

**2021 SUPPORTING STATEMENT**  
**National Organic Program: Strengthening Organic Enforcement (SOE)**  
**OMB NO. 0581-0321**  
**(Final Rule)**

**NOTE:** Upon OMB’s approval of this new information collection for National Organic Program; Strengthening Organic Enforcement (SOE), we will request to merge this collection into currently approved OMB Control Number 0581-0191 National Organic Program Reporting and Recordkeeping Requirements.

**A. Justification.**

**1. EXPLAIN THE CIRCUMSTANCES THAT MAKE THE COLLECTION OF INFORMATION NECESSARY. IDENTIFY ANY LEGAL OR ADMINISTRATIVE REQUIREMENTS THAT NECESSITATE THE COLLECTION.**

The National Organic Program (NOP) is authorized by the Organic Foods Production Act of 1990 (OFPA), as amended, (7 U.S.C. § 6501 *et. seq.*). The Agricultural Marketing Service (AMS) administers the NOP. Under the NOP, AMS oversees national standards for the production and handling of organically produced agricultural products. The NOP is issuing a final rule to amend its regulations.

The OFPA authorizes the improvement and strengthening of organic production and handling production standards (7 U.S.C. 6513(c)) to strengthen oversight and enforcement of the production, handling, and sale of organic agricultural products. The NOP identified the need for many of the amendments as part of its direct experience in administering this program, particularly via complaint investigations and audits of certifying agents. Other final amendments are based on recent amendments to the OFPA included in the Agriculture Improvement Act of 2018;<sup>1</sup> the recommendations of a 2017 Office of Inspector General audit;<sup>2</sup> multiple recommendations of the federal advisory committee to the NOP, the National Organic Standards Board (NOSB), from 2002 to 2018;<sup>3</sup> and industry stakeholder feedback.

This final rule strengthens enforcement with amendments and new requirements to the USDA organic regulations. The amendments in this final rule are intended to: (1) strengthen organic control systems; (2) improve organic import oversight; (3) clarify organic certification standards; and (4) enhance supply chain traceability. Specific provisions require: a new group of handlers, brokers and traders, to become certified as organic in order to trade or broker certified organic products; additional information on nonretail labels; new procedures to strengthen traceability; the use of federated organic certificates; unannounced on-site inspections; import certificates on all imported product; additional inspector training and qualifications; more review of foreign conformity systems; and the development and expansion of electronic data and

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1 [The Agriculture Improvement Act of 2018](https://www.congress.gov/), commonly known as the “2018 farm bill,” is available at <https://www.congress.gov/>

2 The National Organic Program International Trade Arrangements and Agreements Audit Report 01601-0001-21, <https://www.usda.gov/oig/webdocs/01601-0001-21.pdf>, September 2017.

3 NOSB Recommendations, <https://www.ams.usda.gov/rules-regulations/organic/nosb/recommendations>

document management systems governing organic certification of operations and traceability through transactions and trade, and clarified compliance and appeals processes for certifying agents and organic operations.

The final amendments close gaps in the current regulations to build consistent certification practices to deter and detect organic fraud and improve transparency and product traceability. In addition, the final amendments assure consumers that organic products meet a robust, consistent standard and reinforce the value of the organic label. This action and its associated information collection described in this Supporting Statement promulgates changes to the NOP regulations consistent with the OFPA.

**2. INDICATE HOW, BY WHOM, AND FOR WHAT PURPOSE THE INFORMATION IS TO BE USED. EXCEPT FOR A NEW COLLECTION, INDICATE THE ACTUAL USE THE AGENCY HAS MADE OF THE INFORMATION RECEIVED FROM THE CURRENT COLLECTION.**

Reporting and recordkeeping are essential to the integrity of the organic certification system. They create an audit trail that is a critical element in carrying out the mandate of OFPA and NOP. They serve the AMS mission, program objectives, and management needs by providing information on the efficiency and effectiveness of the program. The information affects decisions because it is the basis for evaluating compliance with OFPA and NOP, for administering the program, for management decisions and planning, and for establishing the cost of the program. It supports administrative and regulatory actions in response to noncompliance with OFPA and NOP.

Under the USDA organic regulations each operation is required to maintain and make available upon request, for 5 years, such records as are necessary to verify compliance (§ 205.103). Certifying agents are required to maintain records for 5 to 10 years, depending on the type of record (§ 205.510(b)) and to make these records available for inspection upon request (§ 205.501(a)(9)). Inspectors conduct on-site inspections of certified operations and operations applying for certification and report their findings to the certifying agent. Inspectors may be the agents themselves, employees of the agents, or individual contractors. Certified operations are inspected annually; a certifying agent may call for additional inspections or unannounced inspections on an as needed basis (§ 205.403(a)). Inspectors will need to provide an inspection report to the certifying agent for each operation inspected but are not required to retain the inspection reports (§ 205.403(e)).

Producers and handlers submit applications to their certifying agent. Handlers must determine the percent of organic ingredients in their products and design the appropriate label. Inspectors who perform on-site inspections of farms, handling facilities and processing plants report to the certifying agent. The certifying agent will then inform the applicant and the inspector of the certification decision and issue a certification certificate. After the initial certification, operators annually submit updates to their certifying agent.

Certifying agents must submit Form TM-10CG (Application for Accreditation) to become

accredited by USDA to certify organic production and handling operations. This final rule adds additional recordkeeping and reporting burden hours to Form TM-10CG; the currently obligated PRA burden for Form TM-10CG is 80 hours (0581-0191). The final rule includes new reporting requirements for information that certifying agents must provide to USDA to support their accreditation. USDA auditors review the records, perform a site evaluation, and create and maintain reports. The USDA makes the decision to grant or deny accreditation. Annually, accredited agents submit an update of their certified operations to USDA. USDA audits and inspects certifying agents every two and a half years.

Agents are required to notify certified operations, USDA or State officials when they observe noncompliance to the regulations. Producers, handlers, and certifying agents whose operations are not approved or are proposed as suspended have the right to mediation and appeal of the decision, which requires paperwork. Finally, the producers and handlers store their certification records for 5 years, and certifying agents store records created for operators' certification for 10 years, received from operators for 5 years, and accreditation records for 3 years.

State governments wishing to establish State Organic Programs submit the program for approval by USDA. Persons seeking to add or remove a substance from the National List will have to submit a petition to USDA.

In general, the information collected is used by USDA, State program governing officials, and certifying agents. It is created and submitted by accredited certifying agents, certified organic producers and handlers, those seeking or maintaining accreditation or certification, organic inspectors, State and foreign program officials, and parties interested in changing the National List. Additionally, accredited certifying agents, certified organic producers and handlers, those seeking accreditation or certification, and State and foreign program officials have procedures and space for recordkeeping.

This final rule and new collection amends several sections of the USDA organic regulations, 7 CFR Part 205, to strengthen the National Organic Program's (NOP) ability to oversee and enforce the production, handling, marketing, and sale of organic agricultural products as established by the OFPA. In order to protect organic product integrity and build consumer and industry trust in the USDA organic label, the information collection and recordkeeping inherent to the amendments to §§ 205.2, 205.100, 205.101, 205.103, 205.201, 205.273 205.300–205.302, 205.307, 205.310, 205.400, 205.403–404; 205.406, 205.500, 205.501, 205.504, 205.511, 205.660–205.663, 205.665, 205.680, and 205.681 of the organic regulations are necessary.

These final amendments strengthen organic control systems and integrity throughout the organic supply chain, improve farm to market transparency and traceability, close gaps in the current regulations to build consistent certification practices, deter organic fraud, provide robust enforcement of the USDA organic regulations through a risk-based approach to oversight that benefits stakeholders at all levels of the organic industry and assures consumers that organically produced products meet a consistent standard.

The specific respondents impacted by the final rule are: Producers and Handlers (also called

Operations), Certifying Agents, Inspectors, and Foreign Governments. Final amendments are described below, organized by type of respondents impacted. Headings correlate with the AMS 71 Grid (supplementary document).

## **PRODUCERS AND HANDLERS (OPERATIONS)**

### **Producers and Handlers: Subpart B – Applicability**

The first line in the AMS 71 Grid refers to the additional modest recordkeeping storage time of 15 minutes associated with the new procedures for all organic operations whether applying for organic certification for the first time or already certified. (§205.103)

### **Producers and Handlers: Subpart E – Certification**

a. **New Group of Handlers: Previously Uncertified Handlers.** Traders and brokers of organic products that facilitate the trade of, but do not directly produce, process, or manufacture, agricultural products, that were previously excluded as Handling Operators from certification, must now become certified as organic and must submit initial Organic System Plan (OSP). This reduces the types of uncertified handling operations in the organic supply chain that operate without USDA oversight.

The final amendments will require certification of operations that facilitate the sale or trade of organic products, including but not limited to brokers, importers, traders, processors, grocery wholesalers, those who store organic products, and distributors of organic products. These handlers who were not required to be certified as organic to trade, broker, or distribute organic products will now be required to obtain organic certification by developing an OSP describing the practices and procedures of their operations. The OSP for traders, brokers and grocery wholesalers will be less comprehensive than those required of more complex operations, such as producers and manufacturers. This is not a “lower” level of certification. These businesses are not farming or manufacturing products, so some significant parts of the standards are simply not applicable to their operations.

Change in burden is increased in the final rule due to refinements in NAICS code 425 and the addition of operations from NAICS code 4244 in response to public comment. 2018 Farm Bill mandates traders and brokers must become certified. AMS estimates 855 of the operations in NAICS code 425 which defines a broker, trader or facilitator of transactions of agricultural products domestically plus 1,130 from NAICS code 4244 for domestic Grocery and Related Product Merchant Wholesalers (see RIA) totaling 1985 domestic operations that were formerly excluded from being certified are now required to be certified as organic. To estimate the number of foreign operations impacted, AMS estimates the 1985 domestic operations as 59% and 1379 foreign operations as 41% of total previously excluded handlers globally. In the final rule, AMS estimates 3364 new handlers are impacted in this category compared to the 1922 estimated to be impacted in the proposed rule.

Reporting impacts are estimated at 40 hours for each currently uncertified handling operation to prepare their initial OSP. AMS estimates a recordkeeping burden of 10 hours annually. The estimated annual reporting burden for each entity to update its OSP in future years is 20 hours (§§ 202.2, 205.100, 205.101, and 205.103).

b. New operations seeking certification under current rules submitting their initial organic system plan, and current certified organic operations (farmers and handlers) (OSP) updating their current OSP must now also describe their monitoring procedures for verifying and demonstrating the organic status of their suppliers and the products received to prevent organic fraud. This new procedure will be part of the OSP going forward.

Change in hours due to industry growth. In addition to currently certified operations, AMS expects 2,639 operations will seek organic certification under current rules over the next 12 months, based on the 5.9% rate of growth in number of operations.

AMS estimates that each new applicant seeking certification under current rules and currently certified operation will need 30 minutes to describe the supply chain verification procedures and monitoring practices required by this regulation over and above the current requirements (§§ and 205.201).

c. In response to public comment, greater specificity is required for the Internal Control System (ICS) of producer groups than was originally proposed to ensure the ICS can manage the unique challenges of producer groups that operate as a single operation. The final rule describes the criteria to qualify as a producer group, and how producer group operations can comply with the existing USDA organic regulations.

AMS expects that these requirements will add 11,800 hours of one-time paperwork burden for 5,900 producer group operations<sup>4</sup> to prepare a detailed ICS for their OSP, including procedures to address conflicts of interest and manage the unique challenges of producer group oversight. In addition, AMS is estimating that ICS personnel and producer group members will receive 5 hours of training which calculates to 29,500 hours of burden. (§§ 205.201, 205.400(g) and 205.403).

d. Clarifies how certified operations may submit annual updates to their OSP. This includes the option to only submit practices or procedures that have changed since their last approved OSP, rather than submitting an OSP in its entirety. This will reduce unnecessary paperwork without compromising oversight because operations will continue to maintain an OSP that accurately reflects current practices and procedures of the operation. This codifies current policy and does not modify the paperwork burden (§ 205.406).

## **Producers and Handlers: Subpart D – Labels, Labeling and Market Information**

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<sup>4</sup> Meinshausen F., Richter, T., Blockeel, J., and Huber, B., Group Certification: Internal Control Systems in Organic Agriculture: Significance, Opportunities and Challenges, Research Institute of Organic Agriculture FiBL, March 2019.

e. **NOP Import Certificates** (Form NOP 2110-1<sup>5</sup> approved under 0581-0191): Requires that organic products imported into the United States must be declared as organic at U.S. Ports of Entry and be associated with a NOP Import Certificate (NOP 2110-1).<sup>6</sup> The NOP Import Certificate contains specific information about the quantity and source of a specific physical shipment of imported organic products. NOP Import Certificates are currently used for organic products imported from countries with which the NOP holds equivalency arrangements.

This final rule will expand and make compulsory the use of NOP Import Certificates, regardless of an imported product's country of origin. Burden on traders and grocery wholesalers due to the mandatory use of the NOP Import Certificates (Form NOP 2110-1) is reduced from the proposed rule. In response to public comments, the final rule allows NOP Import Certificates to be issued for a given time period (e.g., quarterly or seasonally) rather than with every shipment as proposed. This will reduce costs and limit disruption to the speed of imports even though the estimated number of annual shipments has increased from 67,023 in 2017 to 80,109 in 2020 due to industry growth.<sup>7</sup>

AMS estimates 3,856 exporters<sup>8</sup> will request from their certifying agents an annual total of 15,424 quarterly NOP Import Certificates, covering 80,109 annual shipments. AMS estimates each exporter and certifying agent will spend 30 minutes to request and approve each NOP Import Certificate. When shipments of organic products arrive at U.S. Ports of Entry, AMS estimates that 1350 importers<sup>9</sup> and their certifying agents will need an average of one tenth (0.1) of an hour, 6 minutes to verify the shipping manifest of 80,109 shipments with their respective quarterly or seasonally issued NOP Import Certificate to verify the accuracy and organic compliance of each shipment (§§ 205.273 and 205.300) (See certifying agent impact below also).

f. **Labeling of bulk nonretail containers** (domestic and international) Clarifies the information that must be provided on nonretail container labels used to ship or store organic products. Along with the production lot number that is already required, nonretail labels will need: (1) a statement identifying the product as organic; and (2) the name of the certifying agent that certified the product. These changes will help maintain the integrity of organic products by reducing misidentification and mishandling, facilitating traceability through the supply chain, reducing organic fraud, and allowing accurate identification of organic product by customs officials and transportation agents.

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5 Office of Management and Budget (OMB) approved form NOP 2110-1 NOP Import Certificate  
<https://www.ams.usda.gov/resources/nop-2110-1>

6 Mandated by The Organic Foods Production Act of 1990 (OFPA), as amended by the Agriculture Improvement Act of 2018.

7 Data source: USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS). Select: Partners, World Total, Product Type, Imports—General, Products: All Aggregates; Product Groups: Organic—Selected:  
<https://apps.fas.usda.gov/gats/default.aspx>

8 NOP International Division reports that 3,303 organic exporters are certified by foreign (non-USDA) certifiers. Plus, the Organic Integrity Database shows that 553 foreign-based handlers are certified by USDA-accredited certifying agents. The total number of NOP Import Certificates assumes each exporter is issued NOP Import Certificates quarterly (four annually).

9 Customs and Border Protection estimates that there are just over 60,000 importers in the United States. We apply the 9% agricultural benchmark and the 25% organic penetration rate used in the excluded handler calculations to estimate a total of 1,350 importers in the United States that handle organic agricultural products

New burden is reduced from the proposed rule due to a narrowing in new requirements (who and what shipments need to be labeled) in response to public comments. 29,929 (existing and new domestic operations, traders, and grocery wholesalers) certified operations will be modifying how they label 195,387 nonretail shipments which are 115,279 (exported shipments) + 80,109 (completely domestic shipments that never leave the US that is also equal to the imported shipments). 3,856 (existing, new, traders, and grocery wholesalers) certified operations will be modifying how they label 80,109 nonretail shipments exported to the US. AMS estimates that 33,785 producers, manufacturers, and handlers would need one-tenth (0.1) of an hour, or 6 minutes, to add the required information to the labels that are displayed on the nonretail containers of an estimated 275,596 annual shipments (§ 205.307).<sup>10</sup>

## ACCREDITED CERTIFYING AGENTS (CERTIFYING AGENTS)

### Certifying Agents: Subpart E – Review of Application

**g. Agents upload all data for each operation into the Organic Integrity Database and issue certificates of organic operation using federated organic certificate template for the first time.**

Requires certifying agents to issue standardized certificates of organic operation generated from the USDA's publicly available Organic Integrity Database (OID). This requires an initial upload of mandatory data for each operation, and maintenance, at least annually, to ensure that data in OID is current and accurate.<sup>11</sup> Currently, 100% of certifying agents have voluntarily uploaded and maintained 50% or more data on all certified operations per the recommendations found in the NOP's Data Quality Best Practices at <https://www.ams.usda.gov/sites/default/files/media/INTEGRITY%20Data%20Quality.pdf><https://www.ams.usda.gov/sites/default/files/media/INTEGRITY%20Data%20Quality.pdf>.

Change in burden is due to industry growth. The final amendments will require a new, one-time burden of reporting hours for certifying agents to upload remaining data pertaining to currently certified operations into OID for the first time. It is estimated that uploading this data into OID will require 30 minutes for each operation and will be performed by administrative support personnel who have a lower wage rate than review and compliance staff (§ 205.404). See OID for details about OID account creation and use: <https://organic.ams.usda.gov/integrity/>.

h. In addition, the final amendments will simultaneously eliminate the requirement to physically mail the Administrator or State Organic Program paper copies of: (1) the list of operations certified annually; or (2) notifications of proposed or executions of adverse actions, approvals, or denials of corrective actions regarding certified operations or operations applying for certification (§§ 205.403, 205.404, and 205.501). We are not showing reductions in hours.

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<sup>10</sup> 29,929 (existing and new domestic operations and traders) certified operations will be modifying how they label 195,387 nonretail shipments and 3,856 (existing, new, and domestic operations and traders) certified operations will be modifying how they label 80,109 nonretail shipments exported to the US.

<sup>11</sup> Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>

## **Certifying Agents: Subpart F – Accreditation of Certifying Agents – Form TM-10CG**

i. Each certifier seeking to continue USDA accreditation will need to develop new certification, enforcement, recordkeeping and personnel qualifications procedures described in detail to document their business practices (§ 205.504). Certifying agents will provide the results of personnel performance evaluations and the internal review of its certification activities as a part of their annual update (§ 205.510). AMS will review that information during its next scheduled on-site assessment to determine sufficiency. All new final reporting requirements in the final rule will add some time for recordkeeping specified below for each USDA accredited certifying agent. Change in burden is due to a net loss of 3 certifying agents from 2017.

j. Requires certifying agents to develop procedures to: (1) identify high-risk operations and agricultural products; (2) conduct supply chain traceability audits, (3) share information with other certifying agents to verify supply chains and conduct investigations, and (4) report credible evidence of organic fraud to the USDA. Due to the complexity of these procedures, AMS estimates each certifying agent will spend two hours documenting these procedures (§§ 205.501 and 205.504) rather than one hour as proposed. The final rule's burden increases due to an increase in time for preparing procedures despite a net loss of certifying agents since 2017.<sup>12</sup>

k. Requires certifying agents to submit their decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions with its administrative policies and procedures provided in §205.504(b). AMS estimates each certifying agent will spend 60 minutes documenting these procedures. The final rule's burden changes due to the net loss of 3 certifying agents since 2017.

l. Requires certifying agents to establish procedures to conduct inspector field evaluations ("witness inspections"), demonstrate that they are sufficiently staffed with qualified personnel, and demonstrate that all inspectors, certification reviewers, and in-field evaluators meet knowledge, skills, and experience qualifications. AMS estimates that each certifying agent will spend 60 minutes to draft policies and procedures for conducting inspector field evaluations. Further, certifying agents must observe an inspector performing an on-site inspection at least once every three years (or annually for inspectors with fewer than three years of experience). AMS estimates each certifying agent will conduct an average of two field evaluations of an inspector and certification review personnel per year, rather than four as proposed, and that this activity will require 7.5 hours per evaluation (§§ 205.2 and 205.501). The final rule's burden is reduced due to net loss of 3 certifying agents since 2017.

m. Inspectors and certification review personnel play a crucial role in determining whether an operation is granted organic certification initially and whether certified operations comply with the USDA organic regulations. Certification review personnel may also serve as inspectors. Through insight gained during regular audits of certifying agents, AMS estimates that all inspectors and certification review staff currently receive at least 10 hours of training per year

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<sup>12</sup> The net value reflects that while some certifiers have been suspended or have surrendered, others have been newly accredited.



from certifying agents on topics related to the USDA organic regulations which are accounted for in the 2020 Information Collections Renewal (OMB Control #: 0581-0191).

In response to public comment, this final rule requires new certification review staff to complete an additional 40 hours of training during their first year, calculated as eight (8) five-hour trainings. Based on an estimated separation rate of 14 percent,<sup>13</sup> AMS estimates that certifying agents will annually hire 35 new certification review staff and hire or contract with 35 inspectors with less than one year of experience to replace the certification review staff and inspectors that exit the labor pool. Training offered by the NOP through its new online Organic Integrity Learning Center (OILC) and training provided by the certifying agents or other providers may qualify towards the required training (§§ 205.2 and 205.501).<sup>14</sup>

n. AMS estimates 30 minutes for certifying agents to work with their exporters to prepare 15,424 NOP Import Certificates (Form NOP 2110-1) associated with 80,019 annual shipments. USDA accredited domestic-based certifiers will work with their foreign-based operations covering 8% of 80,019 annual shipments, ii) USDA accredited foreign-based certifiers to work with their foreign-based operations to prepare the NOP Import Certificate for 46% of 80,019 annual shipments, and iii) foreign-accredited certifiers to work with their foreign-based operations to prepare the NOP Import Certificate for 46% of 80,019 annual shipments.<sup>15</sup>

## INSPECTORS

### Inspectors: Subpart E – On-site Inspections

o. **Inspectors perform on-site inspections.** Requires that certifying agents conduct unannounced inspections on at least 5% of the operations they certify that are performed by inspectors. This is the current recommended practice in NOP Instruction 2609, available at <http://www.ams.usda.gov/sites/default/files/media/2609.pdf>. For the purposes of estimating paperwork impacts, AMS expects that half of the unannounced inspections (2.5% of total inspections) will meet the requirement for a full annual inspection and will not impact current paperwork burden. The remaining half of the unannounced inspections (2.5% of total inspections) will target high-risk operations and supply chains and will not count as a full annual inspection. Examples of targeted, limited-scope unannounced inspections include, but are not limited to, verifying livestock on pasture or performing targeted mass-balance and trace-back audits. AMS estimates that the paperwork impacts associated with these unannounced inspections will average inspectors 5 hours per inspection; half of the estimated 10 hours for a full annual inspection (§ 205.403).

