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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 102, 104, 105, and 116

[Docket No. 93–072–2]

Viruses, Serums, Toxins, and Analogous Products; Licenses, Inspections, Records, and Reports

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the regulations under the Virus-Serum-Toxin Act to clarify certain provisions concerning licenses, inspections, records, and reports. The effect of the rule is to ensure that licensees are aware of the fact that licenses are issued on the condition that the licensee permit inspection of establishments, products, and records, and that a licensee must have at least one product license in order to maintain a valid establishment license. Failure to permit inspection will make the license subject to suspension or revocation. We are also amending the regulations to specify the types of records and reports that must be available for inspection including records describing product development and preparation and market suspensions and recalls. Finally, we are amending the regulations to require that APHIS receive notification immediately if there are indications which raise questions regarding purity, safety, potency, or efficacy of a product, or if it appears there may be a problem regarding the preparation, testing, or distribution of a product. The rule is necessary to clarify and simplify certain provisions of the regulations and to describe required records with greater specificity.

EFFECTIVE DATE: November 8, 1996.

FOR FURTHER INFORMATION CONTACT: Dr. David A. Espeseth, Deputy Director, Veterinary Biologics, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737 1237; 301–734–8245.

SUPPLEMENTARY INFORMATION:

Background

The Virus-Serum-Toxin Act of 1913 (21 U.S.C. 151–159, hereinafter the Act), as amended, is intended to ensure that veterinary biological products shipped in or from the United States are not worthless, contaminated, dangerous, or harmful. To achieve that purpose, the Act requires that such products be prepared in compliance with USDA regulations at an establishment holding an unsuspended and unrevoked USDA establishment license. No products may be imported into the United States without a permit issued by the Administrator. Provisions regarding veterinary biological product licenses, license suspensions, and inspections appear in the regulations at 9 CFR parts 102, 105, and 116.

On March 6, 1995, we published in the Federal Register (60 FR 12159–12162, Docket No. 93–072–1) a proposal to amend parts 102, 104, 105, and 116. We proposed to amend the regulations to clarify that licenses are issued on the condition that the licensee permit inspection of establishments, products, and records, and that a licensee must have at least one product license in order to maintain a valid establishment license. Failure to permit inspection will make the license subject to suspension or revocation. We also proposed to amend the regulations to broaden the scope of records and reports to include records describing product development and preparation, market suspensions, and recalls, which must be available for inspection. Finally, we proposed to amend the regulations to require that APHIS be notified immediately if there are indications which raise questions regarding purity, safety, potency, or efficacy of products, or if a biological product appears to be unsatisfactory or is found to have been prepared, tested, or distributed in violation of the Act and regulations. The rule is necessary to clarify and simplify certain provisions of the regulations.

We solicited comments concerning our proposal for 60 days ending May 5, 1995. We received nine comments by that date. They were from biologics producers, a biologics consultant, and a national trade association. We carefully considered all of the comments we received. They are discussed below.

One commenter expressed general approval of the rule as proposed. The commenter, however, requested definitions of ''raw data,'' ''data collection,'' ''method for changing raw data,'' and ''manufacturing records'' under proposed § 105.1 and ''unsatisfactory'' and ''immediately'' under proposed § 116.5(b).

In response to this comment, APHIS notes that the terms ''raw data,'' ''data collection,'' ''methods for changing raw data,'' and ''manufacturing records'' were not included in the proposed rule. Therefore, APHIS believes that it would be inappropriate for the agency to define these terms. APHIS believes that the use of the phrase ''to be unsatisfactory'' is redundant with the phrase ''to have been prepared, tested, or distributed in violation of the VSTA and regulations'' which appears in the same sentence and has therefore deleted it from the regulations to improve clarity and avoid confusion as to its meaning when used in this context. Similarly, APHIS is removing the reference to violation of the Act or regulations and changing the language regarding preparation, testing, and distribution to more accurately reflect the intent of paragraph (b) of § 116.5. The term ''immediately'' is self-explanatory in that notification should occur without delay at the time a question regarding product purity, safety, potency, or efficacy is raised. Therefore, APHIS is not adding definitions of these terms in response to this comment.

