

C. Proficiency Testing Referral

- We are seeking public comment regarding the feasibility of applying alternative sanctions in cases of PT referral that involve waived testing.
- We are seeking public comment related to applying discretion in situations where we determine that a laboratory has referred its proficiency testing samples to another laboratory and has reported those results from another laboratory as their own, and under what circumstances should that discretion be applied.

D. Histocompatibility

- Virtual crossmatching: We are seeking public comment on the acceptability and application of virtual crossmatching in lieu of physical crossmatching for transplantation.
- Criteria and decision making algorithms: We are seeking public comment on appropriate criteria and decision algorithms under which virtual crossmatching would be an appropriate substitute for physical crossmatching. We are also seeking public comment on the existence of commonly accepted current guidelines for virtual crossmatching in histocompatibility.
- Updating histocompatibility regulations: We are seeking public comment on histocompatibility regulations that are no longer necessary because they are obsolete or redundant with requirements found in other sections of the CLIA regulations. We are also seeking public comment on any histocompatibility regulations that should be modified to reflect current practices.

E. CLIA Fees

- We are seeking public comments (including information such as evidence, research, and trends) on an alternate method to calculate the average hourly rate for each entity as outlined in § 493.649(b). We are also seeking comment on whether the method should be standardized and updated annually or as needed.
- We are seeking public comment on a methodology that would set a fair and reasonable fee for revised certificate requests. We also seek comment as to whether fees should be nominal and, if nominal, whether such fee would cover the costs associated with the task.
- We are seeking public comment to update the fees for determination of program compliance as well as additional fees to accredited laboratories as outlined in §§ 493.643(b) and 493.645(b) respectively. We are also seeking comment on whether fees collected should be subject to the same

ten schedules at § 493.643(c), and whether they should change based on any updates to the methodology for determining the average hourly rate.

- We are seeking public comment on exploring an appropriate methodology for assessing a fair fee for other compliance determination activities to include performing follow-up visits, complaint investigations, and activities associated with imposition of sanctions.

We are also soliciting general feedback from stakeholders on what other areas of CLIA they would potentially have recommendations for changing.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. However, section II of this document does contain a general solicitation of comments in the form of a request for information. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Dated: August 18, 2017.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 20, 2017.

Eric D. Hargan,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2017-27887 Filed 1-5-18; 11:15 am]

BILLING CODE 4120-01-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 170901860-7999-01]

RIN 0648-BH18

Fisheries Off West Coast States; Coastal Pelagic Species Fisheries; Multi-Year Annual Catch Limits for the Finfish Stocks in the Monitored Stock Category

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

ACTION: Proposed rule.

SUMMARY: NMFS issues this proposed rule to amend the regulations governing the fisheries for Coastal Pelagic Species (CPS) off the West coast to include annual catch limits (ACLs, which are the maximum allowable fishing levels for each year, for certain monitored finfish stocks (jack mackerel, central population of northern anchovy, northern subpopulation of northern anchovy) under the CPS Fishery Management Plan (FMP). A final rule published October 26, 2016, established these ACLs for the 2017 fishing year only; the purpose of this proposed rule is to codify these ACLs so they remain effective until revised through some future rulemaking. If the ACL for any one of these stocks is reached or projected to be reached, then fishing for that stock will be closed until it reopens at the start of the next fishing season. This rule is intended to conserve and manage these stocks off the U.S. West Coast.

DATES: Comments must be received by February 8, 2018.

ADDRESSES: You may submit comments on this document, identified by NOAA-NMFS-2017-0155, by any of the following methods:

- *Electronic Submissions:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to

www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2017-0155, click the “Comment Now!” icon, complete the required fields, and enter or attach your comments.

- **Mail:** Submit written comments to Barry A. Thom, Regional Administrator, West Coast Region, NMFS, 501 W. Ocean Blvd., Ste. 420, Long Beach, CA 90802–4250; Attn: Joshua Lindsay.

- **Instructions:** Comments must be submitted by one of the above methods to ensure that the comments are received, documented, and considered by NMFS. 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. All comments received are a part of the public record and will generally be posted for public viewing on www.regulations.gov without change. All personal identifying information (e.g., name, address, etc.) submitted voluntarily by the sender will be publicly accessible. Do not submit confidential business information, or otherwise sensitive or protected information. NMFS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT: Joshua Lindsay, West Coast Region, NMFS, (562) 980–4034.

