

lesion. The device is intended for prescription use by a physician trained in the clinical diagnosis and management of skin cancer (e.g., a dermatologist) as an adjunctive device to aid in the evaluation of lesions suspicious for skin cancer following identification of a suspicious skin lesion. The device is not intended for use as a standalone diagnostic and is not for use to confirm a clinical diagnosis.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Data obtained from premarket clinical performance validation testing, or a combination of premarket clinical performance validation testing and post-market surveillance (in accordance with paragraph (b)(2) of this section), must:

(i) Demonstrate superior accuracy of device-aided users' diagnostic characterization of the indicated lesions compared to the accuracy of unaided users in the intended patient population and under anticipated conditions of use;

(ii) Include an evaluation of patients across risk factors (including age, body site, skin phototype, and other clinical factors as applicable) that represent the intended patient population under anticipated conditions of use; and

(iii) Include standalone device performance testing that demonstrates the accuracy of the device output relative to ground truth in the intended patient population and under anticipated conditions of use, including the following:

(A) Testing must demonstrate at least 90% sensitivity of the device output for lesions with high metastatic potential, or an alternative clinical consideration must be provided to justify lower sensitivity. Clinical justification must be provided to support the reported specificity.

(B) Lesions must be selected by representative users (e.g., dermatologists) and a justification must be provided for the quantity and range of mimic lesions per diagnosis.

(C) Justification must be provided to support the determination of ground truth.

(D) Testing must include a representative range of individuals with different risk factors (including age, body site, skin phototype, and other clinical factors as applicable), and analysis of standalone performance must include subgroup analysis by relevant risk factors.

(2) Data obtained from post-market surveillance must demonstrate, in consideration of the premarket data obtained in accordance with paragraph (b)(1) of this section, that the device performs in accordance with paragraph

(b)(1) of this section, unless FDA determines, based on the totality of the premarket data, that data from post-market surveillance is not required to demonstrate that the device performs as intended. Such post-market surveillance must be conducted per a protocol determined appropriate by FDA to demonstrate that the device performs as intended (in consideration of the premarket data obtained in accordance with paragraph (b)(1) of this section), and must include initiation, enrollment, and reporting requirements to ensure timely periodic updates to FDA on post-market surveillance progress and outcomes.

(3) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including compatibility testing of the device software with specific signal or image acquisition hardware. Testing must include a description of compatible hardware and processes, pre-specified compatibility testing protocols, and dataset(s).

(4) Performance testing must demonstrate device precision, including repeatability and reproducibility of device performance, across operators and challenging use conditions.

(5) Performance testing must demonstrate electromagnetic compatibility, and electrical, mechanical, and thermal safety of any electrical components of the device.

(6) Performance testing must validate reprocessing instructions for reusable components of the device.

(7) Sterilization validation must be conducted for components that must be sterile. Performance testing must also demonstrate continued sterility and package integrity of components that must be sterile, as well as continued device functionality, over the identified shelf life of the device.

(8) The patient-contacting components of the device must be demonstrated to be biocompatible.

(9) Software verification, validation, and hazard analysis must be performed.

(10) A human factors assessment must demonstrate that the device can be safely used by intended users.

(11) Labeling must include:

(i) A summary of standalone and clinical performance testing conducted with the device. The summary must describe performance measures, including sensitivity and specificity, and statistical confidence intervals, as well as performance of the device for all clinically relevant subgroups within the intended patient population;

(ii) A description of the patient population that was used in

development or training of the device algorithm;

(iii) Information related to the limitations of device performance or subpopulations for which the device may not perform as expected or for whom the device has not been validated;

(iv) Information needed to facilitate interpretation of all device outputs, and identification of the risks associated with misinterpretation of the device outputs;

(v) A statement that the device is not intended for use as a standalone diagnostic and is not for use to confirm a clinical diagnosis;

(vi) User qualifications needed for safe use of the device, including a description of user training required prior to use, and a statement that the device is intended to be used by a physician trained in the clinical diagnosis and management of skin cancer (e.g., a dermatologist);

(vii) Warnings to avoid unsafe exposure to any energy-emitting components of the device (e.g., excluding use of the device on lesions close to the eye); and

(viii) Instructions for device maintenance and validated methods and instructions for reprocessing of any reusable components.

