

(3) WARNING NOTICES.—Nothing in this Act shall be construed as requiring the Administrator to institute proceedings for prosecution of minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice of warning.

SEC. 10. [136h] PROTECTION OF TRADE SECRETS AND OTHER INFORMATION.

(a) In General.—In submitting data required by this Act, the applicant may (1) clearly mark any portions thereof which in his opinion are trade secrets or commercial or financial information and (2) submit such marked material separately from other material required to be submitted under this Act.

(b) Disclosure.—Notwithstanding any other provision of this Act and subject to the limitations in subsections (d) and (e) of this section, the Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this Act, information relating to formulas of products acquired by authorization of this Act may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator.

(c) DISPUTES.—If the Administrator proposes to release for inspection information which the applicant or registrant believes to be protected from disclosure under subsection (b), he shall notify the applicant or registrant, in writing, by certified mail. The Administrator shall not thereafter make available for inspection such data until thirty days after receipt of the notice by the applicant or registrant. During this period, the applicant or registrant may institute an action in an appropriate district court for a declaratory judgment as to whether such information is subject to protection under subsection (b).

(d) Limitations.—

(1) All information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered or previously registered pesticide or its separate ingredients, impurities, or degradation products, and any information concerning the effects of such pesticide on any organism or the behavior of such pesticide in the environment, including, but not limited to, data on safety to fish and wildlife, humans and other mammals, plants, animals, and soil, and studies on persistence, translocation and fate in the environment, and metabolism, shall be available for disclosure to the public. The use of such data for any registration purpose shall be governed by section 3 of this Act. This paragraph does not authorize the disclosure of any information that—

(A) discloses manufacturing or quality control processes, (B) discloses the details of any methods for testing, detecting, or measuring the quantity of any deliberately

added inert ingredient of a pesticide, or

(C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide,

unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury

to health or the environment.

(2) Information concerning production, distribution, sale, or inventories of a pesticide that is otherwise entitled to confidential treatment under subsection (b) of this section may be publicly disclosed in connection with a public proceeding to determine whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment, if the Administrator determines that such disclosure is necessary in the public interest.

(3) If the Administrator proposes to disclose information described in clause (A), (B), or (C) of paragraph (1) or in para-

graph (2) of this subsection, the Administrator shall notify by certified mail the submitter of such information of the intent to release such information. The Administrator may not release such information, without the submitter's consent, until thirty days after the submitter has been furnished such notice. Where the Administrator finds that disclosure of information described in clause (A), (B), or (C) of paragraph (1) of this subsection is necessary to avoid or lessen an imminent and substantial risk of injury to the public health, the Administrator may set such shorter period of notice (but not less than ten days) and such method of notice as the Administrator finds appropriate. During such period the data submitter may institute an action in an appropriate district court to enjoin or limit the proposed disclosure. The court may enjoin disclosure, or limit the disclosure or the parties to whom disclosure shall be made. to the extent that—

(A) in the case of information described in clause (A), (B), or (C) of paragraph (1) of this subsection, the proposed disclosure is not required to protect against an unreasonable

risk of injury to health or the environment; or

(B) in the case of information described in paragraph (2) of this subsection, the public interest in availability of the information in the public proceeding does not outweigh the interests in preserving the confidentiality of the information.

(e) DISCLOSURE TO CONTRACTORS.—Information otherwise protected from disclosure to the public under subsection (b) of this section may be disclosed to contractors with the United States and employees of such contractors if, in the opinion of the Administrator, such disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this Act and under such conditions as the Administrator may specify. The Administrator shall require as a condition to the disclosure of information under this subsection that the person receiving it take such security precautions respecting the information as the Administrator shall by regulation prescribe.

(f) Penalty for Disclosure by Federal Employees.—(1) Any office or employee of the United States or former officer or employee of the United States who, by virtue of such employment or official position, has obtained possession of, or has access to, material the disclosure of which is prohibited by subsection (b) of this section, and who, knowing that disclosure of such material is prohibited by such subsection, willfully discloses the material in any manner to any person not entitled to receive it, shall be fined not more than \$10,000 or imprisoned for not more than one year, or both. Section 1905 of title 18 of the United States Code shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported or otherwise obtained under this Act. Nothing in this Act shall preempt any civil remedy under State or Federal law for wrongful disclosure of trade secrets.

(2) For the purposes of this section, any contractor with the United States who is furnished information as authorized by subsection (e) of this section, or any employee of any such contractor,

shall be considered to be an employee of the United States.

(g) DISCLOSURE TO FOREIGN AND MULTINATIONAL PESTICIDE PRO-DUCERS.—(1) The Administrator shall not knowingly disclose information submitted by an applicant or registrant under this Act to any employee or agent of any business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States or to any other person who intends to deliver such data to such foreign or multinational business or entity unless the applicant or registrant has consented to such disclosure. The Administrator shall require an affirmation from any person who intends to inspect data that such person does not seek access to the data for purposes of delivering it or offering it for sale to any such business or entity or its agents or employees and will not purposefully deliver or negligently cause the data to be delivered to such business or entity or its agents or employees. Notwithstanding any other provision of this subsection, the Administrator may disclose information to any person in connection with a public proceeding under law or regulation, subject to restrictions on the availability of information contained elsewhere in this Act, which information is relevant to a determination by the Administrator with respect to whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environment.

(2) The Administrator shall maintain records of the names of persons to whom data are disclosed under this subsection and the persons or organizations they represent and shall inform the applicant or registrant of the names and affiliations of such persons.

(3) Section 1001 of title 18 of the United States Code shall apply to any affirmation made under paragraph (1) of this subsection.

SEC. 11. [136i] USE OF RESTRICTED USE PESTICIDES; APPPLICATORS 11-1.

(a) Certification Procedure.—

(1) FEDERAL CERTIFICATION.—In any State for which a State plan for applicator certification has not been approved by the Administrator, the Administrator, in consultation with the Governor of such State, shall conduct a program for the certification of applicators of pesticides. Such program shall conform to the requirements imposed upon the States under the provisions of subsection (a)(2) of this section and shall not require private applicators to take any examination to establish competency in the use of pesticides. Prior to the implementation of the program, the Administrator shall publish in the Federal Register for review and comment a summary of the Federal plan for applicator certification and shall make generally available within the State copies of the plan. The Administrator shall hold public hearings at one or more locations within the State if so requested by the Governor of such State during the thirty days following publication of the Federal Register notice inviting comment on the Federal plan. The hearings

¹¹⁻¹ Misspelling is so in original.

shall be held within thirty days following receipt of the request from the Governor. In any State in which the Administrator conducts a certification program, the Administrator may require any person engaging in the commercial application, sale, offering for sale, holding for sale, or distribution of any pesticide one or more uses of which have been classified for restricted use to maintain such records and submit such reports concerning the commercial application, sale, or distribution of such pesticide as the Administrator may be regulation prescribe. Subject to paragraph (2), the Administrator shall prescribe standards for the certification of applicators of pesticides. Such standards shall provide that to be certified, an individual must be determined to be competent with respect to the use and handling of pesticides, or to the use and handling of the pesticide or class of pesticides covered by such individual's certification. The certification standard for a private applicator shall, under a State plan submitted for approval, be deemed fulfilled by his completing a certification form. The Administrator shall further assure that such form contains adequate information and affirmations to carry out the intent of this Act, and may include in the form an affirmation that the private applicator has completed a training program approved by the Administrator so long as the program does not require the private applicator to take, pursuant to a requirement prescribed by the Administrator, any examination to establish competency in the use of the pesticide. The Administrator may require any pesticide dealer participating in a certification program to be licensed under a State licensing program approved by him.

