

Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 114-182, title I, §19(p), June 22, 2016, 130 Stat. 510.)

Editorial Notes

AMENDMENTS

2016—Subsec. (b)(2)(B)(ii), (iii). Pub. L. 114-182 redesignated cl. (iii) as (ii) and struck out former cl. (ii) which read as follows: “such hearings shall be held in accordance with section 2605(c)(3) of this title, and”.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94-469, set out as a note under section 2601 of this title.

§ 2624. Repealed. Pub. L. 114-182, title I, § 16, June 22, 2016, 130 Stat. 499

Section, Pub. L. 94-469, title I, §25, Oct. 11, 1976, 90 Stat. 2046; Pub. L. 96-88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695; renumbered title I, Pub. L. 99-519, §3(c)(1), Oct. 22, 1986, 100 Stat. 2989, required a study on indemnification for actions taken by the Administrator under Federal law.

§ 2625. Administration

(a) Cooperation of Federal agencies

Upon request by the Administrator, each Federal department and agency is authorized—

(1) to make its services, personnel, and facilities available (with or without reimbursement) to the Administrator to assist the Administrator in the administration of this chapter; and

(2) to furnish to the Administrator such information, data, estimates, and statistics, and to allow the Administrator access to all information in its possession as the Administrator may reasonably determine to be necessary for the administration of this chapter.

(b) Fees

(1) The Administrator may, by rule, require the payment from any person required to submit information under section 2603 of this title or a notice or other information to be reviewed by the Administrator under section 2604 of this title, or who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 2605(b) of this title, of a fee that is sufficient and not more than reasonably necessary to defray the cost related to such chemical substance of administering sections 2603, 2604, and 2605 of this title, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 2613 of this title information on chemical substances under this subchapter, including contractor costs incurred by the Administrator. In setting a fee under this paragraph, the Administrator shall take into account the ability to pay of the person required to pay such fee and the cost to the Administrator of carrying out the activities described in this paragraph. Such rules may provide for sharing such a fee in any case in which the expenses of testing are shared under section 2603 or 2604 of this title.

(2) The Administrator, after consultation with the Administrator of the Small Business Admin-

istration, shall by rule prescribe standards for determining the persons which qualify as small business concerns for purposes of paragraph (4).

(3) FUND.—

(A) ESTABLISHMENT.—There is established in the Treasury of the United States a fund, to be known as the TSCA Service Fee Fund (in this paragraph referred to as the “Fund”), consisting of such amounts as are deposited in the Fund under this paragraph.

(B) COLLECTION AND DEPOSIT OF FEES.—Subject to the conditions of subparagraph (C), the Administrator shall collect the fees described in this subsection and deposit those fees in the Fund.

(C) USE OF FUNDS BY ADMINISTRATOR.—Fees authorized under this section shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts, and shall be available without fiscal year limitation for use in defraying the costs of the activities described in paragraph (1).

(D) ACCOUNTING AND AUDITING.—

(i) ACCOUNTING.—The Administrator shall biennially prepare and submit to the Committee on Environment and Public Works of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes an accounting of the fees paid to the Administrator under this paragraph and amounts disbursed from the Fund for the period covered by the report, as reflected by financial statements provided in accordance with sections 3515 and 3521 of title 31.

(ii) AUDITING.—

(I) IN GENERAL.—For the purpose of section 3515(c) of title 31, the Fund shall be considered a component of a covered executive agency.

(II) COMPONENTS OF AUDIT.—The annual audit required in accordance with sections 3515 and 3521 of title 31 of the financial statements of activities carried out using amounts from the Fund shall include an analysis of—

(aa) the fees collected and amounts disbursed under this subsection;

(bb) the reasonableness of the fees in place as of the date of the audit to meet current and projected costs of administering the provisions of this subchapter for which the fees may be used; and

(cc) the number of requests for a risk evaluation made by manufacturers under section 2605(b)(4)(C)(ii) of this title.

(III) FEDERAL RESPONSIBILITY.—The Inspector General of the Environmental Protection Agency shall conduct the annual audit described in subclause (II) and submit to the Administrator a report that describes the findings and any recommendations of the Inspector General resulting from the audit.

