

(3) \$95,000,000 for fiscal year 1991, of which not more than \$14,978,200 shall be available for research under this subchapter.

(June 25, 1947, ch. 125, §35, formerly §27, as added Pub. L. 92-516, §2, Oct. 21, 1972, 86 Stat. 998; amended Pub. L. 94-51, July 2, 1975, 89 Stat. 257; Pub. L. 94-109, Oct. 10, 1975, 89 Stat. 571; Pub. L. 94-140, §3, Nov. 28, 1975, 89 Stat. 752; renumbered §31 and amended Pub. L. 95-396, §§24(1), 25, Sept. 30, 1978, 92 Stat. 836, 838; Pub. L. 96-539, §3, Dec. 17, 1980, 94 Stat. 3195; Pub. L. 98-201, §2, Dec. 2, 1983, 97 Stat. 1380; Pub. L. 99-198, title XVII, §1768, Dec. 23, 1985, 99 Stat. 1656; Pub. L. 100-532, title VII, §701, Oct. 25, 1988, 102 Stat. 2679; renumbered §34, Pub. L. 104-170, title I, §121(1), Aug. 3, 1996, 110 Stat. 1492; renumbered §35, Pub. L. 108-199, div. G, title V, §501(f)(1), Jan. 23, 2004, 118 Stat. 422.)

CODIFICATION

Another section 1768 of Pub. L. 99-198 enacted sections 154a and 159 and amended sections 151, 154, and 157 of Title 21, Food and Drugs.

AMENDMENTS

1988—Pub. L. 100-532 amended section generally. Prior to amendment, section read as follows: "There is authorized to be appropriated to carry out this subchapter for the period beginning October 1, 1985, and ending September 30, 1986, \$68,604,200 of which not more than \$11,993,100 shall be available for research under this subchapter."

1985—Pub. L. 99-198 substituted provisions authorizing appropriations of \$68,604,200 for fiscal year 1986 of which not more than \$11,993,100 shall be available for research for former provisions which had authorized appropriations for fiscal years 1973 through 1984.

1983—Pub. L. 98-201 authorized necessary appropriations for period beginning Oct. 1, 1983, and ending Sept. 30, 1984, not in excess of \$64,200,000.

1980—Pub. L. 96-539 inserted provisions authorizing appropriations for period beginning Oct. 1, 1979, and ending Sept. 30, 1980, and for period beginning Oct. 1, 1980, and ending Sept. 30, 1981.

1978—Pub. L. 95-396, §25, substituted appropriations authorization of \$46,636,000 for period beginning Oct. 1, 1976, and ending Sept. 30, 1977, for prior authorization of \$23,600,000 for period beginning Oct. 1, 1976, and ending Mar. 31, 1977, and authorized appropriations of \$54,500,000 for period beginning Oct. 1, 1977, and ending Sept. 30, 1978, and such sums as may be necessary, limited to \$70,000,000, for period beginning Oct. 1, 1978, and ending Sept. 30, 1979.

1975—Pub. L. 94-140 authorized appropriation of \$47,868,000 to carry out provisions of this subchapter for period beginning Oct. 1, 1975, and ending Sept. 30, 1976, and \$23,600,000 for period beginning Oct. 1, 1976, and ending Mar. 31, 1977.

Pub. L. 94-109 inserted provisions authorizing appropriation of \$5,983,500 for period beginning Oct. 1, 1975 and ending Nov. 15, 1975.

Pub. L. 94-51 authorized appropriation of \$11,967,000 to carry out provisions of this subchapter for period beginning July 1, 1975, and ending Sept. 30, 1975.

EFFECTIVE DATE OF 1988 AMENDMENT

Pub. L. 100-532, title VII, §701, Oct. 25, 1988, 102 Stat. 2679, provided that amendment made by Pub. L. 100-532 is effective Oct. 1, 1988.

EFFECTIVE DATE

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

CHAPTER 6A—NATIONAL LABORATORY ACCREDITATION

Sec.
138. Definitions.

Sec.
138a. National Laboratory Accreditation Program.
138b. Accreditation.
138c. Samples.
138d. Application.
138e. Reporting.
138f. Fees.
138g. Public disclosure.
138h. Regulations.
138i. Effect of other laws.

§ 138. Definitions

As used in this chapter:

(1) Agricultural product

The term "agricultural product" means any fresh fruit or vegetable or any commodity or product derived from livestock or fowl, that is marketed in the United States for human consumption.

(2) Certificate

The term "certificate" means a certificate of accreditation issued under this chapter.

(3) Laboratory

The term "laboratory" means any facility or vehicle that is owned by an individual or a public or private entity and is equipped and operated for the purpose of carrying out pesticide residue analysis on agricultural products for commercial purposes.

(4) Pesticide

The term "pesticide" means any substance that alone, in chemical combination, or in any formulation with one or more substances, is defined as a pesticide in section 136(u) of this title.

