

information described in § 312.23(a)(3)(iv).

(q) *Log of outstanding business.* The DSUR may, at the option of the sponsor, include a log of any outstanding business concerning the IND for which the sponsor has requested a reply, comment, or meeting.

(r) *Late-breaking information.* The DSUR must describe any potentially important safety information about the investigational drug or the clinical investigations conducted under the IND that was identified by the sponsor during preparation of the DSUR and after the data lock point.

(s) *Overall safety assessment.* (1) The DSUR must provide an overall safety assessment that is a concise, integrated evaluation of all new clinical, nonclinical, and epidemiological safety information obtained about the drug by the sponsor during the reporting period relative to the sponsor's prior knowledge of the drug, including knowledge obtained by the sponsor during any prior reporting periods. The assessment must include an evaluation of the risks associated with use of the drug that includes an interpretation of new safety information relative to the safety information that was previously obtained by the sponsor. The overall safety assessment must include the following items:

(i) Findings that suggest a significant risk in humans exposed to the drug, with any associated laboratory values, and relationship to dose, duration, or time course of exposure, if known.

(ii) Significant changes in information concerning adverse events that were identified in a previous DSUR.

(iii) Deaths that were previously included in an IND safety report required in § 312.32.

(iv) Subjects who withdrew from a clinical investigation because of an adverse event.

(v) Findings that suggest a significant risk to specific populations.

(vi) Drug overdose, misuse, and abuse cases or findings regarding the potential for abuse to occur.

(vii) Risks associated with long-term exposure.

(viii) Risks associated with the method of administration of the drug, diagnostic procedures related to use of the drug, or other procedures described in a protocol.

(ix) Evidence of clinically significant medication errors.

(x) Drug interactions.

(xi) Any other risks that significantly affect the safety assessment of the drug.

(2) The overall safety assessment must describe the balance between benefits, including theoretical or anticipated

benefits, and cumulative identified risks related to use of the drug. The overall safety assessment must also describe changes to the benefit-risk profile compared to the previous DSUR, based on information obtained during the reporting period.

(t) *Summary of important risks.* The DSUR must provide a cumulative listing, along with a brief description, of all the important known risks and potential risks associated with use of the drug identified by the sponsor during the course of clinical and nonclinical investigations of the drug conducted on behalf of the sponsor. The listing must include a description of each risk. Risks identified by the sponsor in a prior reporting period must be re-evaluated annually, and their descriptions must be updated with any new risk information obtained during the reporting period.

(u) *Conclusion.* The DSUR must briefly summarize the following information:

(1) All changes to the sponsor's previous knowledge of the investigational drug's efficacy and safety resulting from information obtained during this reporting period.

(2) An outline of actions that have been taken by the sponsor during the current reporting period to address emerging safety findings.

(3) All additional actions that will be taken in the future by the sponsor to address emerging safety findings, to the extent known.

Dated: November 29, 2022.

**Robert M. Califf,**

*Commissioner of Food and Drugs.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

**RIN 0648-BL42**

#### **Extension of Public Comment Period for Amendment 123 to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (BSAI FMP); Bering Sea and Aleutian Islands Halibut Abundance-Based Management of Amendment 80 Prohibited Species Catch Limit**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

**ACTION:** Notice; extension of public comment period.

**SUMMARY:** On November 9, 2022, the National Marine Fisheries Service published a Notice of Availability and request for comments on Amendment 123 to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (BSAI FMP), but inadvertently did not include the supporting Amendment text. With this notice, NMFS is extending the public comment period by 60 days to February 7, 2023, to afford the public with additional time to provide comments on Amendment 123.

**DATES:** Comments on Amendment 123 and supporting documents must be received by February 7, 2023 as specified under **ADDRESSES**.

**ADDRESSES:** You may submit comments, identified by NOAA-NMFS-2022-0088, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to <https://www.regulations.gov> and enter NOAA-NMFS-2022-0088 in the Search box. Click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit written comments to Josh Keaton, Acting Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Records Office. Mail comments to P.O. Box 21668, Juneau, AK 99802-1668.

*Instructions:* Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on [www.regulations.gov](http://www.regulations.gov) without change. All personal identifying information (e.g., name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

Electronic copies of Amendment 123 and the final Environmental Impact Statement/Regulatory Impact Review (collectively referred to as the "Analysis") prepared for this proposed rule may be obtained from <https://www.regulations.gov>. The Analysis may also be found on the Alaska Regional Office website at: <https://www.fisheries.noaa.gov/resource/document/final-environmental-impact-statement-bering-sea-and-aleutian-islands-bsai-halibut>.

**FOR FURTHER INFORMATION CONTACT:**

Bridget Mansfield, 907-586-7228.

