

We note the suggestion for a delayed inclusion date of October 1, 2023 made by one of the commenters in light of the additional time needed and requested by some territories. We believe that further delay beyond January 1, 2023 negatively impacts the progress Puerto Rico has made to prepare to participate in the program (for example, Puerto Rico has already invested significantly in consulting costs and begun the request for proposal process for a system contractor). For example, Puerto Rico has indicated it could be ready to participate in the MDRP as early as July 1, 2022, and therefore, an effective date of October 1, 2023 would push back MDRP participation by over a year from that date for the territory that has the overwhelming majority of drug spending, and which stands to benefit most from participation in MDRP.

As for the commenter's request for additional guidance, the delay can be used to help any territory that plans on participating in the program more time to prepare its beneficiaries, pharmacies, and providers. That is because participation in the MDRP will increase the availability of medications that are available in participating territories, but the territories can also use various utilization management techniques, and providers and patients may need time to be educated on how these programs will work. Moreover, a territory participating in MDRP may need technical help from us on reporting its state drug utilization data, and, for example, assuring that all its physician administered drug claims also include National Drug Code (NDC) numbers. Like our state partners, we are available to guide territories that want to participate in MDRP to assure beneficiary access to drugs, as well as to properly invoice participating manufacturers for federal rebates.

Comment: A few commenters noted their general opposition to the expansion of the MDRP beyond the 50 states and DC to include the territories. One commenter remarked that at most, CMS should limit the expansion to only requiring that rebates be paid by the manufacturers to the territories, but not require manufacturers to include sales to the territories in calculation of their AMP or determination of their Best Price because of the enormous burden and compliance concerns that such an expansion would pose on the manufacturer.

A couple of commenters, while supporting the proposed delay of the participation of the territories in the MDRP to April 1, 2024, were still concerned with the decision to include the territories in the definition of "States" and "United States" in the first

place, and urged CMS to address their prior comments requesting the agency to reverse its decision to add the territories to the Medicaid rebate program.

Response: We note that the definitions of "States" and "United States" at § 447.502 were amended to include the U.S. territories for purposes of the MDRP in the COD final rule with a delayed inclusion date. We did not propose to change the underlying policy, only to delay the inclusion date. As such, comments requesting that we revisit the underlying policy are outside the scope of this rulemaking.

After consideration of the comments received regarding the proposed delay of inclusion date for the U.S. territories in the definitions of "States" and "United States" at § 447.502, we are finalizing an inclusion date of January 1, 2023.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 27, 2021.

List of Subjects in 42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 447—PAYMENT FOR SERVICES

■ 1. The authority citation for part 447 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1396r–8.

■ 2. Amend § 447.502 by revising the definitions of "States" and "United States" to read as follows:

§ 447.502 Definitions.

* * * * *

States means the 50 States and the District of Columbia and, beginning January 1, 2023, also includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

United States means the 50 States and the District of Columbia and, beginning January 1, 2023, also includes the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, the Commonwealth of the Northern Mariana Islands, and American Samoa.

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■ 3. Effective July 1, 2022, in paragraph (a), by revising the definition of "Best price" to read as follows:

§ 447.505 Determination of best price.

(a) * * *

Best price means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed. If a manufacturer offers a value-based purchasing arrangement (as defined at § 447.502) to all states, the lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of that value based purchasing arrangement.

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Dated: November 4, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–25009 Filed 11–17–21; 4:15 pm]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 211115–0231]

RIN 0648–BK56

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Biennial Specifications; 2021–2022 and 2022–2023 Specifications for Pacific Mackerel

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

ACTION: Final rule.

SUMMARY: NMFS is implementing allowable catch levels including an overfishing limit, an allowable biological catch, and an annual catch limit for Pacific mackerel in the U.S. exclusive economic zone off the West Coast (California, Oregon and Washington) for the fishing seasons 2021–2022 and 2022–2023. This rule is finalized pursuant to the Coastal Pelagic Species Fishery Management Plan. The

harvest guideline and annual catch target for the 2021–2022 fishing season are 8,323 metric tons (mt) and 7,323 mt, respectively. The harvest guideline and annual catch target for the 2022–2023 fishing season are 5,822 mt and 4,822 mt, respectively. If the fishery attains the annual catch target in either fishing season, the directed fishery will close, reserving the 1,000-mt difference between the harvest guideline and annual catch target as a set-aside for incidental landings and other sources of mortality. This rule is intended to conserve and manage the Pacific mackerel stock off the U.S. West Coast.

