**FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT**

[As Amended Through P.L. 110–246, Effective May 22, 2008]

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**3 FIFRA**

**AN ACT**

**Sec. 1**

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.** ø**7 U.S.C. prec. 121**¿ **SHORT TITLE AND TABLE OF CON- TENTS.**

(a) SHORT TITLE.—This Act may be cited as the ‘‘Federal Insec- ticide, Fungicide, and Rodenticide Act’’.

(b) TABLE OF CONTENTS.— 1–1

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(b) Table of contents. Sec. 2. Definitions.

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(ff) Outstanding data requirement. (gg) To distribute or sell.

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1–1 So in original. The table of contents does not correspond to the contents of the Act. Public Law 104–170 did not make conforming amendments to the table of contents.

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**SEC. 2.** ø**7 U.S.C. 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, desiccant, or nitrogen stabilizer, 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;

(4) in the case of a desiccant, an ingredient which will arti- ficially accelerate the drying of plant tissue; and

(5) in the case of a nitrogen stabilizer, an ingredient which will prevent or hinder the process of nitrification, denitrification, ammonia volatilization, or urease production through action affecting soil bacteria.

(b) ADMINISTRATOR.—The term ‘‘Administrator’’ means the Ad- ministrator of the Environmental Protection Agency.

(c) ADULTERATED.—The term ‘‘adulterated’’ applies to any pes- ticide 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 whol- ly or in part abstracted.

(d) ANIMAL.—The term ‘‘animal’’ means all vertebrate and in- vertebrate 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 11 as au- thorized to use or supervise the use of any pesticide which is classified for restricted use. Any applicator who holds or applies registered pesticides, or uses dilutions of registered pesticides consistent with subsection (ee), only to provide a service of con- trolling 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 the applicator or the applicator’s employer or (if ap- plied without compensation other than trading of personal serv- ices between producers of agricultural commodities) on the property of another person.

(3) COMMERCIAL APPLICATOR.—The term ‘‘commercial appli- cator’’ means an applicator (whether or not the applicator is a private applicator with respect to some uses) who uses or su- pervises the use of any pesticide which is classified for re- stricted use for any purpose or on any property other than as provided by paragraph (2).

(4) UNDER THE DIRECT SUPERVISION OF A CERTIFIED APPLI- CATOR.—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 appli- cator 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 dry- ing of plant tissue.

(h) DEVICE.—The term ‘‘device’’ means any instrument or con- trivance (other than a firearm) which is intended for trapping, de- stroying, 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.

(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.

(l) 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 re- sult in unreasonable adverse effects on the environment or will in- volve unreasonable hazard to the survival of a species declared en- dangered by the Secretary of the Interior under Public Law 91–135. (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;

and

(2) if the pesticide contains arsenic in any form, a state- ment of the percentages of total and water soluble arsenic, cal- culated 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 exam- ple, beetles, bugs, bees, flies, and to other allied classes of arthro- pods 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 lit-

erature accompanying the pesticide or device, except to cur- rent 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 au- thorized by law to conduct research in the field of pes- ticides.

(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 estab-

lished 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 as-

signed 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 con-

spicuousness (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 pur-

chase and use;

(F) the labeling accompanying it does not contain di-

rections for use which are necessary for effecting the pur-

pose for which the product is intended and if complied

with, together with any requirements imposed under sec-

tion 3(d) of this Act, are adequate to protect health and the

environment;

(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 accord-

ance with section 3 of this Act and intended for export, the

label does not contain, in words prominently placed there-

on with such conspicuousness (as compared with other

words, statements, designs, or graphic matter in the label-

ing) as to render it likely to be noted by the ordinary indi-

following: ‘‘Not Registered for Use in the United States of

America’’.

(2) A pesticide is misbranded if—

(A) 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 dis-

played under customary conditions of purchase, except that

a pesticide is not misbranded under this subparagraph if—

(i) the size or form of the immediate container, or

the outside container or wrapper of the retail package,

makes it impracticable to place the ingredient state-

ment 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 out-

side container or wrapper of the retail package, if there be

one, through which the required information on the imme-

diate container cannot be clearly read, a label bearing—

(i) the name and address of the producer, reg-

istrant, or person for whom produced;

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

the pesticide is sold;

(iii) the net weight or measure of the content, ex-

cept that the Administrator may permit reasonable

variations; and

(iv) when required by regulation of the Adminis-

trator to effectuate the purposes of this Act, the reg-

istration 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) NEMATODE.—The term ‘‘nematode’’ means invertebrate ani-

mals of the phylum nemathelminthes and class nematoda, that is,

unsegmented round worms with elongated, fusiform, or saclike bod-

ies 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, partner-

ship, association, corporation, or any organized group of persons

whether incorporated or not.

(t) PEST.—The term ‘‘pest’’ means (1) any insect, rodent, nema-

tode, fungus, weed, or (2) any other form of terrestrial or aquatic

plant or animal life or virus, bacteria, or other micro-organism (ex-

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, repel- ling, or mitigating any pest, (2) any substance or mixture of sub- stances intended for use as a plant regulator, defoliant, or des-

iccant, and (3) any nitrogen stabilizer, except that the term ‘‘pes-

ticide’’ 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 ani- mal drug by a regulation establishing conditions of use for the arti- cle, 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. The term ‘‘pesticide’’ does not include liquid chemical sterilant products (including any sterilant or subordinate disinfectant claims on such products) for use on a critical or semi-critical device, as de- fined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321). For purposes of the preceding sentence, the term

‘‘critical device’’ includes any device which is introduced directly into the human body, either into or in contact with the bloodstream or normally sterile areas of the body and the term ‘‘semi-critical de- vice’’ includes any device which contacts intact mucous membranes but which does not ordinarily penetrate the blood barrier or other- wise enter normally sterile areas of the body.

(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 im- provement, maintenance, survival, health, and propagation of plants, and as are not for pest destruction and are nontoxic, nonpoi- sonous 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 pro- ducing a pesticide. The term ‘‘produce’’ means to manufacture, pre- pare, compound, propagate, or process any pesticide or device or ac- tive ingredient used in producing a pesticide. The dilution by indi- viduals 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 ‘‘pro- tect health and the environment’’ and ‘‘protection of health and the environment’’ mean protection against any unreasonable adverse ef- fects 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 reregistra-

tion.

(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 ENVIRON- MENT.—The term ‘‘unreasonable adverse effects on the environ- ment’’ means (1) 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, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 346a). 2–1 The Adminis- trator shall consider the risks and benefits of public health pes- ticides separate from the risks and benefits of other pesticides. In weighing any regulatory action concerning a public health pesticide under this Act, the Administrator shall weigh any risks of the pes- ticide against the health risks such as the diseases transmitted by the vector to be controlled by the 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 pro- ducing a pesticide is produced, or held, for distribution or sale.

(ee) TO USE ANY REGISTERED PESTICIDE IN A MANNER INCON- SISTENT WITH ITS LABELING.—The term ‘‘to use any registered pes- ticide in a manner inconsistent with its labeling’’ means to use any registered pesticide in a manner not permitted by the labeling, ex- cept 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 pes- ticide against any target pest not specified on the labeling if the ap- plication is to the crop, animal, or site specified on the labeling, un- less 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 ad- verse effect on the environment, (3) employing any method of appli- cation not prohibited by the labeling unless the labeling specifically states that the product may be applied only by the methods speci- fied on the labeling, (4) mixing a pesticide or pesticides with a fer- tilizer 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 Adminis- trator determines to be consistent with the purposes of this Act. After March 31, 1979, the term shall not include the use of a pes- ticide 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.—

2–1 Sec. 304 of P.L. 104–170 amended sec. 2(bb) (7 U.S.C. 136(bb)) by inserting ‘‘(1)’’ and

‘‘, or (2)’’ and all that follows through ‘‘346a).’’, without specifying the Act that was being amended. The amendments were executed to this Act to effectuate the probable intent of Congress.

(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 Adminis- trator 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 deter- mine 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 de- liver. The term does not include the holding or application of reg- istered 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.

(hh) NITROGEN STABILIZER.—The term ‘‘nitrogen stabilizer’’ means any substance or mixture of substances intended for pre- venting or hindering the process of nitrification, denitrification, am- monia volatilization, or urease production through action upon soil bacteria. Such term shall not include—

(1) dicyandiamide;

(2) ammonium thiosulfate; or

(3) any substance or mixture of substances.—

(A) that was not registered pursuant to section 3 prior to January 1, 1992; and

(B) that was in commercial agronomic use prior to Jan- uary 1, 1992, with respect to which after January 1, 1992, the distributor or seller of the substance or mixture has made no specific claim of prevention or hindering of the process of nitrification, denitrification, ammonia volatiliza- tion urease production regardless of the actual use or pur- pose for, or future use or purpose for, the substance or mix- ture.

Statements made in materials required to be submitted to any State legislative or regulatory authority, or required by such au- thority to be included in the labeling or other literature accom- panying any such substance or mixture shall not be deemed a spe- cific claim within the meaning of this subsection.

(jj) 2–2 MAINTENANCE APPLICATOR.—The term ‘‘maintenance ap- plicator’’ means any individual who, in the principal course of such individual’s employment, uses, or supervises the use of, a pesticide not classified for restricted use (other than a ready to use consumer products pesticide); for the purpose of providing structural pest con- trol or lawn pest control including janitors, general maintenance

2–2 So in original (as added by sec. 120 of P.L. 104–170). This subsection should probably be ‘‘(ii)’’ and subsequent subsections should be redesignated accordingly.

personnel, sanitation personnel, and grounds maintenance per- sonnel. The term ‘‘maintenance applicator’’ does not include private applicators as defined in section 2(e)(2); individuals who use anti- microbial pesticides, sanitizers or disinfectants; individuals em- ployed by Federal, State, and local governments or any political subdivisions thereof, or individuals who use pesticides not classified for restricted use in or around their homes, boats, sod farms, nurs- eries, greenhouses, or other noncommercial property.

(kk) SERVICE TECHNICIAN.—The term ‘‘service technician’’ means any individual who uses or supervises the use of pesticides (other than a ready to use consumer products pesticide) for the pur- pose of providing structural pest control or lawn pest control on the property of another for a fee. The term ‘‘service technician’’ does not include individuals who use antimicrobial pesticides, sanitizers or disinfectants; or who otherwise apply ready to use consumer prod- ucts pesticides.

(ll) MINOR USE.—The term ‘‘minor use’’ means the use of a pes- ticide on an animal, on a commercial agricultural crop or site, or for the protection of public health where—

(1) the total United States acreage for the crop is less than

300,000 acres, as determined by the Secretary of Agriculture;

or

(2) the Administrator, in consultation with the Secretary of Agriculture, determines that, based on information provided by an applicant for registration or a registrant, the use does not provide sufficient economic incentive to support the initial reg- istration or continuing registration of a pesticide for such use and—

(A) there are insufficient efficacious alternative reg- istered pesticides available for the use;

(B) the alternatives to the pesticide use pose greater risks to the environment or human health;

(C) the minor use pesticide plays or will play a signifi- cant part in managing pest resistance; or

(D) the minor use pesticide plays or will play a signifi- cant part in an integrated pest management program.

The status as a minor use under this subsection shall continue as long as the Administrator has not determined that, based on exist- ing data, such use may cause an unreasonable adverse effect on the environment and the use otherwise qualifies for such status.

(mm) ANTIMICROBIAL PESTICIDE.—

(1) IN GENERAL.—The term ‘‘antimicrobial pesticide’’ means

a pesticide that—

(A) is intended to—

(i) disinfect, sanitize, reduce, or mitigate growth or

development of microbiological organisms; or

(ii) protect inanimate objects, industrial processes

or systems, surfaces, water, or other chemical sub-

stances from contamination, fouling, or deterioration

caused by bacteria, viruses, fungi, protozoa, algae, or

slime; and

(B) in the intended use is exempt from, or otherwise

not subject to, a tolerance under section 408 of the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 346a and 348) or

a food additive regulation under section 409 of such Act.

(2) EXCLUDED PRODUCTS.—The term ‘‘antimicrobial pes- ticide’’ does not include —

(A) a wood preservative or antifouling paint product for which a claim of pesticidal activity other than or in addi- tion to an activity described in paragraph (1) is made;

(B) an agricultural fungicide product; or

(C) an aquatic herbicide product.

(3) INCLUDED PRODUCTS.—The term ‘‘antimicrobial pes-

ticide’’ does include any other chemical sterilant product (other

than liquid chemical sterilant products exempt under sub-

section (u)), any other disinfectant product, any other industrial

microbiocide product, and any other preservative product that

is not excluded by paragraph (2).

(nn) PUBLIC HEALTH PESTICIDE.—The term ‘‘public health pes-

ticide’’ means any minor use pesticide product registered for use

and used predominantly in public health programs for vector con-

trol or for other recognized health protection uses, including the

prevention or mitigation of viruses, bacteria, or other microorga-

nisms (other than viruses, bacteria, or other microorganisms on or

in living man or other living animal) that pose a threat to public

health.

(oo) VECTOR.—The term ‘‘vector’’ means any organism capable

of transmitting the causative agent of human disease or capable of

producing human discomfort or injury, including mosquitoes, flies,

fleas, cockroaches, or other insects and ticks, mites, or rats.

**SEC. 3.** ø**7 U.S.C. 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 environ- ment, 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

Administrator may be transferred if—

(1) the transfer is from one registered establishment to an-

other 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 requirements 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 direc-

tions for its use;

(D) the complete formula of the pesticide;

(E) a request that the pesticide be classified for general use or for restricted use, or for both; and

(F) 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 con- sider in accordance with the following provisions:

(i) With respect to pesticides containing active in- gredients 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 add- ing 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 consid- ered 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) The period of exclusive data use provided

under clause (i) shall be extended 1 additional year for

each 3 minor uses registered after the date of enact-

ment of this clause [Aug. 3, 1996] and within 7 years

of the commencement of the exclusive use period, up to

a total of 3 additional years for all minor uses reg-

istered by the Administrator if the Administrator, in

consultation with the Secretary of Agriculture, deter-

mines that, based on information provided by an appli-

cant for registration or a registrant, that—

(I) there are insufficient efficacious alternative

registered pesticides available for the use;

(II) the alternatives to the minor use pesticide

pose greater risks to the environment or human

health;

(III) the minor use pesticide plays or will play

a significant part in managing pest resistance; or

(IV) the minor use pesticide plays or will play

a significant part in an integrated pest manage-

ment program.

The registration of a pesticide for a minor use on a

crop grouping established by the Administrator shall

be considered for purposes of this clause 1 minor use

for each representative crop for which data are pro-

vided in the crop grouping. Any additional exclusive

use period under this clause shall be modified as ap-

propriate or terminated if the registrant voluntarily

cancels the product or deletes from the registration the

minor uses which formed the basis for the extension of

the additional exclusive use period or if the Adminis-

trator determines that the registrant is not actually

marketing the product for such minor uses.

(iii) Except as otherwise provided in clause (i), with respect to data submitted after December 31,

1969, by an applicant or registrant to support an appli- cation for registration, experimental use permit, or amendment adding a new use to an existing registra- tion, to support or maintain in effect an existing reg-

istration, or for reregistration, the Administrator may,

without the permission of the original data submitter, consider any such item of data in support of an appli- cation by any other person (hereinafter in this sub- paragraph referred to as the ‘‘applicant’’) within the fif- teen-year period following the date the data were origi- nally submitted only if the applicant has made an offer to compensate the original data submitter and sub- mitted 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 sub- mitter 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 ap- point an arbitrator from the roster of arbitrators main- tained by such Service. The procedure and rules of the Service shall be applicable to the selection of such arbi- trator 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 re- view 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, misrepre- sentation, or other misconduct. The parties to the arbi- tration shall share equally in the payment of the fee and expenses of the arbitrator. If the Administrator de- termines 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 sub- paragraph, or failed to comply with the terms of an agreement or arbitration decision concerning com- pensation under this subparagraph, the original data submitter shall forfeit the right to compensation for the use of the data in support of the application. Not- withstanding any other provision of this Act, if the Ad- ministrator determines that an applicant has failed to participate in a procedure for reaching an agreement or in an arbitration proceeding as required by this sub- paragraph, or failed to comply with the terms of an

agreement or arbitration decision concerning com- pensation 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 sen- tences, 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 registra- tion is denied or canceled under this subparagraph, the Administrator may make such order as the Adminis- trator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Registra- tion action by the Administrator shall not be delayed pending the fixing of compensation.

(iv) 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), (ii), and

(iii), 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 com-

pensate the original data submitter for the use of such

item of data.

(v) The period of exclusive use provided under

clause (ii) shall not take effect until 1 year after enact-

ment of this clause [Aug. 3, 1996], except where an ap-

plicant or registrant is applying for the registration of

a pesticide containing an active ingredient not pre-

viously registered.

(vi) With respect to data submitted after the date

of enactment of this clause [Aug. 3, 1996] by an appli-

cant or registrant to support an amendment adding a

new use to an existing registration that does not retain

any period of exclusive use, if such data relates solely

to a minor use of a pesticide, such data shall not, with-

out the written permission of the original data sub-

mitter, be considered by the Administrator to support

an application for a minor use by another person dur-

ing the period of 10 years following the date of submis-

sion of such data. The applicant or registrant at the

time the new minor use is requested shall notify the

Administrator that to the best of their knowledge the

exclusive use period for the pesticide has expired and

that the data pertaining solely to the minor use of a

pesticide is eligible for the provisions of this para-

graph. If the minor use registration which is supported

by data submitted pursuant to this subsection is volun-

tarily canceled or if such data are subsequently used

to support a nonminor use, the data shall no longer be

subject to the exclusive use provisions of this clause

but shall instead be considered by the Administrator in

accordance with the provisions of clause (i), as appro-

priate.

(G) If the applicant is requesting that the registration or amendment to the registration of a pesticide be expe- dited, an explanation of the basis for the request must be submitted, in accordance with paragraph (10) of this sub- section.

(2) DATA IN SUPPORT OF REGISTRATION.—

(A) IN GENERAL.—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 the

Administrator requires any additional kind of information

under subparagraph (B) of this paragraph, the Adminis-

trator shall permit sufficient time for applicants to obtain

such additional information. The Administrator, in estab-

lishing 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, the public health and agricultural need

for such minor use, and the level and degree of potential

beneficial or adverse effects on man and the environment.

The Administrator shall not require a person to submit, in

relation to a registration or reregistration of a pesticide for

minor agricultural use under this Act, any field residue

data from a geographic area where the pesticide will not be

registered for such use. In the development of these stand-

ards, 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 the Administrator shall make

available to the public the data called for in the registra-

tion statement together with such other scientific informa-

tion as the Administrator deems relevant to the Adminis-

trator’s decision.

