DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2011–F–0549]

Lanxess Corp.; Filing of Food Additive Petition (Animal Use); Calcium Formate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Lanxess Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of calcium formate in poultry and swine feed as a nutrient and digestive aid.

DATES: Submit either electronic or written comments on the petitioner’s environmental assessment by September 8, 2011.

ADDRESSES: Submit electronic comments to: http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Isabel W. Pocurull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–453–6853, e-mail: isabel.pocurull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (section 409(b)(5) [21 U.S.C. 348(b)(5)], notice is given that a food additive petition (FAP 2261) has been filed by Lanxess Corp. (Lanxess), 111 RIDC Park West Dr., Pittsburgh, PA 15275–1112. The petition proposes to amend the food additive regulations in part 573 Food Additives Permitted in Feed and Drinking Water of Animals (21 CFR part 573) to provide for the safe use of calcium formate in poultry and swine feed as a nutrient and digestive aid.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), the Agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Division of Dockets Management (see DATES and ADDRESSES) for public review and comment.

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner’s environmental assessment without further announcement in the Federal Register. If, based on its review, the Agency finds that an environmental impact statement is not required, and this petition results in a regulation, the notice of availability of the Agency’s finding of no significant impact and the evidence supporting that finding will be published with the regulation in the Federal Register in accordance with 21 CFR 25.51(b).

Dated: August 3, 2011.

Bernadette Dunham,
Director, Center for Veterinary Medicine.

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0489]

RIN 1625–AA87

Security Zones; Captain of the Port Lake Michigan Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: Based on a review of safety and security zones around critical infrastructure in the Chicago area, the Captain of the Port Sector Lake Michigan has determined that to better protect such infrastructure, while also mitigating burdens on waterway users, it is necessary to amend these security zones in our regulations. Specifically, the Coast Guard proposes to reduce the size of an existing security zone, disestablish another security zone, and create three new security zones.

DATES: Comments and related materials must reach the Coast Guard on or before September 8, 2011.

ADDRESSES: You may submit comments identified by Coast Guard docket number USCG–2011–0489 to the Docket Management Facility at the U.S. Department of Transportation. To avoid duplication, please use only one of the following methods:

(1) Online: http://www.regulations.gov.


(3) Hand delivery: Room W12–140 on the Ground Floor of the West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.


FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call MST1 Brenden Otjen Coast Guard Marine Safety Unit, Willowbrook, IL at (630) 986–2155. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All comments received will be posted, without change, to http://www.regulations.gov and will include any personal information you have provided. We have an agreement with the Department of Transportation (DOT) to use the Docket Management Facility. Please see “Privacy Act” paragraph below.

Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2011–0489), indicate the specific section of this document to which each comment...
applies, and give the reason for each comment. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission. You may submit your comments and material by electronic means, mail, fax, or delivery to the Docket Management Facility at the address under ADDRESSES; but please submit your comments and material by only one means. If you submit them by mail or delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Viewing Comments and Documents
To view comments, as well as documents mentioned in this preamble as being available in the docket, go to http://www.regulations.gov at any time. Enter the docket number for this rulemaking (USCG–2011–0489) in the “Keyword” box, and click “Search.” You may also visit either the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, D.C. 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays; or the U.S. Coast Guard Marine Safety Unit Chicago, 555A Plainfield Rd., Willowbrook, IL 60527, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Privacy Act
Anyone can search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008 issue of the Federal Register (73 FR 3316).

Public Meeting
We do not now plan to hold a public meeting. But you may submit a request for one to the Docket Management Facility at the address under ADDRESSES explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the Federal Register.

Background and Purpose
The Coast Guard recently worked with local governmental agencies to review the safety and security zones around critical infrastructure in the Chicago area. Based on this review, the Captain of the Port Sector Lake Michigan had determined that to better protect critical infrastructure while also mitigating burdens on waterway users it is necessary to reduce the size of an existing security zone, disestablish an existing security zone, and establish three new security zones.

Discussion of Proposed Rule
For the reasons discussed in the preceding paragraph, the Captain of the Port Sector Lake Michigan proposes to amend 33 CFR 165.904 and 910. Specifically, this proposed rule would reduce the size of the safety and security zone entitled Lake Michigan at Chicago Harbor & Burnham Park Harbor-Safety and Security Zone, which is located at 33 CFR 165.904. The revised zone will be significantly reduced in size due to the disestablishment of Meigs Airfield and the need to secure only Burnham Park harbor during high profile visits that require security zone enforcement. This proposed reduction of the Chicago Harbor & Burnham Park Harbor-Safety and Security Zone would result in the zone encompassing all U.S. navigable waters of Lake Michigan within Burnham Park Harbor shoreward of a line across the entrance of the harbor connecting coordinates 41°51′09″ N, 87°36′36″ W and 41°51′11″ N, 87°36′22″ W.

In addition to reducing the size of the security zone described in § 165.904(a), this proposed rule would also disestablish a security zone. Specifically, this proposed rule would disestablish the security zone in 33 CFR 165.910(a)(1) entitled Security Zones; Captain of the Port Lake Michigan; Navy Pier Northside. Finally, this proposed rule would establish three new security zones in 33 CFR 165.910. The first new security zone would be located in the vicinity of the Jardine Water Treatment Plant, Chicago, Illinois. The Jardine Water Filtration Plant security zone would encompass all U.S. navigable waters of Lake Michigan within an arc of a 100-yard radius with its center located on the approximate position 41°53′46″ N, 87°36′23″ W.