**Grace R. Graham,**

*Deputy Commissioner for Policy, Legislation, and International Affairs.*

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## DEPARTMENT OF AGRICULTURE

### Forest Service

#### 36 CFR Part 251

#### RIN 0596-AD12

#### Definition of a Ski Area

**AGENCY:** Forest Service, Agriculture (USDA).

**ACTION:** Final rule.

**SUMMARY:** The United States Department of Agriculture, Forest Service (Forest Service or Agency) is issuing a final rule revising the definition of a ski area in its special use regulations. The revised definition aligns more closely with the Forest Service's statutory authority for ski area administration and reduces burden on the agency and special use permit holders.

**DATES:** The final rule is effective April 24, 2026.

**FOR FURTHER INFORMATION CONTACT:** Sean Wetterberg, National Winter Sports

Program Manager at 385–235–0318. Individuals who are deaf, hard of hearing, or have a speech disability may call 711 to reach the Telecommunications Relay Service and then provide the phone number of the person named as a point of contact for further information.

**SUPPLEMENTARY INFORMATION:** The Department defines “ski area” in regulation because it allows the agency to determine what uses qualify for a ski area permit under the National Forest Ski Area Permit Act of 1986 (16 U.S.C. 497b) and importantly, what uses do not. The National Forest Ski Area Permit Act of 1986 is the sole authority for authorizing Nordic and alpine ski areas on National Forest System lands and the Ski Fee Act of 1996 (16 U.S.C. 497c) requires that qualifying ski areas be charged following the Ski Area Permit Rental Charge formula provided in the Act. The Ski Area Recreation Opportunity Enhancement Act of 2011 further amended 16 U.S.C. 497b, adding more details about other recreational activities that may be authorized under a Ski Area Permit beyond skiing and other snow sports. The 2011 Act provides for authorizing only those other recreational uses as the Secretary deems appropriate, describes the requirements of those recreational activities, and lists specific inclusions and exclusions. At 497b(5), a limitation is put on the authorization of those other recreational uses if they would “result in the primary purpose of the ski area permit to be a purpose other than skiing and other snow-sports.” The ski area definition at 36 CFR 251.51 incorporates the primary purpose concept from the statute to clarify the requirement to limit recreational activities other than skiing and other snow sports in ski areas, and to facilitate agency decision making and compliance with law.

The Department issued an interim final rule on June 28, 2013, revising the definition of a ski area to make it consistent with the authority in section 3 of the Ski Area Recreation Opportunity Enhancement Act of 2011, which allows ski areas to provide other types of natural resource-based recreation as long as the primary purpose of the site remains snow sports (78 FR 38842). The definition of a ski area, as promulgated in the 2013 interim final rule, also includes a revenue test to determine if a ski area’s primary purpose is for skiing and snow sports based solely on whether the preponderance of revenue generated by the ski area comes from those activities. This revenue test was carried forward

from the previous version of the definition of a ski area. The interim final rule implementing the new definition went into effect on July 29, 2013.

The Department received one comment letter during the public comment period that accompanied the interim final rule. The comment submitted by the National Ski Areas Association argued that the revenue test included in the definition is inappropriate for determining whether the primary purpose of a ski area is snow sports because of its lack of basis in statute. The comment suggested that the Department remove the revenue test to preserve the flexibility for four-season operations that the Ski Area Recreation Opportunity Enhancement Act authorized.

Since the current definition became effective in 2013, the Forest Service has observed that the preponderance of revenue test has not singularly correlated to whether a ski area’s primary purpose is skiing and other snow sports. Rather, experience demonstrates that the agency should be considering multiple factors, assessed on a case-by-case basis, to more accurately determine the primary purpose of a ski area. In addition to revenue, these other factors may include skiing vs. non-skiing comparisons of visitation, acreage, facility square footage, length of season, financial investment, or even a general comparison of whether the permitted area looks and feels primarily like a ski area.

The revenue test has also become less useful in the last decade due to significant fluctuations in seasonal snow conditions. Many ski areas, especially those in southern regions, now rely more on revenue from non-skiing activities to stay solvent between years of greater snowfall. This trend further suggests that the Forest Service should consider multiple factors on a site-specific basis to determine the primary purpose of a ski area, rather than relying solely on the preponderance of revenue.

After consideration of the comment received on the interim final rule, the agency’s experience in implementing the current definition, and changing conditions on the ground, the Department has determined that the preponderance of revenue test currently found at 36 CFR 251.51 is inappropriate. The revenue test is not found in the authorizing statutes, including the Ski Area Recreation Opportunity Enhancement Act of 2011, the Ski Fee Act of 1996, and the National Forest Ski Area Permit Act of 1986. Removing the revenue test from the definition will

align the regulation more closely with statute and provide for additional discretion of authorized officers to determine whether a site and associated facilities qualify as a ski area. Such discretion remains bounded by the statutory requirement in 16 U.S.C. 497b that the primary purpose of a ski area permit be skiing and other snow sports. Therefore, in this final rule, the revenue test is removed.