(B) ADDITIONAL DATA.—(i) If the Administrator deter-

mines that additional data are required to maintain in ef-

fect an existing registration of a pesticide, the Adminis-

trator shall notify all existing registrants of the pesticide to

which the determination relates and provide a list of such

registrants to any interested person.

(ii) Each registrant of such pesticide shall provide evi-

dence 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 in-

tent 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 Ad- ministrator of their agreement to develop jointly, or share in the cost of developing data, the registrants have not fur- ther agreed on the terms of the data development arrange- ment or on a procedure for reaching such agreement, any of such registrants may initiate binding arbitration pro- ceedings by requesting the Federal Mediation and Concilia- tion Service to appoint an arbitrator from the roster of ar- bitrators 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, misrepresen- tation, or other misconduct by one of the parties to the ar- bitration or the arbitrator where there is a verified com- plaint with supporting affidavits attesting to specific in- stances of such fraud, misrepresentation, or other mis- conduct. 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 proce- dures prescribed by clause (iv) if a registrant fails to com- ply 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 ap- propriate steps to secure the data required under this sub- paragraph, to participate in a procedure for reaching agree- ment 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 ad- ditional data is required. The Administrator may include in the notice of intent to suspend such provisions as the Ad- ministrator deems appropriate concerning the continued sale and use of existing stocks of such pesticide. Any sus- pension 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 satis- fied 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 re- quired, and whether the Administrator’s determination with respect to the disposition of existing stocks is con-

sistent 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 re- ceipt of a request for such hearing. Any registration sus- pended 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 submis- sion to handle any subsequent data compensation matters for the joint submitters of such data.

(vi) Upon the request of a registrant the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this sub- paragraph for data required solely to support that minor use until the final deadline for submission of data under section 4 for the other uses of the pesticide established as of the date of enactment of the Food Quality Protection Act of 1996 [Aug. 3, 1996], if—

(I) the data to support other uses of the pesticide on a food are being provided;

(II) the registrant, in submitting a request for such an extension, provides a schedule, including interim dates to measure progress, to assure that the data pro- duction will be completed before the expiration of the extension period;

(III) the Administrator has determined that such extension will not significantly delay the Administra- tor’s schedule for issuing a reregistration eligibility de- termination required under section 4; and

(IV) the Administrator has determined that based on existing data, such extension would not signifi- cantly increase the risk of any unreasonable adverse effect on the environment. 3–1 If the Administrator grants an extension under this clause, the Adminis- trator shall monitor the development of the data and shall ensure that the registrant is meeting the sched- ule for the production of the data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwithstanding the provi- sions of this clause, the Administrator may take action to modify or revoke the extension under this clause if the Administrator determines that the extension for the minor use may cause an unreasonable adverse ef- fect on the environment. In such circumstance, the Ad-

3–1 Indentation of the following sentences of this clause is so in original (as added by sec. 201(c)(1) of P.L. 104–170). Probably should be indented the same as flush matter of this clause.

ministrator shall provide, in writing to the registrant, a notice revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date established by the Administrator for the submission of the data.

(vii) If the registrant does not commit to support a spe- cific minor use of the pesticide, but is supporting and pro- viding data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is sup- porting and providing data in a timely and adequate fash- ion to support other nonfood uses of the pesticide, the Ad- ministrator, at the written request of the registrant, shall not take any action pursuant to this clause in regard to such unsupported minor use until the final deadline estab- lished as of the date of enactment of the Food Quality Pro- tection Act of 1996 [Aug. 3, 1996], for the submission of data under section 4 for the supported uses identified pur- suant to this clause unless the Administrator determines that the absence of the data is significant enough to cause human health or environmental concerns. On the basis of such determination, the Administrator may refuse the re- quest for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall pub- lish in the Federal Register a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily deleted from the reg- istration pursuant to section 6(f)(1). If the Administrator grants an extension under this clause, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meet- ing or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of this subparagraph regarding the continued registration of the affected products with the minor and other uses and shall inform the public of such action in ac- cordance with section 6(f)(2). Notwithstanding the provi- sions of this clause, the Administrator may deny, modify, or revoke the temporary extension under this subpara- graph if the Administrator determines that the continu- ation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(viii)(I) If data required to support registration of a pesticide under subparagraph (A) is requested by a Federal or State regulatory authority, the Administrator shall, to the extent practicable, coordinate data requirements, test protocols, timetables, and standards of review and reduce burdens and redundancy caused to the registrant by mul- tiple requirements on the registrant.

(II) The Administrator may enter into a cooperative agreement with a State to carry out subclause (I).

(III) Not later than 1 year after the date of enactment of this clause [Aug. 3, 1996], the Administrator shall de- velop a process to identify and assist in alleviating future disparities between Federal and State data requirements. (C) SIMPLIFIED PROCEDURES.—Within nine months after the date of enactment of this subparagraph [Sep- tember 30, 1978], the Administrator shall, by regulation, prescribe simplified procedures for the registration of pes- ticides, which shall include the provisions of subparagraph

(D) of this paragraph.

(D) EXEMPTION.—No applicant for registration of a pes-

ticide who proposes to purchase a registered pesticide from

another producer in order to formulate such purchased pes-

ticide into the pesticide that is the subject of the applica-

tion shall be required to—

(i) submit or cite data pertaining to such pur-

chased product; or

(ii) offer to pay reasonable compensation otherwise

required by paragraph (1)(D) of this subsection for the

use of any such data.

(E) MINOR USE WAIVER.—In handling the registration

of a pesticide for a minor use, the Administrator may waive

otherwise applicable data requirements if the Adminis-

trator determines that the absence of such data will not

prevent the Administrator from determining—

(i) the incremental risk presented by the minor use

of the pesticide; and

(ii) that such risk, if any, would not be an unrea-

sonable adverse effect on the environment.

(3) TIME FOR ACTING WITH RESPECT TO APPLICATION.—

(A) IN GENERAL.—The Administrator shall review the

data after receipt of the application and shall, as expedi-

tiously as possible, either register the pesticide in accord-

ance with paragraph (5), or notify the applicant of the Ad-

ministrator’s determination that it does not comply with

the provisions of the Act in accordance with paragraph (6).

(B) IDENTICAL OR SUBSTANTIALLY SIMILAR.—(i) The Ad-

ministrator 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 composi-

tion and labeling to a currently-registered pesticide

identified in the application, or that would differ in

composition and labeling from such currently-reg-

istered pesticide only in ways that would not signifi-

cantly 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 ac-

tion described in clause (i), the Administrator shall—

complete, reject the application;

(II) not later than the applicable decision review

time established pursuant to section 33(f)(4)(B), or, if

no review time is established, not later than 90 days after receiving a complete application, notify the reg- istrant if the application has been granted or denied; and

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

(C) MINOR USE REGISTRATION.—

(i) The Administrator shall, as expeditiously as possible, review and act on any complete application— (I) that proposes the initial registration of a

new pesticide active ingredient if the active ingre- dient is proposed to be registered solely for minor uses, or proposes a registration amendment solely for minor uses to an existing registration; or

(II) for a registration or a registration amend- ment that proposes significant minor uses.

(ii) For the purposes of clause (i)—

(I) the term ‘‘as expeditiously as possible’’ means that the Administrator shall, to the great- est extent practicable, complete a review and eval- uation of all data, submitted with a complete ap- plication, within 12 months after the submission of the complete application, and the failure of the Ad- ministrator to complete such a review and evalua- tion under clause (i) shall not be subject to judicial review; and

(II) the term ‘‘significant minor uses’’ means 3 or more minor uses proposed for every nonminor use, a minor use that would, in the judgment of the Administrator, serve as a replacement for any use which has been canceled in the 5 years pre- ceding the receipt of the application, or a minor use that in the opinion of the Administrator would avoid the reissuance of an emergency exemption under section 18 for that minor use.

(D) ADEQUATE TIME FOR SUBMISSION OF MINOR USE DATA.—If a registrant makes a request for a minor use waiver, regarding data required by the Administrator, pur- suant to paragraph (2)(E), and if the Administrator denies in whole or in part such data waiver request, the registrant shall have a full-time period for providing such data. For purposes of this subparagraph, the term ‘‘full-time period’’ means the time period originally established by the Admin- istrator for submission of such data, beginning with the date of receipt by the registrant of the Administrator’s no- tice of denial.

(4) NOTICE OF APPLICATION.—The Administrator shall pub- lish in the Federal Register, promptly after receipt of the state- ment and other data required pursuant to paragraphs (1) and (2), a notice of each application for registration of any pesticide

son may comment.

(5) APPROVAL OF REGISTRATION.—The Administrator shall

register a pesticide if the Administrator 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 sub- mitted comply with the requirements of this Act;

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

(D) when used in accordance with widespread and com- monly recognized practice it will not generally cause unrea- sonable adverse effects on the environment.

The Administrator shall not make any lack of essentiality a cri- terion for denying registration of any pesticide. Where two pes- ticides meet the requirements of this paragraph, one should not be registered in preference to the other. In considering an ap- plication 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 de- termining that the pesticide’s composition is such as to warrant proposed claims of efficacy. If a pesticide is found to be effica- cious by any State under section 24(c) of this Act, a presump- tion is established that the Administrator shall waive data re- quirements pertaining to efficacy for use of the pesticide in such State.

(6) DENIAL OF REGISTRATION.—If the Administrator deter- mines that the requirements of paragraph (5) for registration are not satisfied, the Administrator shall notify the applicant for registration of the Administrator’s determination and of the Administrator’s reasons (including the factual basis) therefor, and that, unless the applicant corrects the conditions and noti- fies the Administrator thereof during the 30-day period begin- ning with the day after the date on which the applicant re- ceives the notice, the Administrator may refuse to register the pesticide. Whenever the Administrator refuses to register a pesticide, the Administrator shall notify the applicant of the Administrator’s decision and of the Administrator’s reasons (in- cluding 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.—Not- withstanding 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 iden- tical 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 registra-

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 sub- mission 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 pes- ticide 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 signifi- cantly increase the risk of any unreasonable adverse effect on the environment. Notwithstanding the foregoing provi- sions of this subparagraph, no registration of a pesticide may be amended to permit an additional use of such pes- ticide 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 die- tary 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 addi- tional use of such pesticide involves a minor food or feed crop and the Administrator determines, with the concur- rence 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 registra- tion under this subparagraph shall submit such data as would be required to obtain registration of a similar pes- ticide 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 gen- erated, 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 suffi- cient 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

prescribe. A conditional registration under this subpara- graph shall be granted only if the Administrator deter- mines 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 ini- tiate 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 vali- dated test or other significant evidence raising prudent con- cerns of unreasonable adverse risk to man or to the environ- ment. 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.

(9) LABELING.—

(A) ADDITIONAL STATEMENTS.—Subject to subpara- graphs (B) and (C), it shall not be a violation of this Act for a registrant to modify the labeling of an antimicrobial pesticide product to include relevant information on prod- uct efficacy, product composition, container composition or design, or other characteristics that do not relate to any pesticidal claim or pesticidal activity.

(B) REQUIREMENTS.—Proposed labeling information under subparagraph (A) shall not be false or misleading, shall not conflict with or detract from any statement re- quired by law or the Administrator as a condition of reg- istration, and shall be substantiated on the request of the Administrator.

(C) NOTIFICATION AND DISAPPROVAL.—

(i) NOTIFICATION.—A registration may be modified under subparagraph (A) if —

(I) the registrant notifies the Administrator in writing not later than 60 days prior to distribution or sale of a product bearing the modified labeling; and

(II) the Administrator does not disapprove of the modification under clause (ii).

(ii) DISAPPROVAL.—Not later than 30 days after re- ceipt of a notification under clause (i), the Adminis- trator may disapprove the modification by sending the registrant notification in writing stating that the pro- posed language is not acceptable and stating the rea- sons why the Administrator finds the proposed modi- fication unacceptable.

(iii) RESTRICTION ON SALE.—A registrant may not sell or distribute a product bearing a disapproved modification.

(iv) OBJECTION.—A registrant may file an objection in writing to a disapproval under clause (ii) not later than 30 days after receipt of notification of the dis- approval.

trator following receipt and consideration of an objec- tion filed under clause (iv) shall be considered a final agency action.

(D) USE DILUTION.—The label or labeling required under this Act for an antimicrobial pesticide that is or may

be diluted for use may have a different statement of cau-

tion or protective measures for use of the recommended di- luted solution of the pesticide than for use of a concentrate of the pesticide if the Administrator determines that —

(i) adequate data have been submitted to support the statement proposed for the diluted solution uses; and

(ii) the label or labeling provides adequate protec- tion for exposure to the diluted solution of the pes- ticide.

(10) EXPEDITED REGISTRATION OF PESTICIDES.—

(A) Not later than 1 year after the date of enactment of this paragraph [Aug. 3, 1996], the Administrator shall, utilizing public comment, develop procedures and guide- lines, and expedite the review of an application for reg- istration of a pesticide or an amendment to a registration that satisfies such guidelines.

(B) Any application for registration or an amendment, including biological and conventional pesticides, will be considered for expedited review under this paragraph. An application for registration or an amendment shall qualify for expedited review if use of the pesticide proposed by the application may reasonably be expected to accomplish 1 or more of the following:

(i) Reduce the risks of pesticides to human health. (ii) Reduce the risks of pesticides to nontarget or-

ganisms.

(iii) Reduce the potential for contamination of groundwater, surface water, or other valued environ- mental resources.

(iv) Broaden the adoption of integrated pest man- agement strategies, or make such strategies more available or more effective.

(C) The Administrator, not later than 30 days after re- ceipt of an application for expedited review, shall notify the applicant whether the application is complete. If it is found to be incomplete, the Administrator may either reject the request for expedited review or ask the applicant for addi- tional information to satisfy the guidelines developed under subparagraph (A).

(d) CLASSIFICATION OF PESTICIDES.—

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

(A) As a part of the registration of a pesticide the Ad- ministrator 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 reg- istered should be for restricted use, the Administrator shall

uses may be classified by regulation on the initial classi- fication and registered pesticides may be classified prior to reregistration. If some of the uses of the pesticide are clas- sified for general use and other uses are classified for re- stricted use, the directions relating to its general uses shall be clearly separated and distinguished from those direc- tions 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 la- beling 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 reg- istered, 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 en- vironment, the Administrator will classify the pesticide, or the particular use or uses of the pesticide to which the de- termination 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 reg- istered, 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, the Administrator shall classify the pesticide, or the particular use or uses to which the de- termination applies, for restricted use:

(i) If the Administrator classifies a pesticide, or one or more uses of such pesticide, for restricted use because 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 classifica- tion 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 addi- tional regulatory restriction may cause unreasonable adverse effects on the environment, the pesticide shall be applied for any use to which the determination ap- plies only by or under the direct supervision of a cer- tified 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 de- termines that a change in the classification of any use of a pes- ticide from general use to restricted use is necessary to prevent unreasonable adverse effects on the environment, the Adminis- trator shall notify the registrant of such pesticide of such deter- mination 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 section 6(b).

(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 Admin-

istrator to change any such classification from restricted to gen- eral use. Such petition shall set out the basis for the reg- istrant’s position that restricted use classification is unneces- sary because classification of the pesticide for general use would not cause unreasonable adverse effects on the environ- ment. 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 expla- nation therefor and any such denial shall be subject to judicial review under section 16 of this Act.

(e) PRODUCTS WITH SAME FORMULATION AND CLAIMS.—Prod- ucts 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 addi- tional names and labels shall be added to the registration by sup- plemental statements.

(f) MISCELLANEOUS.—

(1) EFFECT OF CHANGE OF LABELING OR FORMULATION.—If the labeling or formulation for a pesticide is changed, the reg- istration shall be amended to reflect such change if the Admin- istrator determines that the change will not violate any provi- sion of this Act.

(2) REGISTRATION NOT A DEFENSE.—In no event shall reg- istration of an article be construed as a defense for the commis- sion 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 pack- aging 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 con- sult with any other Federal agency.

(4) MIXTURES OF NITROGEN STABILIZERS AND FERTILIZER PRODUCTS.—Any mixture or other combination of—

(A) 1 or more nitrogen stabilizers registered under this

Act; and

(B) 1 or more fertilizer products,

shall not be subject to the provisions of this section or sections

4, 5, 7, 15, and 17(a)(2) if the mixture or other combination is accompanied by the labeling required under this Act for the ni- trogen stabilizer contained in the mixture or other combination, the mixture or combination is mixed or combined in accordance with such labeling, and the mixture or combination does not contain any active ingredient other than the nitrogen stabilizer. (g) REGISTRATION REVIEW.—

(1)(A) GENERAL RULE.—

(i) IN GENERAL.—The registrations of pesticides are to be periodically reviewed.

(ii) REGULATIONS.—In accordance with this subpara- graph, the Administrator shall by regulation establish a procedure for accomplishing the periodic review of registra- tions.

(iii) INITIAL REGISTRATION REVIEW.—The Administrator shall complete the registration review of each pesticide or

pesticide case, which may be composed of 1 or more active

ingredients and the products associated with the active in- gredients, not later than the later of—

(I) October 1, 2022; or

(II) the date that is 15 years after the date on which the first pesticide containing a new active ingre- dient is registered.

(iv) SUBSEQUENT REGISTRATION REVIEW.—Not later than 15 years after the date on which the initial registra- tion review is completed under clause (iii) and each 15 years thereafter, the Administrator shall complete a subse- quent registration review for each pesticide or pesticide case.

(v) CANCELLATION.—No registration shall be canceled as a result of the registration review process unless the Ad- ministrator follows the procedures and substantive require- ments of section 6.

(B) DOCKETING.—

(i) IN GENERAL.—Subject to clause (ii), after meeting with 1 or more individuals that are not government em- ployees to discuss matters relating to a registration review, the Administrator shall place in the docket minutes of the meeting, a list of attendees, and any documents exchanged at the meeting, not later than the earlier of—

(I) the date that is 45 days after the meeting; or

(II) the date of issuance of the registration review decision.

(ii) PROTECTED INFORMATION.—The Administrator shall identify, but not include in the docket, any confiden- tial business information the disclosure of which is prohib- ited by section 10.

(C) LIMITATION.—Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pes- ticide pursuant to this Act.

(2)(A) DATA.—The Administrator shall use the authority in subsection (c)(2)(B) to require the submission of data when such data are necessary for a registration review.

(B) DATA SUBMISSION, COMPENSATION, AND EXEMPTION.— For purposes of this subsection, the provisions of subsections (c)(1), (c)(2)(B), and (c)(2)(D) shall be utilized for and be applica- ble to any data required for registration review.

(h) REGISTRATION REQUIREMENTS FOR ANTIMICROBIAL PES-

TICIDES.—

(1) EVALUATION OF PROCESS.—To the maximum extent practicable consistent with the degrees of risk presented by an antimicrobial pesticide and the type of review appropriate to evaluate the risks, the Administrator shall identify and evalu- ate reforms to the antimicrobial registration process that would reduce review periods existing as of the date of enactment of this subsection [Aug. 3, 1996] for antimicrobial pesticide prod-

uct registration applications and applications for amended reg- istration of antimicrobial pesticide products, including—

(A) new antimicrobial active ingredients; (B) new antimicrobial end-use products;

(C) substantially similar or identical antimicrobial pes- ticides; and

(D) amendments to antimicrobial pesticide registra- tions.

(2) REVIEW TIME PERIOD REDUCTION GOAL.—Each reform identified under paragraph (1) shall be designed to achieve the goal of reducing the review period following submission of a complete application, consistent with the degree of risk, to a pe- riod of not more than—

(A) 540 days for a new antimicrobial active ingredient pesticide registration;

(B) 270 days for a new antimicrobial use of a reg- istered active ingredient;

(C) 120 days for any other new antimicrobial product; (D) 90 days for a substantially similar or identical

antimicrobial product;

(E) 90 days for an amendment to an antimicrobial reg-

istration that does not require scientific review of data; and

(F) 120 days for an amendment to an antimicrobial

registration that requires scientific review of data and that

is not otherwise described in this paragraph.

(3) IMPLEMENTATION.—

(A) PROPOSED RULEMAKING.—

(i) ISSUANCE.—Not later than 270 days after the

date of enactment of this subsection [Aug. 3, 1996], the

Administrator shall publish in the Federal Register

proposed regulations to accelerate and improve the re-

view of antimicrobial pesticide products designed to

implement, to the extent practicable, the goals set

forth in paragraph (2).

(ii) REQUIREMENTS.—Proposed regulations issued

under clause (i) shall—

(I) define the various classes of antimicrobial

use patterns, including household, industrial, and

institutional disinfectants and sanitizing pes-

ticides, preservatives, water treatment, and pulp

and paper mill additives, and other such products

intended to disinfect, sanitize, reduce, or mitigate

growth or development of microbiological orga-

nisms, or protect inanimate objects, industrial

processes or systems, surfaces, water, or other

chemical substances from contamination, fouling,

or deterioration caused by bacteria, viruses, fungi,

protozoa, algae, or slime;

(II) differentiate the types of review under-

taken for antimicrobial pesticides;

(III) conform the degree and type of review to

the risks and benefits presented by antimicrobial

pesticides and the function of review under this

Act, considering the use patterns of the product,

toxicity, expected exposure, and product type;

(IV) ensure that the registration process is sufficient to maintain antimicrobial pesticide effi- cacy and that antimicrobial pesticide products con- tinue to meet product performance standards and effectiveness levels for each type of label claim made; and

(V) implement effective and reliable deadlines for process management.

(iii) COMMENTS.—In developing the proposed regu- lations, the Administrator shall solicit the views from registrants and other affected parties to maximize the effectiveness of the rule development process.

(B) FINAL REGULATIONS.—

(i) ISSUANCE.—The Administrator shall issue final

regulations not later than 240 days after the close of

the comment period for the proposed regulations.

(ii) FAILURE TO MEET GOAL.—If a goal described in

paragraph (2) is not met by the final regulations, the

Administrator shall identify the goal, explain why the

goal was not attained, describe the element of the reg-

ulations included instead, and identify future steps to

attain the goal.

(iii) REQUIREMENTS.—In issuing final regulations,

the Administrator shall—

(I) consider the establishment of a certification

process for regulatory actions involving risks that

can be responsibly managed, consistent with the

degree of risk, in the most cost-efficient manner;

(II) consider the establishment of a certifi-

cation process by approved laboratories as an ad-

junct to the review process;

(III) use all appropriate and cost-effective re-

view mechanisms, including—

(aa) expanded use of notification and non-

notification procedures;

(bb) revised procedures for application re-

view; and

(cc) allocation of appropriate resources to

ensure streamlined management of anti-

microbial pesticide registrations; and

(IV) clarify criteria for determination of the

completeness of an application.

(C) EXPEDITED REVIEW.—This subsection does not af-

fect the requirements or extend the deadlines or review pe-

riods contained in subsection (c)(3).

(D) ALTERNATIVE REVIEW PERIODS.—If the final regula-

tions to carry out this paragraph are not effective 630 days

after the date of enactment of this subsection [Aug. 3,

1996], until the final regulations become effective, the re-

view period, beginning on the date of receipt by the Agency

of a complete application, shall be—

(i) 2 years for a new antimicrobial active ingre-

dient pesticide registration;

(ii) 1 year for a new antimicrobial use of a reg-

istered active ingredient;

uct;

(iii) 180 days for any other new antimicrobial prod-

(iv) 90 days for a substantially similar or identical

antimicrobial product;

(v) 90 days for an amendment to an antimicrobial

registration that does not require scientific review of

data; and

(vi) 120 days for an amendment to an anti-

microbial registration that requires scientific review of

data and that is not otherwise described in this sub-

paragraph.

(E) WOOD PRESERVATIVES.—An application for the reg-

istration, or for an amendment to the registration, of a

wood preservative product for which a claim of pesticidal

activity listed in section 2(mm) is made (regardless of any

other pesticidal claim that is made with respect to the

product) shall be reviewed by the Administrator within the

same period as that established under this paragraph for

an antimicrobial pesticide product application, consistent

with the degree of risk posed by the use of the wood pre-

servative product, if the application requires the applicant

to satisfy the same data requirements as are required to

support an application for a wood preservative product that

is an antimicrobial pesticide.

(F) NOTIFICATION.—

(i) IN GENERAL.—Subject to clause (iii), the Admin-

istrator shall notify an applicant whether an applica-

tion has been granted or denied not later than the

final day of the appropriate review period under this

paragraph, unless the applicant and the Administrator

agree to a later date.

(ii) FINAL DECISION.—If the Administrator fails to

notify an applicant within the period of time required

under clause (i), the failure shall be considered an

agency action unlawfully withheld or unreasonably de-

layed for purposes of judicial review under chapter 7 of

title 5, United States Code.

(iii) EXEMPTION.—This subparagraph does not

apply to an application for an antimicrobial pesticide

that is filed under subsection (c)(3)(B) prior to 90 days

after the date of enactment of this subsection [Aug. 3,

1996].

(iv) LIMITATION.—Notwithstanding clause (ii), the

failure of the Administrator to notify an applicant for

an amendment to a registration for an antimicrobial

pesticide shall not be judicially reviewable in a Federal

or State court if the amendment requires scientific re-

view of data within—

(I) the time period specified in subparagraph

(D)(vi), in the absence of a final regulation under

subparagraph (B); or

(II) the time period specified in paragraph

(2)(F), if adopted in a final regulation under sub-

paragraph (B).

(4) ANNUAL REPORT.—

(A) SUBMISSION.—Beginning on the date of enactment of this subsection [Aug. 3, 1996] and ending on the date that the goals under paragraph (2) are achieved, the Ad- ministrator shall, not later than March 1 of each year, pre- pare and submit an annual report to the Committee on Ag- riculture of the House of Representatives and the Com- mittee on Agriculture, Nutrition, and Forestry of the Sen- ate.

(B) REQUIREMENTS.—A report submitted under sub- paragraph (A) shall include a description of—

(i) measures taken to reduce the backlog of pend- ing registration applications;

(ii) progress toward achieving reforms under this subsection; and

(iii) recommendations to improve the activities of the Agency pertaining to antimicrobial registrations.

**SEC. 4.** ø**7 U.S.C. 136a–1**¿ **REREGISTRATION OF REGISTERED PES- TICIDES.**

(a) GENERAL RULE.—The Administrator shall reregister, in ac- cordance 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 Admin- istrator has determined, after November 1, 1984, and before the ef- fective 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 sub- section (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 re- specting 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 in- adequate data within the applicable time period.

(3) The third phase shall include submission to the Admin- istrator by registrants of the information required under sub- section (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 Adminis- trator 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 re- registration 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) REREGISTRATION 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 ingre- dients 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 deter- mined under paragraph (1); and

(D) not later than 10 months after such effective date, list the remainder of the pesticide active ingredients, as de- termined 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 Adminis- trator shall send by certified mail to the registrants of the pes- ticides 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 con- tains 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 REREG-

ISTRATION.—

(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 in- tend to seek reregistration of the pesticide.

(B) If a registrant submits a notice under subpara- graph (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 sub- mitted.

(3) MISSING OR INADEQUATE DATA.—Each registrant of a pesticide that contains an active ingredient listed under sub-

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

(A) in accordance with regulations issued by the Ad- ministrator under section 3, an identification of—

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

(ii) data that were submitted by the registrant pre- viously 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 identi-

fied 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 re-

gard to such cost sharing.

For purposes of a submission by a registrant under subpara-

graph (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 reg-

istrant possesses or has access to the raw data used in or gen-

erated by such study. For purposes of a submission by a reg-

istrant 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 satis-

faction of the Administrator that such data should be consid-

ered to support the registration of the pesticide that is to be re-

registered.

(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 list- ing 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 list- ing of such active ingredient.

On application, the Administrator may extend a time pe- riod prescribed by this subparagraph if the Administrator 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 Adminis- trator, but not more than 48 months after the date the reg- istrant submitted the commitment. The Administrator, on application of a registrant, may extend the period pre- scribed 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. Upon application of a reg- istrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submis- sion of data under this section for the other uses of the pes- ticide established as of the date of enactment of the Food Quality Protection Act of 1996 [Aug. 3, 1996] if—

(i) the data to support other uses of the pesticide on a food are being provided;

(ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data pro- duction will be completed before the expiration of the extension period;

(iii) the Administrator has determined that such extension will not significantly delay the Administra- tor’s schedule for issuing a reregistration eligibility de- termination required under this section; and

(iv) the Administrator has determined that based on existing data, such extension would not signifi- cantly increase the risk of any unreasonable adverse effect on the environment. 4–1 If the Administrator grants an extension under this subparagraph, the Ad- ministrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Adminis- trator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 3(c)(2)(B) or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwith- standing the provisions of this subparagraph, the Ad- ministrator may take action to modify or revoke the extension under this subparagraph if the Adminis- trator determines that the extension for the minor use may cause an unreasonable adverse effect on the envi- ronment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then

4–1 Indentation of the following sentences of this subparagraph is so in original (as added by sec. 201(c)(2) of P.L. 104–170). Probably should be indented the same as flush matter of this subparagraph.

established by the Administrator for submission of the data.

(5) CANCELLATION AND REMOVAL.—

(A) If the registrant of a pesticide does not submit a

notice under paragraph (2) or (3) within the time pre-

scribed by paragraph (4)(A), the Administrator shall issue a notice of intent to cancel the registration of such reg- istrant 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 per- son.

(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 con- taining 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 in- tent to cancel the registrations of all pesticides containing such active ingredient and shall provide 60 days for com- ment on such notice.

(ii) After the 60-day period has expired, the Adminis- trator, 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 fur- nishes 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 pes- ticide 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 Adminis- trator within such time period. If the registrant does not com- mit to support a specific minor use of the pesticide, but is sup- porting and providing data in a timely and adequate fashion to

support uses of the pesticide on a food, or if all uses of the pes- ticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and providing data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pur- suant to this paragraph in regard to such unsupported minor use until the final deadline established as of the date of enact- ment of the Food Quality Protection Act of 1996 [Aug. 3, 1996], for the submission of data under this section for the supported uses identified pursuant to this paragraph unless the Adminis- trator determines that the absence of the data is significant enough to cause human health or environmental concerns. On such a determination the Administrator may refuse the request for extension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Fed- eral Register a notice of the receipt of the request and the effec- tive date upon which the uses not being supported will be vol- untarily deleted from the registration pursuant to section

6(f)(1). If the Administrator grants an extension under this paragraph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section

3(c)(2)(B)(iv) regarding the continued registration of the af- fected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2). Not- withstanding this subparagraph, the Administrator may deny, modify, or revoke the temporary extension under this para- graph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Ad- ministrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registra- tion.

(e) PHASE THREE.—

(1) INFORMATION ABOUT STUDIES.—Each registrant of a pes- ticide that contains an active ingredient listed under subpara- graph (B), (C), or (D) of subsection (c)(2) who has submitted a notice under subsection (d)(2) of an intent to seek the rereg- istration 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 in-

gredient previously submitted by the registrant in support of the registration of a pesticide containing such active in- gredient 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 in- gredient previously submitted by the registrant in support of the registration of a pesticide containing such active in- gredient that may not comply with the requirements of sec- tion 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, mutage- nicity, neurotoxicity, teratogenicity, or residue chemistry of the active ingredient that were submitted to the Adminis- trator 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 be- fore 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) indi- cating 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 Adminis- trator possesses or has access to the raw data used in or generated by the studies that the registrant summarized

under subparagraph (A) or (B); (H) either—

(i) a commitment to submit data to fill each out- standing 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 com- mitment 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 pre-

viously submitted data as if the registrant were now seek-

ing 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 list-

ing 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 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 12 months after the date of publication of the list-

ing 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 Adminis- trator, but not more than 48 months after the date the reg- istrant submitted the commitment under such paragraph. The Administrator, on application of a registrant, may ex- tend 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. Upon appli- cation of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this subparagraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of the date of en- actment of the Food Quality Protection Act of 1996 [Aug.

3, 1996] if—

(i) the data to support other uses of the pesticide on a food are being provided;

(ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data pro- duction will be completed before the expiration of the extension period;

(iii) the Administrator has determined that such extension will not significantly delay the Administra- tor’s schedule for issuing a reregistration eligibility de- termination required under this section; and

(iv) the Administrator has determined that based on existing data, such extension would not signifi- cantly increase the risk of any unreasonable adverse effect on the environment. 4–2 If the Administrator grants an extension under this subparagraph, the Ad- ministrator shall monitor the development of the data and shall ensure that the registrant is meeting the schedule for the production of the data. If the Adminis- trator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 3(c)(2)(B) or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwith- standing the provisions of this subparagraph, the Ad- ministrator may take action to modify or revoke the extension under this subparagraph if the Adminis- trator determines that the extension for the minor use may cause an unreasonable adverse effect on the envi- ronment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then

4–2 Indentation of the following sentences of this subparagraph is so in original (as added by sec. 201(c)(2) of P.L. 104–170). Probably should be indented the same as flush matter of this subparagraph.

established by the Administrator for submission of the data.

(3) CANCELLATION.—

(A) If the registrant of a pesticide fails to submit the

information required by paragraph (1) within the time pre-

scribed by paragraph (2), the Administrator, by order and without hearing, shall cancel the registration of such pes- ticide. If the registrant does not commit to support a spe- cific minor use of the pesticide, but is supporting and pro- viding data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is sup- porting and providing data in a timely and adequate fash- ion to support other nonfood uses of the pesticide, the Ad- ministrator, at the written request of the registrant, shall not take any action pursuant to this subparagraph in re- gard to such unsupported minor use until the final dead- line established as of the date of enactment of the Food Quality Protection Act of 1996 [Aug. 3, 1996], for the sub- mission of data under this section for the supported uses identified pursuant to this subparagraph unless the Ad- ministrator determines that the absence of the data is sig- nificant enough to cause human health or environmental concerns. On the basis of such determination, the Adminis- trator may refuse the request for extension by the reg- istrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Register a no- tice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily de- leted from the registration pursuant to section 6(f)(1). If the Administrator grants an extension under this subpara- graph, the Administrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Administrator determines that the reg- istrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with section 3(c)(2)(B)(iv) regarding the contin- ued registration of the affected products with the minor and other uses and shall inform the public of such action in accordance with section 6(f)(2). Notwithstanding this subparagraph, the Administrator may deny, modify, or re- voke the temporary extension under this subparagraph if the Administrator determines that the continuation of the minor use may cause an unreasonable adverse effect on the environment. In the event of modification or revocation, the Administrator shall provide, in writing, to the registrant a notice revoking the temporary extension and establish a new effective date by which the minor use shall be deleted from the registration.

(B)(i) If the registrant of a pesticide submits the infor- mation required by paragraph (1) within the time pre- scribed 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 con- form its submission 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 reg- istrant a reasonable period of time to make any necessary

changes or corrections.

(iii)(I) If the Administrator determines that the reg- istrant 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 hear- ing or further notice at the end of 30 days after receipt by the registrant of the notice unless during that time a re- quest for a hearing is made by the registrant.

(III) If a hearing is requested, a hearing shall be con- ducted 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 deter- mination 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 sec- tion 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 re- quired under paragraph (1).

(f) PHASE FOUR.—

(1) INDEPENDENT REVIEW AND IDENTIFICATION OF OUT-

STANDING 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 re- view of the Administrator under this subparagraph, the Administrator may require a registrant seeking reregistra- tion to submit complete copies of studies summarized under subsection (e)(1).

(B) The Administrator shall independently identify and publish in the Federal Register the outstanding data re- quirements for each active ingredient that is listed under subparagraph (B), (C), or (D) of subsection (c)(2) and that is contained in a pesticide to be reregistered under this sec-

tion. The Administrator, at the same time, shall issue a no- tice under section 3(c)(2)(B) for the submission of the addi- tional 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 ac- tive 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 ac- tive 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 ac- tive 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 rea- sonable period of time, as determined by the Adminis- trator, but not to exceed 48 months after the issuance of such notice. The Administrator, on application of a reg- istrant, may extend the period prescribed by the preceding sentence by no more than 2 years if extraordinary cir- cumstances beyond the control of the registrant prevent the registrant from submitting data within such prescribed period. Upon application of a registrant, the Administrator shall, in the case of a minor use, extend the deadline for the production of residue chemistry data under this sub- paragraph for data required solely to support that minor use until the final deadline for submission of data under this section for the other uses of the pesticide established as of the date of enactment of the Food Quality Protection Act of 1996 [Aug. 3, 1996] if—

(i) the data to support other uses of the pesticide on a food are being provided;

(ii) the registrant, in submitting a request for such an extension provides a schedule, including interim dates to measure progress, to assure that the data pro- duction will be completed before the expiration of the extension period;

(iii) the Administrator has determined that such extension will not significantly delay the Administra- tor’s schedule for issuing a reregistration eligibility de- termination required under this section; and

(iv) the Administrator has determined that based on existing data, such extension would not signifi- cantly increase the risk of any unreasonable adverse effect on the environment. 4–3 If the Administrator grants an extension under this subparagraph, the Ad- ministrator shall monitor the development of the data

4–3 Indentation of the following sentences of this subparagraph is so in original (as added by sec. 201(c)(2) of P.L. 104–170). Probably should be indented the same as flush matter of this subparagraph.

schedule for the production of the data. If the Adminis- trator determines that the registrant is not meeting or has not met the schedule for the production of such data, the Administrator may proceed in accordance with clause (iv) of section 3(c)(2)(B) or other provisions of this section, as appropriate, regarding the continued registration of the affected products with the minor use and shall inform the public of such action. Notwith- standing the provisions of this subparagraph, the Ad- ministrator may take action to modify or revoke the extension under this subparagraph if the Adminis- trator determines that the extension for the minor use may cause an unreasonable adverse effect on the envi- ronment. In such circumstance, the Administrator shall provide written notice to the registrant revoking the extension of time for submission of data. Such data shall instead be due in accordance with the date then established by the Administrator for submission of the data.

(3) SUSPENSIONS AND PENALTIES.—The Administrator shall issue a notice of intent to suspend the registration of a pes- ticide in accordance with the procedures prescribed by section

3(c)(2)(B)(iv) if the Administrator determines that (A) tests nec- essary to fill an outstanding data requirement for such pes- ticide have not been initiated within 1 year after the issuance of a notice under paragraph (1)(B), or (B) progress is insuffi- cient to ensure submission of the data referred to in clause (A) within the time period prescribed by paragraph (2)(B) or the re- quired data have not been submitted to the Administrator within such time period. If the registrant does not commit to support a specific minor use of the pesticide, but is supporting and providing data in a timely and adequate fashion to support uses of the pesticide on a food, or if all uses of the pesticide are nonfood uses and the registrant does not commit to support a specific minor use of the pesticide but is supporting and pro- viding data in a timely and adequate fashion to support other nonfood uses of the pesticide, the Administrator, at the written request of the registrant, shall not take any action pursuant to this paragraph in regard to such unsupported minor use until the final deadline established as of the date of enactment of the Food Quality Protection Act of 1996 [Aug. 3, 1996], for the sub- mission of data under this section for the supported uses identi- fied pursuant to this paragraph unless the Administrator deter- mines that the absence of the data is significant enough to cause human health or environmental concerns. On such a de- termination the Administrator may refuse the request for ex- tension by the registrant. Upon receipt of the request from the registrant, the Administrator shall publish in the Federal Reg- ister a notice of the receipt of the request and the effective date upon which the uses not being supported will be voluntarily de- leted from the registration pursuant to section 6(f)(1). If the Ad- ministrator grants an extension under this paragraph, the Ad- ministrator shall monitor the development of the data for the uses being supported and shall ensure that the registrant is meeting the schedule for the production of such data. If the Ad-

has not met the schedule for the production of such data, the

Administrator may proceed in accordance with section

3(c)(2)(B)(iv) regarding the continued registration of the af-

fected products with the minor and other uses and shall inform

the public of such action in accordance with section 6(f)(2). Not-

withstanding this subparagraph, the Administrator may deny,

modify, or revoke the temporary extension under this para-

graph if the Administrator determines that the continuation of

the minor use may cause an unreasonable adverse effect on the

environment. In the event of modification or revocation, the Ad-

ministrator shall provide, in writing, to the registrant a notice

revoking the temporary extension and establish a new effective

date by which the minor use shall be deleted from the registra-

tion.

(g) PHASE FIVE.—

(1) DATA REVIEW.—The Administrator shall conduct a thor-

ough examination of all data submitted under this section con-

cerning an active ingredient listed under subsection (c)(2) and

of all other available data found by the Administrator to be rel-

evant.

(2) REREGISTRATION AND OTHER ACTIONS.—

(A) IN GENERAL.—The Administrator shall make a de-

termination as to eligibility for reregistration—

(i) for all active ingredients subject to reregistra-

tion under this section for which tolerances or exemp-

tions from tolerances are required under the Federal

Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.),

not later than the last date for tolerance reassessment

established under section 408(q)(1)(C) of that Act (21

U.S.C. 346a(q)(1)(C)); and

(ii) for all other active ingredients subject to rereg-

istration under this section, not later than October 3,

2008.

(B) PRODUCT-SPECIFIC DATA.—

(i) IN GENERAL.—Before reregistering a pesticide,

the Administrator shall obtain any needed product-spe-

cific data regarding the pesticide by use of section

3(c)(2)(B) and shall review such data within 90 days

after its submission.

(ii) TIMING.—

(I) IN GENERAL.—Subject to subclause (II), 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.

(II) EXTRAORDINARY CIRCUMSTANCES.—In the

case of extraordinary circumstances, the Adminis-

trator may provide such a longer period, of not

more than 2 additional years, for submission of

data to the Administrator under this subpara-

graph.

(1) for each active ingredient of a pesticide and the review required by subparagraph (B) of this paragraph, the Ad- ministrator shall determine whether to reregister a pes- ticide by determining whether such pesticide meets the re- quirements of section 3(c)(5). If the Administrator deter- mines that a pesticide is eligible to be reregistered, the Ad- ministrator shall reregister such pesticide within 6 months after the submission of the data concerning such pesticide under subparagraph (B).

(D) DETERMINATION TO NOT REREGISTER.—

(i) IN GENERAL.—If after conducting a review

under paragraph (1) or subparagraph (B) of this para-

graph the Administrator determines that a pesticide

should not be reregistered, the Administrator shall

take appropriate regulatory action.

(ii) TIMING FOR REGULATORY ACTION.—Regulatory

action under clause (i) shall be completed as expedi-

tiously as possible.

(E) As soon as the Administrator has sufficient infor-

mation with respect to the dietary risk of a particular ac-

tive ingredient, but in any event no later than the time the

Administrator makes a determination under subparagraph

(C) or (D) with respect to pesticides containing a particular

active ingredient, the Administrator shall—

(i) reassess each associated tolerance and exemp-

tion from the requirement for a tolerance issued under

section 408 of the Federal Food, Drug, and Cosmetic

Act (21 U.S.C. 346a);

(ii) determine whether such tolerance or exemption

meets the requirements of that Act;

(iii) determine whether additional tolerances or ex-

emptions should be issued;

(iv) publish in the Federal Register a notice setting

forth the determinations made under this subpara-

graph; and

(v) commence promptly such proceedings under

this Act and section 408 of the Federal Food, Drug,

and Cosmetic Act as are warranted by such determina-

tions.

(h) COMPENSATION OF DATA SUBMITTER.—If data that are sub-

mitted 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 compensa-

tion 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

INGREDIENTS.—The registrants of pesticides that contain an ac-

tive 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 collec-

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

(i) on submission of information for such ingre- dient 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 Admin-

istrator. 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 reg-

istered 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 pes-

ticides that are registered solely for agricultural or non-

agricultural 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) The Administrator shall exempt any public health

pesticide from the payment of the fee prescribed under

paragraph (3) if, in consultation with the Secretary of

Health and Human Services, the Administrator deter-

mines, based on information supplied by the registrant,

that the economic return to the registrant from sales of the

pesticide does not support the registration or reregistration

of the pesticide.

(C) 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 con-

tained only in pesticides that are not registered for any food or feed use and that are—

(i) sanitizers intended to reduce the number of liv- ing bacteria or viable virus particles on inanimate sur- face 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 irrevers- ibly 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.

(D)(i) Notwithstanding any other provision of this sub-

section, in the case of a small business registrant of a pes-

ticide, the registrant shall pay a fee for the reregistration

of each active ingredient of the pesticide that does not ex-

ceed an amount determined in accordance with this sub-

paragraph.

(ii) If during the 3-year period prior to reregistration

the average annual gross revenue of the registrant from

pesticides 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 unin-

corporated business that—

(I) has 150 or fewer employees; and

(II) during the 3-year period prior to reregistra-

tion, had an average annual gross revenue from chemi-

cals that did not exceed $40,000,000.

(5) MAINTENANCE FEE.—

(A) IN GENERAL.—Subject to other provisions of this

paragraph, each registrant of a pesticide shall pay an an-

nual fee by January 15 of each year for each registration,

except that no fee shall be charged for more than 200 reg-

istrations held by any registrant.

(B) In the case of a pesticide that is registered for a

minor agricultural use, the Administrator may reduce or

waive the payment of the fee imposed under this para-

graph if the Administrator determines that the fee would

significantly reduce the availability of the pesticide for the

use.

(C) TOTAL AMOUNT OF FEES.—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 ag-

gregate amount of $22,000,000 for each of fiscal years 2008 through 2012 4–4

(D) 4–5 MAXIMUM AMOUNT OF FEES FOR REGISTRANTS.— The maximum annual fee payable under this paragraph by—

(i) 4–6 a registrant holding not more than 50 pes- ticide registrations shall be $71,000 for each of fiscal years 2008 through 2012; and

(ii) 4–7 a registrant holding over 50 registrations shall be $123,000 for each of fiscal years 2008 through

2012.

(E) 4–8MAXIMUM AMOUNT OF FEES FOR SMALL BUSI-

NESSES.—

(i) IN GENERAL.—For a small business, the max- imum annual fee payable under this paragraph by—

(I) a registrant holding not more than 50 pes- ticide registrations shall be $50,000 for each of fis- cal years 2008 through 2012; and

(II) a registrant holding over 50 pesticide reg- istrations shall be $86,000 for each of fiscal years

2008 through 2012.

(ii) DEFINITION OF SMALL BUSINESS.—

(I) IN GENERAL.—In clause (i), the term ‘‘small business’’ means a corporation, partnership, or un- incorporated business that—

(aa) has 500 or fewer employees; and

(bb) during the 3-year period prior to the most recent maintenance fee billing cycle, had an average annual global gross revenue from pesticides that did not exceed $60,000,000.

(II) AFFILIATES.—

(aa) IN GENERAL.—In the case of a busi- ness entity with 1 or more affiliates, the gross revenue limit under subclause (I)(bb) shall apply to the gross revenue for the entity and all of the affiliates of the entity, including par- ents and subsidiaries, if applicable.

(bb) AFFILIATED PERSONS.—For the pur- pose of item (aa), persons are affiliates of each other if, directly or indirectly, either person controls or has the power to control the other person, or a third person controls or has the power to control both persons.

(cc) INDICIA OF CONTROL.—For the pur- pose of item (aa), indicia of control include

4–4 Lack of period is so in original (as amended by sec. 4(a) of P.L. 110-94). Probably should add a period at the end.

4–5 Title II of the Emergency Wartime Supplemental Appropriations Act, 2003, P.L. 108–

11, 117 Stat. 603, provided that ‘‘Within 30 days of enactment of this Act, the Adminis- trator of the Environmental Protection Agency shall adjust each ‘maximum annual fee payable’ pursuant to 7 U.S.C. 136a–1(i)(5)(D) and (E) in a manner such that maintenance fee collections made to reach the level authorized in division K of Public Law 108–7 shall be established in the same proportion as those maintenance fee collections authorized in Public Law 107–73.’’.

4–6 Subclause margins are so in original (as added by sec. 501(c)(1)(B)(ii) of P.L. 108–

199). Probably should be further indented.

4–7 Subclause margins are so in original (as added by sec. 501(c)(1)(B)(iii) of P.L. 108–

199). Probably should be further indented.

4–8 See note 4–4.

interlocking management or ownership, iden- tity of interests among family members, shared facilities and equipment, and common use of employees.

(F) The Administrator shall exempt any public health pesticide from the payment of the fee prescribed under paragraph (3) if, in consultation with the Secretary of Health and Humans 4–9 Services, the Administrator deter- mines, based on information supplied by the registrant, that the economic return to the registrant from sales of the pesticide does not support the registration or reregistration of the pesticide.

(G) If any fee prescribed by this paragraph with re- spect to the registration of a pesticide is not paid by a reg- istrant by the time prescribed, the Administrator, by order and without hearing, may cancel the registration.

(H) The authority provided under this paragraph shall terminate on September 30, 2012.

(6) OTHER FEES.—Except as provided in section 33, during

the period beginning on the date of enactment of this section [October 25, 1988] and ending on September 30, 2014, the Ad- ministrator 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 in- gredient 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 ac- tive ingredient shall pay fees in accordance with para- graph (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 con- taining such active ingredient collectively pay more than 25 percent of the total active ingredient rereg- istration fee.

(B) The Administrator, by order, may require any reg- istrant to submit such reports as the Administrator deter- mines to be necessary to allow the Administrator to determine and apportion fees under this subsection, to de- termine the registrant’s eligibility for a reduction or waiver of a fee, or to determine the volume usage for public health pesticides.

4–9 So in original (as added by sec. 232(2) of P.L. 104–170). Probably should be ‘‘Human’’.

(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 sub- section, 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 reappor- tion 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)) regard- ing data concerning an active ingredient and fees for review of such data shall not apply to any person who is the registrant of a pes- ticide 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 reg- istration 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 fund which shall be known as the Reregistration

and Expedited Processing Fund. 4–10

(2) 4–11 SOURCE AND USE.—

(A) All moneys derived from fees collected by the Ad-

ministrator under subsection (i) shall be deposited in the

fund and shall be available to the Administrator, without

fiscal year limitation, specifically to offset the costs of re-

registration and expedited processing of the applications

specified in paragraph (3) and to offset the costs of reg-

istration review under section 3(g). Such moneys derived

from fees may not be expended in any fiscal year to the ex-

tent such moneys derived from fees would exceed money appropriated for use by the Administrator and expended in such year for such costs of reregistration and expedited processing of such applications. The Administrator shall, prior to expending any such moneys derived from fees—

(i) effective October 1, 1997, adopt specific and cost accounting rules and procedures as approved by the General Accounting Office [General Accountability Of- fice] and the Inspector General of the Environmental Protection Agency to ensure that moneys derived from fees are allocated solely to the costs of reregistration and expedited processing of the applications specified in paragraph (3) and to offset the costs of registration review under section 3(g) in the same portion as appro- priated funds;

4–10 Sec. 501(b) of P.L. 104–170 amended sec. 4(k)(1) (7 U.S.C. 136a–1(k)(1)) by inserting

‘‘which shall be known as the Reregistration and Expedited Processing Fund’’, without specifying the Act that was being amended. The amendment was executed to this Act to effectuate the probable intent of Congress.

4–11 Sec. 501(c) of P.L. 104–170 amended sec. 4(k)(2) (7 U.S.C. 136a–1(k)(2)) to read as provided above, without specifying the Act that was being amended. The amendment was executed to this Act to effectuate the probable intent of Congress.

(ii) prohibit the use of such moneys derived from fees to pay for any costs other than those necessary to achieve reregistration and expedited processing of the applications specified in paragraph (3) and to offset the costs of registration review under section 3(g); and

(iii) ensure that personnel and facility costs associ- ated with the functions to be carried out under this paragraph do not exceed agency averages for com- parable personnel and facility costs.

(B) The Administrator shall also—

(i) complete the review of unreviewed reregistra- tion studies required to support the reregistration eli- gibility decisions scheduled for completion in accord- ance with subsection (l)(2); and

(ii) contract for such outside assistance as may be necessary for review of required studies, using a gen- erally accepted competitive process for the selection of vendors of such assistance.

(3) REVIEW OF INERT INGREDIENTS; EXPEDITED PROCESSING OF SIMILAR APPLICATIONS.—

(A) The Administrator shall use for each of the fiscal years 2004 through 2006, approximately $3,300,000, and for each of fiscal years 2008 through 2012, between 1⁄8 and

1⁄7, of the maintenance fees collected in such fiscal year 4–12

to obtain sufficient personnel and resources—

(i) to review and evaluate new inert ingredients;

and

(ii) to ensure the expedited processing and review

of any application that—— 4–13

(I) proposes the initial or amended registration of an end-use pesticide that, if registered as pro- posed, would be identical or substantially similar in composition and labeling to a currently-reg- istered 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 environ- ment;

(II) proposes an amendment to the registra- tion of a registered pesticide that does not require scientific review of data; or

(III) proposes the initial or amended registra- tion of an end use pesticide that, if registered as proposed, would be used for a public health pes- ticide.

4–12 P.L. 107–73 (115 Stat. 686) amended sec. 4(k)(3)(A) by striking ‘‘2001’’ and inserting

‘‘2002’’; and by striking ‘‘1⁄7’’ and inserting ‘‘1⁄10’’. In an earlier enactment, sec. 501(d)(1) of P.L. 104–170 amended sec. 4(k)(3) (7 U.S.C. 136a–1(k)(3)) by striking ‘‘for each of the fiscal years 1992, 1993, and 1994, 1⁄7th of the maintenance fees collected, up to 2 million each year’’ and inserting ‘‘for each of the fiscal years 1997 through 2001, not more than

1⁄7 of the maintenance fees collected in such fiscal year’’, without specifying the Act that was being amended and without including a $ before ‘‘2 million’’. The earlier amendment was executed to this Act, and to strike ‘‘$2 million’’, to effectuate the probable intent of Congress.

4–13 So in original (as added by sec. 501(e)(2)(C) of division G of P.L. 108–199). Probably should be no indent before ‘‘that’’.

(B) Any amounts made available under subparagraph (A) shall be used to obtain sufficient personnel and re- sources to carry out the activities described in such sub- paragraph that are in addition to the personnel and re- sources available to carry out such activities on the date of enactment of this section [October 25, 1988].

(C) 4–14 So long as the Administrator has not met the time frames specified in clause (ii) of section 3(c)(3)(B) with respect to any application subject to section 3(c)(3)(B) that was received prior to the date of enactment of the Food Quality Protection Act of 1996 [Aug. 3, 1996], the Adminis- trator shall use the full amount of the fees specified in sub- paragraph (A) for the purposes specified therein. Once all applications subject to section 3(c)(3)(B) that were received prior to such date of enactment have been acted upon, no limitation shall be imposed by the preceding sentence of this subparagraph so long as the Administrator meets the time frames specified in clause (ii) of section 3(c)(3)(B) on

90 percent of affected applications in a fiscal year. Should the Administrator not meet such time frames in a fiscal year, the limitations imposed by the first sentence of this subparagraph shall apply until all overdue applications subject to section 3(c)(3)(B) have been acted upon.

(4) UNUSED FUNDS.—Money in the fund not currently need- ed to carry out this section shall be—

(A) maintained on hand or on deposit;

(B) invested in obligations of the United States or guaranteed thereby; or

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

(5) 4–15 ACCOUNTING AND PERFORMANCE.—The Adminis- trator shall take all steps necessary to ensure that expendi- tures from fees authorized by subsection (i)(5)(C)(ii) are used only to carry out the goals established under subsection (l). The Reregistration and Expedited Processing Fund shall be des- ignated as an Environmental Protection Agency component for purposes of section 3515(c) of title 31, United States Code. The annual audit required under section 3521 of such title of the fi- nancial statements of activities under this Act under section

3515(b) of such title shall include an audit of the fees collected under subsection (i)(5)(C) and disbursed, of the amount appro- priated to match such fees, and of the Administrator’s attain- ment of performance measures and goals established under subsection (l). Such an audit shall also include a review of the reasonableness of the overhead allocation and adequacy of dis- closures of direct and indirect costs associated with carrying out the reregistration and expedited processing of the applica- tions specified in paragraph (3), and the basis for and accuracy of all costs paid with moneys derived from such fees. The In- spector General shall conduct the annual audit and report the

4–14 Sec. 501(d)(2) of P.L. 104–170 added subpara. (C) to sec. 4(k)(3) (7 U.S.C. 136a–

1(k)(3)), without specifying the Act that was being amended. The amendment was exe- cuted to this Act to effectuate the probable intent of Congress.

4–15 Sec. 501(e) of P.L. 104–170 amended sec. 4(k)(5) (7 U.S.C. 136a–1(k)(5)) to read as provided above, without specifying the Act that was being amended. The amendment was executed to this Act to effectuate the probable intent of Congress.

findings and recommendations of such audit to the Adminis- trator and to the Committees on Agriculture of the House of Representatives and the Senate. The cost of such audit shall be paid for out of the fees collected under subsection (i)(5)(C).

(l) 4–16 PERFORMANCE MEASURES AND GOAL.—The Administrator shall establish and publish annually in the Federal Register per- formance measures and goals. Such measures and goals shall include—

(1) the number of products reregistered, canceled, or amended, the status of reregistration, the number and type of data requests under section 3(c)(2)(B) issued to support product reregistration by active ingredient, the progress in reducing the number of unreviewed, required reregistration studies, the ag- gregate status of tolerances reassessed, and the number of ap- plications for registration submitted under subsection (k)(3) that were approved or disapproved;

(2) the future schedule for reregistrations, including the projection for such schedules that will be issued under sub- section (g)(2)(A) and (B) in the current fiscal year and the suc- ceeding fiscal year; and

(3) the projected year of completion of the reregistrations under this section.

(m) 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).

(n) AUTHORIZATION OF FUNDS TO DEVELOP PUBLIC HEALTH

DATA.—

(1) DEFINITION.—For the purposes of this section, ‘‘Sec- retary’’ means the Secretary of Health and Human Services, acting through the Public Health Service.

(2) CONSULTATION.—In the case of a pesticide registered for use in public health programs for vector control or for other uses the Administrator determines to be human health protec- tion uses, the Administrator shall, upon timely request by the registrant or any other interested person, or on the Administra- tor’s own initiative may, consult with the Secretary prior to taking final action to suspend registration under section

3(c)(2)(B)(iv), or cancel a registration under section 4, 6(e), or

6(f). In consultation with the Secretary, the Administrator shall prescribe the form and content of requests under this section. (3) BENEFITS TO SUPPORT FAMILY.—The Administrator,

after consulting with the Secretary, shall make a determination

whether the potential benefits of continued use of the pesticide for public health or health protection purposes are of such sig- nificance as to warrant a commitment by the Secretary to con- duct or to arrange for the conduct of the studies required by the Administrator to support continued registration under section

3 or reregistration under section 4.

(4) ADDITIONAL TIME.—If the Administrator determines that such a commitment is warranted and in the public inter- est, the Administrator shall notify the Secretary and shall, to the extent necessary, amend a notice issued under section

4–16 Sec. 501(f) of P.L. 104–170 amended sec. 4 (7 U.S.C. 136a–1) by redesignating sub- secs. (l) and (m) as subsecs. (m) and (n), respectively, and inserting a new subsec. (l), with- out specifying the Act that was being amended. The amendments were executed to this Act to effectuate the probable intent of Congress.

3(c)(2)(B) to specify additional reasonable time periods for sub- mission of the data.

(5) ARRANGEMENTS.—The Secretary shall make such ar- rangements for the conduct of required studies as the Secretary finds necessary and appropriate to permit submission of data in accordance with the time periods prescribed by the Adminis- trator. Such arrangements may include Public Health Service intramural research activities, grants, contracts, or cooperative agreements with academic, public health, or other organiza- tions qualified by experience and training to conduct such stud- ies.

(6) SUPPORT.—The Secretary may provide for support of the required studies using funds authorized to be appropriated under this section, the Public Health Service Act, or other ap- propriate authorities. After a determination is made under sub- section (d), the Secretary shall notify the Committees on Appro- priations of the House of Representatives and the Senate of the sums required to conduct the necessary studies.

(7) AUTHORIZATION OF APPROPRIATIONS.—There is author- ized to be appropriated to carry out the purposes of this section

$12,000,000 for fiscal year 1997, and such sums as may be nec- essary for succeeding fiscal years.

**SEC. 5.** ø**7 U.S.C. 136c**¿ **EXPERIMENTAL USE PERMITS.**

(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 de- termination 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 appli- cant of such notification. The Administrator may issue an experi- mental 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 ap- plication for an experimental use permit may be filed at any time. (b) TEMPORARY TOLERANCE LEVEL.—If the Administrator deter- mines that the use of a pesticide may reasonably be expected to re- sult in any residue on or in food or feed, the Administrator may es- tablish 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 experi- mental use permit shall be under the supervision of the Adminis- trator, and shall be subject to such terms and conditions and be for such period of time as the Administrator may prescribe in the per- mit.

(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 unrea- sonable adverse effects on the environment. All results of such stud- ies shall be reported to the Administrator before such pesticide may be registered under section 3.

mental use permit, at any time, if the Administrator finds that its terms or conditions are being violated, or that its terms and condi- tions are inadequate to avoid unreasonable adverse effects on the environment.

(f) STATE ISSUANCE OF PERMITS.—Notwithstanding the fore- going provisions of this section, the Administrator shall, under such terms and conditions as the Administrator may by regulations pre- scribe, 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 experi- mental use permits under this section.

(g) EXEMPTION FOR AGRICULTURAL RESEARCH AGENCIES.—Not- withstanding the foregoing provisions of this section, the Adminis- trator may issue an experimental use permit for a pesticide to any public or private agricultural research agency or educational insti- tution which applies for such permit. Each permit shall not exceed more than a one-year period or such other specific time as the Ad- ministrator may prescribe. Such permit shall be issued under such terms and conditions restricting the use of the pesticide as the Ad- ministrator may require. Such pesticide may be used only by such research agency or educational institution for purposes of experi- mentation.

**SEC. 6.** ø**7 U.S.C. 136d**¿ **ADMINISTRATIVE REVIEW; SUSPENSION.**

(a) EXISTING STOCKS AND INFORMATION.— 6–1

(1) EXISTING STOCKS.—The Administrator may permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled under this section, or sec- tion 3 or 4, to such extent, under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of this Act.

(2) INFORMATION.—If at any time after the registration of a pesticide the registrant has additional factual information re- garding unreasonable adverse effects on the environment of the pesticide, the registrant shall submit such information to the Administrator.

(b) CANCELLATION AND CHANGE IN CLASSIFICATION.—If it ap- pears to the Administrator that a pesticide or its labeling or other material required to be submitted does not comply with the provi- sions of this Act or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable ad- verse effects on the environment, the Administrator may issue a no- tice of the Administrator’s intent either—

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

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

Such notice shall be sent to the registrant and made public. In de- termining 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 agri- cultural commodities, retail food prices, and otherwise on the agri-

6–1 Sec. 106(a)(1) of P.L. 104–170 amended subsec. (a) by striking the heading and in- serting ‘‘(a) EXISTING STOCKS AND INFORMATION.—’’. The second subsec. designation for

‘‘(a)’’ was omitted to effectuate the probable intent of Congress.

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 agricul- tural economy. If the Secretary comments in writing to the Admin- istrator regarding the notice and analysis within 30 days after re- ceiving them, the Administrator shall publish in the Federal Reg- ister (with the notice) the comments of the Secretary and the re- sponse of the Administrator with regard to the Secretary’s com- ments. If the Secretary does not comment in writing to the Admin- istrator regarding the notice and analysis within 30 days after re- ceiving them, the Administrator may notify the registrant and make public the notice at any time after such 30-day period not- withstanding the foregoing 60-day time requirement. The time re- quirements 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 deter- mines 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 sub- section (b) and of submission to the Scientific Advisory Panel pursu- ant to section 25(d) and proceed in accordance with subsection (c). When a public health use is affected, the Secretary of Health and Human Services should provide available benefits and use informa- tion, or an analysis thereof, in accordance with the procedures fol- lowed and subject to the same conditions as the Secretary of Agri- culture in the case of agricultural pesticides. The proposed action shall become final and effective at the end of 30 days from receipt by the registrant, or publication, of a notice issued under paragraph (1), whichever occurs later, unless within that time either (i) the registrant makes the necessary corrections, if possible, or (ii) a re- quest 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 deci- sion pertaining to registration or classification issued after comple- tion of such hearing shall be final. In taking any final action under this subsection, the Administrator shall consider restricting a pes- ticide’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 ac- tion on production and prices of agricultural commodities, retail food prices, and otherwise on the agricultural economy, and the Ad- ministrator 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 re- quired for cancellation or change in classification proceedings, the Administrator may, by order, suspend the registration of the pesticide immediately. Except as provided in paragraph (3), no order of suspension may be issued under this subsection un- less the Administrator has issued, or at the same time issues, a notice of intention to cancel the registration or change the classification of the pesticide under subsection (b). Except as

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 ac- cordance 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 sub- mitted 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 evi- dence 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 de- termines that an emergency exists that does not permit the Ad- ministrator to hold a hearing before suspending, the Adminis- trator may issue a suspension order in advance of notification to the registrant. The Administrator may issue an emergency order under this paragraph before issuing a notice of intention to cancel the registration or change the classification of the pes- ticide under subsection (b) and the Administrator shall proceed to issue the notice under subsection (b) within 90 days of issuing an emergency order. If the Administrator does not issue a notice under subsection (b) within 90 days of issuing an emer- gency order, the emergency order shall expire. In the case of an emergency order, paragraph (2) shall apply except that (A) the order of suspension shall be in effect pending the expeditious completion of the remedies provided by that paragraph and the issuance of a final order on suspension, and (B) no party other than the registrant and the Administrator shall participate ex- cept 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 sus- pension 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 Ad- ministrator shall be subject to immediate review in an action by the registrant or other interested person with the concur- rence of the registrant in an appropriate district court, solely to determine whether the order of suspension was arbitrary, ca- pricious 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 ef- fectiveness of the suspension order, pending the Administra-

tor’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 rel- evant 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 tes- timony 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 wit- ness or the content of documents produced and shall order the pay- ment 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 be- fore the hearing record is closed refer to a Committee of the Na- tional 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 Com- mittee 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 Adminis- trator 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 re- quired by the Administrator for carrying out the purposes of this Act. As soon as practicable after completion of the hearing (includ- ing the report of the Academy) but not later than 90 days there- after, the Administrator shall evaluate the data and reports before the Administrator and issue an order either revoking the Adminis- trator’s notice of intention issued pursuant to this section, or shall issue an order either canceling the registration, changing the classi- fication, 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 can- cel 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 reg- istrant has failed to initiate and pursue appropriate action to-

ward 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 sub- section to such extent, under such conditions, and for such uses as the Administrator may specify if the Administrator deter- mines that such sale or use is not inconsistent with the pur- poses of this Act and will not have unreasonable adverse effects on the environment.

(2) A cancellation proposed under this subsection shall be- come 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 mat- ters for resolution at that hearing shall be whether the reg- istrant 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 determina- tion with respect to the disposition of existing stocks is con- sistent with this Act. A decision after completion of such hear- ing shall be final. Notwithstanding any other provision of this section, a hearing shall be held and a determination made within seventy-five days after receipt of a request for such hearing.

(f) GENERAL PROVISIONS.—

(1) VOLUNTARY CANCELLATION.—

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

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

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

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

(ii) may not approve or reject the request until the termination of the 180-day period beginning on the date of publication of the notice in the Federal Reg- ister, except that the Administrator may waive the

180-day period upon the request of the registrant or if the Administrator determines that the continued use of the pesticide would pose an unreasonable adverse ef- fect on the environment.

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

(2) PUBLICATION OF NOTICE.—A notice of denial of registra- tion, 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 Adminis- trator as undeliverable at that address, if delivery is refused, or if the Administrator otherwise is unable to accomplish deliv- ery 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 no- tice was published in the Federal Register.

(3) TRANSFER OF REGISTRATION OF PESTICIDES REGISTERED FOR MINOR AGRICULTURAL USES.—In the case of a pesticide that is registered for a minor agricultural use:

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

(B) An application for transfer of registration, in con- formance with any regulations the Administrator may adopt with respect to the transfer of the pesticide registra- tions, must be submitted to the Administrator within 30 days of the date of notification provided pursuant to sub- paragraph (A). If such an application is submitted, the Ad- ministrator shall approve the transfer and shall not ap- prove the request for voluntary cancellation or amendment to terminate use unless the Administrator determines that the continued use of the pesticide would cause an unrea- sonable adverse effect on the environment.

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

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

(4) UTILIZATION OF DATA FOR VOLUNTARILY CANCELED PES- TICIDE.—When an application is filed with the Administrator for the registration of a pesticide for a minor use and another registrant subsequently voluntarily cancels its registration for an identical or substantially similar pesticide for an identical or substantially similar use, the Administrator shall process, re- view, and evaluate the pending application as if the voluntary cancellation had not yet taken place except that the Adminis- trator shall not take such action if the Administrator deter- mines that such minor use may cause an unreasonable adverse effect on the environment. In order to rely on this subsection,

the applicant must certify that it agrees to satisfy any out- standing data requirements necessary to support the rereg- istration of the pesticide in accordance with the data submis- sion schedule established by the Administrator.

(g) NOTICE FOR STORED PESTICIDES WITH CANCELED OR SUS-

PENDED REGISTRATIONS.—

(1) IN GENERAL.—Any producer or exporter of pesticides,

registrant of a pesticide, applicant for registration of a pes-

ticide, 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 no-

tify the Administrator and appropriate State and local officials

of—

(A) such possession,

(B) the quantity of such pesticide such person pos-

sesses, 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 of-

fice of the Environmental Protection Agency which has jurisdic-

tion 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

16.

**SEC. 7.** ø**7 U.S.C. 136e**¿ **REGISTRATION OF ESTABLISHMENTS.**

(a) REQUIREMENT.—No person shall produce any pesticide sub- ject 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), the Administrator shall register the establishment and assign it an establishment number.

(c) INFORMATION REQUIRED.—

(1) Any producer operating an establishment registered

under this section shall inform the Administrator within 30

days after it is registered of the types and amounts of pes-

ticides and, if applicable, active ingredients used in producing

pesticides—

(A) which the producer is currently producing;

(B) which the producer has produced during the past

year; and

(C) which the producer has sold or distributed during

the past year.

The information required by this paragraph shall be kept cur-

rent 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 Ad-

ministrator for the purpose of issuing a stop sale order pursu-

ant to section 13, inform the Administrator of the name and ad-

dress of any recipient of any pesticide produced in any reg-

istered establishment which the producer operates.

tion 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 estab- lishment shall be considered confidential and shall be subject to the provisions of section 10.

**SEC. 8.** ø**7 U.S.C. 136f**¿ **BOOKS AND RECORDS.**

(a) REQUIREMENTS.—The Administrator may prescribe regula- tions requiring producers, registrants, and applicants for registra- tion to maintain such records with respect to their operations and the pesticides and devices produced as the Administrator deter- mines 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 per- son who sells or offers for sale, delivers or offers for delivery any pesticide or device subject to this Act, shall, upon request of any of- ficer or employee of the Environmental Protection Agency or of any State or political subdivision, duly designated by the Administrator, 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 con- signee; or (2) in the event of the inability of any person to produce records containing such information, all other records and informa- tion relating to such delivery, movement, or holding of the pesticide or device. Any inspection with respect to any records and informa- tion 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.** ø**7 U.S.C. 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 pes- ticides 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 reg-

of determining compliance with section 19.

(2) Before undertaking such inspection, the officers or employ-

ees 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 state-

ment as to the reason for the inspection, including a statement as

to whether a violation of the law is suspected. If no violation is sus-

pected, an alternate and sufficient reason shall be given in writing.

Each such inspection shall be commenced and completed with rea-

sonable promptness. If the officer or employee obtains any samples,

prior to leaving the premises, the officer or employee 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 jurisdic-

tion that there is reason to believe that the provisions of this Act

have been violated, officers or employees duly designated by the Ad-

ministrator 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 con-

signee 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 con-

taining such information, all other records and information re-

lating to such delivery, movement, or holding of the pesticide

or device; and

(3) the seizure of any pesticide or device which is in viola-

tion of this Act.

(c) ENFORCEMENT.—

(1) CERTIFICATION OF FACTS TO ATTORNEY GENERAL.—The

examination of pesticides or devices shall be made in the Envi-

ronmental Protection Agency or elsewhere as the Administrator

may designate for the purpose of determining from such exami-

nations 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 the person’s

views, either orally or in writing, with regard to such con-

templated proceedings, and if in the opinion of the Adminis-

trator it appears that the provisions of this Act have been vio-

lated 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 pro-

ceeding under section 14(a), when the Administrator deter-

poses 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 pro-

ceeding by the Attorney General.

(3) WARNING NOTICES.—Nothing in this Act shall be con-

strued as requiring the Administrator to institute proceedings

for prosecution of minor violations of this Act whenever the Ad-

ministrator believes that the public interest will be adequately

served by a suitable written notice of warning.

**SEC. 10.** ø**7 U.S.C. 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 the applicant’s opinion are trade secrets or commercial or financial in- formation 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 the Administrator’s 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 prod- ucts 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 in- spection information which the applicant or registrant believes to be protected from disclosure under subsection (b), the Adminis- trator shall notify the applicant or registrant, in writing, by cer- tified 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 sub- ject 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 environ-

ment, 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 proc-

esses,

tecting, 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 confiden- tial treatment under subsection (b) of this section may be pub- licly disclosed in connection with a public proceeding to deter- mine whether a pesticide, or any ingredient of a pesticide, causes unreasonable adverse effects on health or the environ- ment, 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. Dur-

ing such period the data submitter may institute an action in

an appropriate district court to enjoin or limit the proposed dis-

closure. 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 unreason- able 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 infor- mation.

(e) DISCLOSURE TO CONTRACTORS.—Information otherwise pro- tected from disclosure to the public under subsection (b) of this sec- tion may be disclosed to contractors with the United States and em- ployees 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 respect- ing the information as the Administrator shall by regulation pre- scribe.

(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 re- spect 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 sub- section (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

PRODUCERS.—(1) The Administrator shall not knowingly disclose in- formation 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 deliv- ering 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 per- son 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 determina- tion 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 appli- cant 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 sub- section.

