# REGULATORY IMPACT ANALYSIS AND PROPOSED REGULATORY FLEXIBILITY THRESHOLD ASSESSMENT AND CERTIFICATION

USDA Agricultural Marketing Service National Organic Program Strengthening Organic Enforcement

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### **EXECUTIVE SUMMARY**

The USDA Agricultural Marketing Service (AMS) proposes amending the USDA organic regulations to strengthen the oversight of organic products. These regulatory changes will build consistent certification practices to deter and detect organic fraud, improve the traceability of organic products throughout the supply chain, and protect organic integrity. To achieve the above objectives, this action proposes key changes to require:

- Certification of brokers, importers, and other types of handlers of organic products;
- Submission of NOP Import Certificates, or equivalent data, for each shipment of organic products entering the United States;
- Development of fraud prevention and supplier verification procedures and trace-back audit processes;
- Identification of products as "organic" on nonretail containers;
- Standardized organic certificates generated from the USDA's Organic Integrity Database (INTEGRITY);
- Minimum standards of knowledge, experience, qualifications, and annual training for inspectors and certifying agent review staff;
- Unannounced inspections of 5% of the operations that each certifying agent certifies;
- Notification of new locations of certifying agent offices;
- Qualification, oversight, and inspection criteria for grower group operations; and
- Conditions for establishing, evaluating, and terminating trade arrangements with other government organic programs.

AMS identified the need for many of the proposed amendments as part of its direct experience in administering the National Organic Program (NOP), particularly through investigations of operations representing products as "organic" and audits of certifying agents. Other proposed amendments are based on recent amendments to the Organic Foods Production Act of 1990 (OFPA)<sup>1</sup> included in the Agriculture Improvement Act of 2018;<sup>2</sup> the recommendations of a 2017 Office of Inspector General audit;<sup>3</sup> the recommendations of a federal advisory committee, the National Organic Standards Board (NOSB); and industry stakeholder feedback. The proposed amendments will assure consumers that organic products meet a robust, consistent standard and reinforce the value of the organic label.

The estimated costs of this proposed rule are predominantly based on increased reporting and recordkeeping requirements. The aggregate costs for those activities are described and quantified in the Paperwork Reduction Act (PRA) section of the Strengthening Organic Enforcement proposed rule.<sup>4</sup> The estimated paperwork costs for each new requirement in the proposed rule are also summarized in this Regulatory Impact Analysis.

AMS is proposing that all requirements in this proposed rule be implemented no later than one year after the publication date of the final rule.

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<sup>&</sup>lt;sup>1</sup> 7 U.S.C. 6501-6524. Available at: https://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter94&edition=prelim

<sup>&</sup>lt;sup>2</sup> The Agriculture Improvement Act of 2018, Public Law No: 115-334, commonly known as the "2018 farm bill," is available at https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf. See Title X, Section 10104.

<sup>&</sup>lt;sup>3</sup> <u>USDA Office of Inspector General Audit Report 01601-0001-21: National Organic Program International Trade Arrangements and Agreements</u>. September 2017. Available on the USDA website.

<sup>&</sup>lt;sup>4</sup> Additional details in the Information Collection Request (ICR) package: AMS 71 Grid, Supporting Statement and its appendices.

### **COST AND BENEFITS OVERVIEW**

Table 1
Economic Impact of Proposed Rule Discounted at 3% and 7 %

Affected Industry	Proposed Amendments	Annualized Cost <sup>a</sup>	Total Cost⁵
	Imports to the United States	\$143,710 - \$146,778	\$1,308,898 - \$1,752,222
gents	Certificates of Org. Operations & Cont. of Certification	\$26,576 - \$33,532	\$305,407 - \$317,268
Certifying Agents	Personnel Training & Qualifications	\$177,281 - \$181,065	\$1,614,661 - \$2,161,546
tify	On-site inspections	\$103,505 - \$105,715	\$942,719 - \$1,262,018
Cer	Supply Chain Traceability & Organic Fraud Prevention	\$2,466 - \$2,518	\$22,458 - \$30,064
	Mediation	\$172 - \$217	\$1,974 - \$2,050
Excluded	Applicability and Exemptions	\$5,097,411 - \$5,206,221	\$46,426,783 - \$62,151,533
Excl	Imports to the United States	\$19,050 - \$19,457	\$173,509 - \$232,276
fied	Labeling of Nonretail Containers	\$888,372 - \$907,335	\$8,091,215 - \$10,831,709
Certified Operations	Supply Chain Traceability & Organic Fraud Prevention	\$740,270 - \$756,072	\$6,742,318 - \$9,025,941
Above Industries, Discounted Over 15 Years		\$7,205,815 - \$7,351,910	\$65,629,941 - \$87,766,628
Estimated Benefits	Total Expected Benefit of Proposed Rule, Discounted Over 15 Years	\$83,992,975 - \$86,874,833	\$765,000,793 - \$1,037,106,112
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<sup>&</sup>lt;sup>a</sup> These are the estimated 15-year annualized domestic costs for affected industry discounted at 3 and 7 percent.

<sup>&</sup>lt;sup>b</sup> These are the estimated total domestic costs for affected industry in Net Present Value of the stream of future costs, discounted at 3 and 7 percent.

### EXECUTIVE ORDERS 12866 AND 13771

This rule is regulatory and meets the definition of a significant regulatory action under Executive Order 12866, therefore triggering the requirements set forth in Executive Order 13771. AMS estimates that the annualized compliance costs of this rule range between \$7,206,000 (7% discount) and \$7,352,000 (3% discount) over a 15-year period. AMS estimates that the net present value of the future stream of compliance costs of this rule range between \$65,630,000 to \$87,767,000. See Office of Management and Budget's (OMB) Memorandum titled "Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs'" (February 2, 2017).

Executive Orders 12866, 13563, and 13771 control regulatory review. <sup>6,7</sup> Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives, and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. <sup>8</sup> Executive Order 13771 directs Agencies to identify at least two existing regulations to be repealed for every new regulation unless prohibited by law. The total incremental cost of all regulations issued in a given fiscal year must be within the total amount of incremental costs allowed by the Director of OMB, unless otherwise required by law or approved in writing by the Director of OMB.

### NEED FOR THE RULE

Following the inception of the USDA's National Organic Program in 2002, the domestic market for organic products showed a rapid economic expansion and increased integration into global supply chains. Over this same period, the need to modernize oversight and regulatory authority to both maintain organic integrity and address fraudulent activity in the electronic era has become clear. In short, as the organic market matures, so too must the regulation. The amendments of this proposed rule position the USDA to meet current and future oversight objectives, while ensuring consistent standards and enforcement for all organic stakeholders.

The need for more consistent oversight to protect organic integrity is a product of the rapidly expanding organic market, increasingly complex organic supply chains, and price premiums for organic products. When the organic regulations were published in 2000, organic products were marketed mostly locally or regionally, and supply chains tended to be short and transparent; for example, farm to wholesale to retail to consumer. Demand and sales have grown considerably since then; total sales of organic agricultural products in the United States grew from \$3.4 billion

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<sup>&</sup>lt;sup>5</sup> Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs' <a href="https://www.whitehouse.gov/sites/whitehouse.gov/files/briefing-room/presidential-actions/related-omb-material/eo\_iterim\_guidance\_reducing\_regulations\_controlling\_regulatory\_costs.pdf">https://www.whitehouse.gov/sites/whitehouse.gov/files/briefing-room/presidential-actions/related-omb-material/eo\_iterim\_guidance\_reducing\_regulations\_controlling\_regulatory\_costs.pdf</a>.

<sup>&</sup>lt;sup>6</sup> Executive Order 12866, Regulatory Planning and Review, September 30, 1993. https://www.reginfo.gov/public/jsp/Utilities/EO 12866.pdf.

<sup>&</sup>lt;sup>7</sup> Executive Order 13771, Reducing Regulation and Controlling Regulatory Costs, January 30, 2017.

 $<sup>\</sup>underline{https://www.whitehouse.gov/presidential-actions/presidential-executive-order-reducing-regulation-controlling-regulatory-costs/.}$ 

in 1997 to \$55.1 billion in 2019. This significant market growth has attracted more producers, handlers, product suppliers, importers, brokers, distributors, and others to the organic market.

Today's global organic marketplace is marked by a multifaceted supply chain with organic products increasingly sold and handled by entities not regulated by the USDA. Although complex modern supply chains are needed to meet the demand for a wide variety of organic products, each additional transaction or transfer reduces transparency, complicates traceability, and adds an opportunity for accidental mishandling or intentional fraud. The current organic regulations do not address many of these entities and activities; there is a clear need for greater oversight in the organic market to address the fraud and mishandling that is enabled by supply chain complexity.

The absence of direct enforcement authority over some entities in the organic supply chain, in combination with price premiums for organic products, presents the opportunity and incentive for organic fraud, which has been discovered in the organic sector by both the NOP and organic stakeholders. The amendments in this proposed rule are designed to mitigate the occurrence of organic fraud.

Stakeholders have repeatedly called for the NOP to take steps to improve oversight of organic systems and enforcement of the USDA organic regulations. Commonly cited areas for improvement include certification of excluded handlers, organic import oversight, fraud prevention, organic trade arrangements, and organic inspector qualifications. In addition, public discussions on many proposals included in this action occurred during multiple NOSB meetings. <sup>10</sup>

The NOP also identified the need for many of the proposed amendments as part of its direct experience in administering this program, particularly during complaint investigations and audits of certifying agents. Other proposed amendments are based on recent amendments to the OFPA included in the Agriculture Improvement Act of 2018;<sup>11</sup> the recommendations of a 2017 Office of Inspector General audit; the recommendations of a federal advisory committee, the National Organic Standards Board (NOSB); and industry stakeholder feedback. The amendments in this proposed 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.

<sup>&</sup>lt;sup>9</sup> Organic Trade Association, Organic Industry Survey, 2018–2020.

<sup>&</sup>lt;sup>10</sup> The April 2019 NOSB meeting is the most recent example of a public discussion to address fraud concerns in the organic supply chain. A discussion document, meeting transcripts, and public comments are available at: <a href="https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-seattle-wa">https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-seattle-wa</a>

https://www.ams.usda.gov/event/national-organic-standards-board-nosb-meeting-seattle-wa

11 The Agriculture Improvement Act of 2018 (Public Law No: 115-334), commonly known as the "2018 farm bill," is available at https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf. See Title X, Section 10104.