SUPPLEMENTARY INFORMATION: The CPS fishery in the U.S. exclusive economic zone (EEZ) off the West Coast is managed under the CPS FMP, which was developed by the Pacific Fishery Management Council (Council) pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (MSA), 16 U.S.C. 1801 *et seq.* The six species managed under the CPS FMP are Pacific sardine, Pacific mackerel, jack mackerel, northern anchovy (northern and central subpopulations), market squid and krill. The CPS FMP is implemented by regulations at 50 CFR part 660, subpart I.

Management unit stocks in the CPS FMP are classified under three management categories: Active, monitored and prohibited harvest species. Stocks in the active category (Pacific sardine and Pacific mackerel) are managed by regular stock assessments and periodic or annual adjustments of target harvest levels based on those stock assessments. Fisheries for these stocks have biologically significant levels of catch, or biological or socioeconomic considerations requiring this type of relatively intense harvest management procedures. In contrast, stocks in the monitored category (jack mackerel,

northern anchovy, and market squid¹), are managed by means of qualitative comparison to available abundance data without regular stock assessments or annual adjustments to target harvest levels, and then tracking landings against the relevant ACL to ensure overfishing does not occur. Fisheries for monitored stocks do not have biologically significant catch levels and, therefore, do not require intensive harvest management. As a result, monitored stocks have been adequately managed by tracking landings and examining available abundance indices. Species in both categories may be subject to management measures such as catch allocation, gear regulations, closed areas, closed seasons, or other forms of regulation. For example, trip limits and a limited entry permit program are already in place for all CPS finfish. The prohibited harvest species category is comprised only of krill, which is managed by a prohibition on targeting and retention.

In September 2011, NMFS approved Amendment 13 to the CPS FMP, which modified the framework process used to set and adjust fishery specifications and for setting ACLs and accountability measures (AMs). Amendment 13 conformed the CPS FMP with the 2007 amendments to the MSA and the NMFS revised MSA National Standard 1 (NS1) guidelines at 50 CFR 600.310, which for the first time required ACLs be established for management unit species (with exceptions). Specifically, Amendment 13 maintained the existing reference points and the primary harvest control rules for the monitored stocks (jack mackerel, northern anchovy and market squid), including the large uncertainty buffer built into the acceptable biological catch (ABC) control rule for the finfish stocks, as well as the overfishing criteria for market squid, but modified these reference points and control rules to align with the revised NS1 guidelines and to comply with the new statutory requirement to establish a process for setting ACLs and AMs. This included a default management framework under which the overfishing limit (OFL) for each monitored stock was set equal to their existing maximum sustainable yield (MSY) value, if available, and ABC values were reduced from the OFL by 75 percent as an uncertainty buffer (in accordance with the existing ABC control rule, under which ABC equals 25 percent of OFL/MSY). ACLs are then set either equal to or lower than the

ABC; annual catch targets (ACTs), if deemed necessary, can be set less than or equal to the ACL, primarily to account for potential management uncertainty.

Compared to the management framework for stocks in the active category, which utilizes annual estimates of biomass to calculate the applicable annual harvest levels, the ACLs for the monitored finfish stocks are not based on annual estimates of biomass or any single estimate of biomass. As described above, ACLs for monitored finfish are set at the ABC levels, which are no higher than 25 percent of the OFLs. OFLs are set equal to MSY—an estimate that is intended to reflect the largest average fishing mortality rate or yield that can be taken from a stock over the long term. Although the control rules and harvest policies for monitored CPS stocks are simpler than the active category control rules, the inclusion of a large non-discretionary buffer between the OFL and ABC both protects the stock from overfishing and allows for a small sustainable harvest. In recognition of the low fishing effort and landings for these stocks, the Council chose this type of passive framework to manage monitored finfish because the passive framework has proven sufficient to prevent overfishing while allowing for sustainable annual harvests even when the year-to-year biomasses of these stocks fluctuate.