(4) AMOUNT AND ADJUSTMENT OF FEES; RE-FUNDS.—In setting fees under this section, the Administrator shall—

(A) prescribe lower fees for small business concerns, after consultation with the Administrator of the Small Business Administration;

(B) set the fees established under paragraph (1) at levels such that the fees will, in aggregate, provide a sustainable source of funds to annually defray—

(i) the lower of—

(I) 25 percent of the costs to the Administrator of carrying out sections 2603, 2604, and 2605 of this title, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 2613 of this title information on chemical substances under this subchapter, other than the costs to conduct and complete risk evaluations under section 2605(b) of this title; or

(II) \$25,000,000 (subject to adjustment pursuant to subparagraph (F)); and

(ii) the costs of risk evaluations specified in subparagraph (D);

(C) reflect an appropriate balance in the assessment of fees between manufacturers and processors, and allow the payment of fees by consortia of manufacturers or processors;

(D) notwithstanding subparagraph (B)—

(i) except as provided in clause (ii), for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to section 2605(b)(4)(C)(ii) of this title, establish the fee at a level sufficient to defray the full costs to the Administrator of conducting the risk evaluation under section 2605(b) of this title;

(ii) for chemical substances for which the Administrator has granted a request from a manufacturer pursuant to section 2605(b)(4)(C)(ii) of this title, and which are included in the 2014 update of the TSCA Work Plan for Chemical Assessments, establish the fee at a level sufficient to defray 50 percent of the costs to the Administrator of conducting the risk evaluation under section 2605(b) of this title; and

(iii) apply fees collected pursuant to clauses (i) and (ii) only to defray the costs described in those clauses;

(E) prior to the establishment or amendment of any fees under paragraph (1), consult and meet with parties potentially subject to the fees or their representatives, subject to the condition that no obligation under chapter 10 of title 5 or subchapter II of chapter 5 of title 5 is applicable with respect to such meetings;

(F) beginning with the fiscal year that is 3 years after June 22, 2016, and every 3 years thereafter, after consultation with parties potentially subject to the fees and their representatives pursuant to subparagraph (E), increase or decrease the fees established under paragraph (1) as necessary to adjust for inflation and to ensure that funds deposited in the Fund are sufficient to defray—

(i) approximately but not more than 25 percent of the costs to the Administrator of carrying out sections 2603, 2604, and 2605 of this title, and of collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 2613 of this title information on chemical substances under this subchapter, other than the costs to conduct and com-

plete risk evaluations requested under section 2605(b)(4)(C)(ii) of this title; and

(ii) the costs of risk evaluations specified in subparagraph (D); and

(G) if a notice submitted under section 2604 of this title is not reviewed or such a notice is withdrawn, refund the fee or a portion of the fee if no substantial work was performed on the notice.

(5) **MINIMUM AMOUNT OF APPROPRIATIONS.**—Fees may not be assessed for a fiscal year under this section unless the amount of appropriations for the Chemical Risk Review and Reduction program project of the Environmental 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 that program project for fiscal year 2014.

(6) **TERMINATION.**—The authority provided by this subsection shall terminate at the conclusion of the fiscal year that is 10 years after June 22, 2016, unless otherwise reauthorized or modified by Congress.

(c) Action with respect to categories

(1) Any action authorized or required to be taken by the Administrator under any provision of this chapter with respect to a chemical substance or mixture may be taken by the Administrator in accordance with that provision with respect to a category of chemical substances or mixtures. Whenever the Administrator takes action under a provision of this chapter with respect to a category of chemical substances or mixtures, any reference in this chapter to a chemical substance or mixture (insofar as it relates to such action) shall be deemed to be a reference to each chemical substance or mixture in such category.

(2) For purposes of paragraph (1):

(A) The term “category of chemical substances” means a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter, except that such term does not mean a group of chemical substances which are grouped together solely on the basis of their being new chemical substances.

(B) The term “category of mixtures” means a group of mixtures the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in the mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for classification as such for purposes of this chapter.