### **BASELINE**

### Data Sources

This baseline describes the size and rates of growth of the U.S. marketplace for organic products. AMS used multiple data sources, listed below, to describe the baseline and inform our assumptions for the cost analysis:

- Research Institute of Organic Agriculture (FiBL) & The International Federation of Organic Agriculture Movements (IFOAM) – Organics International. The World of Organic Agriculture – 2017<sup>12</sup>
- Organic Trade Association (OTA) Industry Survey 2017–2020<sup>13</sup>
- Organisation of Economic Co-operation and Development (OECD) "Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact" 2016<sup>14</sup>
- U.S. Department of Agriculture (USDA)
  - o Economic Research Service (ERS)
  - o Foreign Agriculture Service (FAS) 2018<sup>15</sup>
  - National Agricultural Statistics Service (NASS) Organic Surveys various years <sup>16</sup>
  - o Agricultural Marketing Service (AMS)<sup>17</sup>
  - National Organic Program (NOP)<sup>18</sup>
  - o Organic Integrity Database (INTEGRITY)<sup>19</sup>
- U.S. Department of Commerce (DOC) Census 2015<sup>20</sup>
- Welfare Loss Model

### 1. U.S. Consumer Demand and Industry Expansion

Data from 2008 to 2017 show a constant rise in consumer demand for organic products in the United States. <sup>21</sup> During that 10-year timeframe, the average year-to-year growth rate of organic food retail sales was approximately 10.3 percent—see Table 2. The consistent growth rate indicates robust consumer demand, with value of U.S. retail sales of organic products increasing from \$22 billion in 2008 to near \$50 billion in 2017.

<sup>12</sup> https://shop.fibl.org/CHen/mwdownloads/download/link/id/785/?ref=1

<sup>&</sup>lt;sup>13</sup> Organic Industry Surveys, Organic Trade Association: 2017–2020 Surveys.

<sup>&</sup>lt;sup>14</sup> http://www.oecd.org/industry/global-trade-in-fake-goods-worth-nearly-half-a-trillion-dollars-a-year.htm; http://www.oecd.org/governance/trade-in-counterfeit-and-pirated-goods-9789264252653-en.htm

<sup>15</sup> https://apps.fas.usda.gov/gats/default.aspx. GATS Tracking System for imports and exports.

<sup>16</sup> https://www.nass.usda.gov/Surveys/Guide to NASS Surveys/Organic Production/index.php.

<sup>17</sup> https://www.ams.usda.gov/

<sup>18</sup> https://www.ams.usda.gov/rules-regulations/organic

<sup>19</sup> https://organic.ams.usda.gov/integrity/

<sup>&</sup>lt;sup>20</sup> https://www.census.gov/data/tables/2015/econ/susb/2015-susb-annual.html. This data provides the NAICS codes for most U.S. business establishments.

<sup>&</sup>lt;sup>21</sup> OTA, 2018 Organic Industry Survey.

Table 2 U.S. Sales Growth of Organic Products				
U.S. Gross Percentage Year Sales (millions) Growth				
2008	\$22,042	18.9%		
2009	\$23,065	4.6%		
2010	\$24,935	8.1%		
2011	\$27,343	9.7%		
2012	\$30,420	11.3%		
2013	\$34,147	12.3%		
2014	\$38,251	12.0%		
2015	\$42,561	11.3%		
2016	\$46,373	9.0%		
2017	\$49,360	6.4%		

Source: OTA 2018 Organic Industry Survey

The 2018 OTA Organic Industry Survey also shows U.S. demand for organic products across each food market category between 2008 and 2017. The level of demand is depicted as the rate at which retail sales of certified organic food increased relative to the total retail sales for each food category—referred to as penetration rates. Table 3 shows these rates across each food category identified by OTA. All penetration rates are positive over the ten-year period and show increases ranging from 59 to 178 percent, depending on the food category. This is evidence that certified organic food products have become more broadly available to American consumers over time and demonstrates increasing consumer demand for these products.

	Table 3							
		Food	l Market Pei	netration of (	Organic Pr	oducts		
Year	Year Fruit and Vegetable & Egg Beverages Beverages Food Food Breads & Grain Food Condiments Poultry, Fish							Meat, Poultry, Fish
2017	14.1%	8.1%	3.9%	7.0%	6.6%	5.3%	6.4%	0.7%
2008	7.5%	5.0%	2.2%	4.4%	3.9%	3.0%	2.3%	0.3%
% Change 2008 - 2017	88%	62%	77%	59%	69%	77%	178%	133%

Source: OTA 2018 Organic Industry Survey

Overall, the consistent rise in gross sales of organic products in the United States and the increase in the penetration rates across food market categories provide insight into consumer demand. Market penetration of organic products is also visible in retail data.<sup>23</sup> Data sets from the Information Resources Inc. (IRI) InfoScan, according to ERS, show the number of Uniform

<sup>&</sup>lt;sup>22</sup> OTA, 2018 Organic Industry Survey: including Fruit and Vegetables, Dairy, Packed and Prepared Foods, Beverages, Breads and Grains, Snack Foods, Condiments and Meat, Poultry and Fish. The 2019 and 2020 surveys were not available when this assessment was written.

<sup>&</sup>lt;sup>23</sup> Data Set: IRI InfoScan. This data set details store-based scanner data across 17 food and beverage categories and shows the entry and exit of products at the retail store level using Universal Product Codes (UPCs). This dataset accounts for the largest amount of sales possible, which results in data more reflective of larger scale retail stores. IRI data account for just under 50% of all retail food at home sales in the United States.

Product Codes (UPCs) labeled organic in the United States at 24,181 in 2017.<sup>24</sup> ERS confirms this figure represents about 2.36 percent of all UPCs (1,024,312) that are collected by InfoScan.

### 2. Organic Production in the United States (Supply Side Data)

The United States is a top global organic producer—ranking third after Australia and Argentina in number of organic acres—among the 179 countries reporting organic production in 2016.<sup>25</sup> Demand for organic products in the United States is outpacing the supply of organic products produced domestically. National-level data from several USDA agencies depict organic production capacity over time.<sup>26</sup> Organic Surveys administered by NASS show the number of U.S. farm acres certified for organic production up 23 percent between 2008 and 2016 (Table 4).<sup>27</sup> These figures represent a gain of roughly 100,000 certified acres per year over this period. This transition of acreage from conventional to certified organic over this period shows the responsiveness of producers and land owners to the demand for organic food products. NASS data also show an increase in the level of organic farmgate sales (139 percent) between 2008 and 2016 (Table 4).<sup>28</sup>

Table 4 U.S. Organic Farmgate Sales and Acreage under Organic Production					
Year	Year U.S. Org. Farmgate Sales (1000s) U.S. Certified Acre				
2016	\$7,553,872	5,019,496			
2008	\$3,164,995	4,077,337			
% Change 2008–2016	139%	23%			

Source: USDA National Agriculture Statistical Service Organic Surveys 2008 and 2016

Apart from acreage and farmgate revenue, the total number of USDA-certified organic operations has continued to increase (see Table 5 and Figure 1). The number of certified operations in the United States increased approximately 60.1 percent between 2008 and 2017, as compared to a 39 percent increase for foreign-based certified operations over the same period. <sup>29</sup>

<sup>&</sup>lt;sup>24</sup> Data Set: IRI InfoScan. Et al.

<sup>&</sup>lt;sup>25</sup> Source: FIBL & IFOAM – Organics International. The World of Organic Agriculture 2017. Willer and Lernoud. https://shop.fibl.org/CHen/mwdownloads/download/link/id/785/?ref=1

<sup>&</sup>lt;sup>26</sup> AMS makes no assumptions concerning causality between the levels of consumer demand for organic in the U.S. and levels of supply.

<sup>&</sup>lt;sup>27</sup> https://www.nass.usda.gov/Surveys/Guide to NASS Surveys/Organic Production/index.php.

<sup>2017</sup> organic acreage datasets not available at time of analysis.

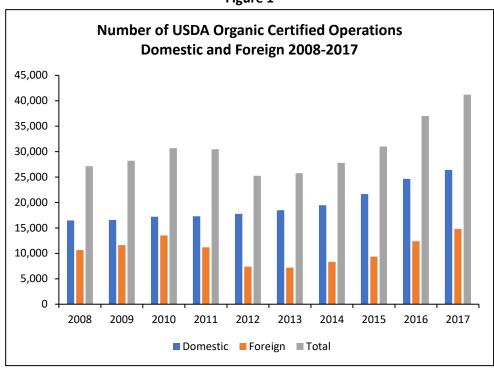
<sup>&</sup>lt;sup>28</sup> https://www.nass.usda.gov/Surveys/Guide\_to\_NASS\_Surveys/Organic\_Production/index.php. 2017 farmgate sales not available at time of analysis.

<sup>&</sup>lt;sup>29</sup> Source: USDA NOP INTEGRITY database <a href="https://organic.ams.usda.gov/integrity/">https://organic.ams.usda.gov/integrity/</a>

Table 5					
Number of	f USDA Org	anic Certified Ope	rations		
Year	Domestic	Foreign	Total		
2008	16,488	10,651	27,139		
2009	16,564	11,636	28,200		
2010	17,195	13,507	30,702		
2011	17,278	11,174	30,463		
2012	17,750	7,381 <sup>30</sup>	25,263		
2013	18,500	7,190	25,750		
2014	19,474	8,340	27,814		
2015	21,666	9,354	31,020		
2016	24,650	12,382	37,032		
2017	26,401	14,797	41,198		
2018	27,494	15,510	43,004		

Source: USDA Accreditation and International Activities

Figure 1



Source: USDA Accreditation and International Activities

U.S. adoption of organic farming systems varies by commodity sectors. For example, organic farming systems were used on over 6 percent of U.S. vegetable acres in 2016, but on less than 0.3 percent of U.S. acres for corn and soybeans, which are the two largest crops in the United States. Organic grains and oilseeds accounted for only 10 percent of the total U.S. organic farm

<sup>&</sup>lt;sup>30</sup> A reduction in the number of USDA-certified organic operations based outside the U.S. reflects the expectation for the U.S. European Union Organic Equivalency Arrangement in 2012. Prior to the Arrangement, operations marketing products in the EU and U.S. required 2 separate certifications. <a href="https://www.usda-eu.org/trade-with-the-eu/trade-agreements/us-eu-organic-arrangement/">https://www.usda-eu.org/trade-with-the-eu/trade-agreements/us-eu-organic-arrangement/</a>

sales, \$7.6 billion, in 2016.<sup>31</sup> While the United States is a major global producer and exporter of conventional grains and oilseeds, domestic organic production of those commodities is insufficient to meet the domestic demands of the organic livestock industry. Due to domestic supply shortages, imports of organic soybeans and corn have increased in recent years. Data also show an increase in imports of organic food products that are not typically produced in the United States, such as tropical fruits, coffee, and cocoa.

	Table 6 Organic Imports			
Year	Value of U.S. organic imports (U.S. dollar)	Yearly Change Percentage		
2011	\$667,419,777	-		
2012	\$495,951,148	-25.7%		
2013	\$1,362,700,947	174.8%		
2014	\$1,256,673,971	-7.8%		
2015	\$1,580,268,480	25.8%		
2016	\$1,689,062,905	6.9%		
2017	\$2,018,613,113	19.5%		
2018	\$2,184,218,958	8.2%		

Source: USDA Global Agricultural Trade System Online

USDA's Global Agricultural Trade System (GATS) provides insight to the emerging foreign industries' response to growing U.S. consumer demand for organic products. Data in Table 6 show the value of tracked U.S. organic imports in 2018 at \$2.18 billion, up 8.2 percent from \$2.02 billion in 2017, and up 227 percent from \$667 million in 2011. Part of the increase in import value reflects increases in the number of organic items for which trade data were collected during this period. Currently, fewer than 100 commodities are tracked as organic imports and exports and distinguished separately from their conventionally produced counterparts. Data are available for selected organic fresh fruit and vegetable exports and selected organic imports that include tropical produce, coffee, olive oil, grains, and oilseeds. For a few commodities, including apples, roasted coffee, cultivated blueberries, and pears, data on both organic exports and imports are available.

