

control is returned to neutral following the initial roll input.

These special conditions differ from similar special conditions previously issued on this topic. These special conditions are limited to the roll axis only, whereas other special conditions also included pitch and yaw axes. Special conditions are no longer needed for the yaw axis because § 25.351 was revised at Amendment 25–91 to take into account effects of an electronic flight-control system. No special conditions are needed for the pitch axis because the method that Mitsubishi proposed for the pitch maneuver takes into account effects of an electronic flight-control system.

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

Applicability

As discussed above, these special conditions are applicable to the Model MRJ–200 airplanes. Should Mitsubishi apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on one model of airplanes. It is not a rule of general applicability.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Mitsubishi Model MRJ–200 airplanes.

In lieu of compliance to 14 CFR 25.349(a), the following conditions, speeds, and flight-deck roll-control motions (except as the motions may be limited by pilot effort) must be considered in combination with an airplane load factor of zero, and of two-thirds of the positive maneuvering factor used in design. In determining the resulting control-surface deflections, the torsional flexibility of the wing must be

considered in accordance with § 25.301(b).

(a) Conditions corresponding to steady rolling velocities must be investigated. In addition, conditions corresponding to maximum angular acceleration must be investigated for airplanes with engines or other weight concentrations outboard of the fuselage. For the angular acceleration conditions, zero rolling velocity may be assumed in the absence of a rational time-history investigation of the maneuver.

(b) At V_A , sudden movement of the flight-deck roll control up to the limit is assumed. The position of the flight-deck roll control must be maintained until a steady roll rate is achieved, and then must be returned suddenly to the neutral position.

(c) At V_C , the flight-deck roll control must be moved suddenly and maintained so as to achieve a roll rate not less than that obtained in special condition (b).

(d) At V_D , the flight-deck roll control must be moved suddenly and maintained so as to achieve a roll rate not less than one third of that obtained in special condition (b).

Victor Wicklund,

Manager, Transport Standards Branch, Policy and Innovation Division, Aircraft Certification Service.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 922

[Docket No. 160413330–6330–01]

RIN 0648–BF99

Delay of Discharge Requirements for U.S. Coast Guard Activities in Greater Farallones and Cordell Bank National Marine Sanctuaries

AGENCY: Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Final rule; notification of delay of effectiveness for discharge requirements with regard to U.S. Coast Guard activities.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) expanded the boundaries of Gulf of the Farallones National Marine Sanctuary (now renamed Greater Farallones National Marine Sanctuary or GFNMS)

and Cordell Bank National Marine Sanctuary (CBNMS) to an area north and west of their previous boundaries with a final rule published on March 12, 2015. The final rule entered into effect on June 9, 2015. At that time, NOAA postponed, with regard to U.S. Coast Guard (USCG) activities, the effectiveness of the discharge requirements for six months in the regulations for both sanctuaries in the newly added areas. Since then, NOAA published four documents to extend the postponement of the discharge requirements to provide adequate time for completion of an environmental assessment, and subsequent rulemaking regarding USCG activities, as appropriate. The current extension would end on December 9, 2017. This document, published concurrently with a proposed rule to address discharges by the USCG and an environmental assessment, will extend the postponement of the discharge requirements for USCG activities in the expansion areas of GFNMS and CBNMS for one year beyond the end of the current extension to provide adequate time for completion, if appropriate, of a final environmental assessment and final rule. This extension will end on December 9, 2018, or 30 days after publication of a final rule, whichever comes first.

DATES: The effectiveness for the discharge requirements in both CBNMS and GFNMS expansion areas with regard to USCG activities is December 9, 2018.

ADDRESSES: Copies of documents relating to the expansion, including the Final Environmental Impact Statement (FEIS), final management plans, and the final rule published on March 12, 2015, can be viewed or downloaded at https://farallones.noaa.gov/manage/expansion_cbgf.html.

FOR FURTHER INFORMATION CONTACT: Maria Brown, Greater Farallones National Marine Sanctuary Superintendent, at Maria.Brown@noaa.gov or 415–561–6622.

SUPPLEMENTARY INFORMATION:

I. Background

On March 12, 2015, NOAA expanded the boundaries of Gulf of the Farallones National Marine Sanctuary (now renamed Greater Farallones National Marine Sanctuary or GFNMS) and Cordell Bank National Marine Sanctuary (CBNMS) to an area north and west of their previous boundaries with a final rule (80 FR 13078). The final rule entered into effect on June 9, 2015 (80 FR 34047). In the course of the rulemaking to expand GFNMS and

CBNMS, NOAA learned from U.S. Coast Guard (USCG) that the discharge regulations had the potential to impair the operations of USCG vessels and aircraft conducting law enforcement and on-water training exercises in GFNMS and CBNMS expansion areas. The USCG supports national marine sanctuary management by providing routine surveillance and dedicated law enforcement of the National Marine Sanctuaries Act (NMSA) and sanctuary regulations. To ensure that the March 12, 2015, rule did not undermine USCG's ability to perform its duties, at that time, NOAA postponed the effectiveness of the discharge requirements in both sanctuaries' regulations with regard to USCG activities in the expansion areas for six months. Four additional six-month postponements of the effectiveness of the discharge requirements were published in the **Federal Register** on December 1, 2015 (80 FR 74985), May 31, 2016 (81 FR 34268), December 6, 2016 (81 FR 87803), and June 7, 2017 (82 FR 26339) to provide adequate time for completion of an environmental assessment and to determine NOAA's next steps. Without further NOAA action, the discharge regulations will become effective, with regard to USCG activities, on December 9, 2017.

However, NOAA is currently considering whether, among other things, to exempt certain USCG activities in sanctuary regulations and is concurrently publishing a proposed rule and draft environmental analysis to seek comment on the potential exemption. NOAA is therefore postponing the effectiveness of the discharge requirements in the expansion areas of both sanctuaries with regard to USCG activities for one year until December 9, 2018, or 30 days after publication of a final rule, whichever comes first, to provide adequate time for completion of a final environmental assessment and final rule, as appropriate. The proposed rule and related environmental analysis associated with this action will give the public, other federal agencies, and interested stakeholders an opportunity to comment on various alternatives that are being considered.

II. Classification

A. National Environmental Policy Act

NOAA previously conducted an environmental analysis under the National Environmental Policy Act (NEPA) as part of the rulemaking process leading to the expansion of CBNMS and GFNMS, which addressed regulations regarding the discharge of any matter or material in the

sanctuaries. Potential environmental impacts of the decision to postpone effectiveness are sufficiently encompassed within the impacts analysis of the environmental baseline and the no action alternative presented in that analysis. Should NOAA decide to amend the regulations governing discharges for USGS activities in CBNMS and GFNMS, any additional environmental analysis required under NEPA would be prepared and released for public comment.

B. Executive Order 12866: Regulatory Impact

This action has been determined to be not significant under Executive Order 12866.

C. Executive Order 13771: Regulatory Reform

This action is not expected to be an Executive Order 13771 regulatory action because this action is not significant under Executive Order 12866.

D. Administrative Procedure Act

The Assistant Administrator of National Ocean Service (NOS) finds good cause pursuant to 5 U.S.C. 553(b)(B) to waive the notice and comment requirements of the Administrative Procedure Act (APA) because this action is administrative in nature. This action postpones the effectiveness of the discharge requirements in the regulations for CBNMS and GFNMS in the areas added to the sanctuaries' boundaries in 2015, that underwent notice and comment review, with regard to USCG activities for one year to provide adequate time for public scoping, completion of an environmental assessment, and concurrent rulemaking on how to address the USCG activities, as appropriate. The substance of the underlying regulations currently remains unchanged. Therefore, providing notice and opportunity for public comment under the APA would serve no useful purpose. For the reasons above, the Assistant Administrator also finds good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness and make this action effective immediately upon publication.

Authority: 16 U.S.C. 1431 *et seq.*

Dated: November 14, 2017.

Nicole R. LeBoeuf,

Deputy Assistant Administrator for Ocean Services and Coastal Zone Management, National Ocean Service.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA-2013-N-0013]

Sanitary Transportation of Human and Animal Food: What You Need to Know About the Food and Drug Administration Regulation; Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a guidance for industry entitled "Sanitary Transportation of Human and Animal Food: What You Need to Know About the FDA Regulation—Small Entity Compliance Guide." The small entity compliance guide (SECG) is intended to help small entities comply with the final rule entitled "Sanitary Transportation of Human and Animal Food."

DATES: The announcement of the guidance is published in the **Federal Register** on November 22, 2017.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the