

associated with testing and results interpretation, including controls, procedures, and user training requirements, as appropriate.

(ii) Specification of the criteria for test result interpretation and reporting, including device cut-off(s) (*i.e.*, clinical threshold(s) or the medical decision point(s) between positive and negative results) or other relevant criteria that distinguishes positive and negative or quantitative results. This information must include the rationale for the chosen cut-off(s) to include the upper reference of normal, or other relevant criteria and results supporting validation of the cut-off(s) evaluating borderline samples around the clinical threshold(s). Scoring criteria for all applicable signals must be included.

(iii) Device performance data demonstrating appropriate analytical sensitivity from studies using interphase nuclei from intended use specimen type(s) that are considered karyotypically normal, or through an alternative approach, as determined to be appropriate by FDA (*e.g.*, probe sensitivity and probe limits).

(iv) Device performance data demonstrating appropriate analytical specificity of the device for the intended use specimen type(s), as determined to be appropriate by FDA (*e.g.*, probe specificity, interference study, cross-reactivity and cross contamination testing).

(v) Device performance data demonstrating appropriate precision and reproducibility of the device using clinical specimens representing the intended use specimen type(s) and intended use biomarker(s) from the intended use population and investigating major sources of variability (*e.g.*, multiple reagent lots, operators, instruments over multiple days, and inter- and intra-reader precision). Surrogate samples that adequately represent the intended use specimen type(s) and intended use biomarker(s) may be appropriate, as determined by FDA, to supplement clinical specimens. If the device will be used at more than one site, data must demonstrate adequate reproducibility across multiple intended use sites. Additionally, precision and reproducibility of the device must be evaluated with specimens near the clinical decision threshold(s) and near the limits of reportable range. Additionally, device performance data demonstrating appropriate precision must be included from studies evaluating the different signals and associated cut-offs and controls, as determined to be appropriate by FDA. Furthermore, precision of the device must be

evaluated per specimen and in aggregate.

(vi) Device performance data demonstrating appropriate device robustness, as determined to be appropriate by FDA. The study must assess the tolerance ranges for various critical test and specimen parameters, as applicable.

(vii) Device performance data demonstrating linearity of quantitative results using samples covering the device measuring range, as applicable.

(viii) Device performance data demonstrating appropriate specimen stability based on the intended use specimen type(s) of the device, as applicable.

(ix) Clinical data generated using well-characterized clinical specimens representative of the intended use population demonstrating appropriate clinical performance of the device for its intended use, as determined to be appropriate by FDA.

(2) Labeling must include:

(i) An appropriate summary, as determined by FDA, of the performance studies performed and the results of those studies, including those that relate to all design verification and validation special controls.

(ii) A limiting statement, as appropriate, that explains that the test results are intended to be interpreted by a qualified or appropriately trained reader in conjunction with other diagnostic laboratory test results and/or pathology test results, relevant clinical information, and proper controls.

(iii) Language indicating that the test system is indicated for use with a corresponding FDA-approved oncology therapeutic product and device labeling must be consistent with the information set forth in the corresponding FDA-approved oncology therapeutic product labeling.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026-16727 Filed 8-14-26; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 9

[Docket No. TTB-2024-0007; T.D. TTB-206; Ref: Notice No. 235]

RIN 1513-AD08

Establishment of the Columbia Hills Viticultural Area

AGENCY: Alcohol and Tobacco Tax and Trade Bureau, Treasury.

ACTION: Final rule; Treasury decision.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) establishes the 29,387-acre “Columbia Hills” American viticultural area (AVA) in Klickitat County, Washington. The newly established AVA is located entirely within the existing Columbia Valley viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase.

DATES: This final rule is effective September 16, 2026.

FOR FURTHER INFORMATION CONTACT:

Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW, Box 12, Washington, DC 20005; phone 202-453-1039, ext. 175.

SUPPLEMENTARY INFORMATION: In accordance with 5 U.S.C. 553(b)(4), a summary of this rule may be found at <https://www.regulations.gov/docket/TTB-2024-0007>.