The second new security zone would be located in the vicinity of the Wilson Avenue Crib, Chicago, Illinois. It would encompass all U.S. navigable waters of Lake Michigan within the arc of a circle with a 100-yard radius with its center in approximate position 41°58′00″ N, 87°35′30″ W. The third new security zone would be located in the vicinity of the new Four Mile Intake Crib in Chicago, Illinois. It would encompass all U.S. navigable waters of Lake Michigan within the arc of a circle with a 100-yard radius with its center in approximate position 41°52′40″ N, 87°32′45″ W.

In accordance with 33 CFR 165.33, no person or vessel would be able to enter or remain in one of the security zones discussed in this proposed rule without permission of the Captain of the Port Sector Lake Michigan. The Captain of the Port Sector Lake Michigan, at his or her discretion, may permit persons and vessels to enter the security zones addressed in this proposed rule. For instance, the Captain of the Port Sector Lake Michigan may permit those U.S. Coast Guard certificated passenger vessels that normally load and unload passengers at the north side of Navy Pier to operate in the Jardine Water Filtration Plant security zone.

Regulatory Analyses
We developed this proposed rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review
This proposed rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. We conclude that this proposed rule is not a significant regulatory action because we anticipate that it would have minimal impact on the economy, would not interfere with other agencies, would not adversely alter the budget of any grant or loan recipients, and would not raise any novel legal or policy issues. The security zones amended and established by this proposed rule would be relatively small and enforced for relatively short time. Also, each security zone is designed to minimize its impact on navigable waters. Furthermore, each security zone has been designed to allow vessels to transit unrestricted to portions of the waterways not affected by the security zones. Thus, restrictions on vessel movements within that particular area are expected to be minimal. Under certain conditions, moreover, vessels may still transit through each security zone when permitted by the Captain of the Port.
Collection of Information

This proposed rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this proposed rule would not result in such an expenditure, we do discuss the effects of this proposed rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not affect the taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This proposed rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a “significant energy action” under that order because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This proposed rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.1D and Department of Homeland Security Management Directive 5100.1, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f), and have made a preliminary determination that this action is not likely to have a significant effect on the human environment. This proposed rule involves the establishing, disestablishing, and changing of security zones and therefore, is categorically excluded under paragraph 34(g) of the Instruction. A preliminary environmental analysis check list supporting this preliminary
determination is available in the docket where indicated under ADDRESSES. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR Part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

1. The authority citation for part 165 continues to read as follows:

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, and 160.5;

2. Amend §165.904 by revising paragraph (a) to read as follows:

§165.904 Lake Michigan at Chicago Harbor & Burnham Park Harbor—Safety and Security Zone.

(a) Location. All waters of Lake Michigan within Burnham Park Harbor shoreward of a line across the entrance of the harbor connecting coordinates 41°51′09″ N, 87°36′22″ W and 41°51′11″ N, 87°36′22″ W.

3. In §165.910, revise paragraph (a)(1) to read as follows:

§165.910 Security Zones; Captain of the Port Lake Michigan.

(a) * * *

(1) Jardine Water Filtration Plant.

(i) Location. All waters of Lake Michigan within the arc of a 100-yard radius with its center located on the north wall of Jardine Water Filtration Plant, approximate position 41°53′46″ N, 87°36′23″ W; (NAD 83)

(10) Wilson Avenue Intake Crib. All waters of Lake Michigan within the arc of a circle with a 100-yard radius of the Wilson Avenue Crib with its center in approximate position 41°58′00″ N, 87°35′30″ W. (NAD 83)

(11) Four Mile Intake Crib. All waters of Lake Michigan within the arc of a circle with a 100-yard radius of the Four Mile Crib with its center in approximate position 41°52′40″ N, 87°32′45″ W. (NAD 83)

Dated: July 21, 2011.

M.W. Sibley,
Captain, U.S. Coast Guard, Captain of the Port, Sector Lake Michigan.

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52


Approval and Promulgation of Air Quality Implementation Plans; Ohio; Reasonably Available Control Technology, Oxides of Nitrogen, Cleveland Ozone Non-Attainment Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to approve, under the Clean Air Act (CAA), revisions to the Ohio State Implementation Plan (SIP) submitted on January 3, 2008 and June 1, 2011. These revisions incorporate provisions related to the implementation of nitrogen oxides (NOx) Reasonably Available Control Technology (RACT) for major sources in the former Cleveland-Akron-Lorain moderate ozone nonattainment area. These rules are not required because, as established in section 182(f) of the CAA, NOx emission control requirements do not apply if the resulting emission reductions are not needed to demonstrate attainment of the 8-hour ozone standard, which is the case for the former Cleveland-Akron-Lorain moderate ozone nonattainment area. However, these rules are being submitted and approved for their SIP strengthening effect as the control requirements in the submitted rules result in a RACT level of control.

DATES: Comments must be received on or before September 8, 2011.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2008–0032, by one of the following methods:

- E-mail: mooney.john@epa.gov.
- Fax: (312) 692–2511.

Hand Delivery: John Mooney, Chief, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office normal hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2008–0032. EPA’s policy is that all comments received will be included in the public docket without change and may be made available online at http://www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through http://www.regulations.gov or e-mail. The http://www.regulations.gov Web site is an ``anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment.

If you send an e-mail comment directly to EPA without going through http://www.regulations.gov your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional instructions on submitting comments, go to section I of the SUPPLEMENTARY INFORMATION section of this document.

Docket: All documents in the docket are listed in the http://www.regulations.gov index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy.

Publicly available docket materials are available either electronically in http://www.regulations.gov or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation...