

Rule and initiated before January 20, 2020.

OHRP has considered this request. One of the objectives of the revised Common Rule's single IRB requirement is to reduce administrative costs of cooperative research. For cooperative research that already has been initially approved by multiple IRBs, the cost savings associated with reduced IRB reviews would not be achieved by making the single IRB requirement applicable to such cooperative research. Members of the regulated community report that transitioning cooperative research from multiple IRBs to a single IRB would, conversely, be costly for most institutions. Further, excepting such research from the single IRB mandate would not adversely affect the rights and welfare of the research subjects. For these reasons, OHRP has decided to except cooperative research approved before January 20, 2020, from the single IRB mandate. This general exception does not apply to NIH research; an NIH-specific exception is discussed *infra*.

OHRP has determined that a relatively small number of HHS protocols (other than NIH research) will be eligible for exception. OHRP surveyed the HHS agency, other than NIH, that OHRP expects conducts or supports the majority of such human subjects research. Based on the information provided by that agency, OHRP understands that this agency is supporting five ongoing cooperative research studies that are subject to the revised Common Rule. Approximately three to five additional cooperative research studies supported by this agency that would be subject to the revised Common Rule are expected to be initiated before January 20, 2020.

#### Cooperative Research Conducted or Supported by NIH

The NIH policy on the use of a single IRB for multi-site research has been in effect since January 25, 2018. It requires all U.S. sites participating in NIH-funded multi-site (*i.e.*, two or more sites) studies involving non-exempt human subjects research where the sites are following the same protocol to use a single IRB for the review. Exceptions to this policy are made where review by the proposed IRB is prohibited by a federal, tribal, or state law, regulation, or policy, or if there is a compelling justification for the exception. NIH determines whether to grant an exception after an assessment of the need. NIH's single IRB policy is largely coextensive with the Common Rule single IRB requirement, although NIH designed its policy to exclude certain

categories of cooperative research (*e.g.*, training protocols for activities that do not involve human subjects research at initiation). NIH also has issued case-specific exceptions to its single IRB policy for particular research studies. However, on January 20, 2020, the revised Common Rule single IRB requirement will take effect for certain studies, regardless of whether they are subject to NIH's policy, which would require this NIH-conducted or supported research to use a single IRB review structure.

As stated above, if more than one IRB initially reviewed and approved cooperative research, imposition of the single IRB mandate in mid-stream could result in increased costs and burdens to regulated entities, rather than cost savings. Excepting such NIH-conducted or supported research from mandated single IRB review will not adversely affect the rights and welfare of the research subjects. Further, NIH has given thoughtful consideration to these research contexts, and already determined that single IRB review should not be required. NIH deliberately structured its single IRB policy such that certain research would fall outside the scope of coverage. Likewise, in issuing case-by-case exceptions to its single IRB policy, NIH concluded that single IRB review is not appropriate for those particular research contexts. Thus, OHRP has decided to except NIH cooperative research from the Common Rule single IRB mandate if either (a) the NIH single IRB policy does not apply, and the research was initially approved by an IRB before January 20, 2020, or (b) NIH excepted the research from its single IRB policy before January 20, 2020. For more information on the NIH single IRB policy, see: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>.

This exception is an exercise of OHRP's enforcement discretion, as specifically permitted by 45 CFR 46.114(b)(2), that affects relatively few research protocols for a limited time. As required by 45 CFR 46.114(b)(2), OHRP determines and documents that using a single IRB is not appropriate for the described categories of research, and, for the reasons stated above, OHRP excepts this research from the single IRB mandate. The full text of the exception is listed below, and may also be found in the "Single IRB Requirement" tab in the "Regulations, Policy, & Posting" section of the OHRP website (see <https://www.hhs.gov/ohrp/regulations-and-policy/index.html>).

## II. Determination of Exception: Required Use of Single Institutional Review Board for Cooperative Research

The Office for Human Research Protections (OHRP) has determined that for HHS cooperative research subject to the 2018 Requirements, and for purposes of 45 CFR 46.114(b)(2)(ii), an institution may continue to use multiple IRBs, in lieu of a single IRB, for the following research:

(1) Cooperative research conducted or supported by HHS agencies other than the National Institutes of Health (NIH), if an IRB initially approved the research before January 20, 2020.

(2) Cooperative research conducted or supported by NIH if either:

a. The NIH single IRB policy does not apply, and the research was initially approved by an IRB before January 20, 2020, or

b. NIH excepted the research from its single IRB policy before January 20, 2020.

Note that this determination is only made for purposes of section 46.114(b)(2)(ii)—namely, for determining whether certain cooperative research may be excepted from the single IRB mandate. This determination does not prevent, nor should it be viewed as discouraging, the voluntary use of a single IRB in cooperative research subject to the 2018 Requirements that would fall within the above two categories. Further, note that category (2)(b), above, applies for the duration of NIH's exception from its policy for the particular research study; categories (1) and (2)(a) apply for the duration of the research.

Dated: November 12, 2019.

**Jerry Menikoff,**

*Director, Office for Human Research Protections.*

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 180713633-9174-02]

RTID 0648-XY016

#### Fisheries of the Exclusive Economic Zone Off Alaska; Atka Mackerel in the Bering Sea and Aleutian Islands Management Area

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

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS is prohibiting directed fishing for Atka mackerel in the Bering Sea subarea and Eastern Aleutian District (BS/EAI) of the Bering Sea and Aleutian Islands management area (BSAI) by vessels participating in the BSAI trawl limited access sector. This action is necessary to prevent exceeding the 2019 total allowable catch (TAC) of Atka mackerel in the BS/EAI allocated to vessels participating in the BSAI trawl limited access sector.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), November 19, 2019, through 2400 hrs, A.l.t., December 31, 2019.

**FOR FURTHER INFORMATION CONTACT:** Steve Whitney, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2019 TAC of Atka mackerel, in the BS/EAI, allocated to vessels participating in the BSAI trawl limited access sector fishery was established as a directed fishing allowance of 2,050 metric tons by the final 2019 and 2020 harvest specifications for groundfish in the BSAI (84 FR 9000, March 13, 2019).

In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Atka mackerel in the BS/EAI by vessels participating in the BSAI trawl limited access sector fishing. While this closure is effective, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

#### Classification

This action responds to the best available information recently obtained from the fishing. The Assistant Administrator for Fisheries, NOAA, (AA) finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such a requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from

responding to the most recent fisheries data in a timely fashion and would delay the closure of the Atka mackerel directed fishing in the BS/EAI for vessels participating in the BSAI trawl limited access sector fishing. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 18, 2019.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: November 19, 2019.

**Jennifer M. Wallace,**

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

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 180713633-9174-02]

RIN 0648-XY017

#### Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Ocean Perch in the Bering Sea and Aleutian Islands Management Area

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

**ACTION:** Temporary rule; closure.

**SUMMARY:** NMFS is prohibiting directed fishing for Pacific ocean perch in the Eastern Aleutian district (EAI) of the Bering Sea and Aleutian Islands management area (BSAI) by vessels participating in the BSAI trawl limited access sector fishery. This action is necessary to prevent exceeding the 2019 total allowable catch (TAC) of Pacific ocean perch in the EAI allocated to vessels participating in the BSAI trawl limited access sector fishery.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), November 19, 2019, through 2400 hrs, A.l.t., December 31, 2019.

**FOR FURTHER INFORMATION CONTACT:** Steve Whitney, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2019 TAC of Pacific ocean perch, in the EAI, allocated to vessels participating in the BSAI trawl limited access sector fishery was established as a directed fishing allowance of 973 metric tons by the final 2019 and 2020 harvest specifications for groundfish in the BSAI (84 FR 9000, March 13, 2019).

In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for Pacific ocean perch in the EAI by vessels participating in the BSAI trawl limited access sector fishery. While this closure is effective, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

#### Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, (AA) finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such a requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of the Pacific ocean perch directed fishery in the EAI for vessels participating in the BSAI trawl limited access sector fishery. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 18, 2019.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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