Background on Viticultural Areas

TTB Authority

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury (Secretary) to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated certain administrative and enforcement authorities to the TTB Administrator through Treasury Order 120-01.

Part 4 of the TTB regulations (27 CFR part 4) authorizes TTB to establish definitive viticultural areas and regulate the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) sets forth standards for the preparation and submission to TTB of petitions for the establishment or modification of American viticultural areas (AVAs) and lists the approved AVAs.

Definition

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region having distinguishing features as described in part 9 of the regulations and, once approved, a name and a delineated boundary codified in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to the wine's geographic origin. The establishment of AVAs allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of an AVA is neither an approval nor an endorsement by TTB of the wine produced in that area.

Requirements

Section 4.25(e)(2) of the TTB regulations (27 CFR 4.25(e)(2)) outlines the procedure for proposing an AVA and allows any interested party to petition TTB to establish a grape-growing region as an AVA. Section 9.12 of the TTB regulations (27 CFR 9.12) prescribes standards for petitions to establish or modify AVAs. Petitions to establish an AVA must include the following:

- Evidence that the area within the proposed AVA boundary is nationally or locally known by the AVA name specified in the petition;
- An explanation of the basis for defining the boundary of the proposed AVA;
- A narrative description of the features of the proposed AVA affecting viticulture, such as climate, geology, soils, physical features, and elevation, that make the proposed AVA distinctive and distinguish it from adjacent areas outside the proposed AVA;
- If the proposed AVA is to be established within, or overlapping, an existing AVA, an explanation that both identifies the attributes of the proposed AVA that are consistent with the existing AVA and explains how the proposed AVA is sufficiently distinct

from the existing AVA and therefore appropriate for separate recognition;

- The appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed AVA, with the boundary of the proposed AVA clearly drawn thereon; and
- A detailed narrative description of the proposed AVA boundary based on USGS map markings.

Columbia Hills Petition

TTB received a petition to establish the "Columbia Hills" AVA submitted on behalf of the owner of Cascade Cliffs Vineyard and Winery, which is located within the proposed AVA. The proposed Columbia Hills AVA is located in Klickitat County, Washington, and is entirely within the established Columbia Valley AVA (27 CFR 9.74). Within the proposed AVA, there are approximately 338 acres of vineyards owned by 19 different property owners, as well as 4 wineries. The distinguishing features of the proposed Columbia Hills are its topography, soils, and climate.

The proposed AVA is situated on the southern slopes of the Columbia Hills, a 35-mile-long ridgeline that parallels the north side of the Columbia River between Rowena Gap and the mouth of Rock Creek in Klickitat County, Washington. Erosion of the generally flat-lying layers of bedrock by ice-age flooding created a series of south-facing stepped terraces within the proposed AVA. Large, gently-sloped gravel bars deposited by ice-age floods also exist within the proposed AVA. The petition states that these gently-sloped terraces and gravel bars provide excellent locations for vineyards within the otherwise steeply sloped valley of the Columbia River.

The soils of the proposed Columbia Hills AVA are divided into two main soil map units—the Cheviot—Horseflat—Rockly—Kiona unit, which is described as "well-drained soils that formed in colluvium and residuum derived from basalt mixed with loess;" and the Ewall-Dallesport-Rock Outcrop unit, which consists of wind-deposited sand that was draped over the bedrock and gravel bars that were left behind when the ice-age floods ceased. The soils of the proposed AVA are well drained to excessively well drained and are typically much coarser than the loess-based soils that are common elsewhere in the Columbia River basin. The petition states that the coarse soils warm more quickly than finer soils and encourage vines to root deeply.

According to the petition, 80 percent of the land in the proposed Columbia

Hills AVA is within a mile of the Columbia River, which acts as a thermal reservoir to moderate the climate near its shores. Due to its proximity to the river, the proposed AVA generally has warmer growing season temperatures than the surrounding regions, particularly during the early morning hours. Average growing season temperatures within the proposed AVA range from 63.9 to 67.7 degrees Fahrenheit (F), with average growing season maximum temperatures between 74.5 and 80.2 degrees F and average growing season minimum temperatures between 53 and 55.3 degrees F.

The average number of frost-free days within the proposed AVA ranges between 194 and 254 days. The average number of growing degree days (GDDs)¹ ranges from 3,091 to 3,588. Average annual rainfall amounts within the proposed AVA are generally between 10 and 20 inches. The petition states that the warm climate of the proposed AVA aids and accelerates the ripening of grapes and allows for the cultivation of warmer climate grape varieties such as Grenache and Mourvedre.

To the north of the proposed AVA, the topography is much steeper, higher, and less impacted by ice-age flooding than the proposed AVA. Soils are generally deep and derived from loess. Growing season average temperatures are lower, ranging from 57 to 59.5 degrees F, as are average growing season maximum and minimum temperatures, which range from 72 to 77 degrees F and 42 to 43 degrees F, respectively. Average annual GDD accumulations to the north of the proposed AVA are also lower, ranging from 1,834 to 2,309 GDDs. The average frost-free period to the north ranges from 142 to 164 days.

To the east of the proposed Columbia Hills AVA is the established The Burn of Columbia Valley AVA (27 CFR 9.276), which is relatively flat and has higher elevations that were less impacted by ice-age floods. The soils are primarily from the Van Nostern—Morrow—Bakeoven soil unit and contain large amounts of loess. Annual precipitation rates average less than 10 inches.

South of the proposed AVA, elevations are generally lower and the slopes have a northerly aspect. Soils are generally deep and derived from loess.

¹ See Albert J. Winkler et al., *General Viticulture* (Berkeley: University of California Press, 2nd ed.), pages 61–64 (1974). In the Winkler climate classification system, annual heat accumulation during the growing season, measured in annual GDDs, defines climatic regions. One GDD accumulates for each degree Fahrenheit (F) that a day's mean temperature is above 50 degrees F, the minimum temperature required for grapevine growth.

Temperatures are lower than within the proposed AVA, with average growing season temperatures ranging from 58 to 59.7 degrees F. Average annual maximum and minimum growing season temperatures range from 70 to 75 degrees F and 44 to 46 degrees F, respectively. The average frost-free period ranges from 163 to 174 days, and annual GDD accumulations range from 2,006 to 2,255 GDDs.

West of the proposed Columbia Hills AVA is the established Columbia Gorge AVA (27 CFR 9.178), which has higher elevations and a more diverse topography. Soils within the established Columbia Gorge AVA are also more diverse than within the proposed AVA due to large variations in bedrock, elevation, and slope angles.

Temperatures are lower to the west of the proposed AVA, with average growing season temperatures ranging from 58.7 to 62 degrees F. Average GDD accumulations range from 2,107 to 2,647 GDDs.

Notice of Proposed Rulemaking and Comments Received

TTB published Notice No. 235 in the *Federal Register* on December 5, 2024 (89 FR 96623), proposing to establish the Columbia Hills AVA. In the notice, TTB summarized the evidence from the petition regarding the name, boundary, and distinguishing features of the proposed AVA. The notice also included the information from the petition comparing the distinguishing features of the proposed AVA to the surrounding areas. For a detailed description of the evidence and for a detailed comparison of the proposed AVA to the surrounding areas, see Notice No. 235.

In Notice No. 235, TTB solicited comments on the accuracy of the name, boundary, and other required information submitted in support of the petition. In addition, given the proposed Columbia Hills AVA's location within the Columbia Valley AVA, TTB solicited comments on whether the evidence submitted in the petition sufficiently differentiates it from the established AVA. TTB also requested comments on whether the features of the proposed AVA are so distinguishable from the established AVA that the proposed AVA should no longer be part of the established AVA. The comment period closed February 3, 2025.