(2) STATE CERTIFICATION.—If any State, at any time, desires to certify applicators of pesticides, the Governor of such State shall submit a State plan for such purpose. The Administrator shall approve the plan submitted by any State, or any modifi-

cation thereof, if such plan in his judgment-

(A) designates a State agency as the agency responsible

for administering the plan throughout the State;

(B) contains satisfactory assurances that such agency has or will have the legal authority and qualified personnel necessary to carry out the plan;

(C) gives satisfactory assurances that the State will devote adequate funds to the administration of the plan;

(D) provides that the State agency will make such reports to the Administrator in such form and containing such information as the Administrator may from time to time require; and

(E) contains satisfactory assurances that State standards for the certification of applicators of pesticides conform with those standards prescribed by the Administrator

under paragraph (1).

Any State certification program under this section shall be maintained in accordance with the State plan approved under this section.

(b) STATE PLANS.—If the Administrator rejects a plan submitted under this paragraph, he shall afford the State submitting the plan due notice and opportunity for hearing before so doing. If the Administrator approves a plan submitted under this paragraph, then such State shall certify applicators of pesticides with respect to such State. Whenever the Administrator determines that a State is not administering the certification program in accordance with the plan approved under this section, he shall so notify the State and provide for a hearing at the request of the State, and, if appropriate corrective action is not taken within a reasonable time, not to exceed ninety days, the Administrator shall withdraw approval of such plan.

(c) Instruction in Integrated Pest Management Techniques.—Standards prescribed by the Administrator for the certification of applicators of pesticides under subsection (a), and the State plans submitted to the Administrator under subsections (a) and (b), shall include provisions for making instructional materials concerning integrated pest management techniques available to individuals at their request in accordance with the provisions of section 23(c) of this Act, but such plans may not require that any individual receive instruction concerning such techniques or be shown to be competent with respect to the use of such techniques. The Administrator and States implementing such plans shall provide that all interested individuals are notified of the availability of such instructional materials.

(d) In General.—No regulations prescribed by the Administrator for carrying out the provisions of this Act shall require any private applicator to maintain any records or file any reports or other documents.

(e) Separate Standards.—When establishing or approving standards for licensing or certification, the Administrator shall establish separate standards for commercial and private applicators.

SEC. 12. [136j] UNLAWFUL ACTS.

(a) In General.—

(1) Except as provided by subsection (b), it shall be unlawful for any person in any State to distribute or sell to any person—

(A) any pesticide that is not registered under section 3 or whose registration has been canceled or suspended, except to the extent that distribution or sale otherwise has been authorized by the Administrator under this Act;

(B) any registered pesticide if any claims made for it as a part of its distribution or sale substantially differ from any claims made for it as a part of the statement required in connection with its registration under section 3;

(C) any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under section 3;

(D) any pesticide which has not been colored or discolored pursuant to the provisions of section 25(c)(5);

(E) any pesticide which is adulterated or misbranded; or

(F) any device which is misbranded.

(2) It shall be unlawful for any person—

(A) to detach, alter, deface, or destroy, in whole or in part, any labeling required under this Act;

(B) to refuse to—

(i) prepare, maintain, or submit any records required by or under section 5, 7, 8, 11, or 19;

(ii) submit any reports required by or under section

5, 6, 7, 8, 11, or 19; or

(iii) allow any entry, inspection, copying of records,

or sampling authorized by this Act;

(C) to give a guaranty or undertaking provided for in subsection (b) which is false in any particular, except that a person who receives and relies upon a guaranty authorized under subsection (b) may give a guaranty to the same effect, which guaranty shall contain, in addition to his own name and address, the name and address of the person residing in the United States from whom he received the guaranty or undertaking;

(D) to use for his own advantage or to reveal, other than to the Administrator, or officials or employees of the Environmental Protection Agency or other Federal executive agencies, or to the courts, or to physicians, pharmacists, and other qualified persons, needing such information for the performance of their duties, in accordance with such directions as the Administrator may prescribe, any information acquired by authority of this Act which is confiden-

tial under this Act;
(E) who is a registrant, wholesaler, dealer, retailer, or other distributor to advertise a product registered under this Act for restricted use without giving the classification

of the product assigned to it under section 3;

(F) to distribute or sell, or to make available for use, or to use, any registered pesticide classified for restricted use for some or all purposes other than in accordance with section 3(d) and any regulations thereunder. It shall not be unlawful to sell, under regulations issued by the Administrator, a restricted use pesticide to a person who is not a certified applicator for application by a certified applicator:

(G) to use any registered pesticide in a manner inconsistent with its labeling:

(H) to use any pesticide which is under an experimental use permit contrary to the provisions of such permit;

(I) to violate any order issued under section 13;

(J) to violate any suspension order issued under section

3(c)(2)(B), 4, or 6;
(K) to violate any cancellation order issued under this Act or to fail to submit a notice in accordance with section 6(a):

(L) who is a producer to violate any of the provisions of

section 7;

(M) to knowingly falsify all or part of any application for registration, application for experimental use permit, any

information submitted to the Administrator pursuant to section 7, any records required to be maintained pursuant to this Act, any report filed under this Act, or any information marked as confidential and submitted to the Administrator under any provision of this Act;

(N) who is a registrant, wholesaler, dealer, retailer, or other distributor to fail to file reports required by this Act;

(O) to add any substance to, or take any substance from, any pesticide in a manner that may defeat the purpose of this Act; or 12-1

(P) to use any pesticide in tests on human beings unless such human beings (i) are fully informed of the nature and purposes of the test and of any physical and mental health consequences which are reasonably foreseeable therefrom, and (ii) freely volunteer to participate in the test. ¹²⁻²

- (Q) to falsify all or part of any information relating to the testing of any pesticide (or any ingredient, metabolite, or degradation product thereof), including the nature of any protocol, procedure, substance, organism, or equipment used, observation made, or conclusion or opinion formed, submitted to the Administrator, or that the person knows will be furnished to the Administrator or will become a part of any records required to be maintained by this Act;
- (R) to submit to the Administrator data known to be false in support of a registration; or
- (S) to violate any regulation issued under section 3(a) or 19.

(b) Exemptions.—The penalties provided for a violation of para-

graph (1) of subsection (a) shall not apply to—

- (1) any person who establishes a guaranty signed by, and containing the name and address of, the registrant or person residing in the United States from whom he purchased or received in good faith the pesticide in the same unbroken package, to the effect that the pesticide was lawfully registered at the time of sale and delivery to him, and that it complies with the other requirements of this Act, and in such case the guarantor shall be subject to the penalties which would otherwise attach to the person holding the guaranty under the provisions of this Act;
- (2) any carrier while lawfully shipping, transporting, or delivering for shipment any pesticide or device, if such carrier upon request of any officer or employee duly designated by the Administrator shall permit such officer or employee to copy all of its records concerning such pesticide or device;

(3) any public official while engaged in the performance of

his official duties;

(4) any person using or possessing any pesticide as provided by an experimental use permit in effect with respect to such pesticide and such use or possession; or

¹²⁻¹So in original. "or" should be struck.
¹²⁻²So in original. Period should be a semicolon.