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<sup>13</sup> The US Bureau of Labor and Statistics reports that the average separation rate (which captures both labor force exits and transfers in occupation) for agricultural inspectors is 14 percent. <https://www.bls.gov/news.release/jolts.t16.htm>

<sup>14</sup> Ten hours of training are accounted for in the 2020 Information Collections Renewal for NOP (AMS-NOP-19-0090; OMB Control Number: 0581-0191). Our internal on-site accreditation audit checklist used by our accreditation audit team includes a question on training. With the implementation of this rule, the specific hours of training offered by the 75 certifying agents will be documented.

<sup>15</sup> Estimate of number of imports coming into the United States in 2020: 80,019. Data Source: USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS). Select: Partners, World Total, Product Type, Imports - General, Products: All Aggregates; Product Groups: Organic - Selected: <https://apps.fas.usda.gov/gats/default.aspx>.

p. Requires new inspectors to complete an additional 40 hours of training in their first year. Through two audits every 5 years, AMS estimates that inspectors currently receive at least 10 hours of training per year on topics related to the USDA organic regulations which are accounted for in the 2020 Information Collections Renewal (OMB Control #: 0581-0191).<sup>16</sup> Inspectors play a crucial role in determining whether an operation is granted organic certification initially and whether certified operations are compliant with the USDA organic regulations. AMS is requiring an additional 40 hours of training in their first year, calculated as eight (8) five-hour trainings. Training offered by the NOP through its new online Organic Integrity Learning Center (OILC) at <https://www.ams.usda.gov/services/organic-certification/training>, and training provided by the certifying agents or other providers may qualify towards the required training (§§ 205.2, 205.501, and 205.665).

## **FOREIGN GOVERNMENTS**

### **Foreign Governments: Subpart F – Recognition and equivalence of foreign governments**

q. Clarifies AMS responsibilities for equivalent organic conformity systems and trade determinations with foreign governments.<sup>17</sup> The OFPA at § 6505(b), and the current USDA organic regulations at § 205.500(c), provide the authority to establish trade determinations. The final regulations describe the criteria, scope, and other parameters for ongoing peer review audits of foreign organic conformity systems to determine whether the USDA should continue, revise, or terminate such trade arrangements. These audits of trade arrangements will occur as needed and will result in new periodic paperwork impacts for foreign governments during the year of their review. AMS averages paperwork impacts for foreign governments 8 hours per year (§ 205.511). AMS estimates 10 hours of recordkeeping per year.

### **3. DESCRIBE WHETHER, AND TO WHAT EXTENT, THE COLLECTION OF INFORMATION INVOLVES THE USE OF AUTOMATED, ELECTRONIC, MECHANICAL, OR OTHER TECHNOLOGICAL COLLECTION TECHNIQUES OR OTHER FORMS OF INFORMATION TECHNOLOGY, E.G. PERMITTING ELECTRONIC SUBMISSION OF RESPONSES, AND THE BASIS FOR THE DECISION FOR ADOPTING THIS MEANS OF COLLECTION. ALSO DESCRIBE ANY CONSIDERATION OF USING INFORMATION TECHNOLOGY TO REDUCE BURDEN.**

Currently, the USDA encourages operations, handlers, and certifiers to use any electronic means available to them to create, submit and store records, including keeping database records of products produced; to maintain business accounting records; and to send documents over the internet. AMS is committed to complying with the e-Government Act, which requires

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<sup>16</sup> Ten hours of training are accounted for in the 2020 Information Collections Renewal for NOP (AMS-NOP-19-0090; OMB Control Number: 0581-0191). Our internal on-site accreditation audit checklist used by our accreditation audit team includes a question on training. With the implementation of this rule, the specific hours of training offered by the 75 certifying agents will be documented.

<sup>17</sup> Currently, the United States has established organic trade arrangements with Canada, the European Union, Mexico, Israel, Japan, New Zealand, Korea, and Switzerland.

Government agencies, in general, to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. Experience with the industry indicates that all certifiers use electronic data creation, storage and the internet. Certifying agents will be able to submit documentation through OID or via e-mail to the NOP. These are the preferred methods of submission.

With this final rule, the USDA is requiring certifying agents to issue standardized certificates of organic operations generated from the USDA's publicly available Organic Integrity Database (OID). This would require an initial upload of mandatory data for each operation, and maintenance, at least annually, to ensure that data in OID is current and accurate at <https://organic.ams.usda.gov/integrity/>. All certifying agents have created accounts and voluntarily uploaded at 50% or more of the data that is required by this final amendment. See OID under the Supplementary Documents in ROCIS. Certifying agents will no longer have to physically or electronically mail annual reports and documents related to notices of adverse actions since those updates will be automatically available in OID.

This final rule expands and makes compulsory the use of NOP Import Certificates, regardless of an imported product's country of origin. Specifically, this final rule would require that all imported products intended to be sold, represented, or labeled as organic in the United States must be declared as organic to U.S. Customs and Border Protection (CBP), and that each physical shipment passing through a U.S. Port of Entry must be associated with its respective NOP Import Certificate.

Because the OFPA enables AMS to access information available in CBP's Automated Commercial Environment system (ACE) (7 U.S.C. 6521(c)), AMS expects that ACE will be used to track and store NOP Import Certificates. ACE is an automated and electronic system for processing commercial trade data. ACE is the primary system through which the global trade community files information about imports and exports so that admissibility into the United States can be determined by government agencies (including AMS) to ensure compliance.

**4. DESCRIBE EFFORTS TO IDENTIFY DUPLICATION. SHOW SPECIFICALLY WHY ANY SIMILAR INFORMATION ALREADY AVAILABLE CANNOT BE USED OR MODIFIED FOR USE FOR THE PURPOSE(S) DESCRIBED IN ITEM 2 ABOVE.**

We have made every effort to contact appropriate sources within USDA, other Government agencies, such as CBP, and outside sources to ensure that we are not duplicating information collection. We have made every effort to describe and clarify which of the final amendments (§§ 205.2, 205.100, 205.101, 205.103, 205.201, 205.273 205.300–205.302, 205.307, 205.310, 205.400, 205.403–404, 205.406, 205.500 -501, 205.504, 205.511, 205.660–663, 205.665, 205.680, and 205.681) either make compulsory a previously voluntary data use and paperwork reporting and recordkeeping practice or introduce new data collection and paperwork practices. We encourage organic operations, certifying agents, inspectors, and foreign government respondents to the NOP to reduce their paperwork burden by incorporating the final requirements efficiently.

**5. IF THE COLLECTION OF INFORMATION IMPACTS SMALL BUSINESSES OR OTHER SMALL ENTITIES (ITEM 5 OF THE OMB FORM 83-I), DESCRIBE THE METHODS USED TO MINIMIZE BURDEN.**

The Regulatory Impact Analysis (RIA) and the Regulatory Flexibility Analysis (RFA) indicate that *all (100%)* of the affected businesses in the organic industry are small businesses. AMS has considered the economic impact of this action on small entities and determined that the impact would not be significant. AMS used the following Small Business Administration criteria (13 CFR 121.201) to determine which entities would qualify as small:

- Small agricultural operations, which includes organic producers, which generate \$750,000 or less in annual receipts (North American Industrial Classification System (NAICS) code 111 Crop Production, code 112 Animal Production and Aquaculture);
- Handlers that have 500 or fewer employees (NAICS code 311 Food Manufacturing);
- Excluded handlers that have 250 or fewer employees (NAICS code 425 Wholesale Electronic Markets and Agents and Brokers and NAICS category 4244 Grocery and Related Products Merchant Wholesalers);
- Certifying agents which generate \$16,500,000 or less in annual receipts (NAICS code 54199 All Other Professional, Scientific, and Technical Services).

AMS explored several options to mitigate any negative impacts caused by a reporting or recordkeeping burden. AMS has made every effort possible to secure information about the smallest segments of the industry, to provide open dialogue with them, to develop performance standards with a range of practices, and to accept the required documents reasonably and logically.

**6. DESCRIBE THE CONSEQUENCE TO FEDERAL PROGRAM OR POLICY ACTIVITIES IF THE COLLECTION IS NOT CONDUCTED OR IS CONDUCTED LESS FREQUENTLY, AS WELL AS ANY TECHNICAL OR LEGAL OBSTACLES TO REDUCING BURDEN.**

If the collection of information was not conducted or was conducted less frequently, the Agency would not be able to carry out the intent of Congress as it enforces the OFPA. This oversight, as mandated by the OFPA, includes an annual inspection of certified producers and handlers. The continued accreditation of certifiers requires written documentation of their management activities.

Every attempt possible has been made to create the regulation to incorporate existing documents and allow flexibility. Certified operations will be required only to submit annual updates of information after their initial application has been submitted. Certifying agents and foreign governments are encouraged to use or modify existing documents to meet the requirements of accreditation or trade arrangements, rather than creating new documents.

**7. EXPLAIN ANY SPECIAL CIRCUMSTANCES THAT WOULD CAUSE AN INFORMATION COLLECTION TO BE CONDUCTED IN A MANNER:**

**-REQUIRING RESPONDENTS TO REPORT INFORMATION TO THE AGENCY MORE OFTEN THAN QUARTERLY; NA**

**-REQUIRING RESPONDENTS TO PREPARE A WRITTEN RESPONSE TO A COLLECTION OF INFORMATION IN FEWER THAN 30 DAYS AFTER RECEIPT OF IT; NA**

**-REQUIRING RESPONDENTS TO SUBMIT MORE THAN AN ORIGINAL AND TWO COPIES OF ANY DOCUMENT; NA**

**-REQUIRING RESPONDENTS TO RETAIN RECORDS, OTHER THAN HEALTH, MEDICAL, GOVERNMENT CONTRACT, GRANT-IN-AID, OR TAX RECORDS FOR MORE THAN 3 YEARS;**

The OFPA § 6511(d)(1) requires that producers and handlers maintain records concerning the production and handling of agricultural products sold or labeled as organically produced for 5 years. OFPA § 6515(c)(1) requires any certifying agent to maintain all records concerning its activities for a period of not less than 10 years. The three categories of records with varying retention periods that are addressed in the NOP regulations are: (1) records created by certifying agents regarding applicants for certification and certified operations to be maintained 10 years; (2) records obtained from applicants for certification and certified operations to be maintained 5 years; and (3) other records created or received by certifying agents to be maintained 5 years. The recordkeeping requirements include any pesticide residue test results conducted as required.