The Department has determined that additional notice and comment is not required for this final rule. The interim final rule expressly solicited public comment on the revised definition of a ski area, including the preponderance of revenue test. The final rule is a logical outgrowth of the interim final rule and the comment received because it adopts the precise change requested by the commenter and does not introduce new regulatory concepts or requirements beyond the scope of the interim final rule.

The Department also notes that the interim final rule has been in effect since 2013, and this final rule removes an existing regulatory constraint rather than imposing new obligations. Accordingly, the Department has determined that the final rule does not raise additional notice concerns despite the period between issuance of the interim final rule and adoption of this final rule.

The final rule maximizes the discretion of authorized officers to determine whether a site and associated facilities qualify as a ski area based on any number of relevant factors consistent with statutory limitations. It also reduces the regulatory burden on ski area permit holders should an area not meet the revenue test but is otherwise designed and managed primarily for skiing and other snow sports. The final rule allows additional flexibility in how permit holders set up their operations while allowing them to retain the unique benefits afforded by a ski area term permit. The revised definition in the final rule does not eliminate the possibility that a ski area may be found to no longer qualify as a ski area under the “primary purpose” requirement found in 16 U.S.C. 497b. Ski areas that no longer meet this requirement may seek re-authorization under an authority other than 16 U.S.C. 497b for continued use and occupancy of NFS lands.

## Regulatory Certifications

### *Regulatory Planning and Review*

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office

of Management and Budget will determine whether a regulatory action is significant as defined by E.O. 12866 and will review significant regulatory actions. OIRA has determined that this final rule is not significant as defined by E.O. 12866. E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The Department has developed the final rule consistent with E.O. 13563.

#### *Congressional Review Act*

Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act) (5 U.S.C. 801 *et seq.*), OIRA has designated this final rule as not a major rule as defined by 5 U.S.C. 804(2).

#### *National Environmental Policy Act*

The final rule will revise the definition of a ski area by rescinding the revenue test currently found in the definition. Departmental regulations at 7 CFR 1b.4(c)(20) exclude from documentation in an environmental assessment or environmental impact statement "rules, regulations, or policies to establish servicewide administrative procedures, program processes, or instructions." The Department's assessment is that this final rule falls within this category of actions and that no extraordinary circumstances exist which will require preparation of an environmental assessment or environmental impact statement.

#### *Regulatory Flexibility Act*

The Department has considered this final rule under the Regulatory Flexibility Act (5 U.S.C. 602 *et seq.*). Removing the preponderance of revenue test from the definition of a ski area may benefit large and small ski areas by providing increased flexibility to maintain authorization for skiing and snow sports alongside other authorized year-round uses under a ski area term permit. This final rule will not impose recordkeeping requirements on small entities; will not affect their competitive position in relation to large entities; and will not affect their cash flow, liquidity, or ability to remain in the market. Therefore, the Department has determined that this final rule will not have a significant economic impact on a substantial number of small entities pursuant to the Regulatory Flexibility Act.

#### *Federalism*

The Department has considered this final rule under the requirements of E.O. 13132, *Federalism*. The Department has determined that the final rule conforms with the federalism principles set out in this E.O.; will not impose any compliance costs on the States; and will not have substantial direct effects on the States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, the Department has concluded that this final rule will not have federalism implications.

#### *Consultation and Coordination With Indian Tribal Governments*

E.O. 13175, *Consultation and Coordination With Indian Tribal Governments*, requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. This final rule revises the definition of a ski area by rescinding the revenue test currently found in the definition. The Department has reviewed this final rule in accordance with the requirements of E.O. 13175 and has determined that this final rule could have substantial direct effects on Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes. Therefore, the Department determined that consultation and coordination with Indian Tribal governments is required for this final rule.

*Tribal Summary Impact Statement:* The Forest Service sent out information about the draft final rule, along with an invitation to consult on July 31, 2025. On September 2, 2025, the Forest Service received a request from the Quapaw Nation for maps associated with the final rule. The final rule applies to all ski areas and future ski areas throughout the National Forest System and does not contain a specific spatial component that could be suitably depicted on a map. Therefore, the Forest Service responded that maps are not available for this final rule. On November 18, 2025, the Forest Service

received a letter from the Snoqualmie Tribe expressing frustration with the lack of information provided on the draft final rule and highlighting that Tribal interests could be impacted by the final rule. The Forest Service followed up with the Snoqualmie Tribe to provide any additional information that would be helpful to their understanding and analysis of the final rule. No requests for consultation have been received for this final rule.