(5) any person who ships a substance or mixture of substances being put through tests in which the purpose is only to determine its value for pesticide purposes or to determine its toxicity or other properties and from which the user does not expect to receive any benefit in pest control from its use.

SEC. 13. [136k] STOP SALE, USE, REMOVAL, AND SEIZURE.

(a) Stop Sale, Etc., Orders.—Whenever any pesticide or device is found by the Administrator in any State and there is reason to believe on the basis of inspection or tests that such pesticide or device is in violation of any of the provisions of this Act, or that such pesticide or device has been or is intended to be distributed or sold in violation of any such provisions, or when the registration of the pesticide has been canceled by a final order or has been suspended, the Administrator may issue a written or printed "stop sale, use, or removal" order to any person who owns, controls, or has custody of such pesticide or device, and after receipt of such order no person shall sell, use, or remove the pesticide or device described in the order except in accordance with the provisions of the order.

(b) Seizure.—Any pesticide or device that is being transported or, having been transported, remains unsold or in original unbroken packages, or that is sold or offered for sale in any State, or that is imported from a foreign country, shall be liable to be proceeded against in any district court in the district where it is found and seized for confiscation by a process in rem for condemnation if—

(1) in the case of a pesticide—

(A) it is adulterated or misbranded;

(B) it is not registered pursuant to the provisions of section 3:

(C) its labeling fails to bear the information required by

this Act;

(D) it is not colored or discolored and such coloring or

discoloring is required under this Act; or

(E) any of the claims made for it or any of the directions for its use differ in substance from the representations made in connection with its registration;

(2) in the case of a device, it is misbranded; or

(3) in the case of a pesticide or device, when used in accordance with the requirements imposed under this Act and as directed by the labeling, it nevertheless causes unreasonable adverse effects on the environment.

In the case of a plant regulator, defoliant, or desiccant, used in accordance with the label claims and recommendations, physical or physiological effects on plants or parts thereof shall not be deemed to be injury, when such effects are the purpose for which the plant

regulator, defoliant, or desiccant was applied.

(c) DISPOSITION AFTER CONDEMNATION.—If the pesticide or device is condemned it shall, after entry of the decree, be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs, shall be paid into the Treasury of the United States, but the pesticide or device shall not be sold contrary to the provisions of this Act or the laws of the jurisdiction in which it is sold. On payment of the costs of the condemnation proceedings

and the execution and delivery of a good and sufficient bond conditioned that the pesticide or device shall not be sold or otherwise disposed of contrary to the provisions of the Act or the laws of any jurisdiction in which sold, the court may direct that such pesticide or device be delivered to the owner thereof. The proceedings of such condemnation cases shall conform, as near as may be to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such proceedings shall be at the suit of and in the name of the United States.

(d) Court Costs, Etc.—When a decree of condemnation is entered against the pesticide or device, court costs and fees, storage, and other proper expenses shall be awarded against the person, if

any, intervening as claimant of the pesticide or device.

SEC. 14. [1361] PENALTIES.

(a) CIVIL PENALTIES.—

(1) In GENERAL.—Any registrant, commercial applicator, wholesaler, dealer, retailer, or other distributor who violates any provision of this Act may be assessed a civil penalty by the Ad-

ministrator of not more than \$5,000 for each offense.

(2) PRIVATE APPLICATOR.—Any private applicator or other person not included in paragraph (1) who violates any provision of this Act subsequent to receiving a written warning from the Administrator or following a citation for a prior violation, may be assessed a civil penalty by the Administrator of not more than \$1,000 for each offense: Provided, That any applicator not included under paragraph (1) of this subsection who holds or applies registered pesticides, or use dilutions of registered pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and who violates any provision of this Act may be assessed a civil penalty by the Administrator of not more than \$500 for the first offense nor more than \$1,000 for each subsequent offense.

(3) Hearing.—No civil penalty shall be assessed unless the person charged shall have been given notice and opportunity for a hearing on such charge in the county, parish, or incorpo-

rated city of the residence of the person charged.

(4) DETERMINATION OF PENALTY.—In determining the amount of the penalty, the Administrator shall consider the appropriateness of such penalty to the size of the business of the person charged, the effect on the person's ability to continue in business, and the gravity of the violation. Whenever the Administrator finds that the violation occurred despite the exercise of due care or did not cause significant harm to health or the environment, the Administrator may issue a warning in lieu of assessing a penalty.

(5) REFERENCES TO ATTORNEY GENERAL.—In case of inability to collect such civil penalty or failure of any person to pay all, or such portion of such civil penalty as the Administrator may determine, the Administrator shall refer the matter to the Attorney General, who shall recover such amount by action in

the appropriate United States district court.

(b) CRIMINAL PENALTIES.—

(1) IN GENERAL.—

(A) Any registrant, applicant for a registration, or producer who knowingly violates any provision of this Act shall be fined not more than \$50,000 or imprisoned for not more than 1 year, or both.

(B) Any commercial applicator of a restricted use pesticide, or any other person not described in subparagraph (A) who distributes or sells pesticides or devices, who knowingly violates any provision of this Act shall be fined not more than \$25,000 or imprisoned for not more than 1 year, or both.

(2) PRIVATE APPLICATOR.—Any private applicator or other person not included in paragraph (1) who knowingly violates any provision of this Act shall be guilty of a misdemeanor and shall on conviction be fined not more than \$1,000, or imprisoned for not more than 30 days, or both.

(3) DISCLOSURE OF INFORMATION.—Any person, who, with intent to defraud, uses or reveals information relative to formulas of products acquired under the authority of section 3, shall be fined not more than \$10,000, or imprisoned for not more than three years, or both.

(4) ACTS OF OFFICERS, AGENTS, ETC.—When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any person shall in every case be also deemed to be the act, omission, or failure of such person as well as that of the person employed.

SEC. 15. INDEMNITIES.

(a) GENERAL INDEMNIFICATION.—

(1) IN GENERAL.—Except as otherwise provided in this section, if—

(A) the Administrator notifies a registrant under section 6(c)(1) that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 6(c)(3) has been issued;

(B) the registration in question is suspended under section 6(c), and thereafter is canceled under section 6(b),

6(d), or 6(f); and

(C) any person who owned any quantity of the pesticide immediately before the notice to the registrant under subparagraph (A) suffered losses by reason of suspension or cancellation of the registration;

the Administrator shall make an indemnity payment to the person.

(2) EXCEPTION.—Paragraph (1) shall not apply if the Administrator finds that the person—

(A) had knowledge of facts that, in themselves, would have shown that the pesticide did not meet the requirements of section 3(c)(5) for registration; and

(B) continued thereafter to produce the pesticide without giving timely notice of such facts to the Administrator.

(3) Report.—If the Administrator takes an action under . paragraph (1) that requires the payment of indemnification, the Administrator shall report to the Committee on Agriculture of the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry of the Senate, and the Committees on Appropriations of the House of Representatives and the Senate on—

(A) the action taken that requires the payment of indemnification:

(B) the reasons for taking the action;

(C) the estimated cost of the payment; and

(D) a request for the appropriation of funds for the pay-

(4) Appropriation.—The Administrator may not make a payment of indemnification under paragraph (1) unless a specific line item appropriation of funds has been made in advance for the payment.