**SEC. 11.** ø**7 U.S.C. 136i**¿ **USE OF RESTRICTED USE PESTICIDES; APPLI- CATORS.**

(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 certifi- cation of applicators of pesticides. Such program shall conform to the requirements imposed upon the States under the provi-

sions of subsection (a)(2) of this section and shall not require private applicators to take any examination to establish com- petency 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 avail- able 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 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 per- son 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 para- graph (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 pes- ticides, or to the use and handling of the pesticide or class of pesticides covered by such individual’s certification. The certifi- cation standard for a private applicator shall, under a State plan submitted for approval, be deemed fulfilled by the appli- cator 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 Adminis- trator so long as the program does not require the private ap- plicator 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 pes- ticide dealer participating in a certification program to be li- censed under a State licensing program approved by the Ad- ministrator.

(2) STATE CERTIFICATION.—If any State, at any time, de- sires to certify applicators of pesticides, the Governor of such State shall submit a State plan for such purpose. The Adminis- trator shall approve the plan submitted by any State, or any modification thereof, if such plan in the Administrator’s judgment—

(A) designates a State agency as the agency respon- sible 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 de- vote adequate funds to the administration of the plan;

(D) provides that the State agency will make such re- ports 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 stand- ards for the certification of applicators of pesticides con- form 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 sub- mitted under subsection (a)(2), the Administrator shall afford the State submitting the plan due notice and opportunity for hearing before so doing. If the Administrator approves a plan submitted under subsection (a)(2), 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 pro- gram in accordance with the plan approved under this section, the Administrator 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 TECH- NIQUES.—Standards prescribed by the Administrator for the certifi- cation of applicators of pesticides under subsection (a), and the State plans submitted to the Administrator under subsection (a), shall include provisions for making instructional materials con- cerning integrated pest management techniques available to indi- viduals at their request in accordance with the provisions of section

23(c) of this Act, but such plans may not require that any indi- vidual receive instruction concerning such techniques or be shown to be competent with respect to the use of such techniques. The Ad-

ministrator and States implementing such plans shall provide that

all interested individuals are notified of the availability of such in- structional materials.

(d) IN GENERAL.—No regulations prescribed by the Adminis- trator 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 es- tablish separate standards for commercial and private applicators.

**SEC. 12.** ø**7 U.S.C. 136j**¿ **UNLAWFUL ACTS.**

(a) IN GENERAL.—

(1) Except as provided by subsection (b), it shall be unlaw- ful 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, ex- cept 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 com-

position as described in the statement required in connec- tion with its registration under section 3;

(D) any pesticide which has not been colored or discol- ored 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 re-

quired by or under section 5, 7, 8, 11, or 19;

(ii) submit any reports required by or under sec-

tion 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 author-

ized under subsection (b) may give a guaranty to the same

effect, which guaranty shall contain, in addition to the per-

son’s own name and address, the name and address of the

person residing in the United States from whom the person

received the guaranty or undertaking;

(D) to use for the person’s 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, phar-

macists, and other qualified persons, needing such informa-

tion for the performance of their duties, in accordance with

such directions as the Administrator may prescribe, any in-

formation acquired by authority of this Act which is con-

fidential 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, except that 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 cer-

tified applicator;

(G) to use any registered pesticide in a manner incon-

sistent with its labeling;

(H) to use any pesticide which is under an experi-

mental use permit contrary to the provisions of such per-

mit;

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

(J) to violate any suspension order issued under sec-

tion 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(g);

(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 pursu-

ant to this Act, any report filed under this Act, or any in-

formation marked as confidential and submitted to the Ad-

ministrator 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 pur-

pose of this Act;

(P) to use any pesticide in tests on human beings un-

less 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;

(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

paragraph (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 the person 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 the person, and that it com-

plies with the other requirements of this Act, and in such case

the guarantor shall be subject to the penalties which would oth-

erwise attach to the person holding the guaranty under the

provisions of this Act;

(2) any carrier while lawfully shipping, transporting, or de-

livering 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

the official duties of the public official;

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

(5) any person who ships a substance or mixture of sub- stances 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.** ø**7 U.S.C. 136k**¿ **STOP SALE, USE, REMOVAL, AND SEIZURE.**

(a) STOP SALE, ETC., ORDERS.—Whenever any pesticide or de- vice 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 sus- pended, 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 de- scribed 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 direc- tions for its use differ in substance from the representa- tions 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 accord- ance with the requirements imposed under this Act and as di- rected by the labeling, it nevertheless causes unreasonable ad- verse effects on the environment.

In the case of a plant regulator, defoliant, or desiccant, used in ac- cordance 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 de- vice 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

and the execution and delivery of a good and sufficient bond condi- tioned that the pesticide or device shall not be sold or otherwise dis- posed of contrary to the provisions of the Act or the laws of any ju- risdiction 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 pro- ceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any case, and all such pro- ceedings shall be at the suit of and in the name of the United States.

(d) COURT COSTS, ETC.—When a decree of condemnation is en- tered 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.** ø**7 U.S.C. 136l**¿ **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 Administrator 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, except that any applicator not in- cluded under paragraph (1) of this subsection who holds or ap- plies registered pesticides, or uses dilutions of registered pes- ticides, only to provide a service of controlling pests without de- livering 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 incor-

porated city of the residence of the person charged.

(4) DETERMINATION OF PENALTY.—In determining the amount of the penalty, the Administrator shall consider the ap- propriateness 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 Ad- ministrator finds that the violation occurred despite the exer- cise 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 inabil- ity 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 pro- ducer 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 pes- ticide, 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 impris- oned 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 for- mulas 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.** ø**7 U.S.C. 136m**¿ **INDEMNITIES.**

(a) GENERAL INDEMNIFICATION.—

(1) IN GENERAL.—Except as otherwise provided in this sec-

tion, if—

(A) the Administrator notifies a registrant under sec-

tion 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 pes-

ticide 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 Ad-

ministrator finds that the person—

(A) had knowledge of facts that, in themselves, would

have shown that the pesticide did not meet the require-

ments of section 3(c)(5) for registration; and

(B) continued thereafter to produce the pesticide with-

out 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

payment.

(4) APPROPRIATION.—The Administrator may not make a payment of indemnification under paragraph (1) unless a spe- cific 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 sec- tion 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 sec- tion 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 pes- ticide as an end user, rather than for purposes of distrib- uting or selling it or further processing it for distribution or sale, suffered a loss by reason of the suspension or can- cellation 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 dis- tributor (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, re- imburse such person for the cost of first acquiring the pes- ticide 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 pes- ticide 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 sus- pend a registration or that an emergency order of sus- pension 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 sell- er, 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 pro-

vide reimbursement to such person, as provided

under subparagraph (A), for the loss referred to in

clause (iii), as a result of the insolvency or bank-

ruptcy of the seller and the seller’s resulting in-

ability 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 re-

gard 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 pro-

vided under section 1304 of title 31, United States Code.

(4) ADMINISTRATIVE SETTLEMENT.—An administrative set-

tlement of a claim for such indemnity may be made in accord-

ance 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 be-

fore 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 quan-

tity 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.** ø**7 U.S.C. 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 discre- tion 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 con- troversy as to the validity of any order issued by the Administrator following a public hearing, any person who will be adversely af- fected 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 the Administrator for that purpose, and thereupon the Administrator shall file in the court the record of the proceedings on which the Administrator based the Administrator’s 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 evi- dence 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 certiorari or 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 en- force, and to prevent and restrain violations of, this Act.

(d) NOTICE OF JUDGMENTS.—The Administrator shall, by publi- cation in such manner as the Administrator may prescribe, give no- tice of all judgments entered in actions instituted under the author- ity of this Act.

**SEC. 17.** ø**7 U.S.C. 136o**¿ **IMPORTS AND EXPORTS.**

(a) PESTICIDES AND DEVICES INTENDED FOR EXPORT.—Notwith- standing any other provision this Act, no pesticide or device or ac- tive ingredient used in producing a pesticide intended solely for ex- port 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 pro- ducing 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 reg- istered 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 pes-

ticide 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 offi- cial 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 ef- fective, the Administrator shall transmit through the State Depart- ment 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 sus- pension of the registration of the pesticide and information con- cerning 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 pes- ticides and devices and shall deliver to the Administrator, upon the Administrator’s 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 vio-

lates 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 pes-

ticide 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 re-

fused 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.—

(1) IN GENERAL.—The Administrator shall, in cooperation

with the Department of State and any other appropriate Fed-

eral agency, participate and cooperate in any international ef-

forts to develop improved pesticide research and regulations.

(2) DEPARTMENT OF STATE EXPENSES.—Any expenses in-

curred by an employee of the Environmental Protection Agency

who participates in any international technical, economic, or

policy review board, committee, or other official body that is

meeting in relation to an international treaty shall be paid by

the Department of State.

(e) REGULATIONS.—The Secretary of the Treasury, in consulta-

tion with the Administrator, shall prescribe regulations for the en-

forcement of subsection (c) of this section.

**SEC. 18.** ø**7 U.S.C. 136p**¿ **EXEMPTION OF FEDERAL AND STATE AGEN- CIES.**

The Administrator may, at the Administrator’s discretion, ex- empt any Federal or State agency from any provision of this Act if the Administrator 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 con- cerned if they request such determination.

**SEC. 19.** ø**7 U.S.C. 136q**¿ **STORAGE, DISPOSAL, TRANSPORTATION, AND RECALL.**

(a) STORAGE, DISPOSAL, AND TRANSPORTATION.—

(1) DATA REQUIREMENTS AND REGISTRATION OF PES-

TICIDES.—The Administrator may require under section 3 or 6

that—

(A) the registrant or applicant for registration of a pes- ticide 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 registra- tion of a pesticide;

(B) the labeling of a pesticide contain requirements and procedures for the transportation, storage, and dis- posal 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 pes- ticide; and

(C) the registrant of a pesticide provide evidence of suf- ficient 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 reg-

istration 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 reg- istration of which has been suspended; and

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

(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 quan- tities 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 pes- ticide; 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.

(4) CONTAINER RECYCLING.—The Secretary may promulgate a regulation for the return and recycling of disposable pesticide containers used for the distribution or sale of registered pes- ticide products in interstate commerce. Any such regulation re- quiring recycling of disposable pesticide containers shall not apply to antimicrobial pesticides (as defined in section 2) or other pesticide products intended for non-agricultural uses.

(b) RECALLS.—

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

(2) VOLUNTARY RECALL.—If, after determining under para- graph (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 re- call, the Administrator shall request the registrant of the pes- ticide 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 para- graph (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 fa- cilities to receive and store the pesticide to which the recall program applies, and inform the Administrator of the loca- tion of each such facility;

(B) accept and store at such a facility those existing stocks of such pesticide that are tendered by any other per- son 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 stor- age facility; and

(D) take such reasonable steps as the regulation may prescribe to inform persons who may be holders of the pes-

ticide of the terms of the recall regulation and how those persons may tender the pesticide and arrange for transpor- tation 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 re- call 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 sub- section (a) may require the recall of existing stocks of the pes- ticide except as provided by this subsection.

(c) STORAGE COSTS.—

(1) SUBMISSION OF PLAN.—A registrant who wishes to be- come 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 stor- age 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 reg- istrant, 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 Adminis- trator 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 ap- proval of the plan by the Administrator or the date of can- cellation 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 ap- proval of the plan by the Administrator or the date of can- cellation 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 Ad- ministrator 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 ac- cordance 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 sub- stance 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 sub- section (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, includ- ing 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 compli-

ance with the regulations referred to in paragraph (1) not later

than 5 years after the effective date of this subsection [Decem-

ber 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 proce-

dures and standards for the removal of pesticides from con-

tainers prior to disposal.

(B) The regulations may—

(i) specify, for each major type of pesticide con-

tainer, 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 rins- ing of containers imposed under the Solid Waste Dis- posal Act (42 U.S.C. 6901 et seq.).

(C) The Administrator may, at the discretion of the Ad- ministrator, exempt products intended solely for household use from the requirements of this subsection.

(2) COMPLIANCE.—Effective beginning 5 years after the ef- fective 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 Admin- istrator 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 formula-

tions 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 Fed-

eral agencies, State agencies, industry groups, and en-

vironmental 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.—

(1) IN GENERAL.—Nothing in this section shall diminish the

authorities or requirements of the Solid Waste Disposal Act (42

U.S.C. 6901 et seq.).

(2) ANTIMICROBIAL PRODUCTS.—A household, industrial, or

institutional antimicrobial product that is not subject to regula-

tion under the Solid Waste Disposal Act (42 U.S.C. 6901 et

seq.) shall not be subject to the provisions of subsections (a),

(e), and (f), unless the Administrator determines that such

product must be subject to such provisions to prevent an unrea-

sonable adverse effect on the environment.

**SEC. 20.** ø**7 U.S.C. 136r**¿ **RESEARCH AND MONITORING.**

(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 pur- poses of this Act, and the Administrator shall conduct research into integrated pest management in coordination with the Secretary of Agriculture. The Administrator shall also take care to ensure that such research does not duplicate research being undertaken by any other Federal agency.

(b) NATIONAL MONITORING PLAN.—The Administrator shall for- mulate 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 moni- toring plan. The Administrator shall establish procedures for the monitoring of man and animals and their environment for inci- dental pesticide exposure, including, but not limited to, the quan- tification 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.** ø**7 U.S.C. 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) SECRETARY OF HEALTH AND HUMAN SERVICES.—The Admin- istrator, before publishing regulations under this Act for any public health pesticide, shall solicit the views of the Secretary of Health and Human Services in the same manner as the views of the Sec- retary of Agriculture are solicited under section 25(a)(2).

(c) VIEWS.—In addition to any other authority relating to public hearings and solicitation of views, in connection with the suspen- sion or cancellation of a pesticide registration or any other actions authorized under this Act, the Administrator may, at the Adminis- trator’s 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 the Adminis-

trator deems proper.

(d) 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.** ø**7 U.S.C. 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 uni- formity of regulations.

**SEC. 23.** ø**7 U.S.C. 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 In- dian tribe to cooperate in the enforcement of this Act, and to assist States and Indian tribes in implementing cooperative en- forcement programs through grants-in-aid; and

(2) to assist States in developing and administering State programs, and Indian tribes that enter into cooperative agree- ments, 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 nec- essary for the Administrator to provide through cooperative agree- ments an amount equal to 50 percent of the anticipated cost to each State or Indian tribe, as agreed to under such cooperative agree- ments, 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 In- dian tribe shall be reduced in a like proportion in allocating avail- able funds.

(b) CONTRACTS FOR TRAINING.—In addition, the Administrator may enter into contracts with Federal, State, or Indian tribal agen- cies 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 pes- ticide users about accepted uses and other regulations made under this Act.

**SEC. 24.** ø**7 U.S.C. 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 prohib- ited by this Act.

(b) UNIFORMITY.—Such State shall not impose or continue in ef- fect 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 Admin- istrator. Such registration shall be deemed registration under section 3 for all purposes of this Act, but shall authorize dis- tribution 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 inten- tion to disapprove and the reasons therefor, and provide the State time to respond. The Administrator shall not prohibit or

section (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 Adminis- trator determines that a registration issued by a State is incon- sistent with the Federal Food, Drug, and Cosmetic Act, or the use of, a pesticide under a registration issued by a State con- stitutes an imminent hazard, the Administrator may imme- diately disapprove the registration.

(4) If the Administrator finds, in accordance with stand- ards 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 ac- cord with the purposes of this Act or has failed to exercise ade- quate controls, the Administrator may suspend the authority of the State to register pesticides until such time as the Adminis- trator 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.** ø**7 U.S.C. 136w**¿ **AUTHORITY OF ADMINISTRATOR.**

(a) IN GENERAL.—

(1) REGULATIONS.—The Administrator is authorized in ac- cordance with the procedure described in paragraph (2), to pre- scribe 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, including pub-

lic health pesticides, and differences in environmental risk and the appropriate data for evaluating such risk between agricul- tural, nonagricultural, and public health pesticides.

(2) PROCEDURE.—

(A) PROPOSED REGULATIONS.—At least 60 days prior to signing any proposed regulation for publication in the Fed- eral Register, the Administrator shall provide the Sec- retary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator re- garding 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 Sec- retary and the response of the Administrator with regard to the Secretary’s comments. If the Secretary does not com- ment in writing to the Administrator regarding the regula- tion within 30 days after receiving it, the Administrator may sign such regulation for publication in the Federal Register any time after such 30-day period notwithstanding 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 Sec- retary of Agriculture with a copy of such regulation. If the Secretary comments in writing to the Administrator re-

ceiving 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 Admin- istrator regarding the regulation within 15 days after re- ceiving 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 sub- section, the Administrator shall include among those fac- tors 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 im- posed 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 Ad-

ministrator 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 Ad-

ministrator 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, the Ad-

ministrator 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.—Simulta-

neously 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 Rep-

resentatives. The rule or regulation shall not become effective

until the passage of 60 calendar days after the rule or regula-

tion is so transmitted.

(b) EXEMPTION OF PESTICIDES.—The Administrator may exempt

from the requirements of this Act by regulation any pesticide which

the Administrator determines either (1) to be adequately regulated

by another Federal agency, or (2) to be of a character which is un-

necessary to be subject to this Act in order to carry out the pur-

poses 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-orga-

nisms on or in living man or other living animals) which is in-

jurious to health or the environment;

(2) to determine any pesticide which contains any sub-

stance 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 pack- age, container, or wrapping in which a pesticide or device is en- closed 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 the Administrator’s determination that application of such provision is necessary to effectuate the purposes of this Act;

(5) to prescribe regulations requiring any pesticide to be colored or discolored if the Administrator 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.—

(1) IN GENERAL.—The Administrator shall submit to an ad- visory 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 regula- tions 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 in- tent and proposed and final forms of regulation may not be modified or waived unless in addition to meeting the require- ments of section 6(b) or 25(a), as applicable, the advisory panel has failed to comment on the proposed action within the pre- scribed 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 pub- lished 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 rec- ommendations. 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 addi- tional 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

on the basis of their professional qualifications to assess the ef- fects of the impact of pesticides on health and the environment. To the extent feasible to insure multidisciplinary representa- tion, 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 re- placement 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 rea- son other than expiration of a term, the Administrator shall ap- point 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 unsatisfac- tory, the Administrator may request an additional set of nomi- nees from the nominating entities. The Administrator may re- quire such information from the nominees to the advisory panel as the Administrator deems necessary, and the Administrator 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 ex- cess 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 Govern- ment the compensation for which exceeds such rate may elect to receive compensation at the rate provided for such other of- fice 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 regard- ing 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 Environ- mental Research, Development, and Demonstration Authoriza- tion Act of 1978. Whenever the Administrator exercises author- ity 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. (2) SCIENCE REVIEW BOARD.—There is established a Science Review Board to consist of 60 scientists who shall be available to the Scientific Advisory Panel to assist in reviews conducted by the Panel. Members of the Board shall be selected in the same manner as members of temporary subpanels created under paragraph (1). Members of the Board shall be com-

pensated in the same manner as members of the Panel.