TTB received five comments in response to Notice No. 235, four of which specifically support the proposed AVA. One comment from a representative of V75 Vineyard (comment 4) describes the area as

having a unique terroir distinct from other grape growing areas in the northwest. Another representative of V75 Vineyard (comment 2) describes the winds, growing degree days, and geology as unique features that support distinguishing this area within the larger Columbia Valley AVA. This commenter also notes the appropriateness of the AVA name for this region. The supporting comments from V75 Vineyard representatives (comments 2, 4, and 5) also express the view that establishing the proposed AVA will provide economic benefits to the region, helping support and market the region's vineyards and wines. A separate comment (comment 3) describes the proposed AVA as "one of the most interesting grape-growing/viticultural areas identified in years."

The remaining comment (comment 1) expressed neither support nor opposition to the proposed AVA and just asked whether the proposed "Columbia Hills" name might be confused with the established Columbia Valley AVA. TTB notes that, as described more fully in the Notice No. 235, the petition provided evidence that the area of the proposed AVA is known by the name "Columbia Hills", which is reflected in the Columbia Hills Natural Area Preserve and Columbia Hills Historical State Park. TTB did not receive any comments in response to Notice No. 235 questioning the sufficiency of the name evidence. As noted below in the section "Impact on Current Wine Labels," because the Columbia Hills AVA is situated within and maintains features consistent with the Columbia Valley AVA, vintners will be able to use "Columbia Hills," "Columbia Valley," or both as appellations of origin for wines made primarily from grapes grown within the Columbia Hills AVA if the wines meet the eligibility requirements for these appellations. As with the establishment of any AVA, the extent to which wine consumers recognize the name of the AVA and associate the name with certain features of the wine depends upon the efforts of vineyard owners and winemakers in the region, which are factors beyond the establishment of the AVA.

TTB Determination

After careful review of the petition and the comments received in response to Notice No. 235, TTB finds that the evidence provided by the petitioner supports establishing the Columbia Hills AVA. Accordingly, under the authority of the FAA Act, section 1111(d) of the Homeland Security Act of 2002, and parts 4 and 9 of the TTB

regulations, TTB establishes the "Columbia Hills" AVA in Klickitat County, Washington, effective 30 days from the publication date of this document.

TTB has also determined that the Columbia Hills AVA will remain part of the established Columbia Valley AVA. As discussed in Notice No. 235, the Columbia Hills AVA shares some broad characteristics with the established AVA. For example, the proposed AVA and the Columbia Valley AVA both have growing seasons longer than 150 days, limited annual rainfall amounts, and GDD accumulations generally over 2,000. Unlike the surrounding Columbia Valley AVA, however, the proposed Columbia Hills AVA is not a large, treeless basin. Instead, the proposed AVA is a region of hillslopes and flood-carved terraces within a deeply incised river valley.

Boundary Description

See the narrative description of the boundary of the Columbia Hills AVA in the regulatory text published at the end of this final rule.

Maps

The petitioners provided the required maps, and they are listed below in the regulatory text. The Columbia Hills AVA boundary may also be viewed on the AVA Map Explorer on the TTB website, at <https://www.ttb.gov/regulated-commodities/beverage-alcohol/wine/ava-map-explorer>.

Impact on Current Wine Labels

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine's true place of origin. For a wine to be labeled with an AVA name or with a brand name that includes an AVA name, at least 85 percent of the wine must be derived from grapes grown within the area represented by that name, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible for labeling with an AVA name and that name appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the AVA name appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label. Different rules apply if a wine has a brand name containing an AVA name that was used as a brand name on a label approved before July 7, 1986. See 27 CFR 4.39(i)(2) for details.

With the establishment of the Columbia Hills AVA, its name,

“Columbia Hills,” will be recognized as a name of viticultural significance under § 4.39(i)(3) of the TTB regulations (27 CFR 4.39(i)(3)). The text of the regulation clarifies this point.

Consequently, wine bottlers using the name “Columbia Hills” in a brand name, including a trademark, or in another label reference as to the origin of the wine, will have to ensure that the product is eligible to use the AVA name as an appellation of origin.