(b) INDEMNIFICATION OF END USERS, DEALERS, AND DISTRIBU-TORS .-

(1) END USERS.—If—

(A) the Administrator notifies a registrant under section 6(c)(1) that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 6(c)(3) has been issued;

(B) the registration in question is suspended under section 6(c), and thereafter is canceled under section 6(b), 6(d),

or 6(f); and

(C) any person who, immediately before the notice to the registrant under subparagraph (A), owned any quantity of the pesticide for purposes of applying or using the pesticide as an end user, rather than for purposes of distributing or selling it or further processing it for distribution or sale, suffered a loss by reason of the suspension or cancellation of the pesticide;

the person shall be entitled to an indemnity payment under

this subsection for such quantity of the pesticide.

- (2) DEALERS AND DISTRIBUTORS.—
 - (A) Any registrant, wholesaler, dealer, or other distributor (hereinafter in this paragraph referred to as a "seller") of a registered pesticide who distributes or sells the pesticide directly to any person not described as an end user in paragraph (1)(C) shall, with respect to any quantity of the pesticide that such person cannot use or resell as a result of the suspension or cancellation of the pesticide, reimburse such person for the cost of first acquiring the pesticide from the seller (other than the cost of transportation, if any), unless the seller provided to the person at the time of distribution or sale a notice, in writing, that the pesticide is not subject to reimbursement by the seller.

(B) If— (i) the Administrator notifies a registrant under section 6(c)(1) that the Administrator intends to suspend a registration or that an emergency order of suspension of a registration under section 6(c)(3) has been issued:

(ii) the registration in question is suspended under section 6(c), and thereafter is canceled under section 6(b), 6(d), or 6(f);

(iii) any person who, immediately before the notice

to the registrant under clause (i)—

(I) had not been notified in writing by the seller, as provided under subparagraph (A), that any quantity of the pesticide owned by such person is not subject to reimbursement by the seller in the event of suspension or cancellation of the pesticide; and

(II) owned any quantity of the pesticide for purposes of—

(aa) distributing or selling it; or

(bb) further processing it for distribution or sale directly to an end user;

suffered a loss by reason of the suspension or cancella-

tion of the pesticide; and

(iv) the Administrator determines on the basis of a claim of loss submitted to the Administrator by the person, that the seller—

(I) did not provide the notice specified in sub-

paragraph (A) to such person; and

(II) is and will continue to be unable to provide reimbursement to such person, as provided under subparagraph (A), for the loss referred to in clause (iii), as a result of the insolvency or bankruptcy of the seller and the seller's resulting inability to provide such reimbursement:

the person shall be entitled to an indemnity payment under this subsection for such quantity of the pesticide.

(C) If an indemnity payment is made by the United States under this paragraph, the United States shall be subrogated to any right that would otherwise be held under this paragraph by a seller who is unable to make a reimbursement in accordance with this paragraph with regard to reimbursements that otherwise would have been made by the seller.

(3) Source.—Any payment required to be made under paragraph (1) or (2) shall be made from the appropriation provided

under section 1304 of title 31, United States Code.

(4) ADMINISTRATIVE SETTLEMENT.—An administrative settlement of a claim for such indemnity may be made in accordance with the third paragraph of section 2414 of title 28, United States Code, and shall be regarded as if it were made under that section for purposes of section 1304 of title 31, United States Code.

(c) Amount of Payment.—

(1) IN GENERAL.—The amount of an indemnity payment under subsection (a) or (b) to any person shall be determined on the basis of the cost of the pesticide owned by the person

(other than the cost of transportation, if any) immediately before the issuance of the notice to the registrant referred to in subsection (a)(1)(A), (b)(1)(A), or (b)(2)(B)(i), except that in no event shall an indemnity payment to any person exceed the fair market value of the pesticide owned by the person immediately before the issuance of the notice.

(2) Special rule.—Notwithstanding any other provision of this Act, the Administrator may provide a reasonable time for use or other disposal of the pesticide. In determining the quantity of any pesticide for which indemnity shall be paid under this section, proper adjustment shall be made for any pesticide

used or otherwise disposed of by the owner.

SEC. 16. [136n] ADMINISTRATIVE PROCEDURE; JUDICIAL REVIEW.

(a) DISTRICT COURT REVIEW.—Except as otherwise provided in this Act, the refusal of the Administrator to cancel or suspend a registration or to change a classification not following a hearing and other final actions of the Administrator not committed to the discretion of the Administrator by law are judicially reviewable by

the district courts of the United States.

- (b) REVIEW BY COURT OF APPEALS.—In the case of actual controversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely affected by such order and who had been a party to the proceedings may obtain judicial review by filing in the United States court of appeals for the circuit wherein such person resides or has a place of business, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Administrator or any officer designated by him for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole. The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.
- (c) JURISDICTION OF DISTRICT COURTS.—The district courts of the United States are vested with jurisdiction specifically to enforce,

and to prevent and restrain violations of, this Act.

(d) NOTICE OF JUDGMENTS.—The Administrator shall, by publication in such manner as he may prescribe, give notice of all judgments entered in actions instituted under the authority of this Act. SEC. 17. F13601 IMPORTS AND EXPORTS.

(a) PESTICIDES AND DEVICES INTENDED FOR EXPORT.—Notwithstanding any other provision this Act, no pesticide or device or

active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this Act—

(1) when prepared or packed according to the specifications or directions of the foreign purchaser, except that producers of such pesticides and devices and active ingredients used in producing pesticides shall be subject to sections 2(p), 2(q) (1) (A), (C), (D), (E), (G), and (H), 2(q) (2) (A), (B), (C) (i) and (iii), and (D),

7, and 8 of this Act; and

(2) in the case of any pesticide other than a pesticide registered under section 3 or sold under section 6(a) (1) of this Act, if, prior to export, the foreign purchaser has signed a statement acknowledging that the purchaser understands that such pesticide is not registered for use in the United States and cannot be sold in the United States under this Act. A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

(b) CANCELLATION NOTICES FURNISHED TO FOREIGN GOVERN-MENTS.—Whenever a registration, or a cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 3 of this

Act and that could be used in lieu of such pesticide.

(c) Importation of Pesticides and Devices.—The Secretary of the Treasury shall notify the Administrator of the arrival of pesticides and devices and shall deliver to the Administrator, upon his request, samples of pesticides or devices which are being imported into the United States, giving notice to the owner or consignee, who may appear before the Administrator and have the right to introduce testimony. If it appears from the examination of a sample that it is adulterated, or misbranded or otherwise violates the provisions set forth in this Act, or is otherwise injurious to health or the environment, the pesticide or device may be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any pesticide or device refused delivery which shall not be exported by the consignee within 90 days from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe. The Secretary of the Treasury may deliver to the consignee such pesticide or device pending examination and decision in the matter on execution of bond for the amount of the full invoice value of such pesticide or device, together with the duty thereon, and on refusal to return such pesticide or device for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of said bond. All charges for storage, cartage, and labor on pesticides or devices which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against

any future importation made by such owner or consignee.

(d) Cooperation in International Efforts.—The Administrator shall, in cooperation with the Department of State and any other appropriate Federal agency, participate and cooperate in any international efforts to develop improved pesticide research and regulations.

(e) REGULATIONS.—The Secretary of the Treasury, in consultation with the Administrator, shall prescribe regulations for the enforcement of subsection (c) of this section.

SEC. 18. [136p] EXEMPTION OF FEDERAL AND STATE AGENCIES.