One commenter requested that the rule for license termination after 5 years of inactivity be withdrawn and replaced with a provision for recertification of the master seed to save the expense of relicensure. The commenter explained that there are situations in which a vaccine for which there has been no need suddenly comes into demand because of a disease condition. The example presented was an erysipelothrix vaccine in turkeys, the need for which is apparently resurfacing after a lapse of 10 years. Other examples of resurfacing vaccines were given, including variant chicken pox in the midwest and California, and Newcastle Disease Bronchitis Vaccine B_1 Type B_1 Strain. The commenter indicated that the latter vaccine has not been made for

17 years, but now has a significant international market.

In response to this commenter, the current regulation provides for the producer to show intent to resume production within 6 months of notification or have the product license or permit terminated. APHIS proposed to amend the regulation to provide the opportunity for the producer to resume production within 6 months of notification or ''within a mutually agreeable period'' should the producer have evidence that the vaccine might be needed in the near future. The proposed amendment allows the licensee to present a case to support a mutually agreeable period of longer than 6 months before production is resumed, if desired. If production is not resumed, the product license would be terminated without prejudice and could be reissued at a later date if master seed and master stocks are maintained and a market develops for the product. The original Outline of Production and licensing data could be resubmitted to support such applications and should only require updating to meet new licensing requirements not addressed when the product was originally licensed. The license applicant should consult with APHIS for guidance prior to applying for reissuance of such licenses. APHIS does not believe that a product license should be maintained when no product is produced or no establishment is maintained to support continuation of licensure. No change to the regulations is made in response to this comment.

One commenter felt that the language in § 116.1 lacked specificity. Another commenter stated that the types of records required for product development and manufacture should be specified. In response to these commenters, APHIS notes that the proposed amendment to § 116.1 adds permittees under the regulations and specifies the types of records that are to be maintained at the permittees place of business. No change to the regulations is made in response to these commenters.

Eight commenters raised concerns about the lack of clear criteria in the proposal for the reporting of production data and consumer complaints. One of the commenters raised the issue of how the firms' submissions of consumer reports will be handled under the Freedom of Information Act (FOIA). Another commenter indicated that many consumer reports may deal with problems related to consumer misuse that is beyond the control of the manufacturer. Consumer reports relevant to this regulation would only be those where there is a valid product-related complaint. The commenter also inquired into how complaints will be resolved by the agency and what the relationship was between consumer reports and the agency's proposed post-licensing monitoring program. One commenter stated that records related to consumer reports are already available for inspection at licensed establishments and questioned whether the submission of additional reports was necessary. Finally, several commenters suggested that the additional reporting requirements would increase the level of paperwork required of both APHIS and the manufacturer. These commenters expressed general concerns about the need to reduce paperwork submissions in order to reduce agency burden and to facilitate agency review of and response to license applications.

In response to these comments, APHIS believes that its intent with regard to reporting of certain consumer complaint reports was misunderstood. The proposed rule was not intended to require the implementation of a comprehensive postlicensing monitoring program but was only intended to ensure that licensees inform APHIS when it appears that a licensed product that has been released for marketing is involved in an unusually high number of consumer complaints or appears or has been found to be in violation of the Act or regulations. Informing APHIS under such situations provides an early warning of possible emerging product-related problems and ensures prompt action if there is a problem. Open communication between licensees and APHIS is essential for accurate responses to consumer inquiries and a rapid resolution of such situations. In response to the comment regarding access to consumer complaints under FOIA, all confidential business information would be protected. APHIS is currently working on regulations regarding FOIA requests related to the monitoring of products.

Based on the comments, APHIS is revising proposed § 116.5 concerning the submission of consumer reports with a more general statement to clarify our intent that APHIS be notified when there are indications which raise questions regarding the purity, safety, potency, or efficacy of a product, or if it appears that there may be a problem regarding the preparation, testing, or distribution of a product.

Some examples of when APHIS should be informed include when there are product-related data, information, or reports to show that a serial is contaminated, that use of a product is associated with a high incidence of adverse reactions, or that a product is associated with the failure to protect against disease. It would be necessary to provide available information describing circumstances surrounding these situations such as contributory factors and plausible options to help resolve the problem. Other examples of such circumstances when notification would be warranted are when consumer reports suggest that the use of a product may pose a risk to the public health, interest, or safety.