**-IN CONNECTION WITH A STATISTICAL SURVEY, THAT IS NOT DESIGNED TO PRODUCE VALID AND RELIABLE RESULTS THAT CAN BE GENERALIZED TO THE UNIVERSE OF STUDY; NA**

**-REQUIRING THE USE OF A STATISTICAL DATA CLASSIFICATION THAT HAS NOT BEEN REVIEWED AND APPROVED BY OMB; NA**

**-THAT INCLUDES A PLEDGE OF CONFIDENTIALITY THAT IS NOT SUPPORTED BY AUTHORITY ESTABLISHED IN STATUE OR REGULATION; NA**

**-THAT IS NOT SUPPORTED BY DISCLOSURE AND DATA SECURITY POLICIES THAT ARE CONSISTENT WITH THE PLEDGE, OR WHICH UNNECESSARILY IMPEDES SHARING OF DATA WITH OTHER AGENCIES FOR COMPATIBLE CONFIDENTIAL USE; NA OR**

**-REQUIRING RESPONDENTS TO SUBMIT PROPRIETARY TRADE SECRET, OR OTHER CONFIDENTIAL INFORMATION UNLESS THE AGENCY CAN DEMONSTRATE THAT IT HAS INSTITUTED PROCEDURES TO PROTECT THE INFORMATION'S CONFIDENTIALITY TO THE EXTENT PERMITTED BY LAW.**

There are no other special circumstances. The collection of information is conducted in a manner consistent with the guidelines in 5 CFR 1320.6.

**8. IF APPLICABLE, PROVIDE A COPY AND IDENTIFY THE DATE AND PAGE NUMBER OF PUBLICATION IN THE FEDERAL REGISTER OF THE AGENCY'S NOTICE, REQUIRED BY 5 CFR 1320.8(d), SOLICITING COMMENTS ON THE INFORMATION COLLECTION PRIOR TO SUBMISSION TO OMB.**

A proposed rule soliciting public comments on this information collection was published in the Federal Register on April 13, 2016 (71 FR 21956). There was a total of 6,675 comments which addressed the proposed requirements. There were no comments received that addressed the burden hours or costs of implementing this rule specifically. Public comments that resulted in changes to burden are summarized below. The burden hours for form TM 10CG are currently approved as 80 hours under information collection 0581-0191.

**-SUMMARIZE PUBLIC COMMENTS RECEIVED IN RESPONSE TO THAT NOTICE AND DESCRIBE ACTIONS TAKEN BY THE AGENCY IN RESPONSE TO THESE COMMENTS. SPECIFICALLY ADDRESS COMMENTS RECEIVED ON COST AND HOUR BURDEN.**

As stated above, no actual comments were received on the information collection cost and hour burdens although changes were made in response to public comments that resulted in changes in burden. These changes are specifically addressed throughout the final rule but are briefly summarized here. The overall number of handlers that were previously excluded that will be impacted by the requirements has increased in response to public comment.<sup>18</sup> Burden on exporters and custom brokers are reduced since NOP Import Certificates will be required periodically (i.e. quarterly or seasonally) to cover multiple shipments rather than requiring an NOP Import Certificate to accompany every shipment of organic product to the United States. Requirements for what shipments are subject to the wholesale product labeling has been narrowed also reducing burden on wholesalers, brokers and traders. In response to public comment, greater specificity is required for the Internal Control System (ICS) of producer groups to ensure the ICS can manage the unique challenges of producer groups that operate as a single operation. This will increase the burden of producer groups. Overall, impact on certifying agents is modestly reduced because requirements for training and evaluation of inspectors and certification review personnel are more narrowly focused on new hires and entrants into organic certification.

**-DESCRIBE EFFORTS TO CONSULT WITH PERSONS OUTSIDE THE AGENCY TO OBTAIN THEIR VIEWS ON THE AVAILABILITY OF DATA, FREQUENCY OF**

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<sup>18</sup> United States Customs and Border Protection (CBP) estimates that there are just over 60,000 importers in the United States. We apply the 9% agricultural benchmark and the 25% organic penetration rate used in the excluded handler calculations to estimate a total of 1,350 importers in the United States that handle organic agricultural products.

**COLLECTION, THE CLARITY OF INSTRUCTIONS AND RECORDKEEPING, DISCLOSURE, OR REPORTING FORMAT (IF ANY), AND ON THE DATA ELEMENTS TO BE RECORDED, DISCLOSED, OR REPORTED.**

This is a final rule with a new collection of paperwork impacts. Over the period from 2002 to 2018, the National Organic Standards Board (NOSB) held public meetings and made multiple recommendations to AMS regarding the USDA organic regulations. These recommendations incorporated public comment and input from certified operations, certifying agents, industry experts, public-interest groups, academia, and the general public.

In July 2018, AMS offered an interactive webinar on the proposed rule topics with open-ended questions that allowed stakeholders to offer public comment through a public on-line chat offered in compliance with OMB's media guidance from 2010.<sup>19</sup> The interactive webinar, associated recording, and the comments provided can be viewed on our website at <https://www.ams.usda.gov/reports/strengthening-organic-enforcement-town-hall-slides>. The proposed rule provided for a 60-day comment period for stakeholders on the accuracy of the information collection request. Additional public comment was gathered through engagement with the National Customs Brokers and Forwarders Association of America (NCBFAA).<sup>20</sup> Overall, commenters were very supportive of changes.

**-CONSULTATION WITH REPRESENTATIVES OF THOSE FROM WHOM INFORMATION IS TO BE OBTAINED OR THOSE WHO MUST COMPILE RECORDS SHOULD OCCUR AT LEAST ONCE EVERY 3 YEARS -- EVEN IF THE COLLECTION OF INFORMATION ACTIVITY IS THE SAME AS IN PRIOR PERIODS. THERE MAY BE CIRCUMSTANCES THAT MAY PRECLUDE CONSULTATION IN A SPECIFIC SITUATION. THESE CIRCUMSTANCES SHOULD BE EXPLAINED.**

All opportunities to seek public engagement and comment from those impacted by the changes have been described above.

**9. EXPLAIN ANY DECISION TO PROVIDE ANY PAYMENT OR GIFT TO RESPONDENTS, OTHER THAN REMUNERATION OF CONTRACTORS OR GRANTEES.**

There would be no payment or gift rendered to any respondent.

**10. DESCRIBE ANY ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS AND THE BASIS FOR THE ASSURANCE IN STATUTE, REGULATION, OR AGENCY POLICY.**

Evaluators reviewing private certifiers' confidential records would be Federal employees

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<sup>19</sup> "Social Media, Web-Based Interactive Technologies, and the Paperwork Reduction Act", Memorandum for the Heads of Executive Departments and Agencies, and Independent Regulatory Agencies, Cass Sunstein, Administrator, Office of Management and Budget (OMB), April 7, 2010.

<sup>20</sup> National Customs Brokers & Forwarders Association of America, Inc.

representing the USDA. The OFPA § 6515(g) states "that any certifying agent shall maintain strict confidentiality with respect to its clients under the applicable organic certification program and may not disclose to third parties (with the exception of the Secretary or the applicable State Program's governing State official) any business-related information concerning such client obtained while implementing this chapter." Section 205.504(b)(4) of the rule further states that a private certifying agent shall establish policies for protecting the confidentiality of client records.

**11. PROVIDE ADDITIONAL JUSTIFICATION FOR ANY QUESTIONS OF A SENSITIVE NATURE, SUCH AS SEXUAL BEHAVIOR AND ATTITUDES, RELIGIOUS BELIEFS, AND OTHER MATTERS THAT ARE COMMONLY CONSIDERED PRIVATE. THIS JUSTIFICATION SHOULD INCLUDE THE REASONS WHY THE AGENCY CONSIDERS THE QUESTIONS NECESSARY, THE SPECIFIC USES TO BE MADE OF THE INFORMATION, THE EXPLANATION TO BE GIVEN TO PERSONS FROM WHOM THE INFORMATION IS REQUESTED, AND ANY STEPS TO BE TAKEN TO OBTAIN THEIR CONSENT.**

There are no questions being requested that are of a sensitive nature. The information we are seeking is directly related to the applicants' business activities as they relate to the NOP.

**12. PROVIDE ESTIMATES OF THE HOUR BURDEN OF THE COLLECTION OF INFORMATION.**

Estimates of the hour burden of collection of information have been summarized on the AMS 71 Grid (supplementary document).

**THE STATEMENT SHOULD:**

**-INDICATE THE NUMBER OF RESPONDENTS, FREQUENCY OF RESPONSE, ANNUAL HOUR BURDEN, AND AN EXPLANATION OF HOW THE BURDEN WAS ESTIMATED. UNLESS DIRECTED TO DO SO, AGENCIES SHOULD NOT CONDUCT SPECIAL SURVEYS TO OBTAIN INFORMATION ON WHICH TO BASE HOUR BURDEN ESTIMATES. CONSULTATION WITH A SAMPLE (FEWER THAN 10) OF POTENTIAL RESPONDENTS IS DESIRABLE. IF THE HOUR BURDEN ON RESPONDENTS IS EXPECTED TO VARY WIDELY BECAUSE OF DIFFERENCE IN ACTIVITY, SIZE, OR COMPLEXITY, SHOW THE RANGE OF ESTIMATED HOUR BURDEN, AND EXPLAIN THE REASONS FOR THE VARIANCE. GENERALLY, ESTIMATES SHOULD NOT INCLUDE BURDEN HOURS FOR CUSTOMARY AND USUAL BUSINESS PRACTICES.**

See below and see the AMS 71 Grid.

**-IF THIS REQUEST FOR APPROVAL COVERS MORE THAN ONE FORM, PROVIDE SEPARATE HOUR BURDEN ESTIMATES FOR EACH FORM AND AGGREGATE THE HOUR BURDENS IN ITEM 13 OF OMB FORM 83-I.**



See below and see the AMS 71 Grid.

**-PROVIDE ESTIMATES OF ANNUALIZED COST TO RESPONDENTS FOR THE HOUR BURDENS FOR COLLECTIONS OF INFORMATION, IDENTIFYING AND USING APPROPRIATE WAGE RATE CATEGORIES.**

These estimates for the burden of collecting information are summarized in the OMB-83-i. AMS has identified four primary types of entities (respondents) that would need to submit and maintain information as a result of this final rule: certified organic operations; certifying agents; organic inspectors; and foreign governments. Three respondent types—certified operations (producers and handlers), certifying agents, and inspectors—have been identified in our currently approved information collection (0581-0191). To implement a 2018 Farm Bill mandate, AMS is requiring certification of additional types of operations in the organic supply chain, and regular audits of trade arrangements with foreign governments.<sup>21</sup> This adds a new type of handler, and foreign governments as a new type of respondent.

To more precisely understand the paperwork impacts of this final rule, AMS has divided the categories of respondents into domestic and foreign, as appropriate. This shows the potential impacts on domestic- versus foreign-based USDA-accredited certifying agents, inspectors, and certified operations, along foreign governments serving as accrediting bodies and their (foreign) accredited certifying agents. AMS estimates: (1) the number of respondents; (2) the hours they spend, annually, creating and storing records to meet the paperwork requirements of the organic labeling program; and, (3) the costs of those activities based on prevailing domestic<sup>22</sup> and foreign<sup>23</sup> wages and benefits.<sup>24</sup>

For the 51,091 reporting and recordkeeping respondents, the total information collection for both reporting and recordkeeping is 364,495 hours with 617,199 total responses and a total cost of \$14,416,897 annually. For each type of respondent, we describe the reporting burden here in question #12 and the recordkeeping burden in question #13.

**TOTAL ALL REPORTING BURDEN COST: \$12,454,097**

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<sup>21</sup> [The Agriculture Improvement Act of 2018](https://www.congress.gov/), commonly known as the “2018 farm bill,” is available at <https://www.congress.gov/>

<sup>22</sup> In this assessment, all domestic labor rates are sourced from the U.S. Bureau of Labor Statistics National Compensation Survey, Occupational Employment and Wages, May 2020: [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm). Domestic benefits are based on a Bureau of Labor Statistics News Release on Employer Costs for Employee Compensation, which states that benefits account for 31.7% of total average employer compensation costs, December 17, 2020. <https://www.bls.gov/news.release/ecec.nr0.htm>

<sup>23</sup> The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents: <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>

<sup>24</sup> Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents. <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>.

