

Strengthening Organic Enforcement Proposed Rule: Comparison of Current and Proposed Regulatory Text

1. Applicability and Exemptions from Certification

| Section | Current Text | Action | Section | Proposed Text |
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| 205.2 | <i>Handle.</i> To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler. | Revise | 205.2 | <i>Handle.</i> To sell, process, or package agricultural products, including but not limited to trading, facilitating sale or trade, brokering, repackaging, labeling, combining, containerizing, storing, receiving, or loading. |
| 205.2 | <i>Handler.</i> Any person engaged in the business of handling agricultural products, including producers who handle crops or livestock of their own production, except such term shall not include final retailers of agricultural products that do not process agricultural products. | Revise | 205.2 | <i>Handler.</i> Any person engaged in the business of handling agricultural products. |
| 205.2 | <i>Handling operation.</i> Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products. | Revise | 205.2 | <i>Handling operation.</i> Any operation or portion of an operation that handles agricultural products, except for operations that are exempt from certification. |
| 205.2 | <i>Retail food establishment.</i> A restaurant; delicatessen; bakery; grocery store; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat-food. | Revise | 205.2 | <i>Retail operation.</i> An operation that sells agricultural products directly to final consumers through in-person and/or virtual transactions. |
| 205.100(a) | (a) Except for operations exempt or excluded in §205.101, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part. | Revise | 205.100(a) | Except for the exempt operations described in §205.101, each operation, or portion of an operation, that produces or handles agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part. |
| 205.101 | Exemptions and exclusions from certification. | Revise | 205.101 | Exemptions from certification. |
| 205.101 | | Add introductory paragraph | 205.101 | The following operations in subparagraphs (a) through (e) of this section are exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under §205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part, including the provisions for prevention of contact of organic products with prohibited |

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| | | | | substances set forth in §205.272, and the specific additional requirements stipulated in §205.101(a) through (f). |
| 205.101(a) | <p><i>Exemptions.</i> (1) A production or handling operation that sells agricultural products as “organic” but whose gross agricultural income from organic sales totals \$5,000 or less annually is exempt from certification under subpart E of this part and from submitting an organic system plan for acceptance or approval under §205.201 but must comply with the applicable organic production and handling requirements of subpart C of this part and the labeling requirements of §205.310. The products from such operations shall not be used as ingredients identified as organic in processed products produced by another handling operation.</p> <p>(2) A handling operation that is a retail food establishment or portion of a retail food establishment that handles organically produced agricultural products but does not process them is exempt from the requirements in this part.</p> <p>(3) A handling operation or portion of a handling operation that only handles agricultural products that contain less than 70 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in this part, except:</p> <p>(i) The provisions for prevention of contact of organic products with prohibited substances set forth in §205.272 with respect to any organically produced ingredients used in an agricultural product;</p> <p>(ii) The labeling provisions of §§205.305 and 205.310; and</p> <p>(iii) The recordkeeping provisions in paragraph (c) of this section.</p> <p>(4) A handling operation or portion of a handling operation that only identifies organic ingredients on the information panel is exempt from the requirements in this part, except:</p> <p>(i) The provisions for prevention of contact of organic products with prohibited substances set forth in §205.272 with respect to any organically produced ingredients used in an agricultural product;</p> <p>(ii) The labeling provisions of §§205.305 and 205.310; and</p> <p>(iii) The recordkeeping provisions in paragraph (c) of this section.</p> | Revise | 205.101(a) | A production or handling operation that sells agricultural products as “organic” but whose gross agricultural income from organic sales totals \$5,000 or less annually. The products from such operations must not be used as ingredients identified as organic in processed products produced by another handling operation. Such operations must comply with the labeling provisions of §205.310. |

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| 205.101(b) | <p><i>Exclusions.</i> (1) A handling operation or portion of a handling operation is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in §205.272 with respect to any organically produced products, if such operation or portion of the operation only sells organic agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” that:</p> <ul style="list-style-type: none"> (i) Are packaged or otherwise enclosed in a container prior to being received or acquired by the operation; and (ii) Remain in the same package or container and are not otherwise processed while in the control of the handling operation. <p>(2) A handling operation that is a retail food establishment or portion of a retail food establishment that processes, on the premises of the retail food establishment, raw and ready-to-eat food from agricultural products that were previously labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” is excluded from the requirements in this part, except:</p> <ul style="list-style-type: none"> (i) The requirements for the prevention of contact with prohibited substances as set forth in §205.272; and (ii) The labeling provisions of §205.310. | Revise | 205.101(b) | A retail operation or a portion of a retail operation that sells, but does not process, organically produced agricultural products. |
| 205.101(c) | <p><i>Records to be maintained by exempt operations.</i> (1) Any handling operation exempt from certification pursuant to paragraph (a)(3) or (a)(4) of this section must maintain records sufficient to:</p> <ul style="list-style-type: none"> (i) Prove that ingredients identified as organic were organically produced and handled; and (ii) Verify quantities produced from such ingredients. <p>(2) Records must be maintained for no less than 3 years beyond their creation and the operations must allow representatives of the Secretary and the applicable State organic programs' governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.</p> | Revise | 205.101(c) | A retail operation or portion of a retail operation that processes agricultural products that were previously labeled for retail sale as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” provided that the products are processed onsite at the point of sale to the final consumer. Such operations must comply with the labeling provisions of §205.310, and must maintain records sufficient to: <ul style="list-style-type: none"> (1) Prove that agricultural products identified as organic were organically produced and handled; and (2) Verify quantities produced or sold from such agricultural products. |

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| 205.101(d) | | Add | 205.101(d) | A handling operation or portion of a handling operation that only handles agricultural products that contain less than 70 percent organic ingredients (as described in §205.301(d)), or that only identifies organic ingredients on the information panel. Such operations must comply with the labeling provisions of §§205.305 and 205.310 and must maintain records sufficient to: (1) Prove that agricultural products identified as organic were organically produced and handled; and (2) Verify quantities produced or sold from such agricultural products. |
| 205.101(e) | | Add | 205.101(e) | An operation that only stores, receives, and/or loads agricultural products, but does not process or alter such agricultural products. |
| 205.101(f) | | Add | 205.101(f) | Records described in subparagraphs (a)–(d) of this section must be maintained for no less than 3 years beyond their creation, and the operations must allow representatives of the Secretary and the applicable State organic programs' governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part. |

2. Imports to the United States

| Section | Current Text | Action | Section | Proposed Text |
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| | | 205.2 | Add new term | <i>Organic exporter.</i> The owner or final exporter of the organic product who facilitates the trade of, consigns, or arranges for the transport/shipping of the organic product from a foreign country. |
| | | 205.2 | Add new term | <i>Organic importer of record.</i> The operation responsible for accepting imported organic products within the United States. |
| | | 205.273 | Add new section | Imports to the United States. |
| | | 205.273 | Add | Each shipment of organic products imported into the United States through U.S. Ports of Entry must be certified pursuant to subpart E of this part, labeled pursuant to subpart D of this part, be declared as organic to U.S. Customs and Border |

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| | | | | Protection, and be associated with a valid NOP Import Certificate (Form NOP 2110-1) or equivalent data source. |
| | | 205.273(a) | Add | Persons exporting organic products to the United States must request an NOP Import Certificate, or provide data through an equivalent data source, from a certifying agent, for each physical shipment of certified organic products prior to their export. Only certifying agents accredited by the USDA or foreign certifying agents authorized under an organic trade arrangement may issue an NOP Import Certificate or approve a listing in an equivalent data source (e.g., a third-party export system). |
| | | 205.273(b) | Add | The certifying agent must review an NOP Import Certificate request, determine whether the shipment complies with the USDA organic regulations, and issue the NOP Import Certificate or equivalent within 30 calendar days of receipt if the shipment complies with the USDA organic regulations. |
| | | 205.273(c) | Add | Each compliant organic shipment must be declared as organic to U.S. Customs and Border Protection through a U.S. Port of Entry by uploading the unique NOP Import Certificate, or equivalent electronic data entry, into the U.S. Customs and Border Protection's Automated Commercial Environment system. |
| | | 205.273(d) | Add | Upon receiving a shipment with organic products, the organic importer of record must ensure the shipment is accompanied by a verified NOP Import Certificate or equivalent; must verify that the shipment contains only the quantity and type of certified organic product specified on the NOP Import Certificate or equivalent; and must verify that the shipment has had no contact with prohibited substances pursuant to §205.272 or exposure to ionizing radiation pursuant to §205.105, since export. |
| | | 205.273(e) | Add | The use of the term equivalent in this section refers to electronic data, documents, identification numbers, databases, or other systems verified as an equivalent data source to the NOP Import Certificate. |
| | Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part and labeled pursuant to this subpart D. | 205.300(c) | Revise | Products produced in a foreign country and exported for sale in the United States must be certified pursuant to subpart E of this part, labeled pursuant to this subpart D, and must comply |

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| | | | | with the requirements in §205.273, Imports to the United States. |

3. Labeling of Nonretail Containers

| Section | Current Text | Action | Section | Proposed Text |
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| 205.307 | Labeling of nonretail containers used for only shipping or storage of raw or processed agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” | Revise title | 205.307 | Labeling of nonretail containers. |
| 205.307(a) | Nonretail containers used only to ship or store raw or processed agricultural product labeled as containing organic ingredients may display the following terms or marks: (1) The name and contact information of the certifying agent which certified the handler which assembled the final product; (2) Identification of the product as organic; (3) Special handling instructions needed to maintain the organic integrity of the product; (4) The USDA seal; (5) The seal, logo, or other identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the finished product. | Revise | 205.307(a) | Nonretail containers used to ship or store certified organic product must display the following: (1) The term, “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” as applicable, to identify the product; (2) The statement, “Certified organic by (name of certifying agent),” or similar phrase, to identify the name of the certifying agent that certified the producer of the product, or, if processed, the certifying agent that certified the last handler that processed the product; and (3) The production lot number of the product, shipping identification, or other information needed to ensure traceability. |
| 205.307(b) | Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the production lot number of the product if applicable. | Revise | 205.307(b) | Nonretail containers used to ship or store certified organic product may display the following: (1) Special handling instructions needed to maintain the organic integrity of the product; (2) The USDA seal. Use of the USDA seal must comply with §205.311; (3) The name and contact information of the certified producer of the product, or if processed, the last certified handler that processed the product; (4) The seal, logo, or other identifying mark of the certifying agent that certified the producer of the product, or if processed, the last handler that processed the product; and/or (5) The business address, website, and/or contact information of the certifying agent. |

4. On-Site Inspections

| Section | Current Text | Action | Section | Proposed Text |
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| 205.403(b) | <p><i>Scheduling.</i> (1) The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part: <i>Except</i>, That, the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.</p> <p>(2) All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.</p> | Redesignate as 205.403(c); add new paragraph (b) | 205.403(b) | <p><i>Unannounced inspections.</i> (1) A certifying agent must, on an annual basis, conduct unannounced inspections of a minimum of five percent of the operations it certifies, rounded up to the nearest whole number.</p> <p>(2) Certifying agents must be able to conduct unannounced inspections of any operation it certifies and must not accept applications or continue certification with operations located in areas where they are unable to conduct unannounced inspections.</p> |
| 205.403(c) | <p><i>Verification of information.</i> The on-site inspection of an operation must verify:</p> <p>(1) The operation's compliance or capability to comply with the Act and the regulations in this part;</p> <p>(2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;</p> <p>(3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.</p> | Redesignate as 205.403(d)(1)–(3); correct “205.200” to “205.201” | 205.403(c) | <p><i>Scheduling.</i> (1) The initial on-site inspection must be conducted within a reasonable time following a determination that the applicant appears to comply or may be able to comply with the requirements of subpart C of this part: <i>Except</i>, That, the initial inspection may be delayed for up to 6 months to comply with the requirement that the inspection be conducted when the land, facilities, and activities that demonstrate compliance or capacity to comply can be observed.</p> <p>(2) All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.</p> |
| 205.403(d) | <p><i>Exit interview.</i> The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and</p> | Redesignate as 205.403(e) | 205.403(d)(1)–(3) | <p><i>Verification of information.</i> The on-site inspection of an operation must verify:</p> <p>(1) The operation's compliance or capability to comply with the Act and the regulations in this part;</p> |

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| | information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern. | | | (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.201, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. |
| | | Add | 205.403(d) (4) | That sufficient quantities of organic product and ingredients are produced or purchased to account for organic product sold or transported; and |
| | | Add | 205.403(d) (5) | That organic products and ingredients are traceable by the operation from the time of production or purchase to sale or transport; and that certifying agents can verify traceability back to the source per §205.501(a)(21). |
| 205.403(e) | <i>Documents to the inspected operation.</i> (1) At the time of the inspection, the inspector shall provide the operation’s authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken. (2) A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent. | Redesignate as 205.403(f) | 205.403(e) | <i>Exit interview.</i> The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern. |
| | | | 205.403(f) | <i>Documents to the inspected operation.</i> (1) At the time of the inspection, the inspector shall provide the operation’s authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken. (2) A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent. |

5. Certificates of Organic Operation

| Section | Current Text | Action | Section | Proposed Text |
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| | | Add new term | 205.2 | <i>INTEGRITY.</i> The National Organic Program’s electronic, web-based reporting tool for the submission of data, completion of certificates of organic operation, and other information, or its successors. |

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| 205.404(b) | The certifying agent must issue a certificate of organic operation which specifies the: (1) Name and address of the certified operation; (2) Effective date of certification; (3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation; and (4) Name, address, and telephone number of the certifying agent. | Revise | 205.404(b) | The certifying agent must issue a certificate of organic operation. The certificate of organic operation must be generated from INTEGRITY and may be provided to certified operations electronically. |
| 205.404(c) | Once certified, a production or handling operation’s organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State organic program’s governing State official, or the Administrator. | Redesignate as 205.404(d); add new paragraph (c) | 205.404(c) | In addition to the certificate of organic operation provided for in §205.404(b), a certifying agent may issue its own addenda to the certificate of organic operation. If issued, any addenda must include: (1) Name, address, and contact information for the certified operation; (2) The certified operation’s unique ID number/code that corresponds to the certified operation’s ID number/code in USDA Organic INTEGRITY; (3) A link to USDA Organic INTEGRITY or a link to the certified operation’s profile in USDA Organic INTEGRITY, along with a statement, “You may verify the certification of this operation at USDA Organic INTEGRITY,” or a similar statement; (4) Name, address, and contact information of the certifying agent; (5) “Addendum issue date;” and (6) “Addendum expiration date,” which must not exceed the expiration date of the certificate of organic operation. |
| | | | 205.404(d) | Once certified, a production or handling operation’s organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State organic program’s governing State official, or the Administrator. |

6. Continuation of Certification

| Section | Current Text | Action | Section | Proposed Text |
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| 205.406(a) | To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent: | Revise | 205.406(a) | To continue certification, a certified operation must annually pay the certification fees and submit the following information to the certifying agent: (1) A summary statement, supported by documentation, |

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| | <p>(1) An updated organic production or handling system plan which includes:</p> <p>(i) A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year’s organic system plan during the previous year; and</p> <p>(ii) Any additions or deletions to the previous year’s organic system plan, intended to be undertaken in the coming year, detailed pursuant to §205.200;</p> <p>(2) Any additions to or deletions from the information required pursuant to §205.401(b);</p> <p>(3) An update on the correction of minor noncompliances previously identified by the certifying agent as requiring correction for continued certification; and</p> <p>(4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.</p> | | | <p>detailing any deviations from, changes to, modifications to, or other amendments made to the organic system plan submitted during the previous year; and</p> <p>(2) Any additions or deletions to the previous year’s organic system plan, intended to be undertaken in the coming year, detailed pursuant to §205.201;</p> <p>(3) Any additions to or deletions from the information required pursuant to §205.401(b); and</p> <p>(4) Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.</p> |
| 205.406(b) | <p>Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall within a reasonable time arrange and conduct an on-site inspection of the certified operation pursuant to §205.403: <i>Except</i>, That, when it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation’s annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months: <i>Provided</i>, That, the annual on-site inspection, required pursuant to §205.403, is conducted within the first 6 months following the certified operation’s scheduled date of annual update.</p> | Revise | 205.406(b) | <p>The certifying agent must arrange and conduct an on-site inspection, pursuant to §205.403, of the certified operation at least once per calendar year.</p> |

7. Paperwork Submissions to the Administrator

| Section | Current Text | Action | Section | Proposed Text |
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| 205.405(c) (3) | <p>Provide notice of approval or denial to the Administrator, pursuant to §205.501(a)(14).</p> | Remove | | |
| 205.501(a) (15) | <p>Submit to the Administrator a copy of:</p> <p>(i) Any notice of denial of certification issued pursuant to §205.405, notification of noncompliance, notification of</p> | Revise | 205.501(a) (15) | <p>Maintain current and accurate data in INTEGRITY for each operation which it certifies;</p> |

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| | noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to §205.662 simultaneously with its issuance; and (ii) A list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year; | | | |

8. Personnel Training and Qualifications

| Section | Current Text | Action | Section | Proposed Text |
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| | | Add new term | 205.2 | <i>Certification review.</i> The act of reviewing and evaluating a certified operation or applicant for certification and determining compliance with the USDA organic regulations. This does not include performing an inspection. |
| 205.501(a) (4) | Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part; | Revise | 205.501(a) (4) | Continuously use a sufficient number of qualified and adequately trained personnel, including inspectors and persons who conduct certification review, to comply with and implement the USDA organic standards; (i) Certifying agents must demonstrate that all inspectors, including staff, volunteers, and contractors, have the required knowledge, skills, and experience to inspect operations of the scope and scale as assigned and to evaluate compliance with the applicable regulations of this part; and (A) Certifying agents must demonstrate that inspectors continuously maintain adequate knowledge and skills about the current USDA organic standards, production and handling practices, certification and inspection, import and/or export requirements, auditing practices and skills in written and oral communications, sample collection, investigation techniques, and preparation of technically accurate inspection documents; and (B) Initially and every year thereafter, inspectors must demonstrate successful completion of a minimum of 20 hours of training in topics that are relevant to inspection. Training may include material delivered via the NOP learning management system, certifying agents, or other relevant training provider; and (C) Certifying agents must demonstrate that inspectors have a minimum of 1 year of field-based experience related to both |

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| | | | | <p>the scope and scale of operations they will inspect before assigning inspection responsibilities;</p> <p>(ii) Certifying agents must demonstrate that all persons who conduct certification review, including staff, volunteers, or contractors, have the knowledge, skills, and experience required to perform certification review of operations of the scope and scale assigned and to evaluate compliance with the applicable regulations of this part; and</p> <p>(A) Certifying agents must demonstrate that all certification review personnel continuously maintain adequate knowledge and skills in the current USDA organic standards, certification and compliance processes, and practices applicable to the type, volume, and range of review activities assigned; and</p> <p>(B) Initially and every year thereafter, all persons who conduct certification review activities must demonstrate successful completion of a minimum of 20 hours of training in topics that are relevant to certification review. Training may include material delivered via the NOP learning management system, certifying agents, or other relevant training provider; and</p> <p>(iii) Certifying agents must maintain current training requirements, training procedures, and training records for all inspectors and persons who conduct certification review activities.</p> |
| 205.501(a) (5) | <p>Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.</p> | Revise | 205.501(a) (5) | <p>Demonstrate that all persons with inspection or certification review responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned;</p> <p>(i) Sufficient expertise must include knowledge of certification to USDA organic standards and evidence of formal education, training, or professional experience in the fields of agriculture, science, or organic production and handling that directly relates to assigned duties.</p> |
| 205.501(a) (6) | <p>Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;</p> | Revise | 205.501(a) (6) | <p>Conduct an annual performance evaluation of all persons who conduct inspections, certification review, or implement measures to correct any deficiencies in certification services;</p> <p>(i) On-site evaluation of inspectors—Certifying agents must observe each inspector performing on-site inspections at least once every three years, or more frequently if warranted; and</p> <p>(A) On-site inspector evaluations must be performed by</p> |

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| | | | | certifying agent personnel who are qualified to evaluate inspectors; (ii) Certifying agents must maintain documented policies, procedures, and records for annual performance evaluations and on-site inspector evaluations. |

9. Oversight of Certification Activities

| Section | Current Text | Action | Section | Proposed Text |
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| | | Add new term | 205.2 | <i>Certification activity.</i> Any business conducted by a certifying agent, or by a person acting on behalf of a certifying agent, including but not limited to: certification management; administration; application review; inspection planning; inspections; sampling; inspection report review; material review; label review; records retention; compliance review; investigating complaints and taking adverse actions; certification decisions; and issuing transaction certificates. |
| | | Add new term | 205.2 | <i>Certification office.</i> Any site or facility where certification activities are conducted, except for certification activities that occur at certified operations or applicants for certification, such as inspections and sampling. |
| | | Add | 205.501(a) (22) | Notify AMS not later than 90 calendar days after certification activities begin in a new certification office. The notification must include the countries where the certification activities are being provided, the nature of the certification activities, and the qualifications of the personnel providing the certification activities. |
| 205.640 | Fees and other charges equal as nearly as may be to the cost of the accreditation services rendered under the regulations, including initial accreditation, review of annual reports, and renewal of accreditation, shall be assessed and collected from applicants for initial accreditation and accredited certifying agents submitting annual reports or seeking renewal of accreditation in accordance with the following provisions: | Revise introductory paragraph | 205.640 | Fees and other charges equal as nearly as may be to the cost of the services rendered under the regulations, including initial accreditation, review of annual reports, and renewal of accreditation, shall be reviewed, assessed, and collected from applicants in accordance with the following provisions: |
| 205.665(a) | <i>Notification.</i> When an inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certifying agent. Such notification shall provide: | Revise | 205.665(a) | <i>Notification.</i> (1) A written notification of noncompliance will be sent to the certifying agent when: (i) An inspection, review, or investigation of an accredited certifying agent by the Program Manager reveals any noncompliance with the Act or regulations in this part; or |

| Section | Current Text | Action | Section | Proposed Text |
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| | (1) A description of each noncompliance; (2) The facts upon which the notification of noncompliance is based; and (3) The date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible. | | | (ii) The Program Manager determines that the certification activities of the certifying agent, or any person performing certification activities on behalf of the certifying agent, are not compliant with the Act or the regulations in this part; or (iii) The Program Manager determines that the certification activities at a certification office, and/in specific countries, are not compliant with the Act or the regulations in this part. (2) Such notification must provide: (i) A description of each noncompliance; (ii) The facts upon which the notification of noncompliance is based; and (iii) The date by which the certifying agent must rebut or correct each noncompliance and submit supporting documentation of each correction when correction is possible. |

10. Accepting Foreign Conformity Assessment Systems

| Section | Current Text | Action | Section | Proposed Text |
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| | | 205.2 | Add new term | <i>Conformity assessment system.</i> All activities undertaken by a government to ensure that the applicable technical requirements for the production, handling, and processing of organic agricultural products are fully and consistently applied from product to product. |
| | | 205.2 | Add new term | <i>Technical requirements.</i> A system of relevant laws, regulations, regulatory practices, and procedures that address the production, handling, and processing of organic agricultural products. |
| 205.500(c) | In lieu of accreditation under paragraph (a) of this section, USDA will accept a foreign certifying agent's accreditation to certify organic production or handling operations if: (1) USDA determines, upon the request of a foreign government, that the standards under which the foreign government authority accredited the foreign certifying agent meet the requirements of this part; or (2) The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government. | Remove | | |
| | | Add new section | 205.511 | Accepting foreign conformity assessment systems. |

| Section | Current Text | Action | Section | Proposed Text |
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| | | Add | 205.511(a) | Foreign product may be certified under the USDA organic regulations by a USDA-accredited certifying agent and imported for sale in the United States. Foreign product that is produced and handled under another country’s organic certification program may be sold, labeled, or represented as organically produced in the United States if AMS determines that such organic certification program provides technical requirements and a conformity assessment system governing the production and handling of such products that are at least equivalent to the requirements of the Act and the regulations in this part (“equivalence determination”). |
| | | Add | 205.511(b) | Countries desiring to establish eligibility of product certified under that country’s organic certification program to be sold, labeled or represented as organically produced in the United States may request an equivalence determination from AMS. A foreign government must maintain compliance and enforcement mechanisms to ensure that its organic certification program is fully meeting the terms and conditions of any equivalence determination provided by AMS pursuant to this section. To request this determination, the requesting country must submit documentation that fully describes its technical requirements and conformity assessment system. If AMS determines it can proceed, AMS will conduct an assessment of the country’s organic certification program to evaluate whether it is equivalent. |
| | | Add | 205.511(c) | AMS will describe the scope of an equivalence determination. |
| | | Add | 205.511(d) | AMS will conduct reviews on a two-year cycle, beginning at the close of the prior review, to assess the effectiveness of the foreign government’s organic certification program. AMS will reassess a country’s organic certification program that AMS has recognized as equivalent every five years to verify that the foreign government’s technical requirements and conformity assessment program continue to be at least equivalent to the requirements of the Act and the regulations of this part, and will determine whether the equivalence determination should be continued. |
| | | Add | 205.511(e) | AMS may terminate an equivalence determination if the terms or conditions established under the determination are not met; if AMS determines that the country’s technical |

| Section | Current Text | Action | Section | Proposed Text |
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| | | | | requirements and/or conformity assessment program are no longer equivalent; if AMS determines that the foreign government's organic control system is inadequate to ensure that the country's organic certification program is fully meeting the terms and conditions under the determination; or for other good cause. |

11. Compliance—General

| Section | Current Text | Action | Section | Proposed Text |
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| 205.660(c) | The Program Manager may initiate suspension or revocation of a certifying agent's accreditation if the certifying agent fails to meet, conduct, or maintain accreditation requirements pursuant to the Act or this part. | Redesignate as 205.660(d); add new paragraph (c) | 205.660(c) | The Program Manager may initiate enforcement action against any person who sells, labels, or provides other market information concerning an agricultural product if such label or information implies, directly or indirectly, that such product is produced or handled using organic methods, if the product was produced or handled in violation of the Organic Foods Production Act or the regulations in this part. |
| 205.660(d) | Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663, and §205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts. | Redesignate as 205.660(e) | 205.660(d) | The Program Manager may initiate suspension or revocation of a certifying agent's accreditation if the certifying agent fails to meet, conduct, or maintain accreditation requirements pursuant to the Act or this part. |
| | | | 205.660(e) | Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663, and §205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts. |

12. Noncompliance Procedure for Certified Operations

| Section | Current Text | Action | Section | Proposed Text |
|-------------------|---|--------|-------------------|--|
| 205.100(c) | Any operation that: | Revise | 205.100(c) | Any person or responsibly connected person that: |
| | | Add | 205.662(e) (3) | Within 3 business days of issuing a notification of suspension or revocation, or the effective date of an operation's surrender, the certifying agent must update the operation's status in INTEGRITY. |
| 205.662(f) (1) | A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in | Revise | 205.662(f) (1) | A certified operation or a person responsibly connected with an operation whose certification has been suspended may at |

| Section | Current Text | Action | Section | Proposed Text |
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| | the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. | | | any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification, or submit a request for eligibility to be certified. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part. |
| 205.662(g)(1) | Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than the amount specified in §3.91(b)(1) of this title per violation. | Revise | 205.662(g)(1) | Knowingly sells or labels a product as organic, except in accordance with the Act, shall be subject to a civil penalty of not more than the amount specified in §3.91(b)(1)(xxxvii) of this title per violation. |

13. Mediation

| Section | Current Text | Action | Section | Proposed Text |
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| 205.663 | Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent. If the certifying agent rejects the request for mediation, the certifying agent shall provide written notification to the applicant for certification or certified operation. The written notification shall advise the applicant for certification or certified operation of the right to request an appeal, pursuant to §205.681, within 30 days of the date of the written notification of rejection of the request for mediation. If mediation is accepted by the certifying agent, such mediation shall be conducted by a qualified mediator mutually agreed upon by the parties to the mediation. If a State organic program is in effect, the mediation procedures established in the State organic program, as approved by the Secretary, will be followed. The parties to the mediation shall have no more than 30 days to reach an agreement following a mediation session. If mediation is unsuccessful, the applicant for certification or certified operation shall have 30 days from termination of mediation to appeal the certifying agent's decision pursuant to §205.681. Any agreement reached during or as a result of the mediation process shall be in compliance with the Act and the regulations in this part. The Secretary | Revise | 205.663 | (a) A certifying agent must submit with its administrative policies and procedures provided in §205.504(b): decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions. (b) A certified operation or applicant for certification may request mediation to resolve a denial of certification or proposed suspension or proposed revocation of certification issued by a certifying agent or State organic program. (1) A certified operation or applicant for certification must submit any request for mediation in writing to the applicable certifying agent or State organic program within 30 calendar days of receipt of the notice of proposed suspension or proposed revocation of certification or denial of certification. (2) A certifying agent or State organic program may accept or reject a request for mediation based on its own decision criteria. (i) If a certifying agent rejects a mediation request, it must provide this rejection in writing to the applicant for certification or certified operation. The rejection must include the right to request an appeal, pursuant to §205.681, within 30 calendar days of the date of the written notification of rejection of the request for mediation. (c) Both parties must agree on the person conducting the mediation. |

| Section | Current Text | Action | Section | Proposed Text |
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| | <p>may review any mediated agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part.</p> | | | <p>(d) If a State organic program is in effect, the parties must follow the mediation procedures established in the State organic program and approved by the Secretary.</p> <p>(e) The parties to the mediation have a maximum of 30 calendar days to reach an agreement following a mediation session. Successful mediation results in a settlement agreement agreed to in writing by both the certifying agent and the certified operation. If mediation is unsuccessful, the applicant for certification or certified operation has 30 calendar days from termination of mediation to appeal the denial of certification or proposed suspension or revocation pursuant to §205.681.</p> <p>(f) Any settlement agreement reached through mediation must comply with the Act and the regulations in this part. The Secretary may review any mediated settlement agreement for conformity to the Act and the regulations in this part and may reject any agreement or provision not in conformance with the Act or the regulations in this part.</p> <p>(g) The Program Manager may propose mediation and enter into a settlement agreement at any time to resolve any adverse action notice that it has issued.</p> |

14. Adverse Action Appeal Process—General

| Section | Current Text | Action | Section | Proposed Text |
|------------|--|--------------|------------|--|
| | | Add new term | 205.2 | <p><i>Adverse action.</i> A noncompliance decision that adversely affects certification, accreditation, or a person subject to the Act, including a proposed suspension or revocation; a denial of certification, accreditation, or reinstatement; a cease and desist notice; or a civil penalty.</p> |
| 205.680(a) | <p>Persons subject to the Act who believe they are adversely affected by a noncompliance decision of the National Organic Program's Program Manager may appeal such decision to the Administrator.</p> | Revise | 205.680(a) | <p>Persons subject to the Act who believe they are adversely affected by an adverse action of the National Organic Program's Program Manager, may appeal such decision to the Administrator.</p> |
| 205.680(b) | <p>Persons subject to the Act who believe that they are adversely affected by a noncompliance decision of a State organic program may appeal such decision to the State organic program's governing State official who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary.</p> | Revise | 205.680(b) | <p>Persons subject to the Act who believe they are adversely affected by an adverse action of a State organic program may appeal such decision to the State organic program's governing State official who will initiate handling of the appeal pursuant to appeal procedures approved by the Secretary.</p> |

| Section | Current Text | Action | Section | Proposed Text |
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| 205.680(c) | Persons subject to the Act who believe that they are adversely affected by a noncompliance decision of a certifying agent may appeal such decision to the Administrator, <i>Except, That</i> , when the person is subject to an approved State organic program, the appeal must be made to the State organic program. | Revise | 205.680(c) | Persons subject to the Act who believe they are adversely affected by an adverse action of a certifying agent may appeal such decision to the Administrator, <i>Except, That</i> when the person is subject to an approved State organic program, the appeal must be made to the State organic program. |
| 205.680(d) | All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. | Redesignate as 205.680(f); add new paragraph (d) | 205.680(d) | Persons subject to the Act who believe they are adversely affected by an adverse action of a certifying agent or a State organic program may request mediation as provided in §205.663. |
| 205.680(e) | All appeals shall be reviewed, heard, and decided by persons not involved with the decision being appealed. | Revise and redesignate as 205.680(g); add new paragraph (e) | 205.680(e) | All appeals must comply with the procedural requirements in §205.681(c) and (d) of the USDA organic regulations. |
| | | | 205.680(f) | All written communications between parties involved in appeal proceedings must be sent to the recipient's place of business by a delivery service which provides dated return receipts. |
| | | Add | 205.680(g) | All appeals must be reviewed, heard, and decided by persons not involved with the adverse action being appealed. |

15. Adverse Action Appeals Process—Appeals

| Section | Current Text | Action | Section | Proposed Text |
|---------------|--|-----------------------------------|---------------|---|
| 205.681(a) | <i>Certification appeals.</i> An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or revocation of certification to the Administrator, <i>Except, That</i> , when the applicant or certified operation is subject to an approved State organic program the appeal must be made to the State organic program which will carry out the appeal pursuant to the State organic program's appeal procedures approved by the Secretary. | Revise introductory paragraph | 205.681(a) | <i>Adverse actions by certifying agents.</i> An applicant for certification may appeal a certifying agent's notice of denial of certification, and a certified operation may appeal a certifying agent's notification of proposed suspension or proposed revocation of certification to the Administrator, <i>Except, That</i> , when the applicant or certified operation is subject to an approved State organic program, the appeal must be made to the State organic program which will carry out the appeal pursuant to the State organic program's appeal procedures approved by the Secretary. |
| 205.681(a)(2) | If the Administrator or State organic program denies an appeal, a formal administrative proceeding will be initiated to deny, suspend, or revoke the certification. Such proceeding shall be conducted pursuant to the U.S. Department of | Revise; replace "will" with "may" | 205.681(a)(2) | If the Administrator or State organic program denies an appeal, a formal administrative proceeding may be initiated to deny, suspend, or revoke the certification. Such proceeding must be conducted pursuant to the U.S. Department of |

| Section | Current Text | Action | Section | Proposed Text |
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| | Agriculture's Uniform Rules of Practice, 7 CFR part 1, subpart H, or the State organic program's rules of procedure. | | | Agriculture's Uniform Rules of Practice, 7 CFR part 1, subpart H, or the State organic program's rules of procedure. |
| 205.681(b) | <i>Accreditation appeals.</i> An applicant for accreditation and an accredited certifying agent may appeal the Program Manager's denial of accreditation or proposed suspension or revocation of accreditation to the Administrator. (1) If the Administrator sustains an appeal, an applicant will be issued accreditation, or a certifying agent will continue its accreditation, as applicable to the operation. (2) If the Administrator denies an appeal, a formal administrative proceeding to deny, suspend, or revoke the accreditation will be initiated. Such proceeding shall be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, Subpart H. | Revise | 205.681(b) | <i>Adverse actions by the NOP Program Manager.</i> A person affected by an adverse action, as defined by 205.2, issued by the NOP Program Manager, may appeal to the Administrator. (1) If the Administrator sustains an appeal, an applicant will be issued accreditation, a certifying agent will continue its accreditation, or an operation will continue its certification, a civil penalty will be waived and a cease-and-desist notice will be withdrawn, as applicable to the operation. (2) If the Administrator denies an appeal, a formal administrative proceeding may be initiated to deny, suspend, or revoke the accreditation or certification and/or levy civil penalties. Such proceeding must be conducted pursuant to the U.S. Department of Agriculture's Uniform Rules of Practice, 7 CFR part 1, subpart H. |
| 205.681(c) | <i>Filing period.</i> An appeal of a noncompliance decision must be filed within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the Administrator or by the State organic program. A decision to deny, suspend, or revoke certification or accreditation will become final and nonappealable unless the decision is appealed in a timely manner. | Revise | 205.681(c) | <i>Filing period.</i> An appeal must be filed in writing within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later. The appeal will be considered "filed" on the date received by the Administrator or by the State organic program. An adverse action will become final and nonappealable unless an appeal is timely filed. |
| 205.681(d) (1) | Appeals to the Administrator must be filed in writing and addressed to: Administrator, USDA, AMS, c/o NOP Appeals Team, 1400 Independence Avenue SW., Room 2648-So., Stop 0268, Washington, DC 20250-0268. | Revise | 205.681(d) (1) | Appeals to the Administrator and Requests for Hearing must be filed in writing and addressed to: 1400 Independence Ave., S.W., Room 2642, Stop 0268, Washington, D.C. 20250, or electronic transmission, NOPAppeals@ams.usda.gov. |
| 205.681(d) (3) | All appeals must include a copy of the adverse decision and a statement of the appellant's reasons for believing that the decision was not proper or made in accordance with applicable program regulations, policies, or procedures. | Revise | 205.681(d) (3) | All appeals must include a copy of the adverse action and a statement of the appellant's reasons for believing that the action was not proper or made in accordance with applicable program regulations, policies, or procedures. |

16. Grower Group Operations

| Section | Current Text | Action | Section | Proposed Text |
|---------|--------------|--------------|------------|---|
| | | Add new term | 205.2 | <i>Grower group member.</i> A person engaged in the activity of growing or gathering a crop and/or wild crop as a member of a grower group operation. |
| | | Add new term | 205.2 | <i>Grower group operation.</i> A single producer consisting of grower group members in geographical proximity governed by an internal control system under an organic system plan certified as a single crop and/or wild crop production and handling operation. |
| | | Add new term | 205.2 | <i>Grower group production unit.</i> A defined subgroup of grower group members in geographical proximity as a part of a single grower group operation that use similar practices and shared resources to grow or gather similar crops and/or wild crops. |
| | | Add new term | 205.2 | <i>Internal control system.</i> An internal quality management system that establishes and governs the review, monitoring, training, and inspection of the grower group operation and the procurement and distribution of shared production and handling inputs and resources, to maintain compliance with the USDA organic regulations as a single producer. |
| | | Add | 205.201(c) | <p>In addition to paragraph (a) of this section, a grower group operation’s organic system plan must describe its internal control system. The description of the internal control system must:</p> <ol style="list-style-type: none"> (1) Define the organizational structure, roles, and responsibilities of all personnel; (2) Identify grower group production units and locations; (3) Define geographical proximity criteria for grower group members and grower group production units; (4) Describe characteristics of high-risk grower group members and grower group production units; (5) Describe shared production practices and inputs; (6) Describe the internal monitoring, surveillance, and auditing methods used to assess the compliance of all grower group members; (7) Describe the system of sanctions for noncompliant grower group members, including procedures to address noncompliances detected among grower group members, impose sanctions, and remove grower group members when |

| Section | Current Text | Action | Section | Proposed Text |
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| | | | | <p>warranted, and procedures for reporting noncompliances to the certifying agent;</p> <p>(8) Describe measures to protect against potential conflicts of interest;</p> <p>(9) Describe how training, production and handling inputs, and other resources are procured and provided to all grower group members and personnel;</p> <p>(10) Have clear policies and procedures to verify the grower group operation’s and grower group members’ compliance with the USDA organic regulations; and</p> <p>(11) Address any other terms or conditions determined by the Administrator to be necessary to enforce compliance with the USDA organic regulations and the Act.</p> |
| | | Add | 205.400(g) | <p>In addition to paragraphs (a) through (f) of this section, a grower group operation must:</p> <p>(1) Be a single producer organized as a person;</p> <p>(2) Sell, label, or represent only crops and/or wild crops as organic;</p> <p>(3) Use centralized processing, distribution, and marketing facilities and systems;</p> <p>(4) Be organized into grower group production units;</p> <p>(5) Ensure that all crops and/or wild crops sold, labeled, or represented as organic are from grower group members only;</p> <p>(6) Ensure that grower group members do not sell, label, or represent their crops and/or wild crops as organic outside of the grower group operation unless they are individually certified;</p> <p>(7) Report to the certifying agent on an annual basis the name and location of all grower group members and grower group production units, and the crops, wild crops, estimated yield, and size of production and harvesting areas of each grower group member and grower group production unit;</p> <p>(8) Conduct internal inspections of each grower group member, at least annually, by internal inspectors, which must include mass-balance audits and reconciliation of each grower group member’s and grower group production unit’s production yield and group sales;</p> <p>(9) Document and report to the certifying agent the use of sanctions to address noncompliant grower group members, at</p> |

| Section | Current Text | Action | Section | Proposed Text |
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| | | | | least annually; and (10) Implement procedures to ensure all production and handling by the grower group operation is compliant with the USDA organic regulations and the Act, including recordkeeping requirements to ensure a complete audit trail from each grower group member and grower group production unit to sale and distribution. |
| 205.403(a)(2) | (i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part. (ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part. (iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official. | Redesignate as 205.403(a)(3); add new paragraph (a)(2) | 205.403(a)(2) | Initial and annual on-site inspections of a grower group operation as defined in §205.2 must: (i) Assess the compliance of the internal control system of the organic system plan, or its capability to comply, with the requirements of §205.400(g)(8). This must include review of the internal inspections conducted by the internal control system. (ii) Conduct witness audits of internal control system inspectors performing inspections of the grower group operation. (iii) Individually inspect at least 1.4 times the square root of the total number of grower group members. This must include an inspection of all grower group members determined to be high risk according to criteria in 205.201(c)(4). At least one grower group member in each grower group production unit as defined in §205.2 must be inspected. |

17. Calculating the Percentage of Organically Produced Ingredients

| Section | Current Text | Action | Section | Proposed Text |
|---------------|--|--------|---------------|--|
| 205.302(a)(1) | Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of the finished product. | Revise | 205.302(a)(1) | Dividing the total net weight (excluding water and salt) of combined organic ingredients at formulation by the total weight (excluding water and salt) of all ingredients. |
| 205.302(a)(2) | Dividing the fluid volume of all organic ingredients (excluding water and salt) by the fluid volume of the finished product (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made on the basis of single-strength concentrations of the ingredients and finished product. | Revise | 205.302(a)(2) | Dividing the fluid volume of all organic ingredients (excluding water and salt) at formulation by the fluid volume of all ingredients (excluding water and salt) if the product and ingredients are liquid. If the liquid product is identified on the principal display panel or information panel as being reconstituted from concentrates, the calculation should be made based on single-strength concentrations of the ingredients and all ingredients. |
| 205.302(a)(3) | For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of | Revise | 205.302(a)(3) | For products containing organically produced ingredients in both solid and liquid form, dividing the combined weight of |

| Section | Current Text | Action | Section | Proposed Text |
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| | the solid ingredients and the weight of the liquid ingredients (excluding water and salt) by the total weight (excluding water and salt) of the finished product. | | | the solid organic ingredients and the weight of the liquid organic ingredients (excluding water and salt) at formulation by the total weight (excluding water and salt) of all ingredients. |

18. Supply Chain Traceability and Organic Fraud Prevention

| Section | Current Text | Action | Section | Proposed Text |
|--------------------|---|--|--------------------|---|
| | | Add new term | 205.2 | <i>Organic fraud.</i> Intentional deception for illicit economic gain, where nonorganic products are labeled, sold, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).” |
| 205.103(b) (2) | Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited; | Revise | 205.103(b) (2) | Fully disclose all activities and transactions of the certified operation in sufficient detail as to be readily understood and audited, including identification in records of products as “100% organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” as applicable; |
| 205.103(b) (3) | Be maintained for not less than 5 years beyond their creation; and | Redesignate as 205.103(b)(4); add new paragraph (b)(3) | 205.103(b) (3) | Include audit trail documentation for product handled or produced by the certified operation; |
| 205.103(b) (4) | Be sufficient to demonstrate compliance with the Act and the regulations in this part. | Redesignate as 205.103(b)(5) | 205.103(b) (4) | Be maintained for not less than 5 years beyond their creation; and |
| | | | 205.103(b) (5) | Be sufficient to demonstrate compliance with the Act and the regulations in this part. |
| 205.201(a) (3) | A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented; | Revise | 205.201(a) (3) | A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented. This must include a description of the monitoring practices and procedures to verify suppliers in the supply chain and organic status of products received, and to prevent organic fraud, as appropriate to the certified operation’s activities; |
| 205.501(a) (10) | Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State organic program’s governing State official or their authorized representatives) any business- | Revise | 205.501(a) (10) | Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (except for the Secretary or the applicable State organic program’s governing State official or their authorized representatives) any business-related information |

| Section | Current Text | Action | Section | Proposed Text |
|----------------|---|---|----------------|--|
| | related information concerning any client obtained while implementing the regulations in this part, except as provided for in §205.504(b)(5); | | | concerning any client obtained while implementing the regulations in this part, except: (i) For information that must be made available to any member of the public, as provided for in §205.504(b)(5); (ii) For enforcement purposes, certifying agents must exchange any compliance-related information that is credibly needed to certify, decertify, or investigate an operation, including for the purpose of verifying supply chain traceability and audit trail documentation; and (iii) If a certified operation's proprietary business information is compliance-related and thus credibly needed to certify, decertify, or investigate that operation, certifying agents may exchange that information for the purposes of enforcing the Act, but the information in question still retains its proprietary character even after it is exchanged and all of the certifying agents that are involved in the exchange still have a duty to preserve the confidentiality of that information after the exchange. |
| 205.501(a)(13) | Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to §205.500; | Revise | 205.501(a)(13) | Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to §205.500. Certifying agents must provide information to other certifying agents to ensure organic integrity or to enforce organic regulations, including to verify supply chain integrity, authenticate the organic status of certified products, and conduct investigations; |
| 205.501(a)(21) | Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary. | Redesignate as 205.501(a)(23); add new paragraph (21) | 205.501(a)(21) | Annually, conduct risk-based supply chain audits to verify organic status of a product(s) of a certified operation(s) it certifies, back to the source(s). |
| | | | 205.501(a)(23) | Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary. |
| 205.504(b)(4) | A copy of the procedures to be used for maintaining the confidentiality of any business-related information as set forth in §205.501(a)(10); | Revise | 205.504(b)(4) | A copy of the procedures to be used for sharing information with other certifying agents and for maintaining the confidentiality of any business-related information as set forth in §205.501(a)(10); |
| | | Add | 205.504(b)(7) | A copy of the criteria to identify high-risk operations and products; and procedures to conduct risk-based supply chain audits, as required in §205.501(a)(21); and procedures to report credible evidence of organic fraud to the Administrator. |

19. Technical Corrections

| Section | Current Text | Action | Section | Proposed Text |
|-------------------|--|--|-------------------|--|
| 205.301(f) (2) | Be produced using ionizing radiation, pursuant to §205.105(f); | Correct reference | 205.301(f) (2) | Be processed using ionizing radiation, pursuant to §205.105(f); |
| 205.301(f) (3) | Be processed using sewage sludge, pursuant to §205.105(g); | Correct reference | 205.301(f) (3) | Be produced using sewage sludge, pursuant to §205.105(g); |
| 205.400(b) | Establish, implement, and update annually an organic production or handling system plan that is submitted to an accredited certifying agent as provided for in §205.200; | Revise; correct “§205.200” to “§205.201” | 205.400(b) | Establish, implement, and update annually an organic production or handling system plan that is submitted to an accredited certifying agent as provided for in §205.201; |
| 205.401(a) | An organic production or handling system plan, as required in §205.200; | Revise; correct “§205.200” to “§205.201” | 205.401(a) | An organic production or handling system plan, as required in §205.201; |