The Administrator may, at his discretion, exempt any Federal or State agency from any provision of this Act if he determines that emergency conditions exist which require such exemption. The Administrator, in determining whether or not such emergency conditions exist, shall consult with the Secretary of Agriculture and the Governor of any State concerned if they request such determination.

SEC. 19. [136q] STORAGE, DISPOSAL, TRANSPORTATION, AND RECALL.

(a) STORAGE, DISPOSAL, AND TRANSPORTATION.—

(1) Data requirements and registration of pesticides.— The Administrator may require under section 3 or 6 that—

(A) the registrant or applicant for registration of a pesticide submit or cite data or information regarding methods for the safe storage and disposal of excess quantities of the pesticide to support the registration or continued registration of a pesticide;

(B) the labeling of a pesticide contain requirements and procedures for the transportation, storage, and disposal of the pesticide, any container of the pesticide, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide;

and

(C) the registrant of a pesticide provide evidence of sufficient financial and other resources to carry out a recall plan under subsection (b), and provide for the disposition of the pesticide, in the event of suspension and cancellation of the pesticide.

(2) Pesticides.—The Administrator may by regulation, or as part of an order issued under section 6 or an amendment to

such an order-

(A) issue requirements and procedures to be followed by any person who stores or transports a pesticide the registration of which has been suspended or canceled;

(B) issue requirements and procedures to be followed by any person who disposes of stocks of a pesticide the regis-

tration of which has been suspended; and

(C) issue requirements and procedures for the disposal of any pesticide the registration of which has been canceled.

(3) CONTAINERS, RINSATES, AND OTHER MATERIALS.—The Administrator may by regulation, or as part of an order issued under section 6 or an amendment to such an order—

(A) issue requirements and procedures to be followed by any person who stores or transports any container of a pesticide the registration of which has been suspended or canceled, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide;

(B) issue requirements and procedures to be followed by any person who disposes of stocks of any container of a pesticide the registration of which has been suspended, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the

pesticide; and

(C) issue requirements and procedures for the disposal of any container of a pesticide the registration of which has been canceled, any rinsate containing the pesticide, or any other material used to contain or collect excess or spilled quantities of the pesticide.

(b) RECALLS.—

(1) In general.—If the registration of a pesticide has been suspended and canceled under section 6, and if the Administrator finds that recall of the pesticide is necessary to protect health or the environment, the Administrator shall order a recall of the pesticide in accordance with this subsection.

(2) Voluntary recall.—If, after determining under paragraph (1) that a recall is necessary, the Administrator finds that voluntary recall by the registrant and others in the chain of distribution may be as safe and effective as a mandatory recall, the Administrator shall request the registrant of the pesticide to submit, within 60 days of the request, a plan for the voluntary recall of the pesticide. If such a plan is requested and submitted, the Administrator shall approve the plan and order the registrant to conduct the recall in accordance with the plan unless the Administrator determines, after an informal hearing, that the plan is inadequate to protect health or the environment.

(3) Mandatory recall.—If, after determining under paragraph (1) that a recall is necessary, the Administrator does not request the submission of a plan under paragraph (2) or finds such a plan to be inadequate, the Administrator shall issue a regulation that prescribes a plan for the recall of the pesticide. A regulation issued under this paragraph may apply to any person who is or was a registrant, distributor, or seller of the pesticide, or any successor in interest to such a person.

(4) RECALL PROCEDURE.—A regulation issued under this subsection may require any person that is subject to the regula-

tion to-

(A) arrange to make available one or more storage facilities to receive and store the pesticide to which the recall program applies, and inform the Administrator of the location of each such facility;

(B) accept and store at such a facility those existing stocks of such pesticide that are tendered by any other

person who obtained the pesticide directly or indirectly from the person that is subject to such regulation;

(C) on the request of a person making such a tender, provide for proper transportation of the pesticide to a storage facility; and

(D) take such reasonable steps as the regulation may prescribe to inform persons who may be holders of the pesticide of the terms of the recall regulation and how those persons may tender the pesticide and arrange for transportation of the pesticide to a storage facility.

(5) CONTENTS OF RECALL PLAN.—A recall plan established

under this subsection shall include—

(A) the level in the distribution chain to which the recall is to extend, and a schedule for recall; and

(B) the means to be used to verify the effectiveness of

the recall.

(6) REQUIREMENTS OR PROCEDURES.—No requirement or procedure imposed in accordance with paragraph (2) of subsection (a) may require the recall of existing stocks of the pesticide except as provided by this subsection.

(c) Storage Costs.—

(1) Submission of plan.—A registrant who wishes to become eligible for reimbursement of storage costs incurred as a result of a recall prescribed under subsection (b) for a pesticide whose registration has been suspended and canceled shall, as soon as practicable after the suspension of the registration of the pesticide, submit to the Administrator a plan for the storage and disposal of the pesticide that meets criteria established by the Administrator by regulation.

(2) REIMBURSEMENT.—Within a reasonable period of time after such storage costs are incurred and paid by the registrant, the Administrator shall reimburse the registrant, on re-

quest, for-

(A) none of the costs incurred by the registrant before the date of submission of the plan referred to in paragraph

(1) to the Administrator;

(B) 100 percent of the costs incurred by the registrant after the date of submission of the plan to the Administrator or the date of cancellation of the registration of the pesticide, whichever is later, but before the approval of the plan by the Administrator;

(C) 50 percent of the costs incurred by the registrant during the 1-year period beginning on the date of the approval of the plan by the Administrator or the date of cancellation of the registration of the pesticide, whichever is

later:

(D) none of the costs incurred by the registrant during the 3-year period beginning on the 366th day following approval of the plan by the Administrator or the date of cancellation of the registration of the pesticide, whichever is later; and

(E) 25 percent of the costs incurred by the registrant during the period beginning on the first day of the 5th

year following the date of the approval of the plan by the Administrator or the date of cancellation of the registration of the pesticide, whichever is later, and ending on the date that a disposal permit for the pesticide is issued by a State or an alternative plan for disposal of the pesticide in accordance with applicable law has been developed.

(d) Administration of Storage, Disposal, Transportation, and

· RECALL PROGRAMS.—

(1) VOLUNTARY AGREEMENTS.—Nothing in this section shall be construed as preventing or making unlawful any agreement between a seller and a buyer of any pesticide or other substance regarding the ultimate allocation of the costs of storage, transportation, or disposal of a pesticide.

(2) RULE AND REGULATION REVIEW.—Section 25(a)(4) shall not apply to any regulation issued under subsection (a)(2) or (b).

(3) LIMITATIONS.—No registrant shall be responsible under this section for a pesticide the registration of which is held by another person. No distributor or seller shall be responsible under this section for a pesticide that the distributor or seller did not hold or sell.

(4) SEIZURE AND PENALTIES.—If the Administrator finds that a person who is subject to a regulation or order under subsection (a)(2) or (b) has failed substantially to comply with that regulation or order, the Administrator may take action under section 13 or 14 or obtain injunctive relief under section 16(c) against such person or any successor in interest of any such person.

(e) CONTAINER DESIGN.—

(1) Procedures.—

(A) Not later than 3 years after the effective date of this subsection [December 24, 1988], the Administrator shall, in consultation with the heads of other interested Federal agencies, promulgate regulations for the design of pesticide containers that will promote the safe storage and disposal of pesticides.