*Estimate of Burden: Public reporting burden for the collection of information is estimated to average 0.56 hours per year per response.*

*Respondents: Certifying agents, certified operations, inspectors, and foreign governments.*

*Estimated Number of Reporting Respondents: 51,091*

*Estimated Number of Reporting Responses: 566,388*

*Estimated Total Annual Burden on Reporting Respondents: 318,859 hours*

*Estimated Total Annual Reporting Responses per Reporting Respondents: 11.09 reporting responses per reporting respondents*

AMS estimates that the public reporting burden for this new collection of information is estimated to be 318,859 hours per year at a total cost of \$12,454,097 with a total number of 51,091 respondents. Respondents are comprised of currently certified operations, operations that will seek certification over the next 12 months, traders that were previously excluded from certification, USDA- and foreign-accredited certifying agents, inspectors, and foreign governments with whom we have trade arrangements. Each of the respondent categories are explained in more detail below.

RESPONDENT CATEGORIES	Number of Respondents	Total Reporting Hours	Total All Reporting Burden Costs
ALL RESPONDENTS - REPORTING BURDEN	51,091	318,859	\$12,454,097

- *New previously excluded handlers.* This final rule would require that operations which facilitate the sale or trade of organic products—including, but not limited to, brokers, importers, traders, those who store organic products, and distributors of organic products—will be required to obtain and maintain certification. AMS estimates 3364 traders with 1985 as domestic-based<sup>25</sup> and 1379 foreign-based traders<sup>26</sup> will need to become certified.
- *Currently certified operations.* There are 42,259 organic operations worldwide with 26,408 operating in the U.S and 18,352 operating in other countries that are currently certified to the USDA organic standards.<sup>27</sup>
- *New operations that are applying under current criteria.* Over the next 12 months, AMS expects 2,501 operations will seek organic certification as required under current rules, based on the 5.9% rate of growth in number of operations observed in the last 12 months.<sup>28</sup>

<sup>25</sup> U.S. Census NAICS Category 425 (Wholesale Electronic Markets and Agents and Brokers) and NAICS code 4244 (Grocery and Related Product Merchant Wholesalers) in response to public comment arrange for the sale of goods owned by others, generally on a fee or commission basis. They act on behalf of the buyers and sellers of goods. This subsector contains agents and brokers as well as business-to-business electronic markets that facilitate trade.

<sup>26</sup> Since U.S. organic operations represent 59% of total operations, the estimate of the number of foreign-based traders and brokers of organic foods are calculated to be 1379 or 41%, of 3364 total brokers, traders and wholesalers globally.

<sup>27</sup> Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>, accessed on September 1, 2021

<sup>28</sup> Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>, calculated on September 1, 2021

- *USDA-accredited certifying agents.* AMS accredits 75 USDA-accredited certifying agents (45 are based in the United States and 30 are headquartered in foreign countries).<sup>29</sup>
- *Foreign governments.* The USDA has negotiated and approved trade arrangements with 8 foreign governments to facilitate the international trade of organic products who will be impacted by the proposals in this rule.<sup>30</sup>
- *Foreign-accredited certifying agents.* We estimate 30 foreign certifying agents accredited by these governments will have reporting burden under this final rule.<sup>31</sup>
- *Inspectors.* AMS estimates that there are approximately 250 independent inspectors<sup>32</sup> currently inspecting crop, livestock, handling, and/or wild crop operations that are, or are seeking, certification.

1) Producers and Handlers (Operations). Domestic and foreign producers and handlers seeking organic certification must submit an OSP that details the practices and activities specific to their operation. Once certified, operations are required to update any changes in their operation or practices to their certifying agent at least annually. Total reporting hours for all producers and handlers, foreign and domestic, are estimated to be 242,815 hours at an annual total cost of \$10,141,555 in Summary Table #1. Additional explanations for detailed breakouts for each type of operation are provided below in sections a) *Previously Excluded Handlers* below and b) *New Applicants and Certified Operations under Current Rules.* They are also broken out as Domestic and Foreign.

<b>SUMMARY TABLE #1</b>		<b>USDA Certified Operations Reporting Burden</b>		
<b>Respondent Categories</b>	<b>Number of Respondents</b>	<b>Wage + Benefits</b>	<b>Total Reporting Hours</b>	<b>Total Reporting Costs</b>
USDA Formerly Excluded Handlers - Domestic	1,985	\$48.64	81,319	\$3,955,091
USDA Formerly Excluded Handlers - Foreign	1,379	\$34.95	59,869	\$2,092,547
<i>USDA Formerly Excluded Handlers - All</i>	<i>3,364</i>		<i>141,188</i>	<i>\$6,047,638</i>
USDA Certified Producers & Handlers - New and Existing Domestic	27,945	\$48.64	39,593	\$1,925,699
USDA Certified Producers & Handlers - New and Existing Foreign	19,419	\$34.95	62,034	\$2,168,218
<i>USDA Certified Producers &amp; Handlers - New and Existing - All</i>	<i>47,364</i>		<i>101,627</i>	<i>\$4,093,917</i>
<b>USDA ORGANIC OPERATIONS - ALL</b>	<b>50,728</b>		<b>242,815</b>	<b>\$10,141,555</b>

a) *New Previously Excluded Handlers.* This final rule would require operations which facilitate the sale or trade of organic products—including, but not limited to, brokers, importers, traders, those who store organic products, and distributors of organic products—to obtain and maintain certification. AMS estimates that 1985 domestic- and 1379 foreign-based operations

29 Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>, accessed on September 1, 2021

30 Canada, the European Union, United Kingdom, Israel, Japan, Mexico, New Zealand, Korea, and Switzerland.

31 An estimate benchmarked on number of USDA foreign-based accredited certifying agents based on our experience.

32 International Organic Inspectors Association (IOIA), [www.ioia.org](http://www.ioia.org)

will need to become certified as a result of this rule.<sup>33</sup> As described in the final rule, the OSPs for these handling operations will be less comprehensive than OSPs for operations that produce or process organic products; therefore, AMS estimates that preparation of an initial OSP will require 40 reporting hours. Updating their OSP in future years is expected to require 20 hours to prepare.

All operations that export organic products to the United States will need to request a NOP Import Certificate, or its equivalent, from their certifying agent for each organic shipment imported to the United States. Operations that import organic products will need to verify that the shipment matches the data on the NOP Import Certificate and the imported products for compliance with the organic standards upon arrival in the United States. In addition, all formerly excluded handlers along with being required to obtain organic certification, will need to comply with the final requirements for labeling nonretail containers and to prepare a fraud prevention plan as a part of preparing their OSP.

AMS estimates the annual reporting impact for all domestic formerly excluded handlers is \$3,955,091. This is based on an estimated 81,319 labor hours at \$48.64 per labor hour, including 31.7% benefits.<sup>34</sup> AMS estimates the annual reporting impact for all foreign based formerly excluded handlers is \$2,092,547. This is based on an estimated 59,869 labor hours per year at \$34.95 per labor hour, which includes 34.63% for benefits.<sup>35</sup> Total reporting labor hours are estimated to be 141,188 at an annual cost of \$6,047,638 for all previously excluded handlers to become certified organic and comply with requirements to prevent fraud and to export or receive imported certified organic product into the United States.

b) *New Operations and Certified Operations under Current Rules.* There are 44,725 organic operations worldwide that are currently certified to the USDA organic standards.<sup>36</sup> Over the next 12 months, AMS expects 2,639 operations will seek organic certification, based on the 5.9% rate of growth in number of operations observed in the last 12 months under the current rules.<sup>37</sup> AMS estimates that 27,945 operations based in the United States, and 19,419 operations based in

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33 U.S. Census NAICS Category 425 (Wholesale Electronic Markets and Agents and Brokers) and NAICS code 4244 (Grocery and Related Product Merchant Wholesalers) in response to public comment arrange for the sale of goods owned by others, generally on a fee or commission basis. They act on behalf of the buyers and sellers of goods. This subsector contains agents and brokers as well as business-to-business electronic markets that facilitate trade. Since U.S. organic operations represent 59% of total operations, the estimate of the number of foreign-based traders and brokers of organic foods are calculated to be 1379 or 41%, of 3364 total brokers, traders and wholesalers globally.

34 For uncertified handlers, AMS chose to use the same labor rate as certified producers and handlers: Occupational Employment Statistics group 11-9013, *Farmers, Ranchers, and Other Agricultural Managers*. . . [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm). Bureau of Labor Statistics News Release on Employer Costs for Employee Compensation, Wages account for 68.3% and Benefits account for 31.7% of total average employer compensation costs, June 18, 2020. [L](#)

35 The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which are 70.3% of U.S. labor rates. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. The source of compensation rates is based on an average of Organization for Economic Co-Operation and Development (OECD) benefits compensation rates at 34.63% of wage rates for countries with USDA-accredited certifying agents. <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>.

36 Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>, accessed on September 1, 2021

37 Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>, calculated on September 1, 2021.

foreign countries, including the respective applicants for certification under the current rules will be impacted by this final rule.

All currently certified organic operations and projected new applicants applying for certification under current rules will need to describe their monitoring procedures for verifying and demonstrating the organic status of their suppliers and the products received to prevent organic fraud of their operation as part of their initial or updated OSP under the new final rules. All certified organic operations and new applicants applying for certification under current rules will need to comply with the nonretail labeling requirements in this final rule. AMS estimates that the average annual reporting burden for all domestic and foreign certified organic producers and handlers certified under current rules is \$4,093,917. This is based on 39,593 hours for domestic operations at \$48.64 per labor hour, including 31.7% benefits,<sup>38</sup> and 62,034 hours per all foreign operations at \$34.95 per labor hour, including 34.63% benefits.<sup>39</sup>

2) *Accredited Certifying Agents*. Certifying agents are State, private, or foreign entities accredited by the USDA, or by foreign government accreditation bodies with whom USDA has trade arrangements, to certify domestic and foreign producers and handlers as organic in accordance with the OFPA and the USDA organic regulations. Certifying agents determine whether a producer or handler meets the organic requirements, using detailed information from the operation about its specific practices and on-site inspection reports from organic inspectors. This final rule is expected to impact 75 USDA-accredited certifying agents with 45 based in the United States and 30 headquartered in foreign countries. Both domestic- and foreign-based USDA-accredited certifying agents certify operations based in the United States and abroad. AMS assumes all currently accredited certifying agents evaluate all types of production and handling operations for compliance with the USDA organic regulations and will be subject to the reporting and recordkeeping burdens of the final amendments.

All USDA certifying agents will need to create new procedures for fraud prevention and supply chain verification and will be required to issue organic certificates generated by OID. Certifying agents will be required to conduct unannounced inspections and ensure that certification review staff and inspectors are qualified and comply with annual training requirements. Certifying agents of operations that export to the United States will need to issue import certificates for all shipments of imported organic products. Certifying agents will also need to submit their decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions in its administrative policies and procedures. AMS will review this information during the accreditation audits of USDA-accredited certifying agents.

In addition, AMS assumes there are 30 foreign government-accredited foreign-based

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38 Occupational Employment Statistics group 11-9013, *Farmers, Ranchers, and Other Agricultural Managers* [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm). Bureau of Labor Statistics on Employer Costs for Employee Compensation, Wages account for 68.3% and Benefits account for 31.7% of total average employer compensation costs, June 18, 2020.

39 The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which are 70.3% of U.S. labor rates. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. The source of compensation rates is based on an average of Organization for Economic Co-Operation and Development (OECD) benefits compensation rates at 34.63% of wage rates for countries with USDA-accredited certifying agents. <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>.

certifying agents that will be issuing NOP Import Certificates, or equivalent, for the foreign-certified organic product shipments verified as compliant with USDA organic regulations for export to the United States.<sup>40</sup> Also, the final rule removes the annual requirement for certifying agents to submit by January 2 an annual list of operations certified. Certifying agents will instead be required to update data in OID for each operation. No changes in the estimations of paperwork impacts are being calculated for allowing electronic submissions of annual reports.

In Summary Table #2 below, AMS projects that the final changes will increase the overall reporting burden for certifying agents. AMS estimates the annual reporting burden hours for all certifying agents, including foreign accredited certifying agents will be 68,243 costing \$2,099,618 with total costs. Both domestic- and foreign- based USDA accredited certifying agent will require 49,818 hours totaling \$1,465,733.

The costs for all domestic-based USDA accredited certifying agents will be \$605,882. This cost is based on an estimated 4,871 labor hours per year for staff with certification review and procedure writing responsibilities at \$47.87 per labor hour, including 31.7% benefits,<sup>41</sup> for a total salary of \$233,194 per year. The estimated cost for domestic certifying agents also includes 14,965 labor hours per year for administrative support staff to upload data about certified operations to OID at \$24.90 per labor hour, including 31.7% benefits,<sup>42</sup> for a total salary of \$372,688 per year.

For all foreign-based USDA-accredited certifying agents, AMS estimates the annual cost will be \$859,851 per year. This cost is based on an estimated 19,583 labor hours per year for staff with certification review and procedure writing responsibilities at \$34.40 per labor hour, including 34.63% benefits,<sup>43</sup> for a total salary component of \$673,733 per year. These estimated costs primarily pertain to the issuance and review of NOP Import Certificates.<sup>44</sup> The estimated cost for foreign-based USDA-accredited certifying agents also includes 10,339 labor hours per year for administrative support staff to upload data about certified operations to OID at \$17.90 per labor hour, including 34.63% benefits,<sup>45</sup> or a total of \$186,118 per year.

40 An estimate benchmarked on the number of foreign-based certifying agents accredited by AMS based on our experience.

41 The labor rate for certification review staff is based on Occupational Employment Statistics group 13-1041, Compliance Officers. Compliance officers examine, evaluate, and investigate eligibility for or conformity with laws and regulations governing contract compliance of licenses and permits, and perform other compliance and enforcement inspection and analysis activities not classified elsewhere. Compliance Officers (bls.gov). Domestic benefits are based on a Bureau of Labor Statistics News Release on Employer Costs for Employee Compensation, which states that benefits account for 31.7% of total average employer compensation costs, December 17, 2020.

42 The labor rate for administrative support staff is based on Occupational Employment Statistics group 43-9199, Office and Administrative Support Workers, who support general office work and data entry functions. Office and Administrative Support Workers, All Other (bls.gov). Domestic benefits are based on a Bureau of Labor Statistics on Employer Costs for Employee Compensation, which states that benefits account for 31.7% of total average employer compensation costs, December 17, 2020.

43 The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents, which were 70.3% of U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents: <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>. Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

44 Office of Management and Budget (OMB) approved form NOP 2110-1 NOP Import Certificate <https://www.ams.usda.gov/resources/nop-2110-1>

45 The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents:



For all foreign accredited certifying agents, AMS estimates the annual cost will be \$633,885. This cost is based on an estimated 18,425 labor hours per year for staff pertain to the issuance and review of NOP Import Certificates,<sup>46</sup> or equivalent data source at \$34.40 per labor hour plus 34.63% benefits.<sup>47</sup>

<b>SUMMARY TABLE #2</b>		<b>Certifying Agents Reporting Burden</b>		
<b>Respondent Categories</b>	<b>Number of Respondents</b>	<b>Wage + Benefits</b>	<b>Total Reporting Hours</b>	<b>Total Reporting Costs</b>
USDA U.S.-Based Certifiers	45	\$47.87	4,871	\$233,194
USDA U.S.-Based Certifiers- data entry	45	\$24.90	14,965	\$372,688
<i>Total USDA U.S.- Based Certifiers</i>	45		19,836	\$605,882
USDA Foreign-Based Certifiers	30	\$34.40	19,583	\$673,733
USDA Foreign-Based Certifiers-data entry	30	\$17.90	10,399	\$186,118
<i>Total USDA Foreign-Based Certifiers</i>	30		29,982	\$859,851
<b><i>Total USDA Certifiers - All</i></b>	<b>75</b>		<b>49,818</b>	<b>\$1,465,733</b>
Foreign Accredited Certifiers	30	\$34.40	18,425	\$633,885
<b>TOTAL CERTIFIERS - ALL</b>	<b>105</b>		<b>68,243</b>	<b>\$2,099,618</b>

3) *Organic Inspectors*. Inspectors conduct on-site inspections of certified operations and operations applying for certification and report the findings to the certifying agent. Inspectors may be independent contractors or employees of certifying agents. Certified operations must be inspected annually; a certifying agent may call for additional inspections or unannounced inspections on an as-needed basis (§ 205.403(a)). Any individual who applies to conduct inspections of operations will need to submit information documenting their qualifications to the certifying agent (§ 205.504(a)(3)). Inspectors provide an inspection report to the certifying agent for each operation inspected (§ 205.403(e)) but are not expected to store the record.

Currently, AMS estimates that inspectors spend 10 hours on average to complete an inspection report for a full annual inspection of an organic operation. AMS projects, on average, that inspectors will spend 5 hours to complete an inspection report for each of the 2.5% of the unannounced inspections that will be additional to the annual full inspection. The additional unannounced inspections are likely to be more limited in scope (such as pasture or dairy

<https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>. Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

46 OMB approved form NOP 2110-1 NOP Import Certificate <https://www.ams.usda.gov/resources/nop-2110-1>

47 The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents: <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>. Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

surveillance, or mass-balance and trace-back audits) under this final rule. Inspectors do not have recordkeeping obligations; certifying agents maintain the records of inspection reports.

According to the International Organic Inspectors Association (IOIA), there are approximately 250 inspectors currently inspecting crop, livestock, handling, and/or wild crop operations that are certified or have applied for certification. To comply with this final rule, AMS estimates that 14 percent, or 35, new inspectors with less than one year of experience must complete 40 hours of training in their first year in addition to the baseline training requirement of 10 hours annually already accounted for in the overall program ICR (0191).<sup>48, 49</sup>

Shown in Summary Table #3, AMS estimates total reporting hours for all USDA inspectors to be 7,741 costing \$210,860 annually. AMS estimates that 148 inspectors are domestic-based. AMS estimates the annual reporting cost for all domestic-based inspectors to be \$140,630. This is based on an estimated 4,567 labor hours per year at \$30.79 per labor hour, including 31.7% benefits.<sup>50</sup> AMS estimates that 102 inspectors are foreign-based. AMS estimates the annual reporting cost for all foreign-based inspectors to be \$70,230. This estimate is based on an estimated 3,174 labor hours per year at \$22.13 labor hour, including 34.63% benefits.<sup>51</sup>

SUMMARY TABLE #3	Inspectors Reporting Burden			
	Number of Respondents	Wage + Benefits	Total Reporting Hours	Total Reporting Costs
USDA U.S.- based Inspectors	148	\$30.79	4,567	\$140,630
USDA Foreign - based inspectors	102	\$22.13	3,174	\$70,230
<b>USDA INSPECTORS- ALL</b>	<b>250</b>		<b>7,741</b>	<b>\$210,860</b>

4). *Foreign Governments*. The USDA has approved trade arrangements with eight foreign governments to facilitate the international trade of organic products.<sup>52</sup> The current regulations address this authority in general terms under § 205.500(c), but do not describe the criteria, scope, and other parameters to establish, oversee, or terminate such arrangements. The final rule describes the use of trade arrangements in more detail; this creates a new type of PRA

<sup>48</sup> Ten hours of training are accounted for in the 2020 Information Collections Renewal for the NOP (AMS-NOP-19-0090; OMB Control Number: 0581-0191). Our internal onsite accreditation audit checklist used by our accreditation audit team includes a question on training. With this rule, the specific hours of training offered by our 75 certifying agents will be documented.

<sup>49</sup> The US Bureau of Labor and Statistics reports that the average separation rate (which captures both labor force exits and transfers in occupation) for agricultural inspectors is 14 percent. <https://www.bls.gov/news.release/jolts.t16.htm>

<sup>50</sup> The labor rate for inspectors is based on Occupational Employment Statistics group 45-2011, *Agricultural Inspectors*. Agricultural inspectors inspect agricultural commodities, processing equipment, facilities, and fish and logging operations to ensure compliance with regulations and laws governing health, quality, and safety. Domestic benefits are based on a Bureau of Labor Statistics on Employer Costs for Employee Compensation, which states that benefits account for 31.7% of total average employer compensation costs, December 17, 2020.

<sup>51</sup> The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents: <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>. Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

<sup>52</sup> Canada, the European Union, Mexico, Israel, Japan, New Zealand, Korea, and Switzerland.



respondent category. The final rule would allow a trade arrangement if AMS determines that the technical requirements and conformity assessment system under which foreign products labeled as organic are produced and handled are at least equivalent to the requirements of the OFPA and the USDA organic regulations. The final rule would also require periodic assessment of trade arrangements.

In Summary Table #4, AMS expects these periodic peer review assessments will be similar in depth and frequency to the audits of accrediting certifying agents under USDA organic regulations and estimates a comparable level of reporting and recordkeeping burden by foreign governments with whom AMS has negotiated trade arrangements. AMS estimates the annual collection cost for all foreign governments with whom we have trade arrangements will be \$2,064. This cost is based on an estimated 60 reporting labor hours at \$34.40 per labor hour, including 34.63% benefits.<sup>53</sup>

<b>SUMMARY TABLE #4</b>	<b>Foreign Government Reporting Burden</b>			
<b>Respondent Categories</b>	<b>Number of Respondents</b>	<b>Wage + Benefits</b>	<b>Total Reporting Hours</b>	<b>Total Reporting Costs</b>
<b>FOREIGN GOVERNMENTS</b>	<b>8</b>	<b>\$34.40</b>	<b>60</b>	<b>\$2,064</b>

**13. PROVIDE AN ESTIMATE OF THE TOTAL ANNUAL COST BURDEN TO RESPONDENTS OF RECORDKEEPERS RESULTING FROM THE COLLECTION OF INFORMATION. (DO NOT INCLUDE THE COST OF ANY HOUR BURDEN SHOWN IN ITEMS 12 AND 14).**

As stated above, AMS has identified four primary types of entities (respondents) that would need to submit and maintain information as a result of this final rule: certified organic operations; accredited certifying agents; organic inspectors; and foreign governments. Three respondent types—certified operations (producers and handlers), certifying agents, and inspectors—have been identified in currently approved information collection (0581-0191). To implement a 2018 Farm Bill mandate, AMS is requiring certification of additional types of operations in the organic supply chain, and regular audits of trade arrangements with foreign governments.<sup>54</sup> This adds new types of handlers as a subcategory of certified operations, and foreign governments as a new type of recordkeeping respondent.

To more precisely understand the paperwork impacts of this final rule, AMS has divided the categories of respondents into domestic and foreign, as appropriate, to show the potential impacts on domestic- versus foreign-based USDA-accredited certifying agents, inspectors, and

<sup>53</sup> The labor rate for certification review staff is based on Occupational Employment Statistics group 13-1041, Compliance Officers. Compliance officers examine, evaluate, and investigate eligibility for or conformity with laws and regulations governing contract compliance of licenses and permits, and perform other compliance and enforcement inspection and analysis activities not classified elsewhere. Compliance Officers (bls.gov). The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which were 70.3% of U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents: <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>. Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents..

<sup>54</sup> [The Agriculture Improvement Act of 2018](https://www.congress.gov/), commonly known as the “2018 farm bill,” is available at <https://www.congress.gov/>

certified operations, along with foreign-accredited certifying agents, and foreign-governments serving as accrediting bodies.

For the 51,091 reporting and recordkeeping respondents, the total information collection for both reporting and recordkeeping is 364,495 hours with 617,199 total responses and a total cost of \$14,416,897 annually. For each type of respondent, we describe the reporting burden in question #12 above and the recordkeeping burden in question #13 here. AMS estimates: (1) the number of respondents; (2) the hours they spend, annually, storing records to meet the paperwork requirements of the organic labeling program; and, (3) the costs of those activities based on prevailing domestic and foreign wages and benefits.

**Total All Recordkeeping Burden Cost: \$1,962,800**

*Estimate of Burden:* Public recordkeeping burden is estimated to be an annual total of 0.90 hours per year per respondent.

*Respondents:* Certifying agents, certified operations, and foreign governments.

*Estimated Number of Recordkeeping Respondents:* 50,811

*Estimated Total Recordkeeping Burden on Respondents:* 45,636 hours.

*Estimated Total Recordkeeping Responses per Recordkeeping Respondents:* 1 recordkeeping response per recordkeeping respondents

AMS estimates that the public recordkeeping burden for this new collection of information is estimated to be 45,636 hours per year at a cost of \$1,962,800 with a total number of 50,811 respondents. Respondents are comprised of currently certified operations, operations that will seek certification over the next 12 months, traders that were previously excluded from certification, USDA-accredited certifying agents, and foreign governments with whom we have trade arrangements. Each of the respondent categories for recordkeeping are explained below.

<b>Respondent Categories</b>	<b>Number of Respondents</b>	<b>Total Recordkeeping Hours</b>	<b>Total Recordkeeping Costs</b>
<b>All Respondents - Recordkeeping Burden</b>	50,811	45,636	\$1,962,800

- *Currently certified operations.* There are 44,725 organic operations worldwide that are currently certified to the USDA organic standards.<sup>55</sup>
- *New operations under current criteria.* Over the next 12 months, AMS expects 2,639 operations will seek organic certification under current rules.<sup>56</sup>
- *New previously excluded handlers.* This final rule would require that operations which facilitate the sale or trade of organic products—including, but not limited to, brokers,

55 Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>, accessed on September 1, 2021

56 Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>, calculated on September 1, 2021

importers, traders, those who store organic products, and distributors of organic products—will be required to obtain and maintain certification. AMS estimates 3364 traders with 1985 as domestic-based<sup>57</sup> and 1379 foreign-based traders<sup>58</sup> will need to become certified.

- *USDA-accredited certifying agents.* AMS accredits 75 USDA-accredited certifying agents; 45 are based in the United States and 30 are in foreign countries.<sup>59</sup>
- *Foreign governments.* The USDA has negotiated and approved trade arrangements with eight foreign governments who will be impacted by this final rule.<sup>60</sup>

1) Producers and handlers. In Summary Table # 5, total recordkeeping hours for all producers and handlers, foreign and domestic, are estimated to be 30,410 hours at an annual total cost of \$1,209,753.08. Additional detailed breakouts for each type of operation are provided in sections a) Previously Excluded Handlers and b) New Applicants and Certified Operations under Current Rules and below. They are also broken out as Domestic and Foreign.

SUMMARY TABLE #5	Certified Operations Recordkeeping Burden & Costs			
	Respondent Categories	Number of Respondents	Wage + Benefits	Total Record Keeping Hours
Previously Excluded Handlers - Domestic	1,985	\$48.64	19,848	\$965,324
Previously Excluded Handlers - Foreign	1,379	\$34.95	13,792	\$482,077
<b>USDA Formerly Excluded Handlers - All</b>	<b>3364</b>		<b>33,640</b>	<b>\$1,447,401</b>
USDA Certified Producers & Handlers - New and Existing Domestic	27,945	\$48.64	6,986	\$339,784
USDA Certified Producers & Handlers - New and Existing Foreign	19,419	\$34.95	4,855	\$169,686
<b>USDA Certified Producers &amp; Handlers - New and Existing - All</b>	<b>47,364</b>		<b>11,841</b>	<b>\$509,470</b>
<b>USDA ORGANIC OPERATIONS - ALL</b>	<b>50,728</b>		<b>45841</b>	<b>\$1,956,871</b>

a) *Previously Excluded Handlers.* This final rule would require operations which facilitate the sale or trade of organic products—including, but not limited to, brokers, importers, traders, those who store organic products, and distributors of organic products—to obtain and maintain certification. AMS estimates that 1985 domestic- and 1379 foreign-based operations will need to become certified as a result of this rule.<sup>61</sup>As described in the final rule, the OSPs for these

57 U.S. Census NAICS Category 425 (Wholesale Electronic Markets and Agents and Brokers) and NAICS code 4244 (Grocery and Related Product Merchant Wholesalers) in response to public comment arrange for the sale of goods owned by others, generally on a fee or commission basis. They act on behalf of the buyers and sellers of goods. This subsector contains agents and brokers as well as business-to-business electronic markets that facilitate trade..

58Since U.S. organic operations represent 59% of total operations, the estimate of the number of foreign-based traders and brokers of organic foods are calculated to be 1379 or 41%, of 3364 total brokers, traders and wholesalers globally.

59 Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>, accessed on September 1, 2021

60 Canada, the European Union, Mexico, Israel, Japan, New Zealand, Korea, and Switzerland.

61 U.S. Census NAICS Category 425 (Wholesale Electronic Markets and Agents and Brokers) and NAICS code 4244 ( Grocery and Related Product Merchant Wholesalers) in response to public comment arrange for the sale of goods owned by others, generally on a fee or commission basis. They act on behalf of the buyers and sellers of goods. This subsector contains agents and

handling operations will be less comprehensive than OSPs for operations that produce or process organic products; therefore, AMS estimates 10 recordkeeping hours.

All operations that export organic products to the United States will need to request a NOP Import Certificate, or its equivalent, from their certifying agent for each organic shipment imported to the United States. Further, operations that import organic products will need to verify that the shipment matches the data on the NOP Import Certificate and the imported products for compliance with the organic standards upon arrival in the United States. All domestic and foreign handlers that will be required to obtain organic certification as a result of this final rule will also need to comply with the requirements for labeling nonretail containers, and for preparing a fraud prevention plan.

AMS estimates the annual recordkeeping impact for all domestic formerly excluded handlers is \$965,324. This is based on an estimated 19,848 labor hours at \$48.64 per labor hour, including 31.7% benefits.<sup>62</sup> AMS estimates the annual recordkeeping impact for all foreign-based handler is \$482,077. This is based on an estimated 13,792 labor hours per year at \$34.95 per labor hour, which includes 35.92% for benefits.<sup>63</sup> Total labor hours are estimated to be 33,640 hours at an annual recordkeeping cost of \$1,447,401 for all formerly uncertified handlers.

b) *New Operations and Certified Operations under Current Rules.* There are 44,725 organic operations worldwide that are currently certified to the USDA organic standards.<sup>64</sup> Over the next 12 months, AMS expects 2,639 operations will seek organic certification, based on the 5.9% rate of growth in number of operations observed in the last 12 months under current rules.<sup>65</sup> AMS estimates that 27,945 operations based in the United States, and 19,419 operations based in foreign countries, including the respective applicants for certification will be impacted by this final rule. All currently certified organic operations and projected new applicants will need to maintain their new monitoring procedures to prevent organic fraud as part of their initial or updated OSP.

AMS estimates that the average annual recordkeeping burden for all 47,364 domestic and foreign certified organic producers and handlers is 11,841 labor hours at an annual total cost of \$509,470. This is based on 6,986 hours for domestic operations at \$48.64 per labor hour,

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brokers as well as business-to-business electronic markets that facilitate trade. Since U.S. organic operations represent 59% of total operations, the estimate of the number of foreign-based traders and brokers of organic foods are calculated to be 1379 or 41%, of 3364 total brokers, traders and wholesalers globally.

62 For uncertified handlers, AMS chose to use the same labor rate as certified producers and handlers: Occupational Employment Statistics group 11-9013, *Farmers, Ranchers, and Other Agricultural Managers*. . . [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm). Bureau of Labor Statistics News Release on Employer Costs for Employee Compensation, Wages account for 68.3% and Benefits account for 31.7% of total average employer compensation costs, June 18, 2020.

63 The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which are 70.3% of U.S. labor rates. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. The source of compensation rates is based on an average of Organization for Economic Co-Operation and Development (OECD) benefits compensation rates at 34.63% of wage rates for countries with USDA-accredited certifying agents. <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>.

64 Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>, accessed on September 1, 2021

65 Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>, calculated on September 1, 2021

including 31.7% benefits,<sup>66</sup> and 4,855 hours per all foreign operations at \$34.95 per labor hour, including 35.92% benefits.<sup>67</sup>

2) *Certifying agents*. Certifying agents are State, private, or foreign entities accredited by the USDA, or foreign government accreditation bodies with whom USDA has trade arrangements, to certify domestic and foreign producers and handlers as organic in accordance with the OFPA and the USDA organic regulations. Certifying agents determine whether a producer or handler meets the organic requirements, using detailed information from the operation about its specific practices and on-site inspection reports from organic inspectors. This final rule is expected to impact 75 USDA-accredited certifying agents with 45 based in the United States and 30 headquartered in foreign countries. Both domestic- and foreign-based USDA-accredited certifying agents certify operations based in the United States and abroad. AMS assumes all currently accredited certifying agents evaluate all types of production and handling operations for compliance with the USDA organic regulations and will be subject to the reporting and recordkeeping burdens of the final amendments.

All USDA-accredited certifying agents will need to create new procedures for fraud prevention and supply chain verification and will be required to update data in OID for each operation and issue organic certificates generated by OID. Certifying agents will be required to conduct unannounced inspections and ensure that certification review staff and inspectors are qualified and comply with annual training requirements. Certifying agents of operations that export to the United States will need to issue import certificates for all shipments of organic products. Certifying agents will also need to submit their decision criteria for acceptance of mediation, and a process for identifying personnel conducting mediation and setting up mediation sessions. All new procedures will be incorporated into their administrative policies and procedures. AMS will review this information during the accreditation audits of USDA-accredited certifying agents.

In addition, AMS assumes there are 30 foreign government-accredited foreign-based certifying agents that will be issuing NOP Import Certificates, or equivalent, for the foreign-certified organic product shipments verified as compliant with USDA organic regulations for export to the United States.<sup>68</sup> Also, the final rule removes the annual requirement for certifying agents to submit by January 2 an annual list of operations certified.

In Summary Table #6, AMS estimates the annual recordkeeping burden hours for both domestic- and foreign- based USDA accredited certifying agent at 75 hours totaling \$3,176. The

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66 Occupational Employment Statistics group 11-9013, *Farmers, Ranchers, and Other Agricultural Managers*. . [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm). Bureau of Labor Statistics News Release on Employer Costs for Employee Compensation, Wages account for 68.3% and Benefits account for 31.7% of total average employer compensation costs, June 18, 2020.

67 The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents which are 70.3% of U.S. labor rates. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. The source of compensation rates is based on an average of Organization for Economic Co-Operation and Development (OECD) benefits compensation rates at 34.63% of wage rates for countries with USDA-accredited certifying agents. <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>.

68 An estimate benchmarked on the number of foreign-based certifying agents accredited by AMS based on our experience.

costs for all domestic-based USDA accredited certifying agents will be \$2,118. This cost is based on an estimated 44 labor hours per year at \$47.87 per labor hour, including 31.7% benefits.<sup>69</sup> For all foreign-based USDA-accredited certifying agents, AMS estimates the annual cost for recordkeeping at \$1,058 per year. This cost is based on an estimated 31 labor hours per year at \$34.40 per labor hour, including 35.92% benefits.<sup>70</sup> For all foreign accredited certifying agents, AMS cannot estimate an annual cost because we have no direct authority over them.

<b>SUMMARY TABLE #6</b>				
<b>Certifying Agents Recordkeeping Burden</b>				
<b>Respondent Categories</b>	<b>Number of Respondents</b>	<b>Wage + Benefits</b>	<b>Total Record keeping Hours</b>	<b>Total Record Keeping Costs</b>
USDA U.S.-Based Certifiers	45	\$47.87	44	\$2,118
<i>Total USDA U.S.- Based Certifiers</i>	45		44	\$2,118
USDA Foreign-Based Certifiers	30	\$34.40	31	\$1,058
<i>Total USDA Foreign-Based Certifiers</i>	30		31	\$1,058
<b>Total USDA Certifiers - All</b>	<b>75</b>		<b>75</b>	<b>\$3,176</b>
<b>TOTAL CERTIFIERS - ALL</b>	<b>105</b>		<b>75</b>	<b>\$3,176</b>

3). *Foreign Governments*. The USDA has negotiated and approved trade determinations with eight foreign governments to facilitate the international trade of organic products.<sup>71</sup> The current regulations address this authority generally under § 205.500(c), but do not describe the criteria, scope, and other parameters to establish, oversee, or terminate such arrangements. The final rule describes trade determinations in more detail and creates a new type of PRA respondent category.

In Summary Table #7, the final rule would allow AMS to determine that the technical requirements and conformity assessment system under which foreign products labeled as organic are produced and handled are at least equivalent to the requirements of the OFPA and the USDA organic regulations. The final rule would also require their periodic assessment. AMS estimates the recordkeeping cost for all foreign governments with whom we have trade determinations will be \$2,752. This cost is based on 80 recordkeeping labor hours at \$24.59 per hour, including 35.92% benefits,<sup>72</sup> per year.

69 The labor rate for certification review staff is based on Occupational Employment Statistics group 13-1041, Compliance Officers. Compliance officers examine, evaluate, and investigate eligibility for or conformity with laws and regulations governing contract compliance of licenses and permits, and perform other compliance and enforcement inspection and analysis activities not classified elsewhere. Compliance Officers (bls.gov). Domestic benefits are based on a Bureau of Labor Statistics News Release on Employer Costs for Employee Compensation, which states that benefits account for 31.7% of total average employer compensation costs, December 17, 2020.

70 The source of the data is based on average World Bank wage rates for countries with USDA-accredited certifying agents, which were 70.3% of U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents: <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>. Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

71 Canada, the European Union, Mexico, Israel, Japan, New Zealand, Korea, and Switzerland.

72 The labor rate for foreign governments is based on Occupational Employment Statistics group 13-1041, Compliance



SUMMARY TABLE #7	Recordkeeping Burden			
	Respondent Categories	Number of Respondents	Wage + Benefits	Total Record Keeping Hours
FOREIGN GOVERNMENTS	8	\$34.40	80.00	\$2,752

**-THE COST ESTIMATE SHOULD BE SPLIT INTO TWO COMPONENTS: (a) A TOTAL CAPITAL AND START-UP COST COMPONENT (ANNUALIZED OVER ITS EXPECTED USEFUL LIFE); AND (b) A TOTAL OPERATION AND MAINTENANCE AND PURCHASE OF SERVICES COMPONENT. THE ESTIMATES SHOULD TAKE INTO ACCOUNT COSTS ASSOCIATED WITH GENERATING, MAINTAINING, AND DISCLOSING OR PROVIDING THE INFORMATION. INCLUDE DESCRIPTIONS OF METHODS USED TO ESTIMATE MAJOR COST FACTORS INCLUDING SYSTEM AND TECHNOLOGY ACQUISITION, EXPECTED USEFUL LIFE OF CAPITAL EQUIPMENT, THE DISCOUNT RATE(S), AND THE TIME PERIOD OVER WHICH COSTS WILL BE INCURRED. CAPITAL AND START-UP COSTS INCLUDE, AMONG OTHER ITEMS, PREPARATIONS FOR COLLECTING INFORMATION SUCH AS PURCHASING COMPUTERS AND SOFTWARE; MONITORING, SAMPLING, DRILLING AND TESTING EQUIPMENT; AND RECORD STORAGE FACILITIES.**

**-IF COST ESTIMATES ARE EXPECTED TO VARY WIDELY, AGENCIES SHOULD PRESENT RANGES OF COST BURDENS AND EXPLAIN THE REASONS FOR THE VARIANCE. THE COST OF PURCHASING OR CONTRACTING OUT INFORMATION COLLECTION SERVICES SHOULD BE A PART OF THIS COST BURDEN ESTIMATE. IN DEVELOPING COST BURDEN ESTIMATES, AGENCIES MAY CONSULT WITH A SAMPLE OF RESPONDENTS (FEWER THAN 10), UTILIZE THE 60-DAY PRE-OMB SUBMISSION PUBLIC COMMENT PROCESS AND USE EXISTING ECONOMIC OR REGULATORY IMPACT ANALYSIS ASSOCIATED WITH THE RULEMAKING CONTAINING THE INFORMATION COLLECTION, AS APPROPRIATE.**

**-GENERALLY, ESTIMATES SHOULD NOT INCLUDE PURCHASES OF EQUIPMENT OR SERVICES, OR PORTIONS THEREOF, MADE: (1) PRIOR TO OCTOBER 1, 1995, (2) TO ACHIEVE REGULATORY COMPLIANCE WITH REQUIREMENTS NOT ASSOCIATED WITH THE INFORMATION COLLECTION, (3) FOR REASONS OTHER THAN TO PROVIDE INFORMATION OR KEEPING RECORDS FOR THE GOVERNMENT, OR (4) AS PART OF CUSTOMARY AND**

Officers. Compliance officers examine, evaluate, and investigate eligibility for or conformity with laws and regulations governing contract compliance of licenses and permits, and perform other compliance and enforcement inspection and analysis activities not classified elsewhere. Compliance Officers (bls.gov). <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. World Bank wage rates for countries with USDA-accredited certifying agents, which were 70.3% of U.S. labor rates in 2020. <https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD>. Agents: <https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP>. Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 34.63% of total compensation in foreign countries with USDA-accredited certifying agents.

## **USUAL BUSINESS OR PRIVATE PRACTICES.**

There are no capital and start-up costs associated with this new collection. Under the NOP (§ 205.103) each operation is required to maintain and make available upon request, for 5 years, such records as are necessary to verify compliance with the NOP. There are no additional costs to maintain the required records.

### **14. PROVIDE ESTIMATES OF ANNUALIZED COST TO THE FEDERAL GOVERNMENT. ALSO, PROVIDE A DESCRIPTION OF THE METHOD USED TO ESTIMATE COST, WHICH SHOULD INCLUDE QUANTIFICATION OF HOURS, OPERATION EXPENSES (SUCH AS EQUIPMENT, OVERHEAD, PRINTING, AND SUPPORT STAFF), AND ANY OTHER EXPENSE THAT WOULD NOT HAVE BEEN INCURRED WITHOUT THIS COLLECTION OF INFORMATION. AGENCIES ALSO MAY AGGREGATE COST ESTIMATES FROM ITEMS 12, 13, AND 14 IN A SINGLE TABLE.**

We estimate the annual cost to operate the NOP at approximately \$12 million. These costs include salaries and benefits; travel and transportation; rent, communications, utilities; printing; contractual services; supplies; and equipment. The NOP currently operates on appropriated funds.

### **15. EXPLAIN THE REASON FOR ANY PROGRAM CHANGES OR ADJUSTMENTS REPORTED IN ITEMS 13 OR 14 OF THE OMB FORM 83-I.**

This is a new collection based on the new requirements described in this final rule entitled Strengthening Organic Enforcement (SOE). There were 44,725 certified organic operations and 75 accredited certifying agents in the OID on September 1, 2021.<sup>73</sup> These numbers form the basis of all calculations and estimations in the economic analyses required for the preparation of this final rule i.e. the Regulatory Impact Analysis (RIA), the Regulatory Flexibility Analysis (RFA), and this Information Collection Request (ICR).

### **16. FOR COLLECTIONS OF INFORMATION WHOSE RESULTS WILL BE PUBLISHED, OUTLINE PLANS FOR TABULATION, AND PUBLICATION. ADDRESS ANY COMPLEX ANALYTICAL TECHNIQUES THAT WILL BE USED. PROVIDE THE TIME SCHEDULE FOR THE ENTIRE PROJECT, INCLUDING BEGINNING AND ENDING DATES OF THE COLLECTION OF INFORMATION, COMPLETION OF REPORT, PUBLICATION DATES, AND OTHER ACTIONS.**

No publication of data obtained through the regulation is planned.

### **17. IF SEEKING APPROVAL TO NOT DISPLAY THE EXPIRATION DATE FOR OMB APPROVAL OF THE INFORMATION COLLECTION, EXPLAIN THE REASONS THAT DISPLAY WOULD BE INAPPROPRIATE.**

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<sup>73</sup>Organic Integrity Database <https://organic.ams.usda.gov/integrity/>



All forms are currently approved under OMB NO. 0581-0191 for the National Organic Program. We will put an expiration date on the forms upon OMB's approval of this new information collection request.

**18. EXPLAIN EACH EXCEPTION TO THE CERTIFICATION STATEMENT IDENTIFIED IN ITEM 19, "CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS," OF OMB FORM 83-I.**

The agency is able to certify compliance with all provisions under Item 19 of OMB Form 83-i.

**B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS**

**THE AGENCY SHOULD BE PREPARED TO JUSTIFY ITS DECISION NOT TO USE STATISTICAL METHODS IN ANY CASE WHERE SUCH METHODS MIGHT REDUCE BURDEN OR IMPROVE ACCURACY OF RESULTS. WHEN ITEM 17 ON THE FORM 83-I IS CHECKED "YES", THE FOLLOWING DOCUMENTATION SHOULD BE INCLUDED IN THE SUPPORTING STATEMENT TO THE EXTENT THAT IT APPLIES TO THE METHODS PROPOSED.**

This information collection does not employ statistical methods.