

drug blocked FDA's approval of Jacobus's drug for *all* uses or indications within the orphan-designated disease (LEMS)—even though Catalyst's drug was approved at that time only for use in the treatment of LEMS in adults. The court concluded that FDA's approval of Jacobus's drug for the treatment of LEMS in children must be set aside. Consistent with the court's decision, the Agency set aside the approval of Jacobus's drug.

## II. Orphan-Drug Exclusivity

The Agency is issuing this statement to address the uncertainty created by the circuit court's decision in *Catalyst*. The court ordered FDA to set aside its approval of Jacobus's drug, and FDA has set aside that approval. This notification announces that, at this time, in matters beyond the scope of that court order, FDA intends to continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. The Agency believes that this approach is appropriate for several reasons. FDA continues to believe that the statutory text does not unambiguously require that orphan-drug exclusivity extend to the entire disease or condition for which a drug received orphan-drug designation if the drug is only approved for some uses within that disease or condition. Further, FDA believes that its statutory interpretation embodied in its regulations best advances the Orphan Drug Act's purposes, appropriately balancing the need to incentivize the development of drugs for rare diseases and conditions with the need to provide patient access to orphan drugs. The regulations accomplish this by tying the scope of orphan-drug exclusivity to only the approved use or indication of the drug, which permits other sponsors to obtain approval of the drug for uses or indications within the same orphan-designated disease or condition that have not yet been approved (*i.e.*, that are "new"). Under the regulations, a drug approved for a new use or indication within the same orphan-designated disease or condition may also be eligible for orphan-drug exclusivity for such use or indication. These regulations incentivize sponsors to continue to develop a drug for use in all persons affected by a rare disease or condition. Thus, FDA believes that continued adherence to its validly promulgated regulations will best serve the public health by facilitating patient access to orphan drugs, especially for difficult-to-study patients such as young children.

## III. Conclusion

For the above reasons, at this time, the Agency intends to continue to apply its longstanding regulations tying the scope of orphan-drug exclusivity to the uses or indications for which the orphan drug was approved.

Dated: January 18, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### 50 CFR Part 17

[Docket No. FWS-R2-ES-2021-0015; FF09E21000 FXES1111090FEDR 234]

RIN 1018-BB27

#### **Endangered and Threatened Wildlife and Plants; Lesser Prairie-Chicken; Threatened Status With Section 4(d) Rule for the Northern Distinct Population Segment and Endangered Status for the Southern Distinct Population Segment; Delay of Effective Date**

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule; delay of effective date.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), are delaying the effective date of a final rule we published on November 25, 2022, and corrected on December 2, 2022, listing two distinct population segments (DPSs) of the lesser prairie-chicken (*Tympanuchus pallidicinctus*) under the Endangered Species Act of 1973, as amended (Act) and establishing measures that are necessary and advisable to provide for the conservation of the Northern DPS pursuant to section 4(d) of the Act. This delay is necessary for the Service to finalize conservation tools and guidance documents to avoid confusion and disruption with Federal agencies in the implementation of section 7 of the Act and to avoid disruption to the public who would be regulated by the rule.

**DATES:** The effective date of the final rule that published on November 25, 2022, at 87 FR 72674, and corrected on December 2, 2022, at 87 FR 73971, is delayed from January 24, 2023, to March 27, 2023.

**ADDRESSES:** This final rule is available on the internet at <https://www.regulations.gov>. For access to the

docket to read the November 25, 2022, final rule or other background documents, including the comments received on that final rule, go to <https://www.regulations.gov> and search for Docket No. FWS-R2-ES-2021-0015.

**FOR FURTHER INFORMATION CONTACT:** Beth Forbus, Regional Endangered Species Program Manager, Southwest Regional Office, 500 Gold Ave. SW, Albuquerque, NM 87102; telephone 505-318-8972. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

On November 25, 2022, we published in the *Federal Register* (87 FR 72674) a final rule listing two DPSs of the lesser prairie-chicken (*Tympanuchus pallidicinctus*), a grassland bird known from southeastern Colorado, western Kansas, eastern New Mexico, western Oklahoma, and the Texas Panhandle. We determined threatened status for the Northern DPS and endangered status for the Southern DPS. This rule will add the DPSs to the List of Endangered and Threatened Wildlife. We also finalized a rule under the authority of section 4(d) of the Act that provides measures that are necessary and advisable to provide for the conservation of the Northern DPS. The rule was to be effective on January 24, 2023; however, with this final rule, we are delaying the effective date to March 27, 2023. This delay will allow us to finalize conservation tools and guidance documents and prevent confusion and disruption with other Federal agencies under section 7 of the Act.

Currently, the lesser prairie-chicken is not listed under the Act. When the November 25, 2022, final rule goes into effect, the Southern DPS will be classified as endangered. This will initiate the prohibitions set forth in section 9 of the Act and the consultation obligations set forth in section 7 of the Act. Also when the final rule goes into effect, the Northern DPS will be classified as threatened with a section 4(d) rule that tailors the prohibitions and exceptions to the prohibitions necessary and advisable for the species. The consultation obligations set forth in section 7 of the Act will also be applicable to the Northern DPS. We recognize that these changes in status

will result in questions and concerns about establishing compliance under the Act for grazing, energy development, infrastructure, and many other projects within the five States that comprise the range of the lesser prairie-chicken.

We are committed to working proactively with stakeholders to conserve and recover lesser prairie-chickens while reducing impacts to landowners, where possible and practicable. For example, we are working with interested parties to establish Service-approved providers of grazing management plans. These plans are necessary under the 4(d) rule to allow for compatible grazing operations to continue without a permit or conservation plan in place. At this time, there is one Service-approved provider of grazing management plans.

We also believe the delay is appropriate to allow industry stakeholders more time to participate in or expand participation in voluntary conservation efforts. Delaying the effective date will allow for additional pre-listing enrollment in conservation plans that are beneficial to the species and will allow the Service to continue to work with interested parties to expand our list of approved parties to develop site-specific grazing management plans.

This 60-day delay of the effective date of the November 25, 2022, final rule (87 FR 72674)—based on the good cause articulated below—is for the purpose of encouraging additional conservation, preventing confusion and disruption for Federal agencies in the implementation of section 7 of the Act, and avoiding disruption to the public who would be regulated by the rule. During this period, we will review any pending enrollments to conservation efforts, review requests to become Service-approved providers of grazing management plans, coordinate with Federal agencies under section 7 of the Act, and coordinate directly with stakeholders to provide clarity regarding potential implications of the listing on their operations. We are, therefore, delaying the effective date of the final rule from January 24, 2023, to March 27, 2023.

## II. Good Cause Under the Administrative Procedure Act

Our delay of the effective date of the listing of the lesser prairie-chicken under the Act from January 24, 2023, to March 27, 2023, effective immediately upon publication of this document in the **Federal Register**, is based on the good-cause exception provided in the Administrative Procedure Act (APA). Pursuant to 5 U.S.C. 553(b)(B) and

(d)(3), we have determined that good cause exists to forgo the requirements to provide prior notice and an opportunity for public comment on this 60-day delay of the effective date of the November 25, 2022, final rule (87 FR 72674), and to make this action announcing the delay effective immediately. Under the totality of the circumstances presented here, notice and comment would be impracticable and contrary to the public interest because it would diminish active efforts to increase conservation efforts and regulate existing grazing practices before interested operators have sufficient time to prepare grazing management plans. These unintended consequences would thwart the conservation purposes of the Act. See *Purdue Univ. v. Scalia*, No. CV–20–3006 (EGS), 2020 WL 7340156, at 8 (D.D.C. Dec. 14, 2020).

As noted above, we are currently working with permit holders to ensure that all interested parties have the opportunity for enrollment in existing candidate conservation agreements with assurances (CCAAs) prior to the effective listing date. By delaying the effective listing date it will allow CCAA permit holders to continue outreach and processing of any new enrollments. Delaying the effective date by 60-day will still require that grazing management plans be in place before the lesser prairie-chicken's primary nesting and brooding season. This is important because nesting is when incidental take from grazing is most likely to occur. This delay in the effective date will still ensure that the conservation-based requirement for grazing management plans is in place before this critical nesting and brooding time of year for the species.

In addition, we are actively working with partners to approve entities for the development of grazing management plans. The further development of this list of approved plan providers will allow for interested parties to be approved and begin working directly with interested landowners to develop grazing management plans. The development of site-specific grazing management plans is necessary and advisable for the lesser prairie-chicken as compatible grazing management is required for habitat management.

Our agency's "due and timely execution of its functions" under the Act would be unavoidably prevented if we allow the effective date to be triggered without the conservation tools and guidance described above. See S. Doc. No. 248, 79th Cong., 2d Sess. at 200 (1946). That is, if the November 25, 2022, final rule listing the lesser prairie-chicken under the Act (87 FR 72674)

becomes effective on January 24, 2023, the Act's and 4(d) rule's prohibitions will go into effect, impacting a large number of projects across the species' range. This will negatively impact conservation of the lesser prairie-chicken because a lack of clarity and guidance would result in fewer operators receiving grazing management plans, which are developed to maintain the vegetative characteristics needed to support the lesser prairie-chicken. Thus, we will not have met our obligations under the Act to ensure the conservation of listed species. See *Tennessee Valley Authority v. Hill*, 437 U.S. 153, 174 (1978) (in enacting the Act, it is "beyond doubt that Congress intended endangered species to be afforded the highest of priorities").

