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#### SUPPLEMENTARY INFORMATION:

##### I. Background

In a document published in the **Federal Register** of July 7, 2021 (86 FR 35806), FDA announced that we had filed a food additive petition (animal use) (FAP 2314) submitted by Biomin Holding GmbH, Biomin Research Center, Technopark 1, 3430 Tulin, Austria. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of fumonisin esterase to degrade fumonisins present in poultry feed.

##### II. Conclusion

FDA concludes that the data establish the safety and utility of fumonisin esterase to degrade fumonisins in poultry feed, and that the food additive regulations 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 documents we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 571.1(h), we will delete from the documents any materials that are not available for public disclosure.

##### IV. Analysis of Environmental Impact

We have determined under 21 CFR 25.32(r) 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 Dockets Management Staff (see **ADDRESSES**) either electronic or written objections. 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.

Any objections received in response to the regulation may be seen in the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <https://www.regulations.gov>.

##### List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

#### **PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS**

■ 1. The authority citation for part 573 continues to read as follows:

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

■ 2. In § 573.485, revise the introductory text and paragraph (c) to read as follows:

##### **§ 573.485 Fumonisin esterase.**

The food additive fumonisin esterase may be safely used to degrade fumonisins in swine and poultry feed in accordance with the following prescribed conditions:

\* \* \* \* \*

(c) The additive is incorporated at a minimum of 15 units of fumonisin esterase activity per kilogram of complete feed:

(1) Complete swine feeds cannot contain more than 10 parts per million of total fumonisins.

(2) Complete feed for poultry being raised for slaughter cannot contain more than 50 parts per million of total fumonisins.

(3) Complete feed for breeding poultry and hens laying eggs for human consumption cannot contain more than 15 parts per million of total fumonisins.

\* \* \* \* \*

Dated: August 24, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2022–18539 Filed 8–26–22; 8:45 am]

**BILLING CODE 4164–01–P**

#### **DEPARTMENT OF HOMELAND SECURITY**

##### **Coast Guard**

##### **33 CFR Part 165**

[Docket Number USCG–2022–0647]

RIN 1625–AA00

##### **Safety Zone; Pacific Airshow, Huntington Beach, California**

**AGENCY:** Coast Guard, Department of Homeland Security (DHS).

**ACTION:** Temporary final rule.

**SUMMARY:** The U.S. Coast Guard is establishing a safety zone offshore of Huntington Beach, CA, in support of the Pacific Airshow. This action is necessary to provide for the safety of life on these navigable waters in the area of the air and water demonstrations and to protect the high concentration of people attending the event. This regulation prohibits vessels from entering into, transiting through, or remaining within the designated area unless specifically authorized by the Captain of the Port, Sector Los Angeles—Long Beach (COTP), or a designated representative.

**DATES:** This rule is effective from 7 a.m. on September 29, 2022, through 5 p.m. on October 2, 2022.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2022–0647 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

**FOR FURTHER INFORMATION CONTACT:** If you have questions about this rule, call or email LCDR Maria Wiener, U.S. Coast Guard Sector Los Angeles—Long Beach; telephone (310) 521–3860, email [D11-SMB-SectorLALB-WWM@uscg.mil](mailto:D11-SMB-SectorLALB-WWM@uscg.mil).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Table of Abbreviations**

CFR Code of Federal Regulations  
DHS Department of Homeland Security  
FR Federal Register  
NPRM Notice of proposed rulemaking  
§ Section  
U.S.C. United States Code

##### **II. Background Information and Regulatory History**

The Coast Guard is issuing this temporary 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 it is impracticable. The Coast Guard did not receive final details for this event until August 9, 2022. There was insufficient time to undergo the full rulemaking process, including providing a reasonable comment period and considering those comments, because the Coast Guard must establish this temporary safety zone by September 29, 2022.

### III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The COTP has determined that potential hazards associated with this event. The sponsor will be conducting an air show in vicinity of the Huntington Beach Pier, for a period of four days. This air show will consist of numerous military and civilian aircraft performing aerobatic maneuvers at high speed within the lateral limits of an aerobatic box that would extend from the surface of the water to 15,000 feet above mean sea level (MSL). The event at Huntington Beach generates over 800 spectator craft in attendance each year. The COTP has determined that potential hazards associated with navigation safety may arise due to multiple low flying aircraft flight paths and stunt performances over the waters off Huntington Beach. This safety zone is to ensure the safety of, and reduce the risk to, the public, and mariners in the vicinity of the aerobatic performance.

### IV. Discussion of the Rule

This rule establishes a safety zone from 7 a.m. on September 29, 2022, through 5 p.m. on October 2, 2022. Based on the safety risks described above, the Coast Guard establishes a safety zone in the vicinity of the Huntington Beach Pier during the Great Pacific Airshow event. The safety zone will encompass all navigable waters from the surface to the sea floor in an area bound by the following coordinates: 33° 38.400' N; 117° 58.834' W, 33° 37.992' N; 117° 59.204' W, 33° 39.625' N; 118° 1.806' W, 33° 40.032' N; 118° 1.437' W. All coordinates displayed are referenced by North American Datum of 1983, World Geodetic System, 1984.