(e) PEER REVIEW.—The Administrator shall, by written proce- dures, 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 agen-

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 nomi- nees maintained by such panel, with respect to the results of any such scientific studies relied upon by the Administrator with re- spect to actions the Administrator may take relating to the change in classification, suspension, or cancellation of a pesticide. When- ever the Administrator determines that circumstances do not per- mit 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 pre- vent an imminent hazard, the Administrator shall promptly there- after provide for the conduct of peer review as provided in this sen- tence. The evaluations and relevant documentation constituting the peer review that relate to the proposed scientific studies and the re- sults of the completed scientific studies shall be included in the sub- mission for comment forwarded by the Administrator to the advi- sory 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 Pro- tection Agency, in the appropriate disciplines.

**SEC. 26.** ø**7 U.S.C. 136w–1**¿ **STATE PRIMARY ENFORCEMENT RESPON- SIBILITY.**

(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 regula- tions, 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 sub- section (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 sec- tion 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 [Sep- tember 30, 1978] not later than six months after that date.

(c) ADMINISTRATOR.—The Administrator shall have primary en- forcement responsibility for those States that do not have primary

enforcement responsibility under this Act. Notwithstanding the pro-

visions of section 2(e)(1) of this Act, during any period when the Ad- ministrator has such enforcement responsibility, section 8(b) of this Act shall apply to the books and records of commercial applicators

tions 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 ap- plication.

**SEC. 27.** ø**7 U.S.C. 136w–2**¿ **FAILURE BY THE STATE TO ASSURE EN- FORCEMENT OF STATE PESTICIDE USE REGULATIONS.**

(a) REFERRAL.—Upon receipt of any complaint or other informa- tion 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 information to the ex- tent 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 in- adequate. The State shall have ninety days after receipt of the no- tice to correct any deficiencies. If after that time the Administrator determines that the State program remains inadequate, the Admin- istrator may rescind, in whole or in part, the State’s primary en- forcement responsibility for pesticide use violations.

(c) CONSTRUCTION.—Neither section 26 of this Act nor this sec- tion 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 Adminis- trator and the State authority is unwilling or unable adequately to respond to the emergency.

**SEC. 28.** ø**7 U.S.C. 136w–3**¿ **IDENTIFICATION OF PESTS; COOPERATION WITH DEPARTMENT OF AGRICULTURE’S PROGRAM.**

(a) IN GENERAL.—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 imple- mentation programs to develop and improve the safe use and effec- tiveness 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.

(b) PEST CONTROL AVAILABILITY.—

(1) IN GENERAL.—The Administrator, in cooperation with the Secretary of Agriculture, shall identify—

(A) available methods of pest control by crop or animal; (B) minor pest control problems, both in minor crops

and minor or localized problems in major crops; and

(C) factors limiting the availability of specific pest con- trol methods, such as resistance to control methods and regulatory actions limiting the availability of control meth- ods.

(2) REPORT.—The Secretary of Agriculture shall, not later than 180 days after the date of enactment of this subsection

[November 28, 1990] and annually thereafter, prepare a report and send the report to the Administrator. The report shall—

(A) contain the information described in paragraph (1) and the information required by section 1651 of the Food, Agriculture, Conservation, and Trade Act of 1990;

(B) identify the crucial pest control needs where a shortage of control methods is indicated by the information described in paragraph (1); and

(C) describe in detail research and extension efforts de- signed to address the needs identified in subparagraph (B).

(c) INTEGRATED PEST MANAGEMENT.—The Administrator, in cooperation with the Secretary of Agriculture, shall develop approaches to the control of pests based on integrated pest manage- ment that respond to the needs of producers, with a special empha- sis on minor pests.

(d) PUBLIC HEALTH PESTS.—The Administrator, in coordination with the Secretary of Agriculture and the Secretary of Health and Human Services, shall identify pests of significant public health im- portance and, in coordination with the Public Health Service, de- velop and implement programs to improve and facilitate the safe and necessary use of chemical, biological, and other methods to combat and control such pests of public health importance.

**SEC. 29.** ø**7 U.S.C. 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 ap- plications for conditional registration under sections 3(c)(7)(B) and

3(c)(7)(C) of this Act that were filed during the immediately pre- ceding 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 condi-

tions in each case, and the quantities produced of such pesticides.

**SEC. 30.** ø**7 U.S.C. 136w–5**¿ **MINIMUM REQUIREMENTS FOR TRAINING OF MAINTENANCE APPLICATORS AND SERVICE TECHNI- CIANS.**

Each State may establish minimum requirements for training of maintenance applicators and service technicians. Such training may include instruction in the safe and effective handling and use of pesticides in accordance with the Environmental Protection Agency approved labeling, and instruction in integrated pest man- agement techniques. The authority of the Administrator with re- spect to minimum requirements for training of maintenance appli- cators and service technicians shall be limited to ensuring that each State understands the provisions of this section.

**SEC. 31.** ø**7 U.S.C. 136w–6**¿ **ENVIRONMENTAL PROTECTION AGENCY MINOR USE PROGRAM.**

(a) The Administrator shall assure coordination of minor use issues through the establishment of a minor use program within the Office of Pesticide Programs. Such office shall be responsible for coordinating the development of minor use programs and policies and consulting with growers regarding minor use issues and reg- istrations and amendments which are submitted to the Environ- mental Protection Agency.

(b) The Office of Pesticide Programs shall prepare a public re- port concerning the progress made on the registration of minor uses, including implementation of the exclusive use as an incentive

for registering new minor uses, within 3 years of the passage of the

Food Quality Protection Act of 1996. [Aug. 3, 1996]

**SEC. 32.** ø**7 U.S.C. 136w–7**¿ **DEPARTMENT OF AGRICULTURE MINOR USE PROGRAM.**

(a) IN GENERAL.—The Secretary of Agriculture (hereinafter in this section referred to as the ‘‘Secretary’’) shall assure the coordi- nation of the responsibilities of the Department of Agriculture re- lated to minor uses of pesticides, including—

(1) carrying out the Inter-Regional Project Number 4 (IR–

4) as described in section 2 of Public Law 89–106 (7 U.S.C.

450i(e)) and the national pesticide resistance monitoring pro-

gram established under section 1651 of the Food, Agriculture,

Conservation, and Trade Act of 1990 (7 U.S.C. 5882);

(2) supporting integrated pest management research;

(3) consulting with growers to develop data for minor uses;

and

(4) providing assistance for minor use registrations, toler-

ances, and reregistrations with the Environmental Protection

Agency.

(b)(1) MINOR USE PESTICIDE DATA.—

(A) GRANT AUTHORITY.—The Secretary, in consultation

with the Administrator, shall establish a program to make

grants for the development of data to support minor use pes-

ticide registrations and reregistrations. The amount of any such

grant shall not exceed 1⁄2 of the cost of the project for which the

grant is made.

(B) APPLICANTS.—Any person who wants to develop data to

support minor use pesticide registrations and reregistrations

may apply for a grant under subparagraph (A). Priority shall

be given to an applicant for such a grant who does not directly

receive funds from the sale of pesticides registered for minor

uses.

(C) DATA OWNERSHIP.—Any data that is developed under a

grant under subparagraph (A) shall be jointly owned by the De-

partment of Agriculture and the person who received the grant.

Such a person shall enter into an agreement with the Secretary

under which such person shall share any fee paid to such per-

son under section 3(c)(1)(F).

(2) MINOR USE PESTICIDE DATA REVOLVING FUND.—

(A) ESTABLISHMENT.—There is established in the Treasury

of the United States a revolving fund to be known as the Minor

Use Pesticide Data Revolving Fund. The Fund shall be avail-

able without fiscal year limitation to carry out the authorized

purposes of this subsection.

(B) CONTENTS OF THE FUND.—There shall be deposited in

the Fund—

(i) such amounts as may be appropriated to support

the purposes of this subsection; and

(ii) fees collected by the Secretary for any data devel-

oped under a grant under paragraph (1)(A).

(C) AUTHORIZATIONS OF APPROPRIATIONS.—There are au-

thorized to be appropriated for each fiscal year to carry out the

purposes of this subsection $10,000,000 to remain available

until expended.

**SEC. 33.** ø**7 U.S.C. 136w–8**¿ **PESTICIDE REGISTRATION SERVICE FEES.** (a) DEFINITION OF COSTS.—In this section, the term ‘‘costs’’, when used with respect to review and decisionmaking pertaining to an application for which registration service fees are paid under

this section, means—

(1) costs to the extent that—

(A) officers and employees provide direct support for

the review and decisionmaking for covered pesticide appli-

cations, associated tolerances, and corresponding risk and

benefits information and analyses;

(B) persons and organizations under contract with the

Administrator engage in the review of the applications, and

corresponding risk and benefits information and assess-

ments; and

(C) advisory committees and other accredited persons

or organizations, on the request of the Administrator, en-

gage in the peer review of risk or benefits information asso-

ciated with covered pesticide applications;

(2) costs of management of information, and the acquisi-

tion, maintenance, and repair of computer and telecommuni-

cation resources (including software), used to support review of

pesticide applications, associated tolerances, and corresponding

risk and benefits information and analyses; and

(3) costs of collecting registration service fees under sub-

sections (b) and (c) and reporting, auditing, and accounting

under this section.

(b) FEES.—

(1) IN GENERAL.—Effective beginning on the effective date

of the Pesticide Registration Improvement Act of 2003, the Ad-

ministrator shall assess and collect covered pesticide registra-

tion service fees in accordance with this section.

(2) COVERED PESTICIDE REGISTRATION APPLICATIONS.—

(A) IN GENERAL.—An application for the registration of

a pesticide covered by this Act that is received by the Ad-

ministrator on or after the effective date of the Pesticide

Registration Improvement Act of 2003 shall be subject to

a registration service fee under this section.

(B) EXISTING APPLICATIONS.—

(i) IN GENERAL.—Subject to clause (ii), an applica-

tion for the registration of a pesticide that was sub-

mitted to the Administrator before the effective date of

the Pesticide Registration Improvement Act of 2003

and is pending on that effective date shall be subject

to a service fee under this section if the application is

for the registration of a new active ingredient that is

not listed in the Registration Division 2003 Work Plan

of the Office of Pesticide Programs of the Environ-

mental Protection Agency.

(ii) TOLERANCE OR EXEMPTION FEES.—The amount

of any fee otherwise payable for an application de-

scribed in clause (i) under this section shall be reduced

by the amount of any fees paid to support the related

petition for a pesticide tolerance or exemption under

the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

301 et seq.).

(C) DOCUMENTATION.—An application subject to a reg- istration service fee under this section shall be submitted with documentation certifying—

(i) payment of the registration service fee; or

(ii) payment of at least 25 percent of the registra-

tion service fee and a request for a waiver from or re-

duction of the remaining amount of the registration

service fee.

(D) PAYMENT.—The registration service fee required

under this subsection shall be due upon submission of the

application.

(E) APPLICATIONS SUBJECT TO ADDITIONAL FEES.—An

application may be subject to additional fees if—

(i) the applicant identified the incorrect registra-

tion service fee and decision review period;

(ii) after review of a waiver request, the Adminis-

trator denies the waiver request; or

(iii) after review of the application, the Adminis-

trator determines that a different registration service

fee and decision review period apply to the application.

(F) EFFECT OF FAILURE TO PAY FEES.—The Adminis-

trator shall reject any application submitted without the

required registration service fee.

(G) NON-REFUNDABLE PORTION OF FEES.—

(i) IN GENERAL.—The Administrator shall retain 25

percent of the applicable registration service fee.

(ii) LIMITATION.—Any waiver, refund, credit or

other reduction in the registration service fee shall not

exceed 75 percent of the registration service fee.

(H) COLLECTION OF UNPAID FEES.—In any case in

which the Administrator does not receive payment of a reg-

istration service fee (or applicable portion of the registra-

tion service fee) by the date that is 30 days after the fee

is due, the fee shall be treated as a claim of the United

States Government subject to subchapter II of chapter 37

of title 31, United States Code.

(3) SCHEDULE OF COVERED APPLICATIONS AND REGISTRATION

SERVICE FEES.—

(A) IN GENERAL.—Not later than 30 days after the ef-

fective date of the Pesticide Registration Improvement Re-

newal Act, the Administrator shall publish in the Federal

Register a schedule of covered pesticide registration appli-

cations and corresponding registration service fees.

(B) REPORT.—Subject to paragraph (6), the schedule

shall be the same as the applicable schedule appearing in

the Congressional Record on pages S10409 through

S10411, dated July 31, 2007.

(4) PENDING PESTICIDE REGISTRATION APPLICATIONS.—

(A) IN GENERAL.—An applicant that submitted a reg-

istration application to the Administrator before the effec-

tive date of the Pesticide Registration Improvement Act of

2003, but that is not required to pay a registration service

fee under paragraph (2)(B), may, on a voluntary basis, pay

a registration service fee in accordance with paragraph

(2)(B).

(B) VOLUNTARY FEE.—The Administrator may not com- pel payment of a registration service fee for an application described in subparagraph (A).

(C) DOCUMENTATION.—An application for which a vol- untary registration service fee is paid under this paragraph shall be submitted with documentation certifying—

(i) payment of the registration service fee; or

(ii) a request for a waiver from or reduction of the

registration service fee.

(5) RESUBMISSION OF PESTICIDE REGISTRATION APPLICA-

TIONS.—If a pesticide registration application is submitted by a

person that paid the fee for the application under paragraph

(2), is determined by the Administrator to be complete, and is

not approved or is withdrawn (without a waiver or refund), the

submission of the same pesticide registration application by the

same person (or a licensee, assignee, or successor of the person)

shall not be subject to a fee under paragraph (2).

(6) FEE ADJUSTMENT.—

(A) IN GENERAL.—Effective for a covered pesticide reg-

istration application received during the period beginning

on October 1, 2008, and ending on September 30, 2010, the

Administrator shall increase by 5 percent the registration

service fee payable for the application under paragraph (3).

(B) ADDITIONAL ADJUSTMENT.—Effective for a covered

pesticide registration application received on or after Octo-

ber 1, 2010, the Administrator shall increase by an addi-

tional 5 percent the registration service fee in effect as of

September 30, 2010.

(C) PUBLICATION.—The Administrator shall publish in

the Federal Register the revised registration service fee

schedules.

(7) WAIVERS AND REDUCTIONS.—

(A) IN GENERAL.—An applicant for a covered pesticide

registration may request the Administrator to waive or re-

duce the amount of a registration service fee payable under

this section under the circumstances described in subpara-

graphs (D) through (G).

(B) DOCUMENTATION.—

(i) IN GENERAL.—A request for a waiver from or re-

duction of the registration service fee shall be accom-

panied by appropriate documentation demonstrating

the basis for the waiver or reduction.

(ii) CERTIFICATION.—The applicant shall provide to

the Administrator a written certification, signed by a

responsible officer, that the documentation submitted

to support the waiver or reduction request is accurate.

(iii) INACCURATE DOCUMENTATION.—An application

shall be subject to the applicable registration service

fee payable under paragraph (3) if, at any time, the

Administrator determines that—

(I) the documentation supporting the waiver

or reduction request is not accurate; or

(II) based on the documentation or any other

information, the waiver or reduction should not

have been granted or should not be granted.

(C) DETERMINATION TO GRANT OR DENY REQUEST.—As soon as practicable, but not later than 60 days, after the date on which the Administrator receives a request for a waiver or reduction of a registration service fee under this paragraph, the Administrator shall—

(i) determine whether to grant or deny the re- quest; and

(ii) notify the applicant of the determination. (D) MINOR USES.—

(i) IN GENERAL.—The Administrator may exempt from, or waive a portion of, the registration service fee for an application for minor uses for a pesticide.

(ii) SUPPORTING DOCUMENTATION.—An applicant requesting a waiver or exemption under this subpara- graph shall provide supporting documentation that demonstrates, to the satisfaction of the Administrator, that anticipated revenues from the uses that are the subject of the application would be insufficient to jus- tify imposition of the full application fee.

(E) IR–4 EXEMPTION.—The Administrator shall exempt an application from the registration service fee if the Ad- ministrator determines that—

(i) the application is solely associated with a toler- ance petition submitted in connection with the Inter- Regional Project Number 4 (IR–4) as described in sec- tion 2 of Public Law 89–106 (7 U.S.C. 450i(e)); and

(ii) the exemption is in the public interest. (F) SMALL BUSINESSES.—

(i) IN GENERAL.—The Administrator shall waive 50 percent of the registration service fees payable by an entity for a covered pesticide registration application under this section if the entity is a small business (as defined in section 4(i)(5)(E)(ii)) at the time of applica- tion.

(ii) WAIVER OF FEES.—The Administrator shall waive 75 percent of the registration service fees pay- able by an entity under this section if the entity—

(I) is a small business (as defined in section

4(i)(5)(E)(ii)) at the time of application; and

(II) has average annual global gross revenues

described in section 4(i)(5)(E)(ii)(I)(bb) that does

not exceed $10,000,000, at the time of application.

(iii) FORMATION FOR WAIVER.—The Administrator

shall not grant a waiver under this subparagraph if

the Administrator determines that the entity submit-

ting the application has been formed or manipulated

primarily for the purpose of qualifying for the waiver.

(iv) DOCUMENTATION.—An entity requesting a

waiver under this subparagraph shall provide to the

Administrator—

(I) documentation demonstrating that the enti-

ty is a small business (as defined in section

4(i)(5)(E)(ii)) at the time of application; and

(II) if the entity is requesting a waiver of 75 percent of the applicable. 33–1 registration service fees payable under this section, documentation demonstrating that the entity has an average an- nual global gross revenues described in section

4(i)(5)(E)(ii)(I)(bb) that does not exceed

$10,000,000, at the time of application.

(G) FEDERAL AND STATE AGENCY EXEMPTIONS.—An

agency of the Federal Government or a State government

shall be exempt from covered registration service fees

under this section.

(8) REFUNDS.—

(A) EARLY WITHDRAWALS.—If, during the first 60 days

after the beginning of the applicable decision time review

period under subsection (f)(3), a covered pesticide registra-

tion application is withdrawn by the applicant, the Admin-

istrator shall refund all but 25 percent of the total registra-

tion service fee payable under paragraph (3) for the appli-

cation.

(B) WITHDRAWALS AFTER THE FIRST 60 DAYS OF DECI-

SION REVIEW TIME PERIOD.—

(i) IN GENERAL.—If a covered pesticide registration

application is withdrawn after the first 60 days of the

applicable decision time review period, the Adminis-

trator shall determine what portion, if any, of the total

registration service fee payable under paragraph (3) for

the application may be refunded based on the propor-

tion of the work completed at the time of withdrawal.