In sum, we find that the totality of the circumstances here—the negative impact to pre-listing conservation efforts and the inability to complete grazing management plans that will be threats to the Service's execution of its statutory functions, among other issues—indicate that there is good cause to forgo notice and comment procedures. It is impractical and contrary to the public interest for the Service to provide notice and an opportunity to comment on a 60-day delay of the effective date of January 24, 2023, for the November 25, 2022, final rule (87 FR 72674).

We also find that there is good cause to make this rule effective immediately instead of waiting until 30 days after publication for it to become effective. The APA normally requires this 30-day "grace period" to give affected parties time to adjust their behavior before a final rule takes effect. See, e.g., *Riverbend Farms, Inc. v. Madigan*, 958 F.2d 1479, 1485 (9th Cir. 1992). However, the APA provides an exception to this 30-day grace period for good cause (5 U.S.C. 553(d)). There is good cause to allow this 60-day delay of the effective date of the November 25, 2022, final rule to go into effect immediately because the delay preserves the status quo, and there is no change to which parties would need time to adjust their behavior. Further, if this rule delaying the effective date were itself not to become effective for 30 days, then the November 25, 2022, final rule would go into effect on January 24, 2023. That result would create the same issues as discussed above, with the added confusion of reverting to the pre-listing status quo for some duration of time.

We, therefore, conclude that we have good cause to issue this final rule, effective immediately, delaying the effective date of the November 25, 2022,

final rule (87 FR 72674) from January 24, 2023, to March 27, 2023.

### III. Authority

The authorities for this action are 16 U.S.C. 1361–1407, 1531–1544, and 4201–4245, unless otherwise noted; and 5 U.S.C. 551 *et seq.*

**Martha Williams,**

*Director, U.S. Fish and Wildlife Service.*

[FR Doc. 2023–01290 Filed 1–23–23; 8:45 am]

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## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 220216–0049; RTID 0648–XC710]

#### Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Using Trawl Gear in the Western Regulatory Area of the Gulf of Alaska

**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 cod by catcher vessels using trawl gear in the Western Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the A season allowance of the 2023 total allowable catch of Pacific cod by catcher vessels using trawl gear in the Western Regulatory Area of the GOA.

**DATES:** Effective 1200 hours, Alaska local time (A.l.t.), January 22, 2023, through 1200 hours, A.l.t., June 10, 2023.

**FOR FURTHER INFORMATION CONTACT:** Abby Jahn, 907–586–7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (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 A season allowance of the 2023 Pacific cod total allowable catch (TAC) apportioned to catcher vessels using

trawl gear in the Western Regulatory Area of the GOA is 1,397 metric tons (mt) as established by the final 2022 and 2023 harvest specifications for groundfish in the GOA (87 FR 11599, March 2, 2022) and inseason adjustment (87 FR 80088, December 29, 2022).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the A season allowance of the 2023 Pacific cod TAC apportioned to catcher vessels using trawl gear in the Western Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 1,297 mt and is setting aside the remaining 100 mt as bycatch to support other anticipated groundfish fisheries. 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 cod by catcher vessels using trawl gear in the Western Regulatory Area of the GOA.

While this closure is effective the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

#### 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 the closure of Pacific cod by catcher vessels using trawl gear in the Western Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of January 18, 2023.

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: January 18, 2023.

**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. 220216–0049; RTID 0648–XC692]

#### Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Using Trawl Gear in the Central Regulatory Area of the Gulf of Alaska

**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 cod by catcher vessels using trawl gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the A season allowance of the 2023 total allowable catch of Pacific cod by catcher vessels using trawl gear in the Central Regulatory Area of the GOA.

**DATES:** Effective 1200 hours, Alaska local time (A.l.t.), January 20, 2023, through 1200 hours, A.l.t., June 10, 2023.

**FOR FURTHER INFORMATION CONTACT:** Abby Jahn, 907–586–7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (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 A season allowance of the 2023 Pacific cod total allowable catch (TAC) apportioned to catcher vessels using trawl gear in the Central Regulatory Area of the GOA is 2,327 metric tons (mt) as established by the final 2022 and 2023 harvest specifications for groundfish in the GOA (87 FR 11599, March 2, 2022) and inseason adjustment (87 FR 80088, December 29, 2022).