APHIS is removing the reference to consumer reports from paragraph (b) of § 116.5 of the proposed rule by removing the phrase ''consumer reports concerning the use of products'' and substituting the phrase ''there are indications which.'' This revision is intended to remove concerns about the reporting of all claims, including those which might be considered frivolous or invalid. The reference to ''immediately report'' has also been revised to read ''immediately notify APHIS concerning'' to provide greater flexibility in the manner in which information is provided to APHIS including telephone, E-mail, facsimile, or letter rather than by ''report'' which suggests a more formal communication. We have included in the regulations for convenience purposes the addresses and phone numbers for these alternative methods of notification. These changes should make it clear that this rule codifies current program practice and does not result in a net increase of the paperwork burden imposed on the manufacturer and the agency.

One commenter objected to use of the term, ''When requested by the Administrator,'' in § 116.5, paragraph (a). The same commenter believed that APHIS should define the rationale for submission more specifically. Another commenter objected to the use of terms, ''complete information'' and ''including but not limited to'' for being ambiguous.

In response to these comments, APHIS notes that these terms are currently used in the regulations in part 116 without further definition. In addition, APHIS believes that the rationale of proposed § 116.5, paragraph (a), is not intended to be significantly different from that of current §§ 116.1 and 116.5. These regulations were last amended in 1974 (39 FR 16853–16873, Docket No. 74–10880, May 10, 1974). Current § 116.1 reads in relevant part as follows:

> Each licensee * * * shall maintain detailed records of information necessary to give a complete accounting of the activities within each establishment. Such activities shall include, but shall not be limited to the items enumerated in this part.

(a) Records shall be made concurrently with the performance of successive steps in the preparation of a biological product. Such records shall include the date and where critical, the time that each essential step was taken, the identity and quantity of ingredients added or removed at each step, and any loss or gain from start to finish in such preparation.

Current § 116.5 reads in relevant part as follows:

When required by the Administrator, reports containing accurate information of production activities in each establishment * * * shall be prepared and forwarded to APHIS. Records necessary to make such reports shall be maintained in each establishment.

The proposed amendment to § 116.5, paragraph (a), merely specifies in greater detail the type of information that should be maintained or submitted to APHIS. As a commenter stated previously, licensed establishments already make available records of consumer reports for inspection. Therefore, much, if not all, of this information should already be available or should already have been made available to APHIS. No change to the regulations is made in response to these comments.

Based on the rationale set forth in the proposed rule and in this document, we are adopting the provisions of the proposal as a final rule, with the changes discussed in this document.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

The rule amends the regulations in 9 CFR parts 102, 104, 105, and 116 to clarify existing provisions concerning licenses, inspections, records, and reports. Licenses are issued on condition that the licensee permit inspection of establishments, products, and records. The rule provides that the failure to permit such inspection will make the license subject to suspension or revocation. In order to hold a valid establishment license, licensees are required to have at least one unexpired, unsuspended, and unrevoked product license. Otherwise, the establishment license will be invalid. We are also making amendments concerning the content of records and reports and the availability of their inspection.

The rule will make clear and unambiguous certain regulatory provisions. No new requirements are added in the rule. Therefore, no adverse economic impact is anticipated to result from the rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. There are no administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB), and there are no new requirements. The assigned OMB control number is 0579–0013.

Regulatory Reform

This action is part of the President's Regulatory Reform Initiative, which, among other things, directs agencies to remove obsolete and unnecessary regulations and to find less burdensome ways to achieve regulatory goals.

List of Subjects

9 CFR Part 102

Animal biologics, Reporting and recordkeeping requirements.

9 CFR Part 104

Animal biologics, Imports, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 105

Animal biologics.

9 CFR Part 116

Animal biologics, Reporting and recordkeeping requirements.

Accordingly, 9 CFR parts 102, 104, 105, and 116 are amended as follows:

PART 102—LICENSES FOR BIOLOGICAL PRODUCTS

1. The authority citation for part 102 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.2(d).

2. In § 102.2, the text is designated as paragraph (a) and a new paragraph (b) is added to read as follows:

§ 102.2 Licenses required.