Although the OFLs and ABCs for these monitored finfish stocks were previously established and are not being revised by this rulemaking, understanding these values is relevant to ACLs because generally the ACL for monitored stocks is expected to be set at ABC. Per the framework that was established through Amendment 13, the OFLs for the central subpopulation of northern anchovy and jack mackerel were set based on MSY values that were established through Amendment 8 to the FMP. In 2015, Amendment 14 to the CPS FMP established an F_{MSY} of 0.3 as the MSY reference point for the northern subpopulation of northern anchovy in the CPS FMP. However, because the framework in the FMP for setting ABCs is based on applying a percentage to numerical MSY/OFLs, it was necessary to determine a numerical OFL value through the specifications process. Because the northern subpopulation of the northern anchovy is currently lightly fished and effort has been inconsistent over time, it was determined that using a catch time series as a way of setting the OFL was not appropriate, as it likely was an unreliable indicator of stock status.

¹ Market squid is statutorily exempt from the general requirement to be managed using an ACL because of their short life-cycle.

Therefore, the best available scientific information on the population and biology of northern subpopulation northern anchovy was compiled to develop an OFL. The available information included two separate estimates of biomass, and the average of these two estimates was approximately 130,000 mt. After reviewing this information, the SSC recommended that the OFL be set by multiplying the average of these two biomass estimates (130,000 mt), by an F_{MSY} 0.3. This calculation results in an OFL of 39,000 mt, and with the established uncertainty buffer of 75 percent, an ABC of 9,750 mt.

Through this action, NMFS is proposing to codify in 50 CFR part 660 subpart I ACLs for the three populations of CPS finfish, which were implemented for calendar year 2017 in the final rule published on October 26, 2016, at 81 FR 74309.² The ACLs are: Jack mackerel, 31,000 mt; northern subpopulation of northern anchovy, 9,750 mt; and, central subpopulation of northern anchovy, 25,000 mt. These ACLs were recommended to NMFS by the Council, and were based on recommendations from its advisory bodies according to the framework in the FMP established through Amendment 13.

NMFS notes that although the proposed ACLs are equal to their respective ABCs, NMFS has determined that they are still at a level such that overfishing will not occur. The management framework, including the buffer between the OFL and ABC built into the harvest policy for CPS stocks in the monitored category, was recommended by the Council's SSC, adopted by the Council and approved by NMFS as supported by the best available science and as determined in a manner that appropriately accounts for the various types of scientific uncertainty surrounding the OFL. This framework for accounting for uncertainty was subsequently used to establish the existing OFLs and ABCs for these stocks, and NMFS does not propose to revise the existing OFLs and ABCs by this proposed rule. Additionally, setting lower ACLs or establishing additional ACTs to account for management uncertainty is unnecessary at this time, as managers have the ability to manage and track the landings of these fisheries to ensure the ACLs are not exceeded. Catches of the three finfish stocks in the monitored

category—northern anchovy (northern and central subpopulations) and jack mackerel—have remained well below their respective ACL (previously ABC) levels since implementation of the CPS FMP in 2000, with average catches in the ten-year period from 2006–2015 of approximately 8,000 mt, 295 mt, and 580 mt for the central and northern subpopulations of northern anchovy and jack mackerel, respectively.

This proposed action will allow the proposed ACLs to remain in place for each subsequent calendar year until changed. The Council and NMFS would consider future changes if landings increase and consistently reach the ABC/ACL level, if new scientific information becomes available to warrant changes, or if changes are made in the future to the existing ABCs or OFLs. The ACLs proposed in this action provide a means to monitor these stocks on an annual basis and prevent overfishing, as each year the total harvest of each stock will be assessed against their respective ACLs. These ACLs would remain in place until changed according to the FMP framework. Except for the northern subpopulation of northern anchovy, the OFL and ABC specifications for the rest of these stocks have already been set in the FMP, and NMFS is not establishing or revising them by this action. The OFL and ABC specifications for the northern subpopulation of northern anchovy were established in the final rule published October 26, 2016, which established these ACLs for the 2017 fishing year only.

If an ACL is reached, or is expected to be reached for one of these fisheries, the directed fishery would be closed until the beginning of the next fishing season. The NMFS West Coast Regional Administrator would publish a notice in the **Federal Register** announcing the date of any such closure. Additionally, nearing or exceeding one of these ACLs would trigger a review of whether the fishery should be moved into the actively managed category of the FMP.

Classification

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

This proposed 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 (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities, for the reasons described below.

The primary action being implemented through this rule as it relates to potential economic impacts on small entities is the codification of multi-year ACLs for the two sub-stocks of northern anchovy and for jack mackerel in the U.S. EEZ off the West coast. The CPS FMP and its implementing regulations require NMFS to set ACLs for these fisheries based on the harvest control rules in the FMP.