(d) Assistance office

The Administrator shall establish in the Environmental Protection Agency an identifiable office to provide technical and other nonfinancial assistance to manufacturers and processors of chemical substances and mixtures respecting the requirements of this chapter applicable to such manufacturers and processors, the policy of

the Agency respecting the application of such requirements to such manufacturers and processors, and the means and methods by which such manufacturers and processors may comply with such requirements.

(e) Financial disclosures

(1) Except as provided under paragraph (3), each officer or employee of the Environmental Protection Agency and the Department of Health and Human Services who—

(A) performs any function or duty under this chapter, and

(B) has any known financial interest (i) in any person subject to this chapter or any rule or order in effect under this chapter, or (ii) in any person who applies for or receives any grant or contract under this chapter,

shall, on February 1, 1978, and on February 1 of each year thereafter, file with the Administrator or the Secretary of Health and Human Services (hereinafter in this subsection referred to as the “Secretary”), as appropriate, a written statement concerning all such interests held by such officer or employee during the preceding calendar year. Such statement shall be made available to the public.

(2) The Administrator and the Secretary shall—

(A) act within 90 days of January 1, 1977—

(i) to define the term “known financial interests” for purposes of paragraph (1), and

(ii) to establish the methods by which the requirement to file written statements specified in paragraph (1) will be monitored and enforced, including appropriate provisions for review by the Administrator and the Secretary of such statements; and

(B) report to the Congress on June 1, 1978, and on June 1 of each year thereafter with respect to such statements and the actions taken in regard thereto during the preceding calendar year.

(3) The Administrator may by rule identify specific positions with the Environmental Protection Agency, and the Secretary may by rule identify specific positions with the Department of Health and Human Services, which are of a nonregulatory or nonpolicymaking nature, and the Administrator and the Secretary may by rule provide that officers or employees occupying such positions shall be exempt from the requirements of paragraph (1).

(4) This subsection does not supersede any requirement of chapter 11 of title 18.

(5) Any officer or employee who is subject to, and knowingly violates, this subsection or any rule issued thereunder, shall be fined not more than \$2,500 or imprisoned not more than one year, or both.

(f) Statement of basis and purpose

Any final order issued under this chapter shall be accompanied by a statement of its basis and purpose. The contents and adequacy of any such statement shall not be subject to judicial review in any respect.

(g) Assistant Administrator

(1) The President, by and with the advice and consent of the Senate, shall appoint an Assis-

tant Administrator for Toxic Substances of the Environmental Protection Agency. Such Assistant Administrator shall be a qualified individual who is, by reason of background and experience, especially qualified to direct a program concerning the effects of chemicals on human health and the environment. Such Assistant Administrator shall be responsible for (A) the collection of information, (B) the preparation of studies, (C) the making of recommendations to the Administrator for regulatory and other actions to carry out the purposes and to facilitate the administration of this chapter, and (D) such other functions as the Administrator may assign or delegate.

(2) The Assistant Administrator to be appointed under paragraph (1) shall be in addition to the Assistant Administrators of the Environmental Protection Agency authorized by section 1(d) of Reorganization Plan No. 3 of 1970.

(h) Scientific standards

In carrying out sections 2603, 2604, and 2605 of this title, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science, and shall consider as applicable—

(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

(2) the extent to which the information is relevant for the Administrator’s use in making a decision about a chemical substance or mixture;

(3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

(5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models.

(i) Weight of scientific evidence

The Administrator shall make decisions under sections 2603, 2604, and 2605 of this title based on the weight of the scientific evidence.

(j) Availability of information

Subject to section 2613 of this title, the Administrator shall make available to the public—

(1) all notices, determinations, findings, rules, consent agreements, and orders of the Administrator under this subchapter;

(2) any information required to be provided to the Administrator under section 2603 of this title;

(3) a nontechnical summary of each risk evaluation conducted under section 2605(b) of this title;

(4) a list of the studies considered by the Administrator in carrying out each such risk

evaluation, along with the results of those studies; and

(5) each designation of a chemical substance under section 2605(b) of this title, along with an identification of the information, analysis, and basis used to make the designations.

(k) Reasonably available information

In carrying out sections 2603, 2604, and 2605 of this title, the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator.