A comparison of GATS import data to domestic production data from NASS shows that the value of organic imports as a percentage of the value of U.S. organic farmgate production increased (18.8 percent to 22.5 percent) from 2011 to 2016. While these valuation levels are influenced by several market factors affecting prices such as yield levels, input costs, and inflationary pressure, the increasing proportion of imports may partially reflect how domestic production capacity is not keeping pace with domestic demand.

https://www.nass.usda.gov/Surveys/Guide to NASS Surveys/Organic Production/index.php

<sup>&</sup>lt;sup>31</sup> NASS Organic Production Survey 2017.

<sup>&</sup>lt;sup>32</sup> Source: Department of Commerce, U.S. Census Bureau, Foreign Trade Statistics; USDA-FAS Global Agricultural Trade System database, located at <a href="http://apps.fas.usda.gov/gats/default.aspx">http://apps.fas.usda.gov/gats/default.aspx</a>, makes quarterly import statistics available, beginning in 2011.

<sup>&</sup>lt;sup>33</sup> A set of rules on creating new trade codes determines the number of tracked commodities. More specifically, guidelines set by the U.S. Census Bureau require minimums on market participation to avoid publicly revealing proprietary information. Another necessary condition is that data can only be collected when there are consistent trade flows exceeding value thresholds of \$1 million per year for all shipments exceeding \$5,000.

In summary, the global footprint of organic production is expanding. Acreage of organic farmland and number of certified operations are increasing, both domestically and abroad, and the interconnectedness of the supply chain is widening to meet the growing demand of U.S. consumers. This, in turn, has increased the complexity of international organic supply chains.

### 3. Baseline Projection Given Continued Market Expansion

The historic market data above describe the changing production environment and demand for organic products in the United States. Most of these changes show positive rates of growth, especially at the retail level, which averages approximately 10 percent growth per year over the past 10-year period.<sup>34</sup> Extrapolating from the same data is also useful for estimating the baseline level of the organic market into future years for the purpose of economic impact assessment. See Table 7 below.

Table 7						
Future Mark	Future Market Baseline 2018–2032					
Year-on-Year Market Growth Rates Year U.S. Projected Orga						
-	2017	\$49,360				
8%	2018	\$53,309				
6%	2019	\$56,507				
6%	2020	\$59,898				
6%	2021	\$63,492				
6%	2022	\$67,301				
6%	2023	\$71,339				
5%	2024	\$74,906				
5%	2025	\$78,651				
5%	2026	\$82,584				
5%	2027	\$86,713				
5%	2028	\$91,049				
4%	2029	\$94,691				
4%	2030	\$98,478				
4%	2031	\$102,418				
4%	2032	\$106,514				
4%	2033	\$110,775				

Table 7 draws upon historical organic sales data (i.e., yearly growth rate of sales) to depict a scenario in which future market expansion occurs at or slightly below current U.S. sales growth rates. The scenario proposed in Table 7 assumes that positive rates of growth continue yearly, but diminish over the fifteen-year period. The initial level of 6 percent growth (applied to years 2019–2023) aligns with recent data trends from 2015 to 2017, over which time period growth rates declined from about 11.3 percent (2015) to 6.4 percent (2017). Five percent growth is assigned to the period 2024–2028 and 4 percent growth for 2029–2033. Although the trend depicted in this scenario reflects the maturation of a market through decelerated growth rates, the nominal value of U.S. sales increases approximately 124.4 percent from the 2017 nominal value of \$49.4 billion to roughly \$110.8 billion by 2033.

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<sup>&</sup>lt;sup>34</sup> OTA, 2018 Organic Industry Survey. The 2019 and 2020 surveys were not available when this assessment was written.

### **BENEFITS**

AMS expects that collectively, the proposed requirements will reduce organic fraud in the U.S. market. Therefore, AMS has quantified the estimated benefits of the proposed rule as the value of the projected reduction in organic fraud in the U.S. organic marketplace following implementation. As part of this impact assessment, AMS reviewed economic studies that identify and quantify fraudulent activity in retail markets. These studies provide benchmarks to quantify the benefits of the proposed rule.

Ependitis (1998) posited that the prevalence of fraud amongst organic produce ranged between 15 percent and 40 percent in southern countries of the European Union.<sup>35</sup> Another report (2013, by the European Parliament) ranked products most at risk of food fraud. This report ranked organic goods third of the top 10 products most at risk.<sup>36</sup> Also in 2013, Everstine and Kircher reported that various forms of fraud affect nearly 10 percent of all commercially sold food products.<sup>37</sup>

AMS also reviewed more recent studies from the OECD. In 2019, OECD estimated that counterfeit and pirated goods represented up to 3.3 percent of world trade over the period of 2013 to 2016.<sup>38</sup> The study described rates of fraud for individual categories of goods, including 'foodstuffs' (1.6 percent). AMS compared the 2019 OECD data to a previous assessment also conducted by OECD in 2016, which indicated 2.5 percent of global imports between 2011 and 2013 were counterfeit or pirated goods.<sup>39</sup> Based on these studies, AMS chose a 2 percent fraud benchmark, which aligns with the levels of fraud described in the two OECD studies spanning six years.

The first step in quantifying the economic benefits is to determine the market value of the product category: organic products. Within this category, AMS focused on the value of organic premiums because businesses selling fraudulent organic products at a premium will accrue illicit economic rents from consumers. The premium, therefore, represents the economic market value, because a rational consumer would not pay a price premium for a fraudulent product given the availability of a product substitute. AMS estimated the organic premium of organic imports and the domestic farmgate sales to establish a baseline market valuation for organic products at the beginning of domestic supply chains.

AMS then reviewed data from: (1) 2017 USDA-Foreign Agricultural Service (FAS) value of U.S. organic food imports, (2) 2016 USDA-NASS U.S. organic farm sales, and (3) organic retail premium rates reported by a 2016 USDA-ERS study. <sup>40</sup> These sources were used to estimate the

Department of Agriculture, Economic Research Service, May 2016.

<sup>35</sup> Ependitis, The. 1998. "Organic?" October 22B24, p. 29 (in Greek).

<sup>&</sup>lt;sup>36</sup> European Parliament, Public Health and Food Safety draft report "on the food crisis, fraud in the food chain and the control thereof," (2013/2091(INI)).

http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A7-2013-0434+0+DOC+PDF+V0//EN

<sup>&</sup>lt;sup>37</sup> Estimated by the Food Standards Agency of the U.K., as reported by K. Everstine and A. Kircher, "The Implications of Food Fraud," *Food Quality & Safety* magazine, June/July 2013.

<sup>&</sup>lt;sup>38</sup> OECD/EUIPO (2019), *Trends in Trade in Counterfeit and Pirated Goods*, Illicit Trade, OECD Publishing, Paris/European Union Intellectual Property Office. Available at: https://doi.org/10.1787/9789264252653-en

<sup>&</sup>lt;sup>39</sup> OECD/EUIPO (2016), *Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact*, Illicit Trade, OECD Publishing, Paris. <a href="https://www.oecd-ilibrary.org/governance/trade-in-counterfeit-and-pirated-goods">https://www.oecd-ilibrary.org/governance/trade-in-counterfeit-and-pirated-goods</a> 9789264252653-en <sup>40</sup> Carlson, Andrea and Edward Jaenicke. *Changes in Retail Organic Price Premiums from 2004 to 2010*, ERR-209, U.S.

total premium value of organic products entering domestic supply chains in 2017: approximately \$1.47 billion (U.S. organic imports) and \$3.93 billion (domestic production).

AMS applied the 2 percent organic fraud benchmark to the value of organic imports and domestic production. The results show an estimate of \$30 million in illicit premiums for organic imports and \$79 million for domestic organic farmgate sales. Following the implementation of the proposed rule, AMS expects a reduction in the prevalence of organic fraud to 1 percent (i.e., a reduction of 50%). This would equate to a social welfare gain of approximately \$54 million per year.

AMS estimates the benefits over a 15-year period, based on projected future annual growth rates of the U.S. organic market at 6, 5, and 4 percent, diminishing in 5-year subperiods. Applying a baseline of approximately \$54 million per year, and considering the expected growth of the U.S. organic market, annual benefits from fraud reduction are estimated to reach \$113 million in year 2032. When discounted over the 15-year period, total economic benefits of the proposed rule range from \$725 to \$985 billion. When annualized, the economic benefits range from \$80 to \$83 million. Table 8 below is a summary of the 15-year discounted benefits. Please see Exhibit A for a complete table of estimated benefits over a 15-year period.

Table 8
Estimated Benefits from Mitigation of Fraud in the U.S. Organic Marketplace Over 15
Years

Benefits	Discount Rates	Fraud Reduction from 2% to 1%
Total over 15 Years	3%	\$1,037,106,112
	7%	\$765,000,793
Annualized over 15 Years	3%	\$86,874,833
	7%	\$83,992,975

### PROPOSED AMENDMENTS COST

The subsequent twelve sections identify and explain the cost associated with each of the amendments in the proposed rule. AMS developed these estimates using available qualitative and quantitative data, benchmark studies, cross-agency collaboration, and the best professional judgement of USDA officials having subject matter expertise in economics, trade, supply chains, organic certification and accreditation, and enforcement.

The title of each section identifies the location in the organic regulation that would be amended. Each section begins with a brief background about the proposed amendment, followed by a discussion of the associated costs.

A cost estimate table appears in each section. This table presents the estimated cost to an affected industry (total and annualized) at the industry and per-business levels. Data appearing in each table show discounting of costs at 3 and 7 percent over a 15-year timeline.

Approximately 10.2 percent of the estimated costs of the proposed rule are due to the proposed requirements that certain business operations within the organic supply chain obtain organic certification. These costs are specific to entities located in the United States.

Approximately 89.8 percent of the costs of the proposed rule are due to paperwork and recordkeeping burden. The PRA analysis estimates the costs to affected business in the United States and worldwide, including:

- Domestic and foreign-based USDA-certified operations
- Domestic and foreign-based USDA-accredited certifying agents
- Future industry entrants
- Foreign governments with trade arrangements

A complete copy of the PRA is included in Exhibit E. This RIA includes a summary of the PRA costs corresponding to each section for the affected domestic entities.