DATES: Effective December 20, 2021.

FOR FURTHER INFORMATION CONTACT:

Taylor Debevec, West Coast Region, NMFS, (562) 619–2052, Taylor.Debevec@noaa.gov.

SUPPLEMENTARY INFORMATION: Under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1801 *et seq.*, NMFS manages the Pacific mackerel fishery in the U.S. exclusive economic zone (EEZ) off the West Coast in accordance with the Coastal Pelagic Species (CPS) Fishery Management Plan (FMP). The CPS FMP and its implementing regulations require NMFS to set annual harvest specifications for the Pacific mackerel fishery based on the annual specification framework and control rules in the FMP. The control rules in the CPS FMP include the harvest guideline (HG) control rule, which in conjunction with the overfishing limit (OFL) and acceptable biological catch (ABC) rules, are used to manage harvest levels for Pacific mackerel. According to the FMP, the quota for the principal commercial fishery, the HG, is determined using the FMP-specified HG formula. The HG is based, in large part, on the current estimate of stock biomass. The biomass estimate is an explicit part of the various harvest control rules for Pacific mackerel, and as the estimated biomass decreases or increases from one year to the next, the resulting allowable catch levels similarly trend. More information on the Pacific Fishery Management Council's (Council) process for developing Pacific mackerel harvest specifications and more detail on the HG control rule are provided in the proposed rule for this action (86 FR 48969; September 1, 2021) and are not repeated here.

The purpose of this final rule is to implement these harvest specifications, which include allowable harvest levels (*i.e.*, annual catch target (ACT) and HG), an annual catch limit (ACL), and annual catch reference points (*i.e.*, OFL and

ABC). The uncertainty surrounding the current biomass estimates for Pacific mackerel for the 2021–2022 and 2022–2023 fishing seasons was taken into consideration in the development of these harvest specifications. The Pacific mackerel fishing season runs from July 1 to June 30. Any Pacific mackerel harvested between July 1, 2021, and the effective date of the final rule would count toward the 2021–2022 ACT and HG.

The Council has recommended, and NMFS is implementing, Pacific mackerel harvest specifications for both the 2021–2022 and 2022–2023 fishing seasons. For the 2021–2022 Pacific mackerel fishing season these include an OFL of 12,145 mt, an ABC and ACL of 9,446 mt, a HG of 8,323 mt, and an annual ACT of 7,323 mt. For the 2022–2023 Pacific mackerel fishing season these include an OFL of 9,644 mt, and ABC and ACL of 7,501 mt, a HG of 5,822 mt, and an ACT of 4,822 mt. These catch specifications are based on the control rules established in the CPS FMP and biomass estimates of 57,832 mt (2021–2022) and 45,925 mt (2022–2023). The biomass estimates are the result of a catch-only stock assessment the NMFS' Southwest Fisheries Science Center completed in June 2021. The Council's Science and Statistical Committee, and the Council approved this stock assessment and resulting biomass estimates as the best scientific information available for management for these two fishing years at the June 2021 Council meeting.

Under this action, in the unlikely event that catch reaches the ACT in either fishing season, directed fishing would close, reserving the difference between the HG and ACT (1,000 mt) as a set-aside for incidental landings in other fisheries and other sources of mortality.¹ For the remainder of the fishing season, incidental landings in CPS fisheries would be constrained to a 45-percent incidental catch allowance (in other words, no more than 45 percent by weight of the CPS landed per trip may be Pacific mackerel); and in non-CPS fisheries, up to 3 mt of Pacific mackerel may be landed incidentally per fishing trip. The incidental set-aside is intended to allow continued operation of fisheries for other stocks, particularly other CPS stocks that may school with Pacific mackerel.

The NMFS West Coast Regional Administrator will publish a notice in the **Federal Register** announcing the date of any closure of directed fishing

¹ Directed fishing for live bait and minor directed fishing is allowed to continue during a closure of the directed fishery.

(when harvest levels reach or exceed the ACT). Additionally, to ensure the regulated community is informed of any closure, NMFS will also make announcements through other means available, including email to fishermen, processors, and state fishery management agencies.