(5) Secretary

The term "Secretary" means the Secretary of Agriculture.

(Pub. L. 101-624, title XIII, §1321, Nov. 28, 1990, 104 Stat. 3562.)

§ 138a. National Laboratory Accreditation Program

(a) Establishment of Program

The Secretary shall administer a National Laboratory Accreditation Program under which laboratories that request accreditation and conduct residue testing of agricultural products, or that make claims to the public or buyers of agricultural products concerning chemical residue levels on agricultural products, shall be determined to meet certain minimum quality and reliability standards.

(b) Standards

The Secretary of Health and Human Services, after consultation with the Secretary and the Administrator of the Environmental Protection Agency, shall establish, through regulations, standards for the National Laboratory Accreditation program¹ that shall include—

- (1) standards applicable to laboratories;
- (2) qualifications for directors and other personnel; and
- (3) standards and procedures for quality assurance programs.

¹ So in original. Probably should be capitalized.

(c) Accrediting bodies

The Secretary of Health and Human Services shall approve State agencies or private, non-profit entities as accrediting bodies to act on behalf of such Secretary in implementing the certification and quality assurance programs in accordance with the requirements of this section. In making such approvals the Secretary of Health and Human Services shall—

(1) oversee and review the performance of any accrediting body acting on behalf of the Secretary to ensure that such accrediting body is in compliance with the requirements of the certification program under this section; and

(2) have the right to obtain from an accrediting body acting on behalf of the Secretary and from any laboratory that may be certified by such a body all records and materials that may be necessary for the oversight and review required by paragraph (1).

(d) Requirements

To be accredited under this chapter, a laboratory shall—

(1) prepare and submit an application for accreditation to the Secretary; and

(2) comply with such terms and conditions as are determined necessary by the Secretary and the Secretary of Health and Human Services.

(e) Exceptions

This chapter shall not apply to—

(1) a laboratory operated by a government agency;

(2) a laboratory operated by a corporation that only performs analysis of residues on agricultural products for such corporation or any wholly owned subsidiary of such corporation and does not make claims to the public or buyers based on such analysis;

(3) a laboratory operated by a partnership that only performs analysis of residues on agricultural products for the partners of such partnership and does not make claims to the public or buyers based on such analysis; or

(4) a laboratory not operated for commercial purposes that performs pesticide chemical residue analysis on agricultural products for research or quality control for the internal use of a person who is initiating the analysis.

(Pub. L. 101-624, title XIII, §1322, Nov. 28, 1990, 104 Stat. 3562.)

§ 138b. Accreditation**(a) In general**

The Secretary shall issue certificates of accreditation to laboratories that meet the requirements of this chapter, as determined by the Secretary.

(b) Requirements for accreditation

To receive accreditation under this chapter, a laboratory shall prepare and submit an application for accreditation to the Secretary and shall complete such required tests, and meet such standards as established under section 138a of this title.

(c) Failure to meet accreditation standards

The Secretary shall deny an application for accreditation or shall revoke any existing ac-

creditation with respect to any laboratory that fails to meet the requirements for accreditation under this chapter.

(d) Limited accreditation

The Secretary may issue certificates of accreditation to laboratories that are limited to specific fields of testing.

(Pub. L. 101-624, title XIII, §1323, Nov. 28, 1990, 104 Stat. 3563.)

§ 138c. Samples**(a) Performance evaluation samples****(1) Provided by Secretary**

The Secretary shall ensure that performance evaluation samples are provided to any laboratory that has applied for accreditation under this chapter.

(2) Analysis by laboratory

A laboratory described in paragraph (1) shall analyze such performance evaluation samples and submit the results of such analysis to the Secretary, as provided for in section 138a of this title.

(3) Testing methods

Samples shall be tested by the laboratory according to methods specifically approved for such purpose by alternate methods of demonstrated adequacy or equivalence, as determined in regulations established under this chapter.

(b) Results of testing**(1) Submission of results**

The laboratory shall submit the results of the tests conducted under subsection (a) to the Secretary on forms provided by the Secretary, on or before the date determined by the Secretary.

(2) Evaluation of tests

The Secretary shall evaluate the results of such tests achieved by the laboratory and shall determine whether such laboratory is capable of undertaking an accurate analysis of chemical residues in agricultural products.

(c) Review of accreditation

The Secretary shall ensure that performance evaluation samples for analysis are provided to laboratories accredited under this chapter not less than two times a year.

(Pub. L. 101-624, title XIII, §1324, Nov. 28, 1990, 104 Stat. 3564.)

§ 138d. Application**(a) Contents of application**

An application for accreditation under this chapter shall be prepared and submitted to the Secretary and shall include—

(1) the name and address of the laboratory;

(2) the name and address of the owners and managers of such laboratory;

(3) a statement concerning the type of analysis the laboratory intends to conduct;

(4) a brief history of the laboratory and its previous operations; and

(5) such other information as may be required by the Secretary.