(B) The regulations shall ensure, to the fullest extent

practicable, that the containers-

(i) accommodate procedures used for the removal of pesticides from the containers and the rinsing of the containers;

(ii) facilitate the safe use of the containers, including elimination of splash and leakage of pesticides from

the containers:

(iii) facilitate the safe disposal of the containers; and (iv) facilitate the safe refill and reuse of the

containers.

- (2) Compliance.—The Administrator shall require compliance with the regulations referred to in paragraph (1) not later than 5 years after the effective date of this subsection [December 24, 1988].
- (f) PESTICIDE RESIDUE REMOVAL.—

(1) Procedures.—

(A) Not later than 3 years after the effective date of this subsection [December 24, 1988], the Administrator shall, in consultation with the heads of other interested Federal agencies, promulgate regulations prescribing procedures and standards for the removal of pesticides from containers prior to disposal.

(B) The regulations may—

(i) specify, for each major type of pesticide container, procedures and standards providing for, at a minimum, triple rinsing or the equivalent degree of pesticide removal;

(ii) specify procedures that can be implemented promptly and easily in various circumstances and con-

ditions;

(iii) provide for reuse, whenever practicable, or

disposal of rinse water and residue; and

(iv) be coordinated with requirements for the rinsing of containers imposed under the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.).

(C) The Administrator may, at the discretion of the Administrator, exempt products intended solely for household

use from the requirements of this subsection.

(2) COMPLIANCE.—Effective beginning 5 years after the effective date of this subsection [December 24, 1988], a State may not exercise primary enforcement responsibility under section 26, or certify an applicator under section 11, unless the Administrator determines that the State is carrying out an adequate program to ensure compliance with this subsection.

(3) SOLID WASTE DISPOSAL ACT.—Nothing in this subsection shall affect the authorities or requirements concerning pesticide containers under the Solid Waste Disposal Act (42 U.S.C.

6901).

(g) PESTICIDE CONTAINER STUDY.—

(1) STUDY.—

(A) The Administrator shall conduct a study of options to encourage or require—

(i) the return, refill, and reuse of pesticide con-

tainers;

(ii) the development and use of pesticide formulations that facilitate the removal of pesticide residues from containers; and

(iii) the use of bulk storage facilities to reduce the number of pesticide containers requiring disposal.

(B) In conducting the study, the Administrator shall— (i) consult with the heads of other interested Federal agencies, State agencies, industry groups, and environmental organizations; and

(ii) assess the feasibility, costs, and environmental benefits of encouraging or requiring various measures or actions.

(2) REPORT.—Not later than 2 years after the effective date of this subsection [December 24, 1988], the Administrator shall

submit to Congress a report describing the results of the study required under paragraph (1).

(h) RELATIONSHIP TO SOLID WASTE DISPOSAL ACT.—Nothing in this section shall diminish the authorities or requirements of the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.).

SEC. 20. [136r] RESEARCH AND MONITORING.

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(a) Research.—The Administrator shall undertake research, including research by grant or contract with other Federal agencies, universities, or others as may be necessary to carry out the purposes of this Act, and he shall conduct research into integrated pest management in coordination with the Secretary of Agriculture. The Administrator shall also take care to insure that such research does not duplicate research being undertaken by any other Federal agency.

(b) NATIONAL MONITORING PLAN.—The Administrator shall formulate and periodically revise, in cooperation with other Federal, State, or local agencies, a national plan for monitoring pesticides.

- (c) Monitoring.—The Administrator shall undertake such monitoring activities, including, but not limited to monitoring in air, soil, water, man, plants, and animals, as may be necessary for the implementation of this Act and of the national pesticide monitoring plan. The Administrator shall establish procedures for the monitoring of man and animals and their environment for incidental pesticide exposure, including, but not limited to, the quantification of incidental human and environmental pesticide pollution and the secular trends thereof, and identification of the sources of contamination and their relationship to human and environmental effects. Such activities shall be carried out in cooperation with other Federal, State, and local agencies.
- SEC. 21. [136s] SOLICITATION OF COMMENTS; NOTICE OF PUBLIC HEARINGS.

(a) Secretary of Agriculture.—The Administrator, before publishing regulations under this Act, shall solicit the views of the Secretary of Agriculture in accordance with the procedure described in section 25(a).

(b) Views.—In addition to any other authority relating to public hearings and solicitation of views, in connection with the suspension or cancellation of a pesticide registration or any other actions authorized under this Act, the Administrator may, at his discretion, solicit the views of all interested persons, either orally or in writing, and seek such advice from scientists, farmers, farm organizations, and other qualified persons as he deems proper.

(c) NOTICE.—In connection with all public hearings under this Act the Administrator shall publish timely notice of such hearings in the Federal Register.

SEC. 22. [136t] DELEGATION AND COOPERATION.

(a) DELEGATION.—All authority vested in the Administrator by virtue of the provisions of this Act may with like force and effect be executed by such employees of the Environmental Protection Agency as the Administrator may designate for the purpose.

(b) COOPERATION.—The Administrator shall cooperate with the Department of Agriculture, any other Federal agency, and any ap-

propriate agency of any State or any political subdivision thereof, in carrying out the provisions of this Act, and in securing uniformity of regulations.

SEC. 23. [136u] STATE COOPERATION, AID, AND TRAINING.

(a) Cooperative Agreements.—The Administrator may enter

into cooperative agreements with States and Indian tribes-

(1) to delegate to any State or Indian tribe the authority to cooperate in the enforcement of this Act through the use of its personnel or facilities, to train personnel of the State or Indian tribe to cooperate in the enforcement of this Act, and to assist States and Indian tribes in implementing cooperative enforcement programs through grants-in-aid; and

(2) to assist States in developing and administering State programs, and Indian tribes that enter into cooperative agreements, to train and certify applicators consistent with the

standards the Administrator prescribes.

Effective with the fiscal year beginning October 1, 1978, there are authorized to be appropriated annually such funds as may be necessary for the Administrator to provide through cooperative agreements an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed to under such cooperative agreements, of conducting training and certification programs during such fiscal year. If funds sufficient to pay 50 percent of the costs for any year are not appropriated, the share of each State and Indian tribe shall be reduced in a like proportion in allocating available funds.

(b) CONTRACTS FOR TRAINING.—In addition, the Administrator may enter into contracts with Federal, State, or Indian tribal agencies for the purpose of encouraging the training of certified applica-

tors.

(c) Information and Education.—The Administrator shall, in cooperation with the Secretary of Agriculture, use the services of the cooperative State extension services to inform and educate pesticide users about accepted uses and other regulations made under this Act.

SEC. 24. [136v] AUTHORITY OF STATES.

(a) In General.—A State may regulate the sale or use of any federally registered pesticide or device in the State, but only if and to the extent the regulation does not permit any sale or use prohibited by this Act.

(b) Uniformity.—Such State shall not impose or continue in effect any requirements for labeling or packaging in addition to or

different from those required under this Act.

(c) Additional Uses.—

(1) A State may provide registration for additional uses of federally registered pesticides formulated for distribution and use within that State to meet special local needs in accord with the purposes of this Act and if registration for such use has not previously been denied, disapproved, or canceled by the Administrator. Such registration shall be deemed registration under section 3 for all purposes of this Act, but shall authorize distribution and use only within such State.