### Applicability and Exemptions from Certification (§§ 205.100–101)

### **Background**

The proposed rule would require the certification of all handlers in the organic supply chain, with limited exemptions (e.g., operations that only store products, retail operations). The USDA organic regulations currently exclude certain types of handling operations from the certification requirement. These "exclusions" may include, for example, brokers, importers, traders and processers. This means that these operations fall outside USDA regulatory oversight authority for compliance with organic handling requirements. These operations are commonly known as and referenced hereafter as 'excluded handlers.' The exclusions from certification create gaps in product traceability for the USDA and certifying agents. From a compliance standpoint, these gaps undermine the integrity of organic supply chains, because excluded handlers are not required to provide all records pertaining to organic products to the USDA, organic operations, or certifying agents. This directly limits compliance verification to organic handling practices across the supply chain continuum.

An illustrative example is the case of imported organic products that are fumigated with prohibited substances upon entry to the United States and consequently lose organic status. In this case, U.S. Customs and Border Protection (CBP) authorities who initially inspect the imported product will notify the importer or broker about the fumigation incident. The importer or broker may not disclose the fumigation incident in future transactions and records of the fumigation incident may not be available to organic handlers or certifying agents. As a result, any certified organic operations or consumers purchasing the product would be unaware that the product is no longer organic. Under the current USDA organic regulations, fumigated organic products lose organic status, if the incident of fumigation is detected/exposed. This rule would increase the availability of information to the supply chain, and presumably the detection of fumigation events, but would not change the consequences because fumigated products would still lose organic status.

This proposed rule would reduce the types of excluded handler operations and close information gaps in the organic supply chain. This action would improve product traceability and clarify USDA authority to oversee and enforce organic handling practices throughout the entire supply chain.

### **Regulatory Impact Analysis**

Identifying the Affected Businesses

To estimate the potential costs of revising the requirements for who needs to be certified, AMS determined (1) how many operations would need to become certified as a result of this proposed rule, and (2) the cost for each (and all) of those operations to obtain organic certification. The estimation of these metrics is described below.

<sup>&</sup>lt;sup>41</sup> Some traders and brokers have voluntarily obtained organic certification.

<sup>&</sup>lt;sup>42</sup> 'Excluded handlers' are businesses that currently are not required to possess organic certification. As a result of the proposed rule, some operations referred to as 'excluded handlers' will be required to obtain organic certification. Throughout the analysis, the term 'excluded handlers' will be used to identify the type of business will be newly required to get organic certification.

<sup>&</sup>lt;sup>43</sup> Supply chain information includes records that help operations verify organic status, including chain of custody of the certified-organic product.

How many operations would need to become certified?

To identify the number of businesses that would need to obtain certification, AMS first determined which category of operations in the North American Industrial Classification System (NAICS)<sup>44</sup> conducts handling activities consistent with those defined in the proposed rule that would be impacted. The definition of *handle*, as amended by the proposed rule, is to sell, process, or package agricultural products, including but not limited to trading, facilitating sale or trade, brokering, repackaging, labeling, combining, containerizing, storing, receiving, or loading. AMS determined that NAICS category 425, *Wholesale Electronic Markets and Agents and Brokers*, contains businesses that conduct specific activities aligned with the amended definition of *handle*, and therefore would need to become certified as a result of this proposed rule.<sup>44</sup>

The U.S. Census specifically defines NAICS category 425 as a subsector that, "arranges for the sale of goods owned by others, generally on a fee or commission basis. This subsector contains agents and brokers as well as business-to-business electronic markets that facilitate wholesale trade." This includes agents, brokers, and business-to-business electronic markets for durable (e.g., automobiles and home appliances) and non-durable (e.g., perishable) goods. As a result, the category includes businesses from many supply chains, not just agriculture. AMS expects only a small percentage of the 42,733 businesses, which are the number of enterprises, would be affected by the proposed rule.

To estimate the percentage of businesses within NAICS category 425 that would be affected by this proposed rule, AMS reviewed and applied industry benchmarks from different segments of the supply chain. AMS is benchmarking because there are limited data available about the number of intermediary businesses transacting organic products in the supply chain. This is primarily because certain businesses transacting organic products are currently not subject to USDA organic regulation. Because little data are available on these "middle-market" businesses within NAICS category 425, AMS assessed data from both farm-gate and retail sales.

### Assumptions

AMS makes the following assumptions as part of this economic analysis:

- 1. Excluded handlers are operations in the supply chain that will need to become certified as a result of this proposed rule. Excluded handlers mostly include businesses selling, trading, brokering, or facilitating the sale or trade of organic products.
- 2. Excluded handers will elect to become certified because the annual costs associated with organic certification are relatively low compared to annual revenues from involvement in organic products.
- 3. Organic products are part of the portfolios of excluded handlers who will need to become certified as a result of the proposed rule.
- 4. Excluded handlers are generally intermediary businesses positioned between the production and retail ends of organic supply chains.

https://www.census.gov/eos/www/naics/2017NAICS/2017 Definition File.pdf

<sup>&</sup>lt;sup>44</sup> Source: North American Industry Classification System (NAICS). <a href="https://www.census.gov/eos/www/naics/">https://www.census.gov/eos/www/naics/</a>

<sup>&</sup>lt;sup>45</sup> Source: U.S. Census. https://www.census.gov/eos/www/naics/2017NAICS/2017 Definition File.pdf

<sup>&</sup>lt;sup>46</sup> Source: U.S. Census, NAICS 425110 and 425120.

<sup>&</sup>lt;sup>47</sup> Non-durable goods include perishable goods such as agricultural products and commodities.

<sup>&</sup>lt;sup>48</sup> https://www2.census.gov/programs-surveys/susb/tables/2015/us enterprise classification 2015.xlsx

### Benchmarks

AMS followed a series of steps to estimate how many businesses in NAICS category 425 would be affected by the proposed rule: (1) AMS estimated how many of the 42,733 total businesses facilitate the sale of agricultural products; then (2) AMS estimated how many among those facilitating the sale of agricultural products also facilitate the sale of organic products.

Benchmarking levels are established using data from several sources, including USDA's National Agricultural Statistical Service (NASS)<sup>49</sup> and ERS,<sup>50</sup> Mintel/SPINS/IRI (IRI),<sup>51</sup> and the Organic Trade Association (OTA).<sup>52</sup>

Estimating the percentage of agriculture as a share of the total economy

To estimate how many businesses within NAICS category 425 facilitate the sale of agricultural products, AMS reviewed benchmark data for U.S. Gross Domestic Product (GDP) and employment levels. Data provided by ERS for these two economic indicators give insight to agriculture's penetration rate in the general economy. Data showed that (a) agriculture, food, and related industries "contributed \$992 billion to U.S. GDP in 2015, a 5.5-percent share" of the economy, <sup>53</sup> and (b) agriculture and related food sectors make up approximately 11 percent of total U.S. employment (2017). <sup>54</sup>

This indicates the agricultural sector comprises approximately 6 and 12 percent of the U.S. economy and employment, respectively. AMS averaged these two data points (9 percent) as a benchmark to apply to NAICS 425. AMS estimates 3,846 (or 9 percent of 42,733) businesses facilitate transactions of agricultural products.

Estimating the percentage of organic as a share of agriculture

To estimate how many of these 3,846 businesses facilitate transactions of organic agricultural products, AMS used data from the agricultural supply chain that quantify organic market share relative to total agricultural market share. Three different areas spanning the length of the agricultural supply chain were assessed: production, intermediary markets, and retail. Given supply chain dynamics and differences between these three market segments, AMS observed different rates of penetration of organic products.

On the production end of the supply chain, 2012 Ag Census shows organic production represents 0.40 percent of total U.S. production acreage <sup>55</sup> and approximately 0.79 percent of the total

<sup>51</sup> Source: Mintel/SPINS/IRI. Specialty Food Association's State of the Specialty Food Industry is a joint research project by Mintel and SPINS/IRI. The research encompasses the three most recent calendar years of sales data and includes figures for 61 specialty food categories, pulled from the SPINS database of mainstream and natural food stores. In addition, Mintel surveyed specialty food manufacturers, importers, distributors, brokers, and retailers.

<sup>&</sup>lt;sup>49</sup> Source: NASS organic surveys. <a href="https://www.nass.usda.gov/Surveys/Guide">https://www.nass.usda.gov/Surveys/Guide</a> to NASS Surveys/Organic Production/

<sup>&</sup>lt;sup>50</sup> Source: ERS. https://www.ers.usda.gov/

<sup>&</sup>lt;sup>52</sup> Source: Organic Trade Association, Organic Industry Survey 2018.

<sup>&</sup>lt;sup>53</sup> Source: USDA Economic Research Service. <a href="https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=58270">https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=58270</a>

detail/?chartId=58270
 Source: USDA Economic Research Service. <a href="https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=58282">https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=58282</a>
 Farm Acres used in 2011 NASS Organic Survey; 2012 Ag Census data provides incomplete acreage data for organic

<sup>&</sup>lt;sup>55</sup> Farm Acres used in 2011 NASS Organic Survey; 2012 Ag Census data provides incomplete acreage data for organic production. 2011 NASS Organic Survey data used.
<a href="http://usda.mannlib.cornell.edu/usda/nass/OrganicProduction/2010s/2012/OrganicProduction-10-04-2012.pdf">http://usda.mannlib.cornell.edu/usda/nass/OrganicProduction/2010s/2012/OrganicProduction-10-04-2012.pdf</a>

market value of farm sales.<sup>56</sup> In both cases, the percentage of agriculture that is organic is below 1 percent.

However, on the retail end of the supply chain, industry survey data show that U.S. organic food sales represent approximately 5.5 percent of total U.S. food sales and 0.89 percent of total U.S. non-food sales.<sup>57</sup> Other retail-level market data aggregated by IRI InfoScan show organic products make up about 2.36 percent of the food and beverage products available in the market place.<sup>58</sup> ERS, which provided the data to AMS, estimates that the InfoScan data set accounts for half of the total number of retail products, and suggests organic products comprise between 5 and 6 percent of all food and beverage products sold in the United States.

Thus, data from both ends of the agricultural supply chain show organic penetration rates ranging from roughly 0.4 percent (production end) to 6 percent (retail end). However, data from the intermediary market located between production and retail ends of the supply chain suggest a higher rate of organic penetration. These data are described below.

AMS identified the higher organic penetration rate in the intermediary market during a review of sales and survey data presented in the State of the Specialty Food Industry 2017 report. This report discusses sales of specialty foods in the United States, including organic products. Qualitatively, data show that between 62–100 percent (81 percent averaged) of intermediary market actors transacting specialty foods—such as brokers, importers, and distributors—anticipate increased demand for organic products. Furthermore, survey results indicated that:<sup>59</sup>

- 62% of brokers identify organic as the food product that interests consumers the most.
- 100% of importers of specialty foods import organic food products.
- 80% of distributors identify organic as the food product that interests consumers the most.
- 40% of respondents anticipate that demand for organic products will grow the most amongst all specialty food categories over the coming three-year period (as of the survey).

Survey data provides one way to assess the relative organic penetration rate in the intermediary market of agricultural supply chains. Using best professional judgement of AMS and ERS officials, AMS selected a benchmark of 25 percent; this is the average (rounded down) of 14.8

<sup>&</sup>lt;sup>56</sup> **Total organic product sales**: The data represent the value of commodities produced according to USDA's National Organic Program and sold from operations during 2012. Crops, livestock, and poultry products were reported individually on the 2012 report form. In 2007, however, these commodities were combined and may have come from either crops or livestock production. The data for the 2012 census years are not directly comparable. **Total market value of agricultural products sold and government payments**: This category represents the value of products sold plus government payments. Total value of products sold combines total sales not under production contract and total sales under production contract. Government payments consist of government payments received from the Conservation Reserve Program (CRP), Wetlands Reserve Program (WRP), Farmable Wetlands Program (FWP), or Conservation Reserve Enhancement Program (CREP), plus government payments received from Federal, State, and local programs other than the CRP, WRP, FWP, and CREP, and Commodity Credit Corporation loans.

<sup>57</sup> Source: Organic Trade Association, Organic Industry Survey 2018.

<sup>&</sup>lt;sup>58</sup> Data Source: IRI InfoScan. This data set details store-based scanner data across for 17 food and beverage categories and shows the entry and exit of products at the retail store level using UPCs. This dataset accounts for the largest amount of sales possible, which results in data more reflective of larger scale retail stores. IRI data account for just under 50% of all retail food at home sales in the United States. Data provided by USDA ERS.

<sup>&</sup>lt;sup>59</sup> Source: State of the Specialty Food Industry, Specialty Food Association, 2017. The report acknowledges that not all specialty foods are organic. <a href="https://www.specialtyfood.com/news/article/state-specialty-food-industry-2017/">https://www.specialtyfood.com/news/article/state-specialty-food-industry-2017/</a>

percent and 35.6 percent, which AMS estimates as the minimum and maximum penetration rates. <sup>60</sup>

Survey data shows specialty food sales at 14.8 percent of total U.S. food sales. AMS expects that the survey responses cited above signal a high probability of increasing penetration rates of organic products among brokers and distributors. The upper-bound estimate, 35.6 percent, is based on AMS' professional judgement and observation of the supply chain. This percentage is based on sales data of organic relative to only specialty foods using 2017 dollars.<sup>61</sup>

AMS applied the two benchmarks identified above to NAICS category 425 to estimate the number of entities potentially affected by the proposed rule. The first benchmark (9 percent) is applied to define the relative percentage of industry that facilitates agriculture transactions within NAICS category 425. The second benchmark (25 percent) defines the estimated population of agricultural industry that facilitates transactions of organic products within the intermediary segment of the supply chain. Therefore, AMS estimates that 961 businesses in NAICS category 425 facilitate sales transactions of organic products and would be affected by the proposed rule. <sup>62</sup>

### Estimated Costs

Handlers that must obtain certification because of this proposed rule will incur costs to obtain that certification. Costs for certification reflect both the application for certification and on-site inspection fees. <sup>63</sup> Costs associated with documentation and additional recordkeeping requirements are described below in the PRA analysis.

In general, AMS expects the certification costs for excluded handlers (those selling, trading, facilitating the sale or trade of, or brokering in agricultural products, which under the current regulation are excluded from certification) to be lower than certification costs for crop, livestock, or processing operations. <sup>64</sup> These costs are a function of how complex the applicant's operation is and the fee-calculation model used by the certifying agent. Generally, more complex operations have higher certification costs because they require lengthier inspections and records audits. For example, an operation certified for crop production is responsible for maintaining compliance to USDA organic regulations across several broad categories, including but not limited to, crop production and management, inputs, natural resources and environment, harvesting, packing and labeling, inventory storage, machinery storage, sanitation, pest management, and record keeping. An inspector reviews each of these practices during an on-site inspection; the more time required to review and collect information, the greater the certification cost to the operation.

<sup>63</sup> Accredited certifying agents independently determine application and inspection fee schedules. See 7 CFR 205.642 "Fees and other charges for certification" <a href="https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=bb6f02225549283976c4dcaea9396ae9&mc=true&n=pt7.3.205&r=PART&ty=HTML#se7.3.205\_1</a>

<sup>&</sup>lt;sup>60</sup> Source: State of the Specialty Food Industry, Specialty Food Association, 2017. The report acknowledges that not all specialty foods are organic. <a href="https://www.specialtyfood.com/news/article/state-specialty-food-industry-2017/">https://www.specialtyfood.com/news/article/state-specialty-food-industry-2017/</a>

<sup>&</sup>lt;sup>61</sup> Calculation: \$45.21 billion (2017 OTA Organic Industry Survey) ÷ \$127 billion (2017 State of the Specialty Food Industry report)

 $<sup>^{62}</sup>$  Estimated for the year 2018.  $961 = 42,733 \times 9\% \times 25\%$ 

<sup>&</sup>lt;sup>64</sup> Handler operations as described here refer to value-added processers, for example, makers of organic soup, cookies, ready-eat meals, etc.

In contrast, the time needed for inspection and audits of excluded handlers is likely to be comparatively less because their operational activities differ from those of a certified organic producer or processer. The activities of excluded handlers generally involve the collection and transmittal of critical information about the sale, custody, or movement of a product to responsible parties in the supply chain. This information is critical to trace-back audits and includes, but is not limited to, phytosanitary certificates from U.S. Ports of Entry or foreign ports, treatment records, bills of lading, and other records from the supply chain. Excluded handler activities may also encompass the coordination of transportation logistics for the organic product, which also are critical for trace-back audits.

Unlike the activities of certified organic producers and processers, the activities performed by excluded handlers may not involve physical possession, title, or custody of the organic product; in addition, they may not store, package, repackage, or process the product. As such, their unique position in the supply chain, access to critical transaction records, and narrow range of activity reduce the scope of on-site inspections to primarily a records audit. Therefore, AMS expects excluded handlers will have lower certification costs, on average, than producers or processers.

### Industry Cost per Operation

Under the current USDA organic regulations, excluded handlers such as brokers and traders are not required to obtain organic certification. Consequently, data on cost of certification for excluded handlers are sparse and these costs must be estimated. To address the lack of data, certifying agents provided AMS with approximated costs of organic certification fees that they expect to charge excluded handlers. Approximately 70 percent of certifying agent respondents indicated they would apply a cost model that blends fixed and variable fees, which aligns with standard industry practice for cost modeling.<sup>65</sup> The yearly certification fees estimated by certifying agents range from \$300 to \$5,200, and average approximately \$1,757.65 The costmodel approach and the average cost estimate (\$1,757) both align with the expectations of AMS staff knowledgeable and experienced in accreditation and certification. AMS also compared the certifying agents' estimated cost range for excluded handlers to the existing cost range for certification, which ranges from \$300 to \$42,000. This shows that the anticipated cost range for excluded handlers falls at the lower end of the fee spectrum, further indication that shorter and less costly inspections will likely apply to the excluded handler population. Using these data and the knowledge of AMS staff experienced in accreditation and certifications, AMS expects the cost per year to excluded handlers affected by the proposed rule would range from approximately \$500 to \$3,500 per operator.

Using the estimated number of businesses that will need to obtain certification and the estimated certification costs from certifying agents, AMS developed two cost scenarios (Tables 9 and 10). In both scenarios, four weighted cost tiers were established to represent the range of expected certification fees. In each table, AMS used the same four price tiers: \$500, \$1,500, \$2,500, and \$3,500, which reflect ranges based on data provided by certifying agents. The same population of industry (961 excluded handlers) was used in each table to represent those businesses facilitating transactions of organic products.

Table 9 below reflects a lower estimated certification cost for excluded handlers (\$1,105,150). This was achieved by weighting the population of affected industry toward the lower end of the

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<sup>&</sup>lt;sup>65</sup> Information voluntarily provided by USDA-accredited certifying agents, 2018.

cost range, assuming that the majority of operations will incur lower annual certification costs within the range. Table 10 provides an alternative scenario, in which the proportion of operations were evenly distributed across the four cost tiers. Table 10 shows a higher total cost (\$1,922,000) to industry than Table 10 (\$1,105,150).

Table 9 Annual Estimated Certification Cost to Excluded Handlers					
Total Af	fected Operations: 961				
Percentage of Operations Per	Percentage of Operations Per Certification Cost Tiers Total Cost per				
Tier	Certification cost fiers	Tier			
<b>55%</b> (528.55 operations)	\$500	\$264,275			
<b>30%</b> (288.30 operations)	\$1,500	\$432,450			
<b>10%</b> (96.10 operations)	\$2,500	\$240,250			
<b>5%</b> (48.05 operations) \$3,500 \$168,175					
	Total Cost	\$1,105,150			

Table 10				
Annual Estimated Ce	rtification Cost to Excluded I	Handlers		
Total Af	fected Operations: 961			
Percentage of Operations Per	Certification Cost Tiers	Total Cost Per		
Tier	Certification Cost Hers	Tier		
<b>25%</b> (240.25 operations)	\$500	\$120,125		
<b>25%</b> (240.25 operations)	\$1,500	\$360,375		
<b>25%</b> (240.25 operations)	\$2,500	\$600,625		
<b>25</b> % (240.25 operations) \$3,500 \$840,875				
	Total Cost	\$1,922,000		

Based on estimates described above, the total certification costs to the affected industry range from \$1.11 million to \$1.92 million for the first year after implementation of the proposed amendments. This equates to approximately \$1,150 to \$2,000 per affected operation. <sup>66</sup> AMS anticipates that it is more likely that industry costs will align with the scenario presented in Table 10 because it uses a cost distribution that reflects paper trace-back audits as the primary activity and cost driver for the certification and inspection of the affected industry. Using a conservative approach, AMS incorporated the higher cost (\$2,000/business) into the regulatory flexibility threshold assessment later in this report.

### **Paperwork Reduction Act**

The proposed amendment described above would directly affect approximately 961 domestic businesses at a cost burden of \$50.86 per hour, including 31.1% benefits, a labor rate associated with their occupational profile. <sup>67,68</sup> The aggregate yearly burden of labor hours for this business community is estimated to be 48,050 hours. This cost is based on the 40 hours of projected time

<sup>&</sup>lt;sup>66</sup> This cost does not include PRA costs.

<sup>67</sup> U.S. Bureau of Labor—Group 11-9013. U.S. Bureau of Labor Statistics, https://www.bls.gov/oes/current/oes119013.htm

<sup>&</sup>lt;sup>68</sup> In this assessment, all 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 14, 2018. <a href="https://www.bls.gov/news.release/eccc.nr0.htm">https://www.bls.gov/news.release/eccc.nr0.htm</a>

to prepare an organic system plan to obtain certification and 10 hours to maintain records related to organic handling.

Therefore, the estimated annual paperwork cost of this proposed amendment is \$2,543 per affected business (48,050 domestic labor hours x \$50.86/hour  $\div$  961 excluded handlers).

### **Estimated Cost Table**

AMS estimates \$4,543 in total costs per affected business per year in current dollars (\$2,000 RIA cost + \$2,453 PRA cost). This dollar estimate represents the first year of the model used to approximate annualized and total costs (to industry and per business). Below is a summary table of the estimated annualized costs and total costs. Please see Exhibit B for the complete cost table for this section.