(ii) TIMING.—The Administrator shall—

(I) make the determination described in clause

(i) not later than 90 days after the date the appli-

cation is withdrawn; and

(II) provide any refund as soon as practicable

after the determination.

(C) DISCRETIONARY REFUNDS.—

(i) IN GENERAL.—In the case of a pesticide registra-

tion application that has been filed with the Adminis-

trator and has not been withdrawn by the applicant,

but for which the Administrator has not yet made a

final determination, the Administrator may refund a

portion of a covered registration service fee if the Ad-

ministrator determines that the refund is justified.

(ii) BASIS.—The Administrator may provide a re-

fund for an application under this subparagraph—

(I) on the basis that, in reviewing the applica-

tion, the Administrator has considered data sub-

mitted in support of another pesticide registration

application; or

(II) on the basis that the Administrator com- pleted portions of the review of the application be- fore the effective date of this section.

(D) CREDITED FEES.—In determining whether to grant a refund under this paragraph, the Administrator shall

33–1 So in original (as amended by sec. 5(c)(2) of Public Law 110–94). Probably should strike the period.

take into account any portion of the registration service fees credited under paragraph (2) or (4).

(c) PESTICIDE REGISTRATION FUND.—

(1) ESTABLISHMENT.—There is established in the Treasury of the United States a Pesticide Registration Fund to be used in carrying out this section (referred to in this section as the

‘‘Fund’’), consisting of—

(A) such amounts as are deposited in the Fund under paragraph (2);

(B) any interest earned on investment of amounts in the Fund under paragraph (5); and

(C) any proceeds from the sale or redemption of invest- ments held in the Fund.

(2) DEPOSITS IN FUND.—Subject to paragraph (4), the Ad- ministrator shall deposit fees collected under this section in the Fund.

(3) EXPENDITURES FROM FUND.—

(A) IN GENERAL.—Subject to subparagraphs (B) and (C) and paragraph (4), the Administrator may make expendi- tures from the Fund—

(i) to cover the costs associated with the review and decisionmaking pertaining to all applications for which registration service fees have been paid under this section; and

(ii) to otherwise carry out this section. (B) WORKER PROTECTION.—

(i) IN GENERAL.—For each of fiscal years 2008 through 2012, the Administrator shall use approxi- mately 1⁄17 of the amount in the Fund (but not less than $1,000,000) to enhance scientific and regulatory activities relating to worker protection.

(ii) PARTNERSHIP GRANTS.—Of the amounts in the Fund, the Administrator shall use for partnership grants—

(I) for each of fiscal years 2008 and 2009,

$750,000; and

(II) for each of fiscal years 2010 through 2012,

$500,000.

(iii) PESTICIDE SAFETY EDUCATION PROGRAM.—Of the amounts in the Fund, the Administrator shall use

$500,000 for each of fiscal years 2008 through 2012 to carry out the pesticide safety education program.

(4) COLLECTIONS AND APPROPRIATIONS ACTS.—The fees au- thorized by this section and amounts deposited in the Fund— (A) shall be collected and made available for obligation

only to the extent provided in advance in appropriations

Acts; and

(B) shall be available without fiscal year limitation. (5) UNUSED FUNDS.—

(A) IN GENERAL.—Amounts in the Fund not currently needed to carry out this section shall be—

(i) 33–2 maintained readily available or on deposit;

(ii) invested in obligations of the United States or guaranteed by the United States; or

33–2 Indentation of clauses (i) through (iii) is so in original (as amended by sec. 5(e)(3)(A)

of Public Law 110–94). Clauses probably should be indented.

(iii) invested in obligations, participations, or other in- struments that are lawful investments for fiduciary, trust, or public funds.

(B) USE OF INVESTMENT INCOME.—After consultation with the Secretary of the Treasury, the Administrator may use income from investments described in clauses (ii) and

(iii) of subparagraph (A) to carry out this section.

(d) ASSESSMENT OF FEES.—

(1) DEFINITION OF COVERED FUNCTIONS.—In this sub- section, the term ‘‘covered functions’’ means functions of the Of- fice of Pesticide Programs of the Environmental Protection Agency, as identified in key programs and projects of the final operating plan for the Environmental Protection Agency sub- mitted as part of the budget process for fiscal year 2002, re- gardless of any subsequent transfer of 1 or more of the func- tions to another office or agency or the subsequent transfer of a new function to the Office of Pesticide Programs.

(2) MINIMUM AMOUNT OF APPROPRIATIONS.—Registration service fees may not be assessed for a fiscal year under this section unless the amount of appropriations for salaries, con- tracts, and expenses for the functions (as in existence in fiscal year 2002) of the Office of Pesticide Programs of the Environ- mental Protection Agency for the fiscal year (excluding the amount of any fees appropriated for the fiscal year) are equal to or greater than the amount of appropriations for covered functions for fiscal year 2002 (excluding the amount of any fees appropriated for the fiscal year).

(3) USE OF FEES.—Registration service fees authorized by this section shall be available, in the aggregate, only to defray increases in the costs associated with the review and decision- making for the review of pesticide registration applications and associated tolerances (including increases in the number of full- time equivalent positions in the Environmental Protection Agency engaged in those activities) over the costs for fiscal year

2002, excluding costs paid from fees appropriated for the fiscal year.

(4) COMPLIANCE.—The requirements of paragraph (2) shall have been considered to have been met for any fiscal year if the amount of appropriations for salaries, contracts, and expenses for the functions (as in existence in fiscal year 2002) of the Of- fice of Pesticide Programs of the Environmental Protection Agency for the fiscal year (excluding the amount of any fees ap- propriated for the fiscal year) is not more than 3 percent below the amount of appropriations for covered functions for fiscal year 2002 (excluding the amount of any fees appropriated for the fiscal year).

(5) SUBSEQUENT AUTHORITY.—If the Administrator does not assess registration service fees under subsection (b) during any portion of a fiscal year as the result of paragraph (2) and is subsequently permitted to assess the fees under subsection (b) during the fiscal year, the Administrator shall assess and col- lect the fees, without any modification in rate, at any time dur- ing the fiscal year, notwithstanding any provisions of sub- section (b) relating to the date fees are to be paid.

(e) REFORMS TO REDUCE DECISION TIME REVIEW PERIODS.—To the maximum extent practicable consistent with the degrees of risk

presented by pesticides and the type of review appropriate to evalu- ate risks, the Administrator shall identify and evaluate reforms to the pesticide registration process under this Act with the goal of re- ducing decision review periods in effect on the effective date of the Pesticide Registration Improvement Act of 2003 for pesticide reg- istration actions for covered pesticide registration applications (in- cluding reduced risk applications).

(f) DECISION TIME REVIEW PERIODS.—

(1) IN GENERAL.—Not later than 30 days after the effective date of the Pesticide Registration Improvement Renewal Act, the Administrator shall publish in the Federal Register a schedule of decision review periods for covered pesticide reg- istration actions and corresponding registration service fees under this Act.

(2) REPORT.—The schedule shall be the same as the appli- cable schedule appearing in the Congressional Record on pages S10409 through S10411, dated July 31, 2007.

(3) APPLICATIONS SUBJECT TO DECISION TIME REVIEW PERI- ODS.—The decision time review periods specified in paragraph (1) shall apply to—

(A) covered pesticide registration applications subject to registration service fees under subsection (b)(2);

(B) covered pesticide registration applications for which an applicant has voluntarily paid registration serv- ice fees under subsection (b)(4); and

(C) covered pesticide registration applications listed in the Registration Division 2003 Work Plan of the Office of Pesticide Programs of the Environmental Protection Agen- cy.

(4) START OF DECISION TIME REVIEW PERIOD.—

(A) IN GENERAL.—Except as provided in subparagraphs (C), (D), and (E), in the case of a pesticide registration ap- plication accompanied by the registration service fee re- quired under this section, the decision time review period begins 21 days after the date on which the Administrator receives the covered pesticide registration application.

(B) COMPLETENESS OF APPLICATION.—

(i) IN GENERAL.—Not later than 21 days after re- ceiving an application and the required registration service fee, the Administrator shall conduct an initial screening of the contents of the application in accord- ance with clause (iii).

(ii) REJECTION.—If the Administrator determines under clause (i) that the application does not pass the initial screening and cannot be corrected within the 21- day period, the Administrator shall reject the applica- tion not later than 10 days after making the deter- mination.

(iii) REQUIREMENTS OF SCREENING.—In conducting an initial screening of an application, the Adminis- trator shall determine whether—

(I)(aa) the applicable registration service fee has been paid; or

(bb) at least 25 percent of the applicable reg- istration service fee has been paid and the applica- tion contains a waiver or refund request for the

outstanding amount and documentation estab- lishing the basis for the waiver request; and

(II) the application contains all the necessary forms, data, and draft labeling, formatted in ac- cordance with guidance published by the Adminis- trator.

(C) APPLICATIONS WITH WAIVER OR REDUCTION RE-

QUESTS.—

(i) IN GENERAL.—In the case of an application sub-

mitted with a request for a waiver or reduction of reg-

istration service fees under subsection (b)(7), the deci-

sion time review period shall be determined in accord-

ance with this subparagraph.

(ii) REQUEST GRANTED WITH NO ADDITIONAL FEES

REQUIRED.—If the Administrator grants the waiver or

reduction request and no additional fee is required, the

decision time review period begins on the earlier of—

(I) the date on which the Administrator grants

the request; or

(II) the date that is 60 days after the date of

receipt of the application.

(iii) REQUEST GRANTED WITH ADDITIONAL FEES RE-

QUIRED.—If the Administrator grants the waiver or re-

duction request, in whole or in part, but an additional

registration service fee is required, the decision time

review period begins on the date on which the Admin-

istrator receives certification of payment of the applica-

ble registration service fee.

(iv) REQUEST DENIED.—If the Administrator denies

the waiver or reduction request, the decision time re-

view period begins on the date on which the Adminis-

trator receives certification of payment of the applica-

ble registration service fee.

(D) PENDING APPLICATIONS.—

(i) IN GENERAL.—The start of the decision time re-

view period for applications described in clause (ii)

shall be the date on which the Administrator receives

certification of payment of the applicable registration

service fee.

(ii) APPLICATIONS.—Clause (i) applies to—

(I) covered pesticide registration applications

for which voluntary fees have been paid under

subsection (b)(4); and

(II) covered pesticide registration applications

received on or after the effective date of the Pes-

ticide Registration Improvement Act of 2003 but

submitted without the applicable registration serv-

ice fee required under this section due to the in-

ability of the Administrator to assess fees under

subsection (d)(1).

(E) 2003 WORK PLAN.—In the case of a covered pes-

ticide registration application listed in the Registration Di-

vision 2003 Work Plan of the Office of Pesticide Programs

of the Environmental Protection Agency, the decision time

review period begins on the date that is 30 days after the

effective date of the Pesticide Registration Improvement

Act of 2003.

(5) EXTENSION OF DECISION TIME REVIEW PERIOD.—The Ad-

ministrator and the applicant may mutually agree in writing to

extend a decision time review period under this subsection.

(g) JUDICIAL REVIEW.—

(1) IN GENERAL.—Any applicant adversely affected by the

failure of the Administrator to make a determination on the ap-

plication of the applicant for registration of a new active ingre-

dient or new use for which a registration service fee is paid

under this section may obtain judicial review of the failure sole-

ly under this section.

(2) SCOPE.—

(A) IN GENERAL.—In an action brought under this sub-

section, the only issue on review is whether the Adminis-

trator failed to make a determination on the application

specified in paragraph (1) by the end of the applicable deci-

sion time review period required under subsection (f) for

the application.

(B) OTHER ACTIONS.—No other action authorized or re-

quired under this section shall be judicially reviewable by

a Federal or State court.

(3) TIMING.—

(A) IN GENERAL.—A person may not obtain judicial re-

view of the failure of the Administrator to make a deter-

mination on the application specified in paragraph (1) be-

fore the expiration of the 2-year period that begins on the

date on which the decision time review period for the appli-

cation ends.

(B) MEETING WITH ADMINISTRATOR.—To be eligible to

seek judicial review under this subsection, a person seek-

ing the review shall first request in writing, at least 120

days before filing the complaint for judicial review, a deci-

sion review meeting with the Administrator.

(4) REMEDIES.—The Administrator may not be required or

permitted to refund any portion of a registration service fee

paid in response to a complaint that the Administrator has

failed to make a determination on the covered pesticide reg-

istration application specified in paragraph (1) by the end of

the applicable decision review period.

(h) ACCOUNTING.—The Administrator shall—

(1) provide an annual accounting of the registration service

fees paid to the Administrator and disbursed from the Fund, by

providing financial statements in accordance with—

(A) the Chief Financial Officers Act of 1990 (Public

Law 101–576; 104 Stat. 2838) and amendments made by

that Act; and

(B) the Government Management Reform Act of 1994

(Public Law 103–356; 108 Stat. 3410) and amendments

made by that Act;

(2) provide an accounting describing expenditures from the

Fund authorized under subsection (c); and

(3) provide an annual accounting describing collections and

expenditures authorized under subsection (d).

(i) AUDITING.—

(1) FINANCIAL STATEMENTS OF AGENCIES.—For the purpose of section 3515(c) of title 31, United States Code, the Fund shall be considered a component of an executive agency.

(2) COMPONENTS.—The annual audit required under sec- tions 3515(b) and 3521 of that title of the financial statements of activities under this section shall include an analysis of—

(A) the fees collected under subsection (b) and dis- bursed;

(B) compliance with subsection (f);

(C) the amount appropriated to meet the requirements

of subsection (d)(1); and

(D) the reasonableness of the allocation of the over-

head allocation of costs associated with the review and de-

cisionmaking pertaining to applications under this section.

(3) INSPECTOR GENERAL.—The Inspector General of the En-

vironmental Protection Agency shall—

(A) conduct the annual audit required under this sub-

section; and

(B) report the findings and recommendations of the

audit to the Administrator and to the appropriate commit-

tees of Congress.

(j) PERSONNEL LEVELS.—All full-time equivalent positions sup-

ported by fees authorized and collected under this section shall not

be counted against the agency-wide personnel level goals of the En-

vironmental Protection Agency.

(k) REPORTS.—

(1) IN GENERAL.—Not later than March 1, 2005, and each

March 1 thereafter through March 1, 2014, the Administrator

shall publish an annual report describing actions taken under

this section.

(2) CONTENTS.—The report shall include—

(A) a review of the progress made in carrying out each

requirement of subsections (e) and (f), including—

(i) the number of applications reviewed, including

the decision times for each application specified in sub-

section (f);

(ii) the number of label amendments that have

been reviewed using electronic means;

(iii) the amount of money from the Reregistration

and Expedited Processing Fund used to carry out inert

ingredient review and review of similar applications

under section 4(k)(3);

(iv) the number of applications completed for iden-

tical or substantially similar applications under section

3(c)(3)(B), including the number of such applications

completed within 90 days pursuant to that section;

(v) the number of actions pending in each category

of actions described in subsection (f)(3), as well as the

number of inert ingredients;

(vi) to the extent determined appropriate by the

Administrator and consistent with the authorities of

the Administrator and limitations on delegation of

functions by the Administrator, recommendations for—

(I) expanding the use of self-certification in all

appropriate areas of the registration process;

(II) providing for accreditation of outside re- viewers and the use of outside reviewers to con- duct the review of major portions of applications; (III) reviewing the scope of use of the notifica-

tion process to cover broader categories of registra- tion actions;

(IV) providing for electronic submission and

review of labels, including process improvements to further enhance the procedures used in elec- tronic label review; and

(V) the allowance and use of summaries of acute toxicity studies; and

(vii) the use of performance-based contracts, other contracts, and procurement to ensure that—

(I) the goals of this Act for the timely review of applications for registration are met; and

(II) the registration program is administered in the most productive and cost effective manner practicable;

(B) a description of the staffing and resources relating to the costs associated with the review and decisionmaking pertaining to applications;

(C) a review of the progress in meeting the timeline re- quirements of section 4(g);

(D) a review of the progress in carrying out section

3(g), including—

(i) the number of pesticides or pesticide cases re- viewed;

(ii) a description of the staffing and resources re- lating to the costs associated with the review and deci- sion making relating to reregistration and registration review for compliance with the deadlines specified in this Act;

(iii) to the extent determined appropriate by the Administrator and consistent with the authorities of the Administrator and limitations on delegation of functions by the Administrator, recommendations for— (I) process improvements in the handling of

registration review under section 3(g);

(II) providing for accreditation of outside re- viewers and the use of outside reviewers in the registration review process; and

(III) streamlining the registration review proc- ess, consistent with section 3(g);

(E) a review of the progress in meeting the timeline re- quirements for the review of antimicrobial pesticide prod- ucts under section 3(h); and

(F) a review of the progress in carrying out the review of inert ingredients, including the number of applications pending, the number of new applications, the number of applications reviewed, staffing, and resources devoted to the review of inert ingredients and recommendations to im- prove the timeliness of review of inert ingredients.

(3) METHOD.—The Administrator shall publish a report re- quired by this subsection by such method as the Administrator determines to be the most effective for efficiently disseminating

the report, including publication of the report on the Internet site of the Environmental Protection Agency.

(l) SAVINGS CLAUSE.—Nothing in this section affects any other duties, obligations, or authorities established by any other section of this Act, including the right to judicial review of duties, obliga- tions, or authorities established by any other section of this Act.

(m) TERMINATION OF EFFECTIVENESS.—

(1) IN GENERAL.—Except as provided in paragraph (2), the authority provided by this section terminates on September 30,

2012.

(2) PHASE OUT.—

(A) FISCAL YEAR 2013.—During fiscal year 2013, the re- quirement to pay and collect registration service fees ap- plies, except that the level of registration service fees pay- able under this section shall be reduced 40 percent below the level in effect on September 30, 2012.

(B) FISCAL YEAR 2014.—During fiscal year 2014, the re- quirement to pay and collect registration service fees ap- plies, except that the level of registration service fees pay- able under this section shall be reduced 70 percent below the level in effect on September 30, 2012.

(C) SEPTEMBER 30, 2014.—Effective September 30, 2014, the requirement to pay and collect registration service fees terminates.

(D) DECISION REVIEW PERIODS.—

(i) PENDING APPLICATIONS.—In the case of an ap- plication received under this section before September

30, 2012, the application shall be reviewed in accord- ance with subsection (f).

(ii) NEW APPLICATIONS.—In the case of an applica- tion received under this section on or after September

30, 2012, subsection (f) shall not apply to the applica- tion.

**SEC. 34.** ø**7 U.S.C. 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. 35.** ø**7 U.S.C. 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.