* * * * *

(b) An applicant who applies for an establishment license must also apply for at least one product license. An establishment license will not be issued without a license authorizing the production of a biological product in the establishment.

3. In § 102.4, paragraph (f) is revised, paragraph (g) is redesignated as paragraph (h), and new paragraph (g) is added to read as follows:

§ 102.4 U.S. Veterinary Biologics Establishment License.

* * * * *

(f) When a licensee no longer holds at least one unexpired, unsuspended, or unrevoked product license authorizing the preparation of a biological product, or is in the process of obtaining a product license, the establishment license shall no longer be valid and shall be returned to the Administrator. In the case where an establishment license expires or is suspended or revoked, any product license authorizing preparation of a product at such establishment shall be invalid indefinitely or for as long as the suspension is in effect.

(g) Any license issued under this part to establishments in which biological products are prepared shall be issued on condition that the licensee permit the inspection of such establishments, products, product preparation, and all relevant records as provided in part 115 of this subchapter. Failure to permit inspection may result in the license being suspended or revoked.

* * * * *

PART 104—PERMITS FOR BIOLOGICAL PRODUCTS

4. The authority citation for part 104 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.2(d).

5. In § 104.6, paragraph (b), the words ''Veterinary Services'' are removed and the words ''Animal and Plant Health Inspection Service'' are added in their place.

6. In part 105, the heading for the part is revised to read as follows:

PART 105—SUSPENSION, REVOCATION, OR TERMINATION OF BIOLOGICAL LICENSES OR PERMITS

7. The authority citation for part 105 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.2(d).

8. In § 105.1, paragraphs (a)(4) and (a)(5) are redesignated paragraphs (a)(5) and (a)(6), new paragraph (a)(4) is added, and redesignated paragraph (a)(5) is revised to read as follows:

§ 105.1 Suspension or revocation.

* * * * *

(a) * * *

(4) The licensee, permittee, or the foreign manufacturer has failed to maintain and make available for inspection records in connection with the development and preparation of product, has failed to provide complete and accurate information when requested, or has failed to provide complete and accurate information in the Outline of Production or in reports and records;

(5) The licensee or permittee has violated or failed to comply with any provision of the Virus-Serum-Toxin Act or the regulations in this subchapter;

* * * * *

9. Section 105.4 is revised to read as follows:

§ 105.4 Termination of licenses and permits for inactivity.

(a) If a biological product has not been prepared by a licensee, or imported by a permittee for a period of 5 years or more, the Administrator may require the licensee to show intent to resume production, or the permittee to show intent to resume importation, within 6 months of notification. If the licensee does not resume preparation, or the permittee does not resume importation, within 6 months of notification, or within a mutually agreeable period, the product license, or permit, may be terminated by the Administrator.

(b) When a license or permit is terminated, the licensee or permittee shall continue to be subject to the applicable records provisions of § 116.8.

10. In part 116, the heading for the part is revised to read as follows:

PART 116—RECORDS AND REPORTS

11. The authority citation for part 116 continues to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.2(d).

12. In § 116.1, paragraphs (a), (b), and (c) are redesignated as paragraphs (a)(1), (a)(2), and (a)(3), respectively; redesignated paragraph (a)(1) is revised; the introductory paragraph is designated as paragraph (a) and is revised; and new paragraphs (b) and (c) are added to read as follows:

§ 116.1 Applicability and general considerations.

(a) Each licensee, permittee, and foreign manufacturer of biological products imported into the United States shall maintain, at the licensed or foreign establishment in which the products are prepared, detailed records of information necessary to give a complete accounting of all the activities within each establishment. Such records shall include, but shall not be limited to, the items enumerated in this part.

(1) Records shall be made concurrently with the performance of successive steps in the development and preparation of biological products, including new products under development. Such records shall include the date and where critical, the time that each essential step was taken, the identity and quantity of ingredients added or removed at each step, and any gain or loss of product from the beginning to the end of product preparation.

* * * * *

(b) In the case of imported products, each permittee shall maintain at the permittee's place of business detailed and accurate records that are relevant to each imported product and that include, but are not limited to, importation documents, sampling records, test summaries, shipping records, and inventory and disposition records as required in § 116.2.

(c) When authorized by the Administrator, the licensee, permittee, or foreign manufacturer may maintain and retain records required under this part at an alternative location. Such authorization shall be confirmed by the filing of an addendum to the plot plan legend. The addendum shall list the location of the records and the condition of their storage and shall permit the inspection of the records by APHIS inspectors, or foreign inspectors acting on behalf of APHIS.

(Approved by the Office of Management and Budget under control number 0579–0013)

§§ 116.2, 116.3, 116.4, and 116.6 [Amended]

13. At the end of §§ 116.2, 116.3, 116.4, and 116.6, the reference to OMB control number ''0579–0059'' is removed and the number ''0579–0013'' is added in its place.

14. Section 116.5 is revised to read as follows:

§ 116.5 Reports.

(a) When required by the Administrator, reports containing accurate and complete information concerning biological products, including but not limited to, product development and preparation, and market suspensions and recalls, shall be prepared and submitted to the Animal and Plant Health Inspection Service by the licensee, permittee, or foreign manufacturer (whose products are being imported or offered for importation). Unless otherwise authorized by the Administrator, records necessary to make such reports shall be maintained in each establishment.

(b) If, at any time, there are indications which raise questions regarding purity, safety, potency, or efficacy of a product, or if it appears that there may be a problem regarding preparation, testing, or distribution of a product, the licensee, permittee, or foreign manufacturer shall immediately notify Veterinary Biologics Field Operations, APHIS, 223 South Walnut Avenue, Ames, Iowa 50010, concerning the circumstances and the action taken, if any. Notification may be either by mail, electronic mail, facsimile, or telephone. If by electronic mail, vbfo@aphis.usda.gov. If by facsimile, Area Code (515) 232–7120. If by telephone, Area Code (515) 232–5785.

(Approved by the Office of Management and Budget under control number 0579–0013)

15. In § 116.7, the second sentence is revised to read as follows:

§ 116.7 Test records.

* * * Summaries of such tests shall be prepared from such records and submitted to the Animal and Plant Health Inspection Service using APHIS Form 2008 or an acceptable equivalent form prior to release of the serial or subserial. * * *

* * * * *

16. Section 116.8 is revised to read as follows:

§ 116.8 Completion and retention of records.

All records (other than disposition records) required by this part shall be completed by the licensee, permittee, or foreign manufacturer before any portion of a serial of any product may be marketed in the United States or exported. All records shall be retained at the licensed or foreign establishment or permittee's place of business for a period of two years after the expiration date of a product, or for such longer period as may be required by the Administrator.

(Approved by the Office of Management and Budget under control number 0579–0013)

Done in Washington, DC, this 4th day of October 1996.

A. Strating,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–25931 Filed 10–8–96; 8:45 am]

BILLING CODE 3410–34–P

FEDERAL RESERVE SYSTEM

12 CFR Part 245

[Regulation V; Docket No. R–0928]

Loan Guarantees for Defense Production

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is repealing its Regulation V on loan guarantees for defense production as obsolete. This action does not represent any policy change, but rather eliminates an outmoded regulation and reduces regulatory burden.

EFFECTIVE DATE: October 9, 1996.

FOR FURTHER INFORMATION CONTACT: Oliver Ireland, Associate General Counsel (202–452–3625), Heatherun Allison, Attorney (202–452–3565), Legal Division; for users of the Telecommunications Device for the Deaf (TDD) *only*, Dorothea Thompson (202–452–3544); Board of Governors of the Federal Reserve System, Washington, DC 20551.

SUPPLEMENTARY INFORMATION:

I. Background

Pursuant to Section 303 of the Riegle Community Development and Regulatory Improvement Act of 1994, requiring the Board of Governors of the Federal Reserve System (the Board) to conduct a review of its regulations and written policies in order to improve efficiency, reduce unnecessary costs, eliminate unwarranted constraints on credit availability, and to remove inconsistencies and outmoded and duplicative requirements, the Board proposed to repeal Regulation V, concerning the loan guarantee program under the Defense Production Act of 1950 (50 U.S.C. app. 2061) (the Act). The Board requested public comment on this proposed regulatory change on May 28, 1996 (61 FR 26471). Board staff also solicited the views of the guaranteeing departments and agencies (as defined in the Act) consistent with Executive Order 12919 (June 3, 1994) and Executive Order 10789 (November 14, 1958) (as amended), implementing the Act.

Authority for Regulation V

The Board promulgated Regulation V (12 CFR 245) pursuant to the Act ''to facilitate the financing of contracts or other operations deemed necessary to national defense production.'' Section 301(a)(1) of the Act allows the President to authorize ''guaranteeing agencies'' to enter into guarantees with public or private financing institutions concerning contracts ''deemed by the guaranteeing agency to be necessary to expedite or expand production and deliveries or services under Government contracts for the procurement of industrial resources or critical technology items essential to the national defense, or for the purpose of financing any contractor, subcontractor or other person in connection with or in contemplation of the termination, in the interest of the United States, of any contract made for the national defense; * * * .'' Section 301(a)(1) of the Act defines ''guaranteeing agencies'' as the Department of Defense, the Department of Energy, the Department of Commerce, ''and such other agencies of the United States engaged in procurement for the national defense as he may designate.''

Exec. Order No. 12919 (1994) provides that ''the head of each Federal department or agency engaged in procurement for the national defense * * * and the President and chairman of the Export-Import Bank of the United States'' is authorized to guarantee public or private financing institutions as provided in Section 301 of the Act.[1] In furtherance of this authorization, Exec. Order No. 12919 provides that ''The Board of Governors of the Federal Reserve System is authorized, after consultation with heads of guaranteeing departments and agencies, the Secretary of the Treasury, and the Director, OMB, to prescribe regulations governing procedures, forms, rates of interest, and fees for [loan] guarantee contracts.'' Exec. Order No. 12919, 59 FR 29525 (1994).[2] The Board exercised this authorization in implementing Regulation V in the 1950s. Regulation V was modified and streamlined in 1979.

Purpose of Regulation V

The loan guarantee provisions of the Act were intended to permit defense agencies to enter into defense-related contracts without regard to whether appropriations had been made for the underlying projects. Without the appropriations, defense agencies would lack the legal authority to make progress payments to defense contractors. Without progress payments, contractors would not have the working capital to perform their contracts unless they could obtain financing from private banking institutions, which might be reluctant to lend for the performance of contracts if the funds for the contract had not been appropriated. Thus, while the Act contemplates that defense-contract funding would be obtained from private banks, the loan guarantees provisions of the Act would enable the funding and therefore the continued production of items deemed necessary to the national defense by ensuring private banks of repayment when the contract was completed. Regulation V sets forth applicable procedures, forms, fees, charges and rates of interest for these loan guarantees, in which a Federal Reserve Bank acts as the fiscal agent of one or more specified federal departments or agencies for the guarantee by that department or agency of a defense production loan made by a private financing institution.

Decline in Use of Regulation V

The Act and the Executive Orders implementing it have periodically expired and subsequently been reauthorized. However, in 1975, the Act was amended to make the guarantee provisions unnecessary for most practical purposes. These amendments provided that ''all authority hereby or hereafter extended under title III [relating to expansion of productive capacity and supply, including loan guarantee provisions] shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.'' 50 U.S.C. app. 2166(a). Thus, under the 1975 amendments, defense agencies that have authority to authorize loan guarantees have authority to do so only if funds have been appropriated for the contract in question. Once funds have been appropriated, however, there is little need for the guarantee, because the appropriated funds can be paid timely in accordance with the defense contracts. Notwithstanding the 1975 amendments, the loan guarantee

[1] The ''head of each Federal department or agency engaged in procurement for the national defense'' is defined as the head of each of the departments and agencies listed in Exec. Order No. 10789 (1958), consisting of the following Departments: Defense, Army, Navy, Air Force, Treasury, Interior, Agriculture, Commerce, Transportation, Nuclear Regulatory Commission, General Services Administration, National Aeronautics & Space Administration, Tennessee Valley Authority, General Printing Office, and Federal Emergency Management Agency. Exec. Order No. 10789, 23 FR 8897 (1958), as amended.

[2] A similar provision was formerly set forth in Section 302(c) of Exec. Order No. 10480 (1953). Exec. Order No. 10480 was revoked by Exec. Order No. 12919 (1994).