(l) Policies, procedures, and guidance

(1) Development

Not later than 2 years after June 22, 2016, the Administrator shall develop any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments to this chapter made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(2) Review

Not later than 5 years after June 22, 2016, and not less frequently than once every 5 years thereafter, the Administrator shall—

(A) review the adequacy of the policies, procedures, and guidance developed under paragraph (1), including with respect to animal, nonanimal, and epidemiological test methods and procedures for assessing and determining risk under this subchapter; and

(B) revise such policies, procedures, and guidance as the Administrator determines necessary to reflect new scientific developments or understandings.

(3) Testing of chemical substances and mixtures

The policies, procedures, and guidance developed under paragraph (1) applicable to testing chemical substances and mixtures shall—

(A) address how and when the exposure level or exposure potential of a chemical substance or mixture would factor into decisions to require new testing, subject to the condition that the Administrator shall not interpret the lack of exposure information as a lack of exposure or exposure potential; and

(B) describe the manner in which the Administrator will determine that additional information is necessary to carry out this subchapter, including information relating to potentially exposed or susceptible populations.

(4) Chemical substances with completed risk assessments

With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to June 22, 2016, the Administrator may publish proposed and final rules under section 2605(a) of this title that are consistent with the scope of the completed risk assessment for the chemical substance and con-

sistent with other applicable requirements of section 2605 of this title.

(5) Guidance

Not later than 1 year after June 22, 2016, the Administrator shall develop guidance to assist interested persons in developing and submitting draft risk evaluations which shall be considered by the Administrator. The guidance shall, at a minimum, address the quality of the information submitted and the process to be followed in developing draft risk evaluations for consideration by the Administrator.

(m) Report to Congress

(1) Initial report

Not later than 6 months after June 22, 2016, the Administrator shall submit to the Committees on Energy and Commerce and Appropriations of the House of Representatives and the Committees on Environment and Public Works and Appropriations of the Senate a report containing an estimation of—

(A) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under section 2605(b)(4)(C)(i) of this title, and the resources necessary to conduct the minimum number of risk evaluations required under section 2605(b)(2) of this title;

(B) the capacity of the Environmental Protection Agency to conduct and publish risk evaluations under section 2605(b)(4)(C)(ii) of this title, the likely demand for such risk evaluations, and the anticipated schedule for accommodating that demand;

(C) the capacity of the Environmental Protection Agency to promulgate rules under section 2605(a) of this title as required based on risk evaluations conducted and published under section 2605(b) of this title; and

(D) the actual and anticipated efforts of the Environmental Protection Agency to increase the Agency's capacity to conduct and publish risk evaluations under section 2605(b) of this title.

(2) Subsequent reports

The Administrator shall update and resubmit the report described in paragraph (1) not less frequently than once every 5 years.

(n) Annual plan

(1) In general

The Administrator shall inform the public regarding the schedule and the resources necessary for the completion of each risk evaluation as soon as practicable after initiating the risk evaluation.

(2) Publication of plan

At the beginning of each calendar year, the Administrator shall publish an annual plan that—

(A) identifies the chemical substances for which risk evaluations are expected to be initiated or completed that year and the resources necessary for their completion;

(B) describes the status of each risk evaluation that has been initiated but not yet completed; and

(C) if the schedule for completion of a risk evaluation has changed, includes an updated schedule for that risk evaluation.

(o) Consultation with Science Advisory Committee on Chemicals**(1) Establishment**

Not later than 1 year after June 22, 2016, the Administrator shall establish an advisory committee, to be known as the Science Advisory Committee on Chemicals (referred to in this subsection as the “Committee”).

(2) Purpose

The purpose of the Committee shall be to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this subchapter.

(3) Composition

The Committee shall be composed of representatives of such science, government, labor, public health, public interest, animal protection, industry, and other groups as the Administrator determines to be advisable, including representatives that have specific scientific expertise in the relationship of chemical exposures to women, children, and other potentially exposed or susceptible subpopulations.

(4) Schedule

The Administrator shall convene the Committee in accordance with such schedule as the Administrator determines to be appropriate, but not less frequently than once every 2 years.