The establishment of the Columbia Hills AVA will not affect the existing Columbia Valley AVA, and any bottlers using “Columbia Valley” as an appellation of origin or in a brand name for wines made from grapes grown within the Columbia Valley AVA will not be affected by the establishment of this new AVA. The establishment of the Columbia Hills AVA will allow vintners to use “Columbia Hills,” “Columbia Valley,” or both as appellations of origin for wines made primarily from grapes grown within the Columbia Hills AVA if the wines meet the eligibility requirements for these appellations.

Regulatory Flexibility Act

TTB certifies that this regulation will not have a significant economic impact on a substantial number of small entities. The regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of an AVA name would be the result of a proprietor's efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

Executive Order 12866

It has been determined that this final rule is not a significant regulatory action as defined by Executive Order 12866, as amended. Therefore, no regulatory assessment is required.

Drafting Information

Karen A. Thornton of the Regulations and Rulings Division drafted this final rule.

List of Subjects in 27 CFR Part 9

Wine.

The Regulatory Amendment

For the reasons discussed in the preamble, TTB amends title 27, chapter I, part 9, Code of Federal Regulations, as follows:

PART 9—AMERICAN VITICULTURAL AREAS

■ 1. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

Subpart C—Approved American Viticultural Areas

■ 2. Add § 9.301 to read as follows:

§ 9.301 Columbia Hills.

(a) *Name.* The name of the viticultural area described in this section is “Columbia Hills”. For purposes of part 4 of this chapter, “Columbia Hills” is a term of viticultural significance.

(b) *Approved maps.* The two United States Geological Survey (USGS) 1:100,000 scale topographic maps used to determine the boundary of the viticultural area are as follows:

- (1) Hood River OR–WA, 1982; and
- (2) Goldendale, WA–OR, 1980.

(c) *Boundary.* The Columbia Hills viticultural area is located in Klickitat County, Washington. The boundary of the Columbia Hills viticultural area is as described as follows:

(1) The beginning point is on the Hood River map at the intersection of the northern shoreline of the Columbia River and an unnamed creek due east of the marked “Cold Spring.” From the beginning point, proceed northerly along the unnamed creek to its intersection with the 300-meter elevation contour; then

(2) Proceed east along the 300-meter elevation contour to the eastern boundary of the Hood River map; then

(3) Proceed north along the map boundary for approximately 400 feet; then

(4) Proceed east onto the 320-meter elevation contour on the Goldendale map and continue east along the 320-meter elevation contour to its intersection with the boundary between Range 18 East and Range 19 East, south of Sand Spring Canyon; then

(5) Proceed southeast in a straight line for 9,000 feet (1.7 miles) to the intersection of the boundary between sections 31 and 32, T3N/R19E and the northern shoreline of the Columbia River; then

(6) Proceed west along the northern shoreline of the Columbia River, returning to the beginning point.

Signed: August 11, 2026.

Mary G. Ryan,
Administrator.

Approved: August 12, 2026.

Kevin M. Salinger,
Acting Assistant Secretary of the Treasury
(Tax Policy).

[FR Doc. 2026–16701 Filed 8–14–26; 8:45 am]

BILLING CODE 4810–31–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2026–1058]

RIN 1625–AA00

Safety Zone; Fox River, Green Bay, WI

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters on the Fox River, in Green Bay, WI. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards associated with an overwater fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Lake Michigan, or their designated representative.

DATES: This rule is effective on September 5, 2026, from 9 p.m. to 9:45 p.m.

ADDRESSES: To view available documents go to <https://www.regulations.gov> and search for USCG–2026–1058.

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, contact MSTC Dylan Caikowski, Sector Lake Michigan, Waterways Management Division, U.S. Coast Guard; telephone (571) 608–0739, or email D09-SMB-SecLakeMichigan-WWM@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background and Authority

The Coast Guard received notification that fireworks will be launched from land adjacent to the Fox River in Green Bay, WI. The Captain of the Port (COTP) Sector Lake Michigan has determined that potential hazards associated with fireworks are a safety concern for anyone within 500 feet of the fireworks display.

Therefore, the COTP is issuing this rule under the authority in 46 U.S.C. 70034, which is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone.