Formerly, the special unit for absorbed dose was the rad 1 rad = .01 J/kg = .01 Gy*Ionizing radiation.*

Any type of radiation consisting of charged particles or uncharged particles, or both, that as a result of physical interaction, creates ions by either primary or secondary processes. Charged particles could be positive or negative electrons, protons, or other heavy ions, and uncharged particles could be X-rays, gamma rays, or neutrons. (Note: positive electrons, protons, heavy ions, or neutrons are not approved for food irradiation.)

Irradiation

The purposeful application of ionizing radiation (gamma rays, x-rays, or electrons) to a product (device or material) to achieve a desired benefit. Gamma rays in commercial irradiation come from radioactive cobalt-60 (^{60}Co) or cesium-137 (^{137}Cs). X-rays (technically referred to as bremsstrahlung) are obtained using high energy electrons from an electron accelerator striking a target. Electrons from an accelerator can also be used to penetrate the product directly.

Kilogray (kGy)

Measure of absorbed dose. 1kGy = 1,000 Gy

Label Dosimeter

A device that can be affixed to an article to be irradiated, and which exhibits a quantifiable change in property which can be related to absorbed dose. This change in property can be measured in situ. (Note: as of 1994, no such devices that have the properties of a dosimeter are commercially available for the levels appropriate to quarantine treatments.)

Measurement Traceability

The ability to demonstrate and document on a continuing basis that the measurement results from a particular measurement system are in agreement with comparable measurement results obtained with a national standard (or some identifiable and accepted standard) to a specified uncertainty.

Pest (Plant)

Any biotic agent capable of causing damage to plants or plant products.

Phytosanitary Treatment

Subjecting or exposing a plant or plant product to a process, action, chemical or a physical influence proved to have a measurable deleterious effect on pest organisms.

Probit 9 (Mortality)

A statistical estimation of 99.99683 percent mortality in a population of live organisms, corresponding to a survival rate of 32 individuals per million.

Process Load

A volume of material with a specified loading configuration irradiated as a single entity.

Quarantine Security

A management decision concerning the safety of a defined level of pest risk. Additional mitigation is not required when quarantine security is achieved.

Rad (rad or Radiation Absorbed Dose)

Special unit for absorbed dose that is being superseded by the gray (Gy)

1 rad = 0.01 J/kg = 0.01 Gy

1 kilorad (krad) = 10 J/kg = 10 Gy

1 megarad (Mrad) = 1,000 J/kg = 1,000 Gy = 10 kGy

1Gy = 100 rads

1 kilogray = 100,000 rads

Radiation-Sensitive Indicators

Materials such as coated or impregnated adhesive-backed substrates, inks, or coatings that may be affixed to, or printed on the irradiation container and that undergo a visual change when exposed to ionizing radiation. These indicators, sometimes referred to as go/no-go indicators, are not dosimeters and are not a substitute for proper dosimetry.

Systems Approach

A combination of multiple safeguards, treatments or other mitigation measures. At least two mitigation measures must act independently to reduce risk.

Validation

Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product (quarantine security) meeting its predetermined specifications and quality characteristics.

Authority: 7 U.S.C. 150dd, 150ee, 150ff, 151–167, 450, 2803, and 2809; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, 371.2(c).

Done in Washington, DC, this 8th day of May 1996.

Terry L. Medley,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96–12185 Filed 5–14–96; 8:45 am]

BILLING CODE 3410–34–P

FEDERAL RESERVE SYSTEM

12 CFR Part 211

[Regulation K; Docket No. R–0911]

International Banking Operations

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: This final rule amends the provisions of Regulation K regarding interstate banking operations of foreign banking organizations. The Riegle-Neal Interstate Banking and Branching Efficiency Act of 1994 (Interstate Act) removed geographic restrictions on interstate banking by foreign banks effective September 29, 1995, and requires certain foreign banks without U.S. deposit-taking offices to select a home state for the first time. The final rule requires these foreign banks to select a home state by June 30, 1996, and removes outdated restrictions on certain mergers by U.S. bank subsidiaries of foreign banks outside the home state of the foreign bank. Obsolete and superseded provisions of Regulation K concerning home state selection also are deleted.

EFFECTIVE DATE: May 9, 1996.

FOR FURTHER INFORMATION CONTACT: Ann E. Misback, Managing Senior Counsel (202/452–3788), Douglas M. Ely, Senior Attorney (202/452–5289), Andres L. Navarrete, Attorney (202/452–2300), Legal Division; Michael G. Martinson, Assistant Director (202/452–3640), Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System. For users of Telecommunication Device for the Deaf [TDD] *only,* please contact Dorothea Thompson (202/452–3544), Board of Governors of the Federal Reserve System, 20th and C Streets NW., Washington, D.C. 20551.

SUPPLEMENTARY INFORMATION:

The Interstate Act amended section 5 of the International Banking Act of 1978 (IBA), which governs interstate banking and branching operations of foreign banks. The Interstate Act also amended the Bank Holding Company Act of 1956 (BHC Act), the Federal Deposit Insurance Act and several other statutes regarding interstate banking operations of bank holding companies, national banks and state banks. In order to implement certain of these changes, the final rule amends the provisions of Regulation K regarding interstate banking operations of foreign banking organizations (12 CFR 211.22).

