

# Rules and Regulations

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 579

[Docket No. FDA-2012-F-0178]

#### Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food; Electron Beam and X-Ray Sources for Irradiation of Poultry Feed and Poultry Feed Ingredients

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the regulations for irradiation of animal feed and pet food to provide for the safe use of electron beam and x-ray sources for irradiation of poultry feed and poultry feed ingredients. This action is in response to a food additive petition filed by Sadex Corp.

**DATES:** This rule is effective May 10, 2013. Submit either electronic or written objections and requests for a hearing by June 10, 2013.

**ADDRESSES:** You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA-2012-F-0178, by any of the following methods:

#### Electronic Submissions

Submit electronic objections in the following ways:

*Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

#### Written Submissions

Submit written objections in the following ways:

*Mail/Hand delivery/Courier (For paper, disk, or CD-ROM submissions):* Division of Dockets Management (HFA-

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

*Instructions:* All submissions received must include the Agency name and [Docket Number] for this rulemaking. All objections received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting objections, see the "Objections" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

*Docket:* For access to the docket to read background documents or objections received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

#### FOR FURTHER INFORMATION CONTACT:

Isabel W. Pocurull, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6853, [isabel.pocurull@fda.hhs.gov](mailto:isabel.pocurull@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In a notice published in the **Federal Register** of February 29, 2012 (77 FR 12226), FDA announced that a food additive petition (animal use) (FAP 2272) had been filed by Sadex Corp., 2650 Murray St., Sioux City, IA 51111. The petition proposed to amend Title 21 of the Code of Federal Regulations (CFR) in part 579 *Irradiation in the Production, Processing, and Handling of Animal Feed and Pet Food* (21 CFR part 579) to provide for the safe use of electron beam and x-ray sources for irradiation of poultry feed and poultry feed ingredients. The notice of filing provided for a 30-day comment period on the petitioner's environmental assessment. One comment was received that was not substantive.

##### II. Conclusion

FDA concludes that the data establish the safety and utility of electron beam and x-ray sources for use as proposed with modification and that the regulations for irradiation of animal feed and pet food should be amended as set forth in this document.

### III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve this petition are available for inspection at the Center for Veterinary Medicine by appointment with the information contact person (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 571.1(h), the Agency will delete from the documents materials that are not available for public disclosure before making the documents available for inspection.

### IV. Environmental Impact

The agency has determined under 21 CFR 25.32(j) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment, nor an environmental impact statement is required.

### V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections by (see **DATES**). Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. It is only necessary to send one set of documents. It is no longer necessary to send three copies of all documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**List of Subjects in 21 CFR Part 579**

Animal feeds, Animal foods,  
Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 579 is amended as follows:

**PART 579—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF ANIMAL FEED AND PET FOOD**

■ 1. The authority citation for 21 CFR part 579 continues to read as follows:

**Authority:** 21 U.S.C. 321, 342, 343, 348, 371.

■ 2. In § 579.40, revise paragraph (a) to read as follows:

**§ 579.40 Ionizing radiation for the treatment of poultry feed and poultry feed ingredients.**

\* \* \* \* \*

(a) *Energy sources.* Ionizing radiation is limited to:

(1) Gamma rays from sealed units of cobalt-60 or cesium-137;

(2) Electrons generated from machine sources at energy levels not to exceed 10 million electron volts;

(3) X-rays generated from machine sources at energies not to exceed 5 million electron volts, except as permitted by § 179.26(a)(4) of this chapter; or

(4) X-rays generated from machine sources using tantalum or gold as the target material and using energies not to exceed 7.5 (MeV).

\* \* \* \* \*

Dated: April 22, 2013.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 2013-11147 Filed 5-9-13; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 165**

[Docket No. USCG-2013-0328]

RIN 1625-AA00

**Safety Zone; Melrose Pyrotechnics Fireworks Display; Chicago Harbor, Chicago, IL**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on

Lake Michigan in Chicago Harbor, Chicago Illinois. This safety zone is intended to restrict vessels from a portion of Chicago Harbor due to a Fireworks display. This temporary safety zone is necessary to protect the surrounding public and vessels from the hazards associated with the fireworks display.

**DATES:** This rule is effective from 5 p.m. on May 18, 2013, until 11:59 p.m. on June 11, 2013. This rule will be enforced from 5 p.m. until 11:59 p.m. on May 18 and June 11, 2013.

**ADDRESSES:** Documents mentioned in this preamble are part of docket USCG-2013-0328. To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary rule, contact or email MST1 Joseph McCollum, U.S. Coast Guard Sector Lake Michigan, at 414-747-7148 or [Joseph.P.McCollum@uscg.mil](mailto:Joseph.P.McCollum@uscg.mil). If you have questions on viewing the docket, call Barbara Hairston, Program Manager, Docket Operations, telephone (202) 366-9826.

**SUPPLEMENTARY INFORMATION:****Table of Acronyms**

DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of Proposed Rulemaking  
TFR Temporary Final Rule

**A. Regulatory History and Information**

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable. The final details for this event were not known to

the Coast Guard until there was insufficient time remaining before the event to publish an NPRM. Thus, delaying the effective date of this rule to wait for a comment period to run would be both impracticable because it would inhibit the Coast Guard's ability to protect spectators and vessels from the hazards associated with a maritime fireworks display, which are discussed further below.

Under 5 U.S.C. 553(d)(3), The Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30 day notice period to run would be impracticable and contrary to the public interest.

**B. Basis and Purpose**

The legal basis for the rule is the Coast Guard's authority to establish regulated navigation areas and limited access areas: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, 160.5; Public Law 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

During the evenings of May 18 and June 11, 2013, Melrose Pyrotechnics will launch a fireworks display from the break wall south of Navy Pier in Chicago Harbor, Chicago, IL. The Captain of the Port, Lake Michigan, has determined that these fireworks displays will pose a significant risk to public safety and property. Such hazards include falling debris and collisions among spectator vessels.

**C. Discussion of the Final Rule**

With the aforementioned hazards in mind, the Captain of the Port, Lake Michigan, has determined that this temporary safety zone is necessary to ensure the safety of spectators and vessels during the fireworks displays within Chicago Harbor. This zone will be effective from 5 p.m. on May 18, 2013, until 11:59 p.m. on June 11, 2013. This zone will be enforced during the fireworks displays between 5 p.m. until 11:59 p.m. on May 18 and June 11, 2013. This zone will encompass all waters of Lake Michigan, Chicago Harbor within an 800 foot radius of an approximate launch position at 41°53'18.0" N, 87°36'11.8" W (NAD 83).

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the Captain of the Port, Lake Michigan, or his designated on-scene representative. The Captain of the Port or his designated on-scene representative may be contacted via VHF Channel 16.