For Regulatory Flexibility Act (RFA) purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual receipts not in excess of \$11 million for all its affiliated operations worldwide.

The average annual per vessel revenue in 2016 for the West Coast CPS finfish small purse seine fleet, as well as the few vessels that target anchovy off of Oregon and Washington, was below \$11 million; therefore, all of these vessels are considered small businesses under the SBA size standards. Because each affected vessel is a small business, this proposed rule has an equal effect on all of these small entities, and therefore will impact a substantial number of these small entities in the same manner. The corresponding annual revenues from these species averaged to about \$62,000 and \$1,900,000, for jack mackerel and northern anchovy, respectively.

The entities that would be affected by the proposed action are the vessels that harvest jack mackerel and northern anchovy as part of the West Coast CPS purse seine fleet. Jack mackerel and northern anchovy are components of the CPS purse seine fishery off the U.S. West Coast, which generally fishes a complex of species, including Pacific sardine, Pacific mackerel and market squid. Currently there are 58 vessels permitted in the Federal CPS limited entry fishery off California. Annually over the past 5 years, as few as 2 and as many as 57 (an average 22) of these CPS vessels landed anchovy and jack mackerel. Approximately 26 baitfish licenses are issued annually in the state of Washington to harvest northern

² An annual catch target of 1,500 mt for the northern subpopulation of northern anchovy was also established by the October 26, 2016, final rule, but is used for internal monitoring rather than regulating the public and therefore need not be codified.

anchovy. Since 2009, the state of Oregon has not required a permit to harvest anchovy in Oregon waters. Jack mackerel is currently not fished in Oregon and Washington.

To evaluate whether this proposed rule could potentially reduce the profitability of the affected vessels, NMFS compared current and average recent historical landings to the ACLs that would be codified in this proposed rule, if approved. The multi-year ACL (maximum fishing level for each year) for the central subpopulation of northern anchovy is 25,000 mt and for the northern subpopulation ACL is 9,750 mt. In 2016, 6,644 mt of the central population of northern anchovy and 7,263 mt of the northern subpopulation of northern anchovy were landed. The annual average harvest from 2007 to 2016 for the central and northern subpopulations of northern anchovy is 7,400 mt and 910 mt, respectively. The jack mackerel ACL is 31,000 mt. In 2016, approximately 374 mt of jack mackerel were landed and average annual landings of jack mackerel over the last 10 years (2007–2016) was 662 mt. Prior landings of these stocks have been well below the proposed ACLs. Therefore, although codifying ACLs for these stocks is considered a new management measure for these fisheries, based on current and historical landings of these stocks, this proposed action is not expected to result in changes in fishery operations. As a

result, it is unlikely that the ACLs that would be codified in this rule, if approved, would limit the profitability of the fleets catching these stocks. Therefore, this action would not have any economic impact, let alone impose a significant economic impact on any of the small entities participating in these fisheries.

Based on the analysis above, the proposed action, if adopted, would not have a significant economic impact on a substantial number of small entities. As a result, an Initial Regulatory Flexibility Analysis is not required, and none has been prepared.

This action does not contain a collection of information requirement for purposes of the Paperwork Reduction Act.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: January 2, 2018.

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 proposed to be 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 § 660.509, paragraph (a) is revised to read as follows:

§ 660.509 Accountability measures (season closures).

(a) *General rule.* When the directed fishery allocation, incidental allocation, or an annual catch limit is reached for any CPS species it shall be closed until the beginning of the next fishing period or season. Regional Administrator shall announce in the **Federal Register** the date of such closure, as well as any incidental harvest level(s) recommended by the Council and approved by NMFS.

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■ 3. In § 660.511, a new paragraph (i) is added to read as follows:

§ 660.511 Catch restrictions.

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(i) The following ACLs apply to fishing for monitored stocks of CPS finfish:

(1) *Jack mackerel*: 31,000 mt.

(2) *Northern Anchovy (N. Subpopulation)*: 9,750 mt.

(3) *Northern Anchovy (Central Subpopulation)*: 25,000 mt.

[FR Doc. 2018–00084 Filed 1–8–18; 8:45 a.m.]

BILLING CODE 3510–22–P