On December 26, 1995, the Board of Governors of the Federal Reserve

System (the Board) requested public comment on a proposed rule (the Proposed Rule) that would require foreign banks with only agencies and subsidiary commercial lending companies in the United States to select a home state, or have a home state designated by the Board. 60 FR 67100. The Proposed Rule also would remove a restriction on the ability of foreign banks to effect major bank mergers through U.S. subsidiary banks located outside the foreign banks' home states, and would delete certain outdated rules governing home state selection.

The comment period ended on February 5, 1996. The Board received a single public comment on the Proposed Rule from a trade association. The Board has considered the comment and has made changes to address it in the final rule. Except as discussed below, the Board's final rule remains unchanged from the Proposed Rule. In addition, the Board requested and received comments on other aspects of the Interstate Act as it applies to foreign banks. The Board will consider these comments in connection with future review of the provisions of Regulation K concerning the interstate operation of foreign banks.

The commenter generally supported the provisions of the Proposed Rule, including its provisions requiring certain foreign banks to select a home state as contemplated by the Interstate Act. The commenter suggested, however, that the deadline for home state selection by these banks be 60 days from the publication of the final rule, rather than March 31, 1996, as proposed in the Proposed Rule. The commenter requested this extension in order to give these banks adequate time to assess the consequences of their decision.

Although the Interstate Act removed the geographic restrictions of the IBA on the interstate acquisition of banks by foreign banks, the home state of a foreign bank continues to affect its options for establishing additional branches in the United States under the IBA. In particular, the location of a foreign bank's home state is a factor determining the ability of the foreign bank to establish further interstate branches pursuant to section 5 (a)(1) and 5 (a)(2) of the IBA, as amended by the Interstate Act. 12 U.S.C. § 3103 (a)(1), (a)(2).

Accordingly, the final rule allows additional time for home state selection by establishing June 30, 1996, as the deadline for such selection. This extension affords foreign banks affected by the rule ample time in which to make an informed home state selection.

The proposed rule provided that, in the event a foreign bank required to select a home state fails to do so, the Board would exercise its authority to determine a foreign bank's home state. In such cases, the Board generally will designate as a foreign bank's home state the state in which the total assets of all its offices, net of claims on affiliates or other offices of the foreign bank, is the largest, as reflected in the foreign bank's most recent report of condition, unless other circumstances warrant designation of a different home state.

Paperwork Reduction Act

In accordance with section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Ch. 35; 5 CFR 1320 Appendix A.1), the Board reviewed the rule under the authority delegated to the Board by the Office of Management and Budget. No collections of information pursuant to the Paperwork Reduction Act are contained in the rule.

Regulatory Flexibility Act Analysis

Pursuant to section 605(b) of the Regulatory Flexibility Act (Pub. L. 96–354, 5 U.S.C. 601 *et seq.*), the Board certifies that the final rule would not have a significant economic impact on a substantial number of small entities that are subject to its regulation.

List of Subjects in 12 CFR Part 211

Exports, Federal Reserve System, Foreign banking, Holding companies, Investments, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, the Board amends 12 CFR Part 211 as set forth below:

PART 211—INTERNATIONAL BANKING OPERATIONS (REGULATION K)

1. The authority citation for Part 211 continues to read as follows:

Authority: 12 U.S.C. 221 *et seq.*, 1818, 1841 *et seq.*, 3101 *et seq.*, 3901 *et seq.*

2. In § 211.22, paragraph (a) is revised; paragraph (c) is removed; and paragraph (d) is redesignated as paragraph (c) to read as follows:

§ 211.22 Interstate banking operations of foreign banking organizations.

(a) *Determination of home state.* (1) A foreign bank (except a foreign bank to which paragraph (a)(2) of this section applies) that has any combination of domestic agencies or subsidiary commercial lending companies that were established before September 29, 1994, in more than one state and have been continuously operated shall select its home state from those states in which such offices or subsidiaries are located. A foreign bank shall do so by filing with the Board a declaration of home state by June 30, 1996. In the absence of such selection, the Board shall designate the home state for such foreign banks.

(2) A foreign bank that, as of September 29, 1994, had declared a home state or had a home state determined pursuant to the law and regulations in effect prior to that date shall have that state as its home state.

(3) A foreign bank that has any branches, agencies, subsidiary commercial lending companies, or subsidiary banks in one state, and has no such offices or subsidiaries in any other states, shall have as its home state the state in which such offices or subsidiaries are located.

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By order of the Board of Governors of the Federal Reserve System, May 9, 1996.

William W. Wiles,

Secretary of the Board.

[FR Doc. 96–12134 Filed 5–14–96; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, and 556

Animal Drugs, Feeds, and Related Products; Gentamicin Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the following actions on two new animal drug applications (NADA's) held by Schering-Plough Animal Health: The combination of two NADA's into one and the withdrawal of the other, the codification of a supplemental NADA approved by letter, the approval of a supplemental NADA that provides for the use of two higher product concentrations at the same dosage and for the same indications, and the addition of a tolerance for residues of gentamicin in chickens.

The approved, combined, and supplemented NADA provides for use of gentamicin sulfate injection for the prevention of early mortality of day-old chickens and 1- to 3-day-old turkeys due to certain infections susceptible to gentamicin.

EFFECTIVE DATE: May 15, 1996

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–133), Food and Drug