(p) Prior actions**(1) Rules, orders, and exemptions**

Nothing in the Frank R. Lautenberg Chemical Safety for the 21st Century Act eliminates, modifies, or withdraws any rule promulgated, order issued, or exemption established pursuant to this chapter before June 22, 2016.

(2) Prior-initiated evaluations

Nothing in this chapter prevents the Administrator from initiating a risk evaluation regarding a chemical substance, or from continuing or completing such risk evaluation, prior to the effective date of the policies, procedures, and guidance required to be developed by the Administrator pursuant to the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(3) Actions completed prior to completion of policies, procedures, and guidance

Nothing in this chapter requires the Administrator to revise or withdraw a completed risk evaluation, determination, or rule under this chapter solely because the action was completed prior to the development of a policy, procedure, or guidance pursuant to the amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act.

(Pub. L. 94-469, title I, §26, Oct. 11, 1976, 90 Stat. 2046; Pub. L. 98-80, §2(c)(2)(A), Aug. 23, 1983, 97 Stat. 485; renumbered title I, Pub. L. 99-519, §3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 114-182, title I, §§17, 19(q), June 22, 2016, 130 Stat. 499, 510; Pub. L. 117-286, §4(a)(69), Dec. 27, 2022, 136 Stat. 4313.)

Editorial Notes

REFERENCES IN TEXT

Reorganization Plan No. 3 of 1970, referred to in subsec. (g)(2), is set out in the Appendix to Title 5, Government Organization and Employees.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act, referred to in subsecs. (l)(1) and (p), is Pub. L. 114-182, June 22, 2016, 130 Stat. 492. For complete classification of this Act to the Code, see Short Title of 2016 Amendment note set out under section 2601 of this title and Tables.

AMENDMENTS

2022—Subsec. (b)(4)(E). Pub. L. 117-286 substituted “chapter 10 of title 5” for “the Federal Advisory Committee Act (5 U.S.C. App.)”.

Subsec. (b)(1). Pub. L. 114-182, §17(1), struck out “of a reasonable fee” before “from any person”, substituted “information under section 2603 of this title or a notice or other information to be reviewed by the Administrator under section 2604 of this title, or who manufactures or processes a chemical substance that is the subject of a risk evaluation under section 2605(b) of this title, of a fee that is sufficient and not more than reasonably necessary to defray the cost related to such chemical substance of administering sections 2603, 2604, and 2605 of this title, and collecting, processing, reviewing, and providing access to and protecting from disclosure as appropriate under section 2613 of this title information on chemical substances under this subchapter, including contractor costs incurred by the Administrator” for “data under section 2603 or 2604 of this title to defray the cost of administering this chapter”, struck out “Such rules shall not provide for any fee in excess of \$2,500 or, in the case of a small business concern, any fee in excess of \$100.” before “In setting a fee”, and substituted “pay such fee and the cost to the Administrator of carrying out the activities described in this paragraph” for “submit the data and the cost to the Administrator of reviewing such data”.

Subsec. (b)(2). Pub. L. 114-182, §17(2)(A), substituted “paragraph (4)” for “paragraph (1)”.

Subsec. (b)(3) to (6). Pub. L. 114-182, §17(2)(B), added pars. (3) to (6).

Subsec. (e). Pub. L. 114-182, §19(q)(1), substituted “Health and Human Services” for “Health, Education, and Welfare” wherever appearing.

Subsec. (g)(1)(A). Pub. L. 114-182, §19(q)(2), substituted “information” for “data”.

Subsecs. (h) to (p). Pub. L. 114-182, §17(3), added subsecs. (h) to (p).

1983—Subsec. (g)(2). Pub. L. 98-80 struck out “(A)” before “be in addition” and “, and (B) be compensated at the rate of pay authorized for such Assistant Administrators” after “No. 3 of 1970”.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94-469, set out as a note under section 2601 of this title.

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions in subsec. (e)(2)(B) of this section relating to annual reports to Congress, see section 3003 of Pub. L. 104-66, as amended, set out as a note under section 1113 of Title 31, Money and Finance, and pages 93 and 164 of House Document No. 103-7.

§ 2626. Development and evaluation of test methods**(a) In general**

The Secretary of Health and Human Services, in consultation with the Administrator and acting through the Assistant Secretary for Health,