#### *Family Policymaking Assessment*

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277), requires Federal agencies to issue a Family Policymaking Assessment for a rule that may affect family well-being. The final rule will have no impact on the autonomy or integrity of the family as an institution. Accordingly, the Department has concluded that it is not necessary to prepare a Family Policymaking Assessment for the final rule.

#### *Takings Implications*

The Department has analyzed the final rule in accordance with the principles and criteria in E.O. 12630, *Governmental Actions and Interference with Constitutionally Protect Property Rights*.

The Department has determined that the final rule will not pose the risk of a taking of private property.

#### *Energy Effects*

The Department has reviewed the final rule under E.O. 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*. The Department has determined that the final rule will not constitute a significant energy action as defined in E.O. 13211.

#### *Civil Justice Reform*

The Department has analyzed the final rule in accordance with the principles and criteria in E.O. 12988, *Civil Justice Reform*. Upon publication of the final rule, (1) all State and local laws and regulations that conflict with the final rule or that impede its full implementation will be preempted; (2) no retroactive effect will be given to this final rule; and (3) it will not require administrative proceedings before parties may file suit in court challenging its provisions.

#### *Unfunded Mandates*

Pursuant to Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538), the Department has assessed the effects of the final rule on

State, local, and Tribal governments and the private sector. The final rule will not compel the expenditure of \$100 million or more, adjusted annually for inflation, in any 1 year by State, local, and Tribal governments in the aggregate or by the private sector. Therefore, a statement under section 202 of the Act is not required.

#### *Paperwork Reduction Act*

The final rule does not contain any recordkeeping or reporting requirements or other information collection requirements as defined in 5 CFR part 1320 that are not already required by law or not already approved for use. Accordingly, the review provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320 do not apply.

#### **List of Subjects in 36 CFR Part 251**

Administrative practice and procedure, Alaska, Electric power, Mineral resources, National forests, Public lands-rights-of-way, Reporting and recordkeeping requirements, Water resources.

Therefore, for the reasons set forth in the preamble, the Department amends chapter II of title 36 of the Code of Federal Regulations as follows:

#### **PART 251—LAND USES**

##### **Subpart B—Special Uses**

- 1. The authority citation for part 251, subpart B continues to read:

**Authority:** 16 U.S.C. 4601–6a, 4601–6d, 472, 497b, 497c, 551, 580d, 1134, 3210; 30 U.S.C. 185; 43 U.S.C. 1740, 1761–1772.

- 2. Amend § 251.51 by revising the definition of “Ski area” to read as follows:

##### **§ 251.51 Definitions.**

\* \* \* \* \*

*Ski area*—a site designed and managed primarily for skiing, which may also include other snow sports. Associated facilities may also support seasonal or year-round natural resource-based recreation activities consistent with applicable law.

\* \* \* \* \*

**Michael K. Boren,**

*Under Secretary, Natural Resources and Environment.*

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#### **ENVIRONMENTAL PROTECTION AGENCY**

##### **40 CFR Part 180**

[EPA–HQ–OPP–2024–0109]; [FRL–13214–01–OCSPF]

##### **Dimethylpolysiloxane in Pesticide Formulations; Exemption From the Requirement for a Tolerance**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of methyl end-capped polydimethylsiloxane (CAS Reg. No 63148–62–9); also known as dimethylpolysiloxane when used as an inert ingredient in a pesticide chemical formulation under 40 CFR 180.960. Momentive Performance Materials, Inc submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of methyl end-capped polydimethylsiloxane on food or feed commodities when used in accordance with these exemptions.

**DATES:** This regulation is effective March 25, 2026. Objections and requests for hearings must be received on or before May 26, 2026 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of this document).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2024–0109, is available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Charles Smith, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; main telephone number: (202) 566–1030; email address: [RDFFRNotices@epa.gov](mailto:RDFFRNotices@epa.gov).

##### **SUPPLEMENTARY INFORMATION:**

##### **I. General Information**

##### *A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is

not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

##### *B. What is EPA’s authority for taking this action?*

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(c)(2)(A)(i) allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” FFDCA section 408(c)(2)(A)(ii) defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .” Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, “available information concerning the cumulative effects of a particular pesticide’s residues” and “other substances that have a common mechanism of toxicity.”

##### *C. How can I file an objection or hearing request?*

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file an objection