On September 1, 2021, NMFS published a proposed rule in the **Federal Register** (86 FR 48969) soliciting public comments through October 1, 2021. NMFS received two comments from private citizens, one supporting the proposed rule and the other suggesting lowering the catch limit to account for uncertainty. In response to the comment on uncertainty, NMFS has determined that scientific uncertainty has been adequately incorporated in this action through the stock assessment modeling and resulting biomass estimate, as well as in the catch limit by reducing the OFL to the ABC/ACL, to the HG, and finally the ACT. The incorporation of uncertainty and precautionary reductions in the catch limit are to prevent overfishing of mackerel. Additionally, NMFS notes that the Pacific mackerel fishery has been managed with annual or biennial stock assessments and precautionary catch levels for at least the last 20 years.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that this rule is consistent with the CPS FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

This final rule has been determined to be not significant for purposes of Executive Order 12866.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration during the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here. No comments were received regarding this certification. As a result, a regulatory flexibility analysis was not required and none was prepared.

This action does not contain a collection-of-information requirement for purposes of the Paperwork Reduction Act. There are no relevant Federal rules that may duplicate, overlap, or conflict with the final action.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: November 15, 2021.

Samuel D. Rauch, III,

*Deputy Assistant Administrator for
Regulatory Programs, National Marine
Fisheries Service.*

For the reasons set out in the preamble, 50 CFR part 660 is amended as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*, 16 U.S.C. 773 *et seq.*, and 16 U.S.C. 7001 *et seq.*

■ 2. In § 660.511, revise paragraphs (i) and (j) to read as follows:

§ 660.511 Catch restrictions.

* * * * *

(i) The following harvest specifications apply for Pacific mackerel:

(1) For the Pacific mackerel fishing season July 1, 2021, through June 30, 2022, the harvest guideline is 8,323 mt and the ACT is 7,323 mt; and

(2) For the Pacific mackerel fishing season July 1, 2022, through June 30, 2023, the harvest guideline is 5,822 mt and the ACT of 4,822 mt.

(j) When an ACT in paragraph (i) of this section has been reached or exceeded, then for the remainder of the Pacific mackerel fishing season, Pacific mackerel may not be targeted and landings of Pacific mackerel may not exceed: 45 percent of landings when Pacific mackerel are landed in CPS fisheries (in other words, no more than 45 percent by weight of the CPS landed per trip may be Pacific mackerel), or up to 3 mt of Pacific mackerel when landed in non-CPS fisheries. The NMFS West Coast Regional Administrator shall announce in the **Federal Register** the date that an ACT is reached or exceeded, and the date and time that the restrictions described in this paragraph (j) go into effect.

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[FR Doc. 2021–25212 Filed 11–18–21; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 210217–0022; RTID 0648–XB595]

Fisheries of the Exclusive Economic Zone Off Alaska; Shortraker Rockfish 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 retention of shortraker rockfish in the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary because the 2021 shortraker rockfish total allowable catch (TAC) in the BSAI has been reached.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), November 16, 2021, through 2400 hours, A.l.t., December 31, 2021.

FOR FURTHER INFORMATION CONTACT: Mary Furuness, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI 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 2021 shortraker rockfish TAC in the BSAI is 425 metric tons (mt) as established by the final 2021 and 2022 harvest specifications for groundfish in the BSAI (86 FR 11449, February 25, 2021). In accordance with § 679.20(d)(2), the Administrator, Alaska Region, NMFS (Regional Administrator) has determined that the 2021 shortraker rockfish TAC in the BSAI has been reached. Therefore, NMFS is requiring that shortraker rockfish in the BSAI be treated in the same manner as a prohibited species, as described under § 679.21(a), for the remainder of the year, except shortraker rockfish in the BSAI caught by catcher vessels using hook-and-line, pot, or jig gear as described in § 679.20(j).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be 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 prohibiting retention of shortraker rockfish in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 12, 2021.

The Assistant Administrator for Fisheries, NOAA 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.

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

Dated: November 16, 2021.

Ngagne Jafnar Gueye,

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

[FR Doc. 2021–25310 Filed 11–16–21; 4:15 pm]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 210217–0022; RTID 0648–XB592]

Fisheries of the Exclusive Economic Zone Off Alaska; Several Groundfish Species 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; apportionment of reserves; request for comments.

SUMMARY: NMFS apportions amounts of the non-specified reserve to the initial total allowable catch (ITAC) of Bering Sea (BS) Pacific ocean perch, BS trawl sablefish, Bering Sea and Aleutian Islands (BSAI) shortraker rockfish, BSAI skates, BSAI sharks, and Central Aleutian Islands and Western Aleutian