**SUPPLEMENTARY INFORMATION:**

On November 9, 2022, the National Marine Fisheries Service published a Notice of Availability (NOA) and request for comments on Amendment 123 to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (BSAI FMP) (87 FR 67665, November 9, 2022). After inquiries from the public, NMFS realized that a supporting document containing the revised BSAI FMP text was not made available for public review with the November 9, 2022 publication of the NOA. The BSAI FMP revised text was posted to [regulations.gov](https://www.regulations.gov) on December 2, 2022. With this notification, NMFS is extending the comment period on the FMP Amendment to provide 60 days from the date of publication of this notification in the **Federal Register**.

NMFS is soliciting public comments on proposed Amendment 123 through the end of the comment period (see **DATES**). NMFS is separately seeking public comment on a proposed rule that would implement Amendment 123.

Respondents do not need to submit the same comments on Amendment 123 and the proposed rule. All relevant written comments received by the end of the applicable comment period, whether specifically directed to the BSAI FMP amendment or the proposed rule will be considered by NMFS in the approval/disapproval decision for Amendments 123 and addressed in the response to comments in the final rule. Comments received after the end of the applicable comment period will not be considered in the approval/disapproval decision on Amendment 123. To be considered, comments must be received, not just postmarked or otherwise transmitted, by the last day of the comment period (see **DATES**).

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: December 6, 2022.

**Jennifer M. Wallace,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 2022-26828 Filed 12-8-22; 8:45 am]

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**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration****50 CFR Part 679**

[Docket No. 221128-0250]

RIN 0648-BL42

**Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands Halibut Abundance-Based Management of Amendment 80 Prohibited Species Catch Limit**

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** NMFS proposes regulations to implement Amendment 123 to the Fishery Management Plan (FMP) for Groundfish of the Bering Sea and Aleutian Islands Management Area (BSAI). If approved, the proposed rule would amend regulations governing limits on Pacific halibut (*Hippoglossus stenolepis*) (halibut) prohibited species catch (PSC), or bycatch, in the BSAI. Namely, the proposed amendment would link the halibut PSC limit to halibut abundance for the Amendment 80 commercial groundfish trawl fleet in the BSAI groundfish fisheries. This action responds to the obligation in section 303(a)(11) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) to minimize bycatch to the extent practicable, and is consistent with the Magnuson-Stevens Act national standards. This action: minimizes halibut PSC to the extent practicable under National Standard 9; ensures that the FMP will continue to achieve optimum yield in the BSAI groundfish fisheries on a continuing basis under National Standard 1; is based upon the best scientific information available under National Standard 2; to the extent it involves an allocation of fishing privileges, is fair and equitable, reasonably promotes conservation by reducing incidental halibut mortality caused by the Amendment 80 trawl fleet, and does not result in any excessive shares of fishing privileges under National Standard 4; and takes into account the importance of fishery resources to fishing communities under National Standard 8. The action is expected to provide incentives for the Amendment 80 fleet to minimize halibut mortality at all times and conserve and improve bycatch

management of the halibut resource, and it may result in additional harvest opportunities in the commercial halibut fishery. This action is intended to promote the goals and objectives of the Magnuson-Stevens Act, other applicable laws, and Amendment 123 to the BSAI FMP.

**DATES:** Submit comments on or before January 23, 2023.

**ADDRESSES:** You may submit comments, identified by NOAA-NMFS-2022-0088, by any of the following methods:

- **Electronic Submission:** Submit all electronic public comments via the Federal eRulemaking Portal. Go to <https://www.regulations.gov> and enter NOAA-NMFS-2022-0088 in the Search box. Click the "Comment Now!" icon, complete the required fields, and enter or attach your comments.

- **Mail:** Submit written comments to Josh Keaton, Acting Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Records Office. Mail comments to P.O. Box 21668, Juneau, AK 99802-1668.

**Instructions:** Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on [www.regulations.gov](https://www.regulations.gov) without change. All personal identifying information (e.g., name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter "N/A" in the required fields if you wish to remain anonymous).

Electronic copies of Amendment 123 may be obtained from <https://www.regulations.gov>. The final Environmental Impact Statement/Regulatory/Impact Review (collectively referred to as the "Analysis") prepared for this proposed rule may be found on the Alaska Regional Office website at: <https://www.fisheries.noaa.gov/resource/document/final-environmental-impact-statement-bering-sea-and-aleutian-islands-bsai-halibut>.

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted by mail to NMFS at the above address; emailed to [OIRA\\_Submission@omb.eop.gov](mailto:OIRA_Submission@omb.eop.gov); or faxed to 202-395-5806.

**FOR FURTHER INFORMATION CONTACT:** Bridget Mansfield, 907-586-7228.

**SUPPLEMENTARY INFORMATION:**