

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

(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 applica-

tion 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 accreditation 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) of this section 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.

(b) Restrictions on submission of application

A laboratory that has been denied, or has lost, accreditation under this chapter shall not reapply for accreditation until the expiration of at least 6 months after such denial or loss of accreditation. Corrective actions taken by the laboratory to address deficiencies upon which the denial or loss of accreditation was based must accompany the reapplication.

(Pub. L. 101-624, title XIII, §1325, Nov. 28, 1990, 104 Stat. 3564.)

§ 138e. Reporting

(a) In general

Each laboratory or individual that performs, brokers, or otherwise arranges for the performance of a pesticide chemical analysis of food shall prepare and submit a report, simultaneously to the Secretary, the Secretary of Health and Human Services, and to the owner of such food, that shall contain any finding of pesticide chemical residues in such food—

- (1) for which no chemical residue tolerance or exemption has been established;
- (2) that is in excess of residue tolerances; or
- (3) for which the chemical residue tolerance has been revoked or the chemical residue is otherwise not permitted by the Environmental Protection Agency.

(b) Timing of report

A laboratory shall submit the report required under subsection (a) of this section to the Secretary, the Secretary of Health and Human Services, and the owner of such food as soon as practicable after the completion of the analysis of such food.

(c) Guidelines

The Secretary shall adopt standardized reporting guidelines to be applied to laboratories under this section and shall provide such guidelines to laboratories accredited under this chapter, as well as other sources of information regarding applicable pesticide chemical tolerances.

(Pub. L. 101-624, title XIII, §1326, Nov. 28, 1990, 104 Stat. 3565.)

§ 138f. Fees

(a) In general

At the time that an application for accreditation is received by the Secretary and annually thereafter, a laboratory seeking accreditation by the Secretary under the authority of this chapter, the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), or the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) shall pay to the Secretary a nonrefundable accreditation fee. All fees collected by the Secretary shall be cred-

ited to the account from which the expenses of the laboratory accreditation program are paid and, subject to subsection (e) of this section, shall be available immediately and remain available until expended to pay the expenses of the laboratory accreditation program.

(b) Amount of fee

The fee required under this section shall be established by the Secretary in an amount that will offset the cost of the laboratory accreditation programs administered by the Secretary under the statutory authorities set forth in subsection (a) of this section.

(c) Reimbursement of expenses

Each laboratory that is accredited under a statutory authority set forth in subsection (a) of this section or that has applied for accreditation under such authority shall reimburse the Secretary for reasonable travel and other expenses necessary to perform onsite inspections of the laboratory.

(d) Adjustment of fees

The Secretary may, on an annual basis, adjust the fees imposed under this section as necessary to support the full costs of the laboratory accreditation programs carried out under the statutory authorities set forth in subsection (a) of this section.

(e) Appropriations prerequisite

No fees collected under this section may be used to offset the cost of laboratory accreditation without appropriations made under subsection (f) of this section.

(f) Authorization of appropriations

There are authorized to be appropriated each fiscal year such sums as may be necessary for laboratory accreditation services under this section.

(Pub. L. 101-624, title XIII, §1327, Nov. 28, 1990, 104 Stat. 3565; Pub. L. 102-237, title X, §1017, Dec. 13, 1991, 105 Stat. 1904.)

REFERENCES IN TEXT

The Federal Meat Inspection Act, referred to in subsec. (a), is titles I to IV of act Mar. 4, 1907, ch. 2907, as added Dec. 15, 1967, Pub. L. 90-201, 81 Stat. 584, and amended, which are classified generally to subchapters I to IV (§601 et seq.) of chapter 12 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 601 of Title 21 and Tables.

The Poultry Products Inspection Act, referred to in subsec. (a), is Pub. L. 85-172, Aug. 28, 1957, 71 Stat. 441, as amended, which is classified generally to chapter 10 (§451 et seq.) of Title 21. For complete classification of this Act to the Code, see Short Title note set out under section 451 of Title 21 and Tables.

AMENDMENTS

1991—Pub. L. 102-237 amended section generally, in subsec. (a), inserting provisions relating to Federal Meat Inspection Act and Poultry Products Inspection Act and provisions relating to crediting and availability of fees, in subsec. (b), substituting provisions relating to fee under this section for provisions relating to fee under subsec. (a) of this section, and provisions relating to laboratory accreditation programs administered by Secretary under statutory authorities set forth in subsec. (a) of this section for provisions relating to program established under this chapter, in sub-