III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because classification of these devices into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Vysis, Inc., dated October 13, 2004.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 866.4700 is added to subpart E to read as follows:

§ 866.4700 Automated fluorescence *in situ* hybridization (FISH) enumeration systems.

(a) *Identification.* An automated FISH enumeration system is a device that consists of an automated scanning microscope, image analysis system, and customized software applications for FISH assays. This device is intended for in vitro diagnostic use with FISH assays as an aid in the detection, counting and classification of cells based on recognition of cellular color, size, and shape, and in the detection and enumeration of FISH signals in interphase nuclei of formalin-fixed, paraffin-embedded human tissue specimens.

(b) *Classification.* Class II (special controls). The special control is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Automated Fluorescence *in situ* Hybridization (FISH) Enumeration Systems.'' See § 866.1(e) for the availability of this guidance document.

Dated: March 10, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–5643 Filed 3–22–05; 8:45 am]

BILLING CODE 4160–01–S

POSTAL SERVICE

39 CFR Part 111

General Information on Postal Service

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The Postal Service will issue a redesigned Domestic Mail Manual (DMM). The redesigned manual is renamed, Mailing Standards of the United States Postal Service, Domestic Mail Manual, and replaces the former Domestic Mail Manual, Issue 58. The redesigned manual is not intended to alter existing standards in DMM 58, and contains the mailing standards effective through January 6, 2005. The new manual presents USPS domestic mailing standards in a manner that increases usability and provides better access to USPS products and services.

DATES: *Effective Date:* This final rule is effective on March 23, 2005. The incorporation by reference of Mailing Standards of the United States Postal Service, Domestic Mail Manual, is approved by the Director of the Federal Register as of March 23, 2005.

FOR FURTHER INFORMATION CONTACT: Sherry L. Freda, (202) 268–7259.

SUPPLEMENTARY INFORMATION: Effective March 20, 2005, the Postal Service will release a redesigned DMM. The redesigned DMM will be issued under a new name, Mailing Standards of the United States Postal Service, Domestic Mail Manual, and will become the official DMM that contains the domestic mailing standards of the Postal Service effective through January 6, 2005. On March 20, the new DMM will be available on line to all Postal employees and customers.

Focusing on who is mailing led the Postal Service to create a series of guides to assist mailers, starting with the consumer in the retail space. DMM 100, A Customer's Guide to Mailing, was launched in September 2002. That work was followed by DMM 200, A Guide to Mailing for Businesses and Organizations, which focuses on the information needs of small and medium volume mailers. We believe these first two provide access to postal services to customers who may not have considered using the mail before. These two guides are now followed by the

Mailing Standards of the United States Postal Service, Domestic Mail Manual, which replaces the current DMM 58.

The redesigned DMM contains all USPS domestic mailing standards, reorganized in a way that is more intuitive to the user. Essentially, the new organization will (1) increase user's ability to find information, (2) increase confidence that users have found all the information they need, and (3) reduce the need to consult multiple chapters of the Manual to locate necessary information.

It is important to note that the redesign of the DMM does not alter and should not be construed as altering existing mailing standards in DMM 58. The Postal Service has not revised any standards based on the DMM redesign. Changes to mailing standards will continue to be published through **Federal Register** notices and the Postal Bulletin, and will appear in the next printed version of Mailing Standards of the United States Postal Service, Domestic Mail Manual, and in the online version available via Postal Explorer (*http//:pe.usps.gov*).

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Incorporation by reference.

■ In view of the considerations discussed above, the Postal Service hereby amends 39 CFR Part 111 as follows:

PART 111—GENERAL INFORMATION ON POSTAL SERVICE

■ 1. The authority citation for part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3626, 5001.

§§ 111.1, 111.2, 111.3, and 111.4 [Amended]

■ 2. Amend §§ 111.1, 111.2, 111.3, and 111.4 by removing ''Domestic Mail Manual'' each time they appear, and adding the words ''Mailing Standards of the United States Postal Service, Domestic Mail Manual'' in their place.

■ 3. Amend § 111.3(f) by adding the following new entry to the end of the table:

§ 111.3 Amendment to the Mailing Standards of the United States Postal Service, Domestic Mail Manual.

* * * * *

(f) * * *

Transmittal letter for issue	Dated	**Federal Register** publication
* *	* * *	* *
Premier Edition	January 6, 2005	[insert FR citation for this Final Rule].

§ 111.4 [Amended]

■ 4. Amend § 111.4 by removing ''March 29, 1979'' and adding ''March 23, 2005'' in its place.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 05–5360 Filed 3–22–05; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2005–0003; FRL–7695–5]

Dinotefuran; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for combined residues of dinotefuran, [*N*-methyl-*N*′-nitro-*N*″-((tetrahydro-3-furanyl)methyl)guanidine] and its metabolites DN [1-methyl-3-(tetrahydro-3-furylmethyl)guanidine] and UF [1-methyl-3-(tetrahydro-3-furylmethyl)urea], expressed as dinotefuran in or on vegetable, fruiting, group 8; vegetable, cucurbit, group 9; brassica, head and stem, subgroup 5A; grape; grape, raisin; potato; potato, chips; potato, granules/flakes; tomato, paste; cotton, undelinted seed; cotton, gin byproducts; and for residues of dinotefuran, [*N*-methyl-*N*′-nitro-*N*″-((tetrahydro-3-furanyl)methyl)guanidine] alone in or on cattle meat, fat, and meat byproducts (mbyp); goat meat, fat, and mbyp; hog meat, fat, and mbyp; horse meat, fat, and mbyp; sheep meat, fat, and mbyp; and milk. Mitsui Chemicals, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective March 23, 2005. Objections and requests for hearings must be received on or before May 23, 2005.

ADDRESSES: To submit a written objection or hearing request follow the detailed instructions as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** EPA has established a docket for this action under docket identification (ID) number OPP–2005–0003. All documents in the docket are listed in the EDOCKET index at *http://www.epa.gov/edocket.* Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in EDOCKET or in hard copy at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Rita Kumar, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8291; e-mail address: *kumar.rita@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS 32532), e.g., agricultural workers; commercial applicators; farmers;