During the enforcement period, vessels are prohibited from entering into, transiting through, or remaining within the designated area unless

authorized by the COTP or his designated representative. The general boating public will be notified prior to the enforcement of the temporary safety zone via Broadcast Notice to Mariners. No vessel or person is permitted to operate in the safety zone without obtaining permission from COTP or the COTP's designated representative. A designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the COTP in the enforcement of the security zone. To seek permission to enter, hail Coast Guard Sector Los Angeles—Long Beach on VHF-FM Channel 16 or (310) 521-3801. Upon being hailed by a Coast Guard vessel or designated representative, by siren, radio, flashing light or other means, the operator of the vessel shall proceed as directed.

### V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

#### A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the size, location, and duration of the safety zone. The size of the zone is the minimum necessary to provide adequate protection for the waterways users, adjoining areas, and the public. The zone will be in place during the scheduled times of 7 a.m. to 5 p.m. Commercial vessel traffic will not be affected by the establishment of the safety zone due to its overall proximity to the shore.

#### B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and

operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A. above, this rule will not have a significant economic impact on any vessel owner or operator. Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

#### C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

#### D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect 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. We have analyzed this rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this 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.

#### *E. 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 rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

#### *F. Environment*

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone encompassing an area in vicinity of Huntington Beach and the Huntington Beach Pier. It is categorically excluded from further review under paragraph L60(a), in Table 3–1 of U.S. Coast Guard Environmental Planning Implementing Procedures. An environmental analysis and checklist supporting this determination and Record of Environmental Consideration (REC) are available in the docket where indicated under **ADDRESSES**.

#### *G. Protest Activities*

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

#### **List of Subjects in 33 CFR Part 165**

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

For the reasons discussed in the preamble, the Coast Guard amends 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:

**Authority:** 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T11–111 to read as follows:

#### **§ 165.T11–111 Safety Zone; Pacific Airshow Huntington Beach, California.**

(a) *Location.* The following area is a safety zone: All navigable waters from the surface to the sea floor consisting of a line connecting the following coordinates: 33° 38.400' N; 117° 58.834' W, 33° 37.992' N; 117° 59.204' W, 33° 39.625' N; 118° 1.806' W, 33° 40.032' N; 118° 1.437' W. All coordinates displayed are referenced by North American Datum of 1983, World Geodetic System, 1984.

(b) *Definitions.* For the purposes of this section, *designated representative* means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sector Los Angeles—Long Beach (COTP) in the enforcement of the security zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP's designated representative.

(2) To seek permission to enter, hail Coast Guard Sector Los Angeles—Long Beach on VHF–FM Channel 16 or call at (310) 521–3801. Those in the security zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(3) Upon being hailed by the COTP's designated representative, by siren, radio, flashing light or other means, the operator of the vessel shall proceed as directed.

(d) *Enforcement period.* The temporary safety zone will be enforced from 7 a.m. to 5 p.m. each day from September 29, 2022, to October 2, 2022.

(e) *Informational broadcasts.* The COTP or a designated representative will inform the public of the enforcement date and times for this safety zone via Local Notices to Mariners.

Dated: August 23, 2022.

**R.D. Manning,**

*Captain, U.S. Coast Guard, Captain of the Port, Sector Los Angeles—Long Beach.*

[FR Doc. 2022–18512 Filed 8–26–22; 8:45 am]

**BILLING CODE 9110–04–P**

## **DEPARTMENT OF HOMELAND SECURITY**

### **Coast Guard**

#### **33 CFR Part 165**

[Docket Number USCG–2022–0648]

RIN 1625–AA00

#### **Safety Zone; Ocean Cup, Catalina Island, CA**

**AGENCY:** Coast Guard, Department of Homeland Security (DHS).

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a safety zone near Ship Rock, Catalina Island, in support of the Ocean Cup Pacific Rum Run. This action is necessary to protect the area near Ship Rock, Catalina Island, public vessels, and the high-speed vessels participating in the event. This regulation would prohibit vessels from entering into, transiting through, or remaining within the designated area during the enforcement period unless specifically authorized by the Captain of the Port, Los Angeles—Long Beach, or his designated representative.

**DATES:** This rule is effective from 7 a.m. to 10 a.m. on September 30, 2022.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2022–0648 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or email LCDR Maria Wiener, U.S. Coast Guard Sector Los Angeles—Long Beach; telephone (310) 521–3860, email [D11-SMB-SectorLALB-WWM@uscg.mil](mailto:D11-SMB-SectorLALB-WWM@uscg.mil).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Table of Abbreviations**

CFR Code of Federal Regulations  
 DHS Department of Homeland Security  
 E.O. Executive order  
 FR Federal Register  
 LLNR Light List Number  
 NPRM Notice of proposed rulemaking  
 Pub. L. Public Law  
 § Section  
 U.S.C. United States Code