(2) A registration issued by a State under this subsection shall not be effective for more than ninety days if disapproved by the Administrator within that period. Prior to disapproval, the Administrator shall, except as provided in paragraph (3) of this subsection, advise the State of the Administrator's intention to disapprove and the reasons therefor, and provide the State time to respond. The Administrator shall not prohibit or disapprove a registration issued by a State under this subsection (A) on the basis of lack of essentiality of a pesticide or (B) except as provided in paragraph (3) of this subsection, if its composition and use patterns are similar to those of a federally registered pesticide.

(3) In no instance may a State issue a registration for a food or feed use unless there exists a tolerance or exemption under the Federal Food, Drug, and Cosmetic Act that permits the residues of the pesticide on the food or feed. If the Administrator determines that a registration issued by a State is inconsistent with the Federal Food, Drug, and Cosmetic Act, or the use of, a pesticide under a registration issued by a State constitutes an imminent hazard, the Administrator may immediately disap-

prove the registration.

(4) If the Administrator finds, in accordance with standards set forth in regulations issued under section 25 of this Act, that a State is not capable of exercising adequate controls to assure that State registration under this section will be in accord with the purposes of this Act or has failed to exercise adequate controls, the Administrator may suspend the authority of the State to register pesticides until such time as the Administrator is satisfied that the State can and will exercise adequate controls. Prior to any such suspension, the Administrator shall advise the State of the Administrator's intention to suspend and the reasons therefor and provide the State time to respond.

SEC. 25. [136w] AUTHORITY OF ADMINISTRATOR.

(a) In General.—

(1) REGULATIONS.—The Administrator is authorized in accordance with the procedure described in paragraph (2), to prescribe regulations to carry out the provisions of this Act. Such regulations shall take into account the difference in concept and usage between various classes of pesticides and differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.

(2) Procedure.—

(A) Proposed regulations.—At least 60 days prior to signing any proposed regulation for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such regulation within 30 days after receiving it, the Administrator shall publish in the Federal Register (with the proposed regulation) the comments of the Secretary and the response of the Administrator with regard to the Secretary's comments. If the Secretary does not com-

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ing the foregoing 60-day time requirement.

(B) Final regulations.—At least 30 days prior to signing any regulation in final form for publication in the Federal Register, the Administrator shall provide the Secretary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator regarding any such final regulation within 15 days after receiving it, the Administrator shall publish in the Federal Register (with the final regulation) the comments of the Secretary, if requested by the Secretary, and the response of the Administrator concerning the Secretary's comments. If the Secretary does not comment in writing to the Administrator regarding the regulation within 15 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register at any time after such 15-day period notwithstanding the foregoing 30-day time requirement. In taking any final action under this subsection, the Administrator shall include among those factors to be taken into account the effect of the regulation 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 effect.

(C) TIME REQUIREMENTS.—The time requirements imposed by subparagraphs (A) and (B) may be waived or modified to the extent agreed upon by the Administrator

and the Secretary.

(D) Publication in the federal register.—The Administrator shall, simultaneously with any notification to the Secretary of Agriculture under this paragraph prior to the issuance of any proposed or final regulation, publish such

notification in the Federal Register.

(3) Congressional committees.—At such time as the Administrator is required under paragraph (2) of this subsection to provide the Secretary of Agriculture with a copy of proposed regulations and a copy of the final form of regulations, he shall also furnish a copy of such regulations to the Committee on Agriculture of the House of Representatives and the Committee on Agriculture, Nutrition, and Forestry of the Senate.

(4) Congressional review of regulations.—Simultaneously with the promulgation of any rule or regulation under this Act, the Administrator shall transmit a copy thereof to the Secretary of the Senate and the Clerk of the House of Representatives. The rule or regulation shall not become effective until the passage of 60 calendar days after the rule or regulation is so transmitted.

(b) Exemption of Pesticides.—The Administrator may exempt from the requirements of this Act by regulation any pesticide which he determines either (1) to be adequately regulated by an-

other Federal agency, or (2) to be of a character which is unnecessary to be subject to this Act in order to carry out the purposes of this Act.

(c) Other Authority.—The Administrator, after notice and op-

portunity for hearing, is authorized—

(1) to declare a pest any form of plant or animal life (other than man and other than bacteria, virus, and other micro-organisms on or in living man or other living animals) which is injurious to health or the environment;

(2) to determine any pesticide which contains any substance

or substances in quantities highly toxic to man;

(3) to establish standards (which shall be consistent with those established under the authority of the Poison Prevention Packaging Act (Public Law 91-601)) with respect to the package, container, or wrapping in which a pesticide or device is enclosed for use or consumption, in order to protect children and adults from serious injury or illness resulting from accidental ingestion or contact with pesticides or devices regulated by this Act as well as to accomplish the other purposes of this Act;

(4) to specify those classes of devices which shall be subject to any provision of paragraph 2(q)(1) or section 7 of this Act upon his determination that application of such provision is neces-

sary to effectuate the purposes of this Act;

(5) to prescribe regulations requiring any pesticide to be colored or discolored if he determines that such requirement is feasible and is necessary for the protection of health and the environment; and

(6) to determine and establish suitable names to be used in

the ingredient statement.

(d) Scientific Advisory Panel.—The Administrator shall submit to an advisory panel for comment as to the impact on health and the environment of the action proposed in notices of intent issued under section 6(b) and of the proposed and final form of regulations issued under section 25(a) within the same time periods as provided for the comments of the Secretary of Agriculture under such sections. The time requirements for notices of intent and proposed and final forms of regulation may not be modified or waived unless in addition to meeting the requirements of section 6(b) or 25(a), as applicable, the advisory panel has failed to comment on the proposed action within the prescribed time period or has agreed to the modification or waiver. The Administrator shall also solicit from the advisory panel comments, evaluations, and recommendations for operating guidelines to improve the effectiveness and quality of scientific analyses made by personnel of the Environmental Protection Agency that lead to decisions by the Administrator in carrying out the provisions of this Act. The comments, evaluations, and recommendations of the advisory panel submitted under this subsection and the response of the Administrator shall be published in the Federal Register in the same manner as provided for publication of the comments of the Secretary of Agriculture under such sections. The chairman of the advisory panel, after consultation with the Administrator, may create temporary subpanels on specific projects

to assist the full advisory panel in expediting and preparing its evaluations, comments, and recommendations. The subpanels may be composed of scientists other than members of the advisory panel, as deemed necessary for the purpose of evaluating scientific studies relied upon by the Administrator with respect to proposed action. Such additional scientists shall be selected by the advisory panel. The panel referred to in this subsection shall consist of 7 members appointed by the Administrator from a list of 12 nominees, 6 nominated by the National Institutes of Health and 6 by the National Science Foundation, utilizing a system of staggered terms of appointment. Members of the panel shall be selected on the basis of their professional qualifications to assess the effects of the impact of pesticides on health and the environment. To the extent feasible to insure multidisciplinary representation, the panel membership shall include representation from the disciplines of toxicology, pathology, environmental biology, and related sciences. If a vacancy occurs on the panel due to expiration of a term, resignation, or any other reason, each replacement shall be selected by the Administrator from a group of 4 nominees, 2 submitted by each of the nominating entities named in this subsection. The Administrator may extend the term of a panel member until the new member is appointed to fill the vacancy. If a vacancy occurs due to resignation, or reason other than expiration of a term, the Administrator shall appoint a member to serve during the unexpired term utilizing the nomination process set forth in this subsection. Should the list of nominees provided under this subsection be unsatisfactory, the Administrator may request an additional set of nominees from the nominating entities. The Administrator may require such information from the nominees to the advisory panel as he deems necessary, and he shall publish in the Federal Register the name, address, and professional affiliations of each nominee. Each member of the panel shall receive per diem compensation at a rate not in excess of that fixed for GS-18 of the General Schedule as may be determined by the Administrator, except that any such member who holds another office or position under the Federal Government the compensation for which exceeds such rate may elect to receive compensation at the rate provided for such other office or position in lieu of the compensation provided by this subsection. In order to assure the objectivity of the advisory panel, the Administrator shall promulgate regulations regarding conflicts of interest with respect to the members of the panel. The advisory panel established under this section shall be permanent. In performing the functions assigned by this Act, the panel shall consult and coordinate its activities with the Science Advisory Board established under the Environmental Research, Development, and Demonstration Authorization Act of 1978. Whenever the Administrator exercises authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly submit to the advisory panel for comment, as to the impact on health and the environment, the action taken to suspend the registration of such pesticide.

- (e) PEER REVIEW.—The Administrator shall, by written procedures, provide for peer review with respect to the design, protocols, and conduct of major scientific studies conducted under this Act by the Environmental Protection Agency or by any other Federal agency, any State or political subdivision thereof, or any institution or individual under grant, contract, or cooperative agreement from or with the Environmental Protection Agency. In such procedures, the Administrator shall also provide for peer review, using the advisory panel established under subsection (d) of this section or appropriate experts appointed by the Administrator from a current list of nominees maintained by such panel, with respect to the results of any such scientific studies relied upon by the Administrator with respect to actions the Administrator may take relating to the change in classification, suspension, or cancellation of a pesticide. Whenever the Administrator determines that circumstances do not permit the peer review of the results of any such scientific study prior to the Administrator's exercising authority under section 6(c) of this Act to immediately suspend the registration of any pesticide to prevent an imminent hazard, the Administrator shall promptly thereafter provide for the conduct of peer review as provided in this sentence. The evaluations and relevant documentation constituting the peer review that relate to the proposed scientific studies and the results of the completed scientific studies shall be included in the submission for comment forwarded by the Administrator to the advisory panel as provided in subsection (d). As used in this subsection, the term "peer review" shall mean an independent evaluation by scientific experts, either within or outside the Environmental Protection Agency, in the appropriate disciplines. SEC. 26. [136w-1] STATE PRIMARY ENFORCEMENT RESPONSIBILITY.
- (a) In General.—For the purposes of this Act, a State shall have primary enforcement responsibility for pesticide use violations during any period for which the Administrator determines that such State—

(1) has adopted adequate pesticide use laws and regulations, except that the Administrator may not require a State to have pesticide use laws that are more stringent than this Act;

(2) has adopted and is implementing adequate procedures for the enforcement of such State laws and regulations; and

(3) will keep such records and make such reports showing compliance with paragraphs (1) and (2) of this subsection as the Administrator may require by regulation.

(b) Special Rules.—Notwithstanding the provisions of subsection (a) of this section, any State that enters into a cooperative agreement with the Administrator under section 23 of this Act for the enforcement of pesticide use restrictions shall have the primary enforcement responsibility for pesticide use violations. Any State that has a plan approved by the Administrator in accordance with the requirements of section 11 of this Act that the Administrator determines meets the criteria set out in subsection (a) of this section shall have the primary enforcement responsibility for pesticide use violations. The Administrator shall make such determinations with respect to State plans under section 11 of this Act in effect on the

date of enactment of the Federal Pesticide Act of 1978 [September

30, 1978] not later than six months after that date.

(c) Administrator.—The Administrator shall have primary enforcement responsibility for those States that do not have primary enforcement responsibility under this Act. Not withstanding the provisions of section 2(e)(1) of this Act, during any period when the Administrator has such enforcement responsibility, section 8(b) of this Act shall apply to the books and records of commercial applicators and to any applicator who holds or applies pesticides, or use dilutions of pesticides, only to provide a service of controlling pests without delivering any unapplied pesticide to any person so served, and section 9(a) of this Act shall apply to the establishment or other place where pesticides or devices are held for application by such persons with respect to pesticides or devices held for such application.

SEC. 27. [136w-2] FAILURE BY THE STATE TO ASSURE ENFORCEMENT OF STATE PESTICIDE USE REGULATIONS.

(a) Referral.—Upon receipt of any complaint or other information alleging or indicating a significant violation of the pesticide use provisions of this Act, the Administrator shall refer the matter to the appropriate State officials for their investigation of the matter consistent with the requirements of this Act. If, within thirty days, the State has not commenced appropriate enforcement action, the Administrator may act upon the complaint or informa-

tion to the extent authorized under this Act.

(b) Notice.—Whenever the Administrator determines that a State having primary enforcement responsibility for pesticide use violations is not carrying out (or cannot carry out due to the lack of adequate legal authority) such responsibility, the Administrator shall notify the State. Such notice shall specify those aspects of the administration of the State program that are determined to be inadequate. The State shall have ninety days after receipt of the notice to correct any deficiencies. If after that time the Administrator determines that the State program remains inadequate, the Administrator may rescind, in whole or in part, the State's primary enforcement responsibility for pesticide use violations.

(c) Construction.—Neither section 26 of this Act nor this section shall limit the authority of the Administrator to enforce this Act, where the Administrator determines that emergency conditions exist that require immediate action on the part of the Administrator and the State authority is unwilling or unable adequately to re-

spond to the emergency.

SEC. 28. [136w-3] IDENTIFICATION OF PESTS; COOPERATION WITH DE-PARTMENT OF AGRICULTURE'S PROGRAM.

The Administrator, in coordination with the Secretary of Agriculture, shall identify those pests that must be brought under control. The Administrator shall also coordinate and cooperate with the Secretary of Agriculture's research and implementation programs to develop and improve the safe use and effectiveness of chemical, biological, and alternative methods to combat and control pests that reduce the quality and economical production and distribution of agricultural products to domestic and foreign consumers.

SEC. 29. [136w-4] ANNUAL REPORT.

The Administrator shall submit an annual report to Congress before February 16 of each year and the first report shall be due February 15, 1979. The report shall include the total number of applications for conditional registration under sections 3(c)(7)(B) and 3(c)(7)(C) of this Act that were filed during the immediately preceding fiscal year, and, with respect to those applications approved, the Administrator shall report the Administrator's findings in each case, the conditions imposed and any modification of such conditions in each case, and the quantities produced of such pesticides. SEC. 30. [136x] SEVERABILITY.

If any provision of this Act or the application thereof to any person or circumstance is held invalid, the invalidity shall not affect other provisions or applications of this Act which can be given effect without regard to the invalid provision or application, and to this end the provisions of this Act are severable.

SEC. 31. [136y] AUTHORIZATION FOR APPROPRIATIONS.

There is authorized to be appropriated to carry out this Act (other than section 23(a))—

(1) \$83,000,000 for fiscal year 1989, of which not more than \$13,735,500 shall be available for research under this Act:

(2) \$95,000,000 for fiscal year 1990, of which not more than \$14,343,600 shall be available for research under this Act; and

(3) \$95,000,000 for fiscal year 1991, of which not more than \$14.978,200 shall be available for research under this Act.