		Table 11 Economic Impact: Applicability and Exemptions from Certification				
		Cost to Affected Industry Cost Per Excluded Handler				
Affected Industry	Number Affected	Annualized Cost <sup>a</sup>	Total Cost <sup>b</sup>	Annualized Cost	Total Cost	
Excluded Handlers	961	\$5,097,411 - \$5,206,221	\$46,426,783 - \$62,151,533	\$5,304 - \$5,418	\$48,311 - \$64,674	

<sup>&</sup>lt;sup>a</sup> These are the 15-year annualized domestic costs for affected industry discounted at 3 and 7 percent

For detailed background analysis and proposed regulatory text, see the Strengthening Organic Enforcement proposed rule preamble, Section III, Chapter 1.

<sup>&</sup>lt;sup>b</sup> These are the total domestic costs for affected industry in Net Present Value discounted at 3 and 7 percent

### Imports to the United States (§ 205.273)

### **Background**

The proposed rule would require the use of NOP Import Certificates to document the status of organic products imported into the United States. The proposed rule would require that each shipment of organic products imported into the United States through U.S. Ports of Entry must be declared as organic to U.S. Customs and Border Protection (CBP), and be associated with a valid NOP Import Certificate or equivalent data source.

The NOP Import Certificate is a type of transaction certificate that contains detailed information about the quantity and source of organic product being imported into the United States. These records support traceability in organic supply chains and accountability of buyers and sellers. Currently, NOP Import Certificates are required only when organic products are imported to the United States from a country or region subject to the conditions of a USDA equivalency arrangement. <sup>69</sup> This limited use of NOP Import Certificates undermines the integrity of organic supply chains and complicates oversight activities. Expanding a mandatory requirement to all shipments of organic imports would enhance oversight by assisting trace-back audits and noncompliance investigations and deterring organic fraud.

### **Cost Analysis**

This proposed amendment will affect will certifying agents and importers. AMS' estimated cost of this proposed amendment is based on increased reporting and recordkeeping. The proposed rule would require that imported shipments of organic product be associated with a valid NOP Import Certificate that is available electronically 70 and uploaded to CBP's Automated Commercial Environment (ACE) system. 71 Certifying agents already have procedures for reviewing and approving NOP Import Certificates for organic products imported to the United States under equivalency arrangements.

The USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS) showed 67,023 shipments of organic product coming into the United States in 2017. According to INTEGRITY, 32 USDA-accredited certifying agents based in foreign countries certify 92% of the foreign operations certified under USDA organic standards. Of the 46 domestic-based USDA accredited certifying agents, 16 certifying agents certify 8% of the foreign operations certified under USDA. This means that 30 domestic-based USDA-accredited certify agents only certify domestic-based operations and therefore do not issue NOP Import Certificates. AMS estimates

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<sup>&</sup>lt;sup>69</sup> The USDA has established organic equivalency arrangements with Canada, the European Union, the United Kingdom (effective January 2021), Switzerland, Japan, Taiwan, and South Korea. Organic imports from Canada must be accompanied by an attestation statement that the products comply with the terms of the United States-Canada Organic Equivalency Arrangement. Organic imports from the European Union, the United Kingdom, Switzerland, Japan, Taiwan, and South Korea must be accompanied by an NOP Import Certificate.

<sup>&</sup>lt;sup>70</sup> NOP Form 2110-1 is currently used; the proposed rule will require the use of this form in electronic format.

<sup>&</sup>lt;sup>71</sup> ACE is an automated electronic system for processing commercial trade data and is the primary system used by the global trade community to file information about imports to ensure admissibility into the United States.

<sup>&</sup>lt;sup>72</sup> 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: <a href="https://apps.fas.usda.gov/gats/default.aspx">https://apps.fas.usda.gov/gats/default.aspx</a>

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

there are 32 foreign-accredited certifying agents that certify foreign operations under trade arrangements, and therefore may issue NOP Import Certificates. <sup>74,75</sup>

Therefore, the proposed amendment identified above directly affects 46 certifying agents headquartered in the United States who certify foreign operations who export to the United States. AMS assessed the cost burden at \$45.91 per hour, a labor rate associated with certifying agents' occupational profile. AMS estimates that U.S. certifying agents will review and approve a total of 5,361 NOP Import Certificates for shipments of organic products imported into the United States as a result of this proposed rule. Further, AMS estimates that certifying agents will spend 30 minutes to review and approve each NOP Import Certificate, for a total of 2,681 labor hours. This estimate accounts for the time for certifying agents to review and verify data on NOP Import Certificates submitted by exporters seeking to export organic products to the United States. Therefore, the estimated annual cost of this proposed amendment is \$2,676 per certifying agent (2,681 domestic labor hours x \$45.91/hour ÷ 46 Certifying Agents).

In addition, AMS estimated the costs for importers to verify that the information on the NOP Import Certificate is consistent with the actual shipment. AMS estimates that importers (961 entities) will need 6 minutes to compare an import certificate to a shipping manifest and that each importer will review 70 certificates per year (based on the 67,023 shipments to the United States annually).

Exporters shipping organic product to the United States are based overseas and costs associated with their compliance are not included in this economic impact assessment. However, AMS accounted for costs for exporters to report mandatory data for NOP Import Certificates in the PRA analysis. AMS estimates that exporters will need 30 minutes to report data for each NOP Import Certificate and that each exporter will request 70 import certificates per year.

### **Estimated Cost Table**

AMS estimates \$2,676 in total costs per certifying agent and \$355 in total costs per importer per year in current dollars. This dollar estimate represents the first year of the model used to approximate annualized and total costs (to industry and per business). Below is a summary table of the estimated annualized and total costs. Please see Exhibit B for a complete cost table for this section.

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<sup>&</sup>lt;sup>74</sup> An estimate based on the number of foreign-based USDA-accredited certifying agents.

<sup>&</sup>lt;sup>75</sup> Currently, the United States has established organic trade arrangements with Canada, the European Union, the United Kingdom (effective January 2021), India, Israel, Japan, New Zealand, South Korea, Taiwan, and Switzerland.

<sup>&</sup>lt;sup>76</sup> U.S. Bureau of Labor—Group 13-1041: U.S. Bureau of Labor Statistics. <a href="https://www.bls.gov/oes/current/oes131041.htm">https://www.bls.gov/oes/current/oes131041.htm</a>

<sup>&</sup>lt;sup>77</sup> 8% of 67,023 shipments of organic product coming into the United States. 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: <a href="https://apps.fas.usda.gov/gats/default.aspx">https://apps.fas.usda.gov/gats/default.aspx</a>.

<sup>&</sup>lt;sup>78</sup> \$2,676 reflects an even distribution of labor hours associated with the proposed regulatory requirement among all certifying agents headquartered in the United States (46). Not all certifying agents will issue import certificates. AMS anticipates that approximately 16 of the 46 certifying agents located in the United States are likely to share the cost burden given AMS' understanding of certifying agent activities related to NOP Import Certificates. The concentration of labor burden would result in approximately \$7,693 per certifying agent, for each of these 16 certifying agents, were these the only agents to issue import certificates, and \$0 cost burden for the remaining 30 certifying agents.

		Table 12 Economic Impact: Imports to the United States			
		Cost to Affec	cted Industry Cost Per Business		Business
Affected Industry	Number Affected	Annualized Cost <sup>a</sup>	Total Cost <sup>b</sup>	Annualized Cost	Total Cost
Certifying Agents	46	\$143,710 - \$146,778	\$1,308,898 - \$1,752,222	\$3,124 - \$3,191	\$28,454 - \$38,092
Excluded Handlers - Importers	961	\$19,050 - \$19,457	\$173,509 - \$232,276	\$20	\$181 - \$242

For detailed background analysis and proposed regulatory text, see the Strengthening Organic Enforcement proposed rule preamble, Section III, Chapter 2.

<sup>&</sup>lt;sup>a</sup> These are the 15-year annualized domestic costs for affected industry discounted at 3 and 7 percent <sup>b</sup> These are the total domestic costs for affected industry in Net Present Value discounted at 3 and 7 percent

### **Labeling of Nonretail Containers (§ 205.307)**

### **Background**

The proposed rule would clarify labeling requirements for nonretail containers used to ship or store organic products. Specifically, labels on nonretail containers would need to identify the organic status of the contents and the certifying agent. Current USDA organic regulations require only a production lot number; additional information is optional. As a result, information shown on nonretail labels can vary. This variability is detrimental to the integrity and oversight of organic products as they move through the supply chain because a product that is not clearly identified as organic is more vulnerable to mishandling. AMS has observed that some nonretail labels currently display optional information. AMS considers the clear disclosure of a product's organic status on the non-retail label as supportive to traceability and protective of organic integrity. As such, the proposed rule would standardize regulatory requirements for nonretail labels to align with best practices observed across industry.

The proposed amendments would not affect the option to list additional information, beyond what is required, on nonretail labels such as special handling instructions, the USDA organic seal, and/or contact information for the certifying agent of the products in the container.

### **Cost Analysis**

The proposed requirements for nonretail container labels would affect certified operations. The estimated cost of this proposed amendment is based on reporting and recordkeeping requirements. This amendment will improve the consistent display of product-specific information on nonretail labels by requiring (1) the identity of the certifying agent that certified the product, and (2) designation of the contents within the nonretail container as either "100 percent organic," "organic," or "made with organic." Portions of industry may already meet or exceed these requirements.

This proposed amendment directly affects certified operations located in the United States. AMS assessed the cost burden at \$50.86 per hour, a labor rate associated with the occupational profile of certified operations. <sup>80</sup> The aggregate yearly burden of labor hours for certified operations as a result of this proposed amendment is estimated to be 14,960 labor hours.

Therefore, the estimated annual paperwork cost of this proposed amendment is \$31 per certified operation (14,960 domestic labor hours x \$50.86/hour  $\div$  24,933 certified operations).

### **Estimated Cost Table**

AMS estimates \$31 in total costs per certified operation per year in current dollars. This dollar estimate represents the first year of the model used to approximate annualized and total costs (to

<sup>&</sup>lt;sup>79</sup> Although a production lot number is required, many labels include additional information that is described as optional in the USDA organic regulations (§ 205.307). This optional information includes the name and contact information of the certifying agent of the handler that assembled the final product, identification of the product as organic, special handling instructions, the USDA seal, and/or the logo or identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the finished product.

<sup>80</sup> U.S. Bureau of Labor—Group 11-9013: U.S. Bureau of Labor Statistics. https://www.bls.gov/oes/current/oes119013.htm

industry and per business). Below is a summary table of the annualized and total costs. Please see Exhibit B for a complete cost table for this section.

		Table 13 Economic Impact: Labeling of Nonretail Containers			
		Cost to Affec	cted Industry	Cost Per Certified Operation	
Affected Industry	Number Affected	Annualized Cost <sup>a</sup>	Total Cost <sup>b</sup>	Annualized Cost	Total Cost
Certified Operations	24,933	\$888,372 - \$907,335	\$8,091,215 - \$10,831,709	\$35.63 - \$36.39	\$325 - \$434

For detailed background analysis and proposed regulatory text, see the Strengthening Organic Enforcement proposed rule preamble, Section III, Chapter 3.

<sup>&</sup>lt;sup>a</sup> These are the 15-year annualized domestic costs for affected industry discounted at 3 and 7 percent <sup>b</sup> These are the total domestic costs for affected industry in Net Present Value discounted at 3 and 7 percent

### On-Site Inspections (§ 205.403)

### **Background**

Unannounced inspections are an effective tool to encourage compliance across certified operations within a risk-based framework. The proposed rule would codify practices for unannounced inspections described in NOP Instruction 2609, Unannounced Inspections. <sup>81</sup> Specifically, the proposed rule would require certifying agents to annually conduct unannounced inspections of at least 5 percent of the operations they certify. Current USDA organic regulations allow, but do not require, certifying agents to conduct unannounced inspections. In addition, the regulations do not stipulate any parameters for conducting unannounced inspections. As a result, certifying agents may individually determine the number of unannounced inspections among the operations they certify. <sup>82</sup> The proposed amendment would establish a standard for the minimum number of unannounced inspections to be performed annually. In addition, it would also specify that all regularly scheduled on-site inspections must include trace-back and mass-balance audits, standardizing industry best practice.

### **Cost Analysis**

The cost of this proposed amendment is due to reporting and recordkeeping requirements that affect certifying agents. Since issuing NOP Instruction 2609 in 2012, AMS has observed unannounced inspection practices during audits of certifying agents, and concludes that certifying agents are currently implementing the recommended practice of annually conducting unannounced inspections of at least 5% of the operations they certify. AMS expects that half of the unannounced inspections (2.5% of total inspections) would continue to meet the requirement for a full annual inspection and would not impact current paperwork burden. The remaining half of the unannounced inspections (2.5% of total inspections) would target high-risk operations and supply chains and would 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.

The proposed amendment identified above directly affects 46 USDA-accredited certifying agents headquartered in the United States. AMS estimates that certifiers spend 5 hours, on average, to conduct one unannounced inspection, at \$28.45 per hour. 83 The aggregate yearly burden of labor hours for domestic certifying agents as a result of this proposed amendment is estimated to be 3,116 labor hours.

Therefore, the estimated annual paperwork cost of this proposed amendment is \$1,927 per certifying agent (3,116 domestic labor hours x  $$28.45/hour \div 46$  certifying agents).

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<sup>81</sup> NOP 2609 4.1.1—"We recommend that certifying agents conduct unannounced inspections of 5 percent of their total certified operations per year as a tool in ensuring compliance with the regulations. We also recommend that certifying agents with less than 20 certified operations conduct at least one unannounced inspection per year." <a href="https://www.ams.usda.gov/sites/default/files/media/2609.pdf">https://www.ams.usda.gov/sites/default/files/media/2609.pdf</a>

<sup>&</sup>lt;sup>82</sup> Prior to NOP guidance on this topic, some certifying agents used unannounced inspections as a normal oversight mechanism on a yearly basis, but the frequency of their use varied by certifying agent. The disparity was noted by the National Organic Standards Board (December 2011) and Office of Inspector General (February 2012), each of who submitted recommendations to AMS to address the issue. NOSB Recommendation:

 $<sup>\</sup>underline{https://www.ams.usda.gov/sites/default/files/media/NOP\%20CACC\%20Final\%20Rec\%20on\%20Unannounced\%20Inspections.pdf.}$ 

<sup>83</sup> U.S. Bureau of Labor—Group 45-2011 Agricultural Inspectors. https://www.bls.gov/oes/current/oes452011.htm

### **Estimated Cost Table**

AMS estimates \$1,927 in total costs per certifying agent per year in current dollars. This dollar estimate represents the first year of the model used to approximate annualized and total costs (to industry and per business). Below is a summary table of the annualized and total costs. Please see Exhibit B for a complete cost table for this section.

		Table 14 Economic Impact: On-Site Inspections			
			cted Industry	Cost Per Certifying Agent	
Affected Industry	Number Affected	Annualized Cost <sup>a</sup>	Total Cost <sup>b</sup>	Annualized Cost	Total Cost
Certifying Agents	46	\$103,505 - \$105,715	\$942,719 - \$1,262,018	\$2,250 - \$2,298	\$20,494 - \$27,435

<sup>&</sup>lt;sup>a</sup> These are the 15-year annualized domestic costs for affected industry discounted at 3 and 7 percent

For detailed background analysis and proposed regulatory text, see the Strengthening Organic Enforcement proposed rule preamble, Section III, Chapter 4.

<sup>&</sup>lt;sup>b</sup> These are the total domestic costs for affected industry in Net Present Value discounted at 3 and 7 percent

### Certificates of Organic Operation (§ 205.404) and Continuation of Certification (§ 205.406)

### **Background**

The proposed rule would establish the requirement that certifying agents must issue certificates of organic operation ("certificates") generated through INTEGRITY, the NOP's electronic data warehouse.84

Current USDA organic regulations do not include standards mandating certifying agents' use of or reporting to INTEGRITY. As a result, certifying agents report varying levels of information to the database and few generate organic certificates using INTEGRITY. Variances in data reporting hinder supply chain verification activities conducted by certifying agents and industry stakeholders because it takes longer to authenticate certificates to confirm certification status of a specific operation or product. This adversely impacts oversight.

By requiring certificates generated from INTEGRITY, the proposed rule would improve the consistent availability of useful data throughout the supply chain and reduce transaction times for verifying the organic status of an operation or product. The proposed rule would ensure that organic certificates are available electronically and have the same format and type of information.

The proposed rule would also clarify reporting requirements for annually updating organic system plans for continuation of certification. The proposed rule clarifies that to continue certification, operations need to submit only the sections of their organic system plan (OSP) that have changed from the prior-approved OSP. This would eliminate the submission of redundant information; certified operations would no longer need to resubmit unchanged information each year. The proposed changes would not alter the requirement for certified operations to maintain an updated OSP or notify their certifying agents of a change that may affect compliance with the USDA organic regulations.

In summary, amendments to the current regulations would standardize organic certificates and eliminate a paperwork redundancy. These amendments would strengthen organic supply chain integrity, enhance oversight, and streamline administrative procedures.

### **Cost Analysis**

These sections of the proposed rule would affect certifying agents. AMS expects the cost associated with these amendments to be limited to paperwork costs only. Currently, certifying agents must keep operation-specific data in the USDA's electronic Organic INTEGRITY Database. The proposed rule would require a one-time upload of additional data. A portion of the required data have already been submitted and are currently available in INTEGRITY.

The proposed amendments will improve consistency of information available to industry and increase efficiency of the continuation of certification process for both certified operations and certifying agents.

<sup>84</sup> INTEGRITY is a USDA-hosted electronic web-based system. INTEGRITY is administered by the NOP and updated by USDA-accredited certifying agents. INTEGRITY makes information about certified organic operations available to the public and ensures certification data is readily available to the NOP, organic certifying agents, and state and federal agencies.

These proposed amendments directly affect 46 USDA-accredited certifying agents headquartered in the United States. The hourly cost burden is \$23.73 per hour, a labor rate associated with the occupational profile for record and data entry to upload data to generate organic certificates. AMS estimates the aggregate burden of labor hours to upload additional operation-specific data to INTEGRITY is 13,771 labor hours. This burden is assumed to be non-recurring and is expected only in the first year following implementation of a final rule, when certifying agents will need to complete data entry into INTEGRITY for all operations. 86

Therefore, the estimated annual paperwork cost of this proposed amendment is \$7,104 per certifying agent (13,771 labor hours x \$23.73/hour  $\div$  46 certifying agents). This cost is non-recurring. The \$7,104 cost applies only to the first year after publication of the final rule. The yearly cost of this proposed amendment to certifying agents in all subsequent years of the 15-year assessment is estimated at \$0 per year.

### **Estimated Cost Table**

AMS estimates \$7,104 in total costs per certifying agent per year in current dollars. This dollar estimate represents the first year of the model used to approximate annualized and total costs (to industry and per business). Below is a summary table of the annualized and total costs. Please see Exhibit B for a complete cost table for this section.

		Certificate of Organ	Table 15 Economic Imp nic Operations and (		nuation of Certification		
		Cost to Affec	cted Industry	Cost Per Certifying Agent			
Affected Industry	Number Affected	Annualized Cost <sup>a</sup>	Total Cost <sup>b</sup>	Annualized Cost	Total Cost		
Certifying Agents	46	\$26,576 - \$33,532	\$305,407 - \$317,268	\$578 - \$729	\$6,639 - \$6,897		

<sup>&</sup>lt;sup>a</sup> These are the 15-year annualized domestic costs for affected industry discounted at 3 and 7 percent

For detailed background analysis and proposed regulatory text, see the Strengthening Organic Enforcement proposed rule preamble, Section III, Chapters 5 and 6.

<sup>&</sup>lt;sup>b</sup> These are the total domestic costs for affected industry in Net Present Value discounted at 3 and 7 percent

<sup>&</sup>lt;sup>85</sup> U.S. Bureau of Labor—Group 43-9199 Office and Administrative Support Workers, All Other. https://www.bls.gov/oes/current/oes439199.htm

<sup>&</sup>lt;sup>86</sup> The data entry is considered a non-recurring activity that will be completed in the first year after publication of the final rule.

### Paperwork Submission to the Administrator (§ 205.405)

### **Background**

The proposed amendment eliminates the regulatory requirement that certifying agents provide certain notices to the Administrator, including notices of noncompliance and their resolution, and proposed and final adverse actions.

### **Cost Analysis**

These sections of the proposed rule would affect certifying agents. AMS anticipates zero cost to industry because the proposed amendment eliminates a requirement for certifying agents to submit various compliance notifications to AMS. This would be replaced by a requirement for certifying agents to maintain updated data on the organic status of the operations they certify in INTEGRITY (see related section on Certificates of Organic Operation: § 205.404, Section III, Chapters 5–6 of the Strengthening Organic Enforcement proposed rule preamble). The availability of information electronically (through INTEGRITY) simultaneously fulfills each proposed regulatory requirement and eliminates the procedural redundancy of submitting certain notifications to the Administrator.

The proposed amendment identified above does not create a new labor burden for any U.S. industry. Any labor burden associated with electronic data entry is separately addressed above under the chapter titled, "Certificates of Organic Operation and Continuation of Certification." Therefore, the estimated cost associated with this proposed amendment is \$0.

For detailed background analysis and proposed regulatory text, see the Strengthening Organic Enforcement proposed rule preamble, Section III, Chapter 7.

### Personnel Training and Qualifications (§ 205.501)

### **Background**

Certification review personnel and organic inspectors are critical to robust organic oversight. The proposed rule would set skill and experience qualifications and annual training requirements for certification reviewers and organic inspectors to ensure that they are proficient in the USDA organic regulations, production techniques, and oversight practices as applicable to the type of operations they inspect and review.

Certification reviewers examine organic system plans, inspection reports, responses to noncompliance findings, and other documents necessary to determine whether an operation is compliant with the USDA organic regulations. Inspectors conduct on-site inspections of certified operations or operations seeking certification. Inspections may be announced in advance as part of the annual inspection cycle, or inspection may be unannounced, with a specific focus on one aspect of an operation. During the annual inspection, the inspector primarily reviews all records related to organic production and handling, observes conditions of the production/handling facility, conducts paper audits, collects samples for residue testing, and provides a report of the inspection to the certifying agent. Current USDA organic regulations do not require specific qualifications or training for individuals who conduct certification review activities or organic inspections. The proposed requirements will ensure that inspectors and certification reviewers are competent to inspect and evaluate operations for compliance with the USDA organic regulations.

### **Cost Analysis**

The proposed rule would affect certifying agents and inspectors. NOP staff familiar with accreditation audits report that inspectors and reviewers already complete some training on a yearly basis.<sup>87</sup> This is demonstrated by certifying agents' annual reports submitted to the NOP that document staff trainings each year. Such trainings are focused on organic regulation, production techniques, and oversight practices. The proposed rule would standardize industry practice while clarifying qualification and training criteria requirements.

To lower potential cost to certifying agents and inspectors, AMS released the Organic Integrity Learning Center (OILC), a web-based learning management system that has free online courses related to organic production, certification and oversight. These courses may be combined with annual training provided by certifying agents to fulfill the annual 20-hour training requirement in this proposed rule.<sup>88</sup>

The proposed amendment identified above directly affects 46 USDA-accredited certifying agents, plus approximately 150 certification reviewers and 150 inspectors based in the United States. AMS estimates the aggregate labor hour burden shared among certifying agents, certification reviewers, and inspectors to be 4,433 per year. Most of these labor hours (approximately 67 percent) are due to the requirement for reviewers and inspectors to individually complete 20 hours of training per year. <sup>89</sup> A portion of those hours account for the estimated costs for certifying agents to observe inspectors conducting an inspection at least once

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<sup>&</sup>lt;sup>87</sup> Internal AMS accreditation oversight.

<sup>88</sup> Organic Integrity Learning Center: https://www.ams.usda.gov/services/organic-certification/training.

<sup>&</sup>lt;sup>89</sup> The PRA estimates inspectors and reviewers currently participate in 10 hours of training a year.

every three years. AMS estimates that these groups currently complete 10 hours of training yearly. Therefore, this proposed rule would add an additional 10 hours of annual training to fulfill the 20-hour requirement. Labor hours are divided among two occupational groups, certification review personnel and inspectors, at costs of \$45.91/hour<sup>90</sup> and \$28.45,<sup>91</sup> respectively.

Therefore, the estimated annual cost of this proposed amendment is \$3,300 per certifying agent  $((1,473 \text{ labor hours } \times \$45.91/\text{hour}) + (2,960 \text{ labor hours } \times \$28.45) \div 46)$ .

### **Estimated Cost Table**

AMS estimates \$3,300 in total costs per certifying agent per year in current dollars. This dollar estimate represents the first year of the model used to approximate annualized and total costs (to industry and per business). Below is a summary table of the annualized and total costs. Please see Exhibit B for a complete cost table for this section.

		Table 16 Economic Impact: Personnel Training and Qualifications			
		Cost to Affec	cted Industry	Cost Per Certifying Agent	
Affected Industry	Number Affected	Annualized Cost <sup>a</sup>	Total Cost <sup>b</sup>	Annualized Cost	Total Cost
Certifying Agents	46	\$177,281 - \$181,065	\$1,614,661 - \$2,161,546	\$3,854 - \$3,936	\$35,101 - \$46,990

<sup>&</sup>lt;sup>a</sup> These are the 15-year annualized domestic costs for affected industry discounted at 3 and 7 percent

For detailed background analysis and proposed regulatory text, see the Strengthening Organic Enforcement proposed rule preamble, Section III, Chapter 8.

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<sup>&</sup>lt;sup>b</sup> These are the total domestic costs for affected industry in Net Present Value discounted at 3 and 7 percent

<sup>&</sup>lt;sup>90</sup> U.S. Bureau of Labor Statistics—Group 13-1041 Compliance Officers: <a href="https://www.bls.gov/oes/current/oes131041.htm">https://www.bls.gov/oes/current/oes131041.htm</a>

<sup>91</sup> U.S. Bureau of Labor Statistics—Group 45-2011 Agricultural Inspectors: https://www.bls.gov/oes/current/oes452011.htm

<sup>&</sup>lt;sup>92</sup> The cost to inspectors is included in the costs to Certifying Agents.

# Oversight of Certification Activities (§§ 205.501 and 205.665) and Accepting Foreign Conformity Assessment Systems (§ 205.511)

### **Background**

International trade is critically important to the economic vitality of the organic sector and is a major engine of U.S. economic growth. AMS currently has 10 trade arrangements with other countries related to the trade of organic products. <sup>93</sup> The conditions governing such arrangements are important enforcement tools to ensure compliance with the Act and the organic regulations in foreign countries where the USDA has no direct oversight. The current USDA organic regulations authorize these arrangements but do not describe the scope or other parameters to establish, oversee, or terminate trade arrangements. The proposed rule would describe the USDA's process to establish, assess, continue, and terminate trade arrangements by amending the USDA organic regulations to align with practices that are consistent with NOP guidance. <sup>94</sup>

In addition to trade arrangements, the proposed rule also amends other portions of the organic regulations to enhance global oversight. These proposed amendments clarify that the NOP can initiate enforcement action against a certifying agent based on either (1) the actions of a person acting on behalf of a certifying agent (e.g., a subcontractor), or (2) the actions of an individual certification office. This clarification is necessary because both subcontractors and multiple certification offices are commonly used by certifying agents to conduct certification activities (e.g., inspections and review of applications, inspection reports, labels, and input materials) in different countries and regions. AMS also proposes that certifying agents notify the NOP within 90 days of the opening of a new certification office. This will provide the NOP with information necessary to monitor and oversee the certification activities performed at these locations.

The above proposed changes are necessary to improve transparency of AMS' procedures for trade arrangements to ensure that they protect organic integrity and to improve the oversight of certification activities globally.

### **Cost Analysis**

The proposed rule would affect foreign governments, and the certifying agents they accredit, who currently have, or will seek, a trade arrangement with AMS regarding the trade of organic products. Because the proposed amendments affect the procedures and processes related to trade arrangements between AMS and foreign governments, AMS anticipates zero cost to domestic industry. S As such, there are no new burdens created that would adversely affect operations or consumers located in the United States. Therefore, AMS estimates \$0 in total costs per business per year in current dollars.

For detailed background analysis and proposed regulatory text, see the Strengthening Organic Enforcement proposed rule preamble, Section III, Chapters 9 and 10.

<sup>&</sup>lt;sup>93</sup> Equivalency is an arrangement in which countries establish that their organic certification designations are equivalent to each other. Recognition is an arrangement where AMS recognizes foreign governments as the competent authority to accredit foreign certifying agents to certify under the USDA organic regulations.

<sup>&</sup>lt;sup>94</sup> NOP-2100 Equivalence Determination Procedure (effective 10/29/2015) and NOP-2200 Recognition and Monitoring of Foreign Government Conformity Assessment Systems (effective 5/6/2015).

<sup>&</sup>lt;sup>95</sup> Office of Management and Budget Circular A-4: <a href="https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf">https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf</a>

### Compliance (§§ 205.660–661), Noncompliance Procedure for Certified Operations (§ 205.662), Mediation (§ 205.663), and Adverse Action Appeal Process (§§ 205.680–681)

#### **Background**

The proposed rule would clarify and revise the USDA organic regulations concerning AMS enforcement authority and mediation and appeal procedures. The current regulations address these topics in two regulatory sections: (a) Compliance and (b) Adverse Action Appeal Process. First, AMS is proposing to explicitly state the authority of NOP to take enforcement actions against uncertified operations for violations of the Organic Foods Production Act or the USDA organic regulations. Secondly, AMS is clarifying procedures for mediation to incentivize the use of this process as an alternative option to resolve disputes over noncompliance issues between certifying agents and operations. In addition, the proposed rule would clarify which actions may be appealed.

In summary, amendments to the current regulation would clearly communicate USDA enforcement authority and mediation procedures, and clarify the administrative appeal process.

#### **Cost Analysis**

These sections of the proposed rule would affect certifying agents, certified operations, operators responsibly connected to certified operations, applicants for organic certification, and uncertified operations. The estimated costs of these amendments are based on a new reporting and recordkeeping requirement for certifying agents. The proposed amendments would require certifying agents to submit to the NOP 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 would spend one hour documenting these procedures. AMS expects that many certifiers already have these procedures because mediation is already provided for under the current regulations as an option that certifying agents must provide to operations before suspending or revoking certification.

Therefore, the cost of this proposed amendment is one hour of time per domestic certifying agent, at \$45.91/hour, including 31.7% benefits. 96 AMS estimates a one-time total cost of \$2,112 for all certifying agents. Table 17 shows the annualized and total costs for all certifying agents and per certifying agent to develop the mediation procedures. Please see Exhibit B for a complete cost table for this section.

For detailed background analysis and proposed regulatory text, see the Strengthening Organic Enforcement proposed rule preamble, Section III, Chapters 11–15.

<sup>&</sup>lt;sup>96</sup> U.S. Bureau of Labor Statistics—Group 13-1041 Compliance Officers: https://www.bls.gov/oes/current/oes131041.htm

#### **Estimated Cost Table**

		Table 17 Economic Impact: Mediation Procedures												
		Cost to Affected Industry Cost Per Certifying Agen												
Affected Industry	Number Affected	Annualized Cost <sup>a</sup>	Total Cost <sup>b</sup>	Annualized Cost	Total Cost									
Certifying Agents	46	\$172 - \$217	\$1,974- \$2,050	\$3.73 - \$4.71	\$42.91 - \$44.57									

<sup>&</sup>lt;sup>a</sup> These are the 15-year annualized domestic costs for affected industry discounted at 3 and 7 percent <sup>b</sup> These are the total domestic costs for affected industry in Net Present Value discounted at 3 and 7 percent

#### Grower Group Operations (§§ 205.201, 205.400, and 205.403)

#### **Background**

This proposed rule would clarify certification requirements for grower group operations. A grower group operation is a single producer consisting of grower group members organized under a central management and marketing system and regulated as a single certified operation. Grower group operations tend to be composed of many small, individual producers distributed over a geographic area with uniform practices. <sup>97</sup> Individual grower group members grow one or more similar commodities and aggregate them at the grower group's centralized facility for subsequent marketing, with revenue and costs shared among membership. This structure creates unique challenges and oversight complexities for certifying agents. The current USDA organic regulations do not specifically mention grower group operations; therefore, clarification of the regulations is needed to address the complexities presented by grower group operations.

This proposed rule describes criteria to qualify as a grower group operation, sets requirements for internal control systems that oversee a grower group's compliance, and establishes certifying agents' responsibilities for oversight and inspection of these operations.

#### **Cost Analysis**

This proposed amendment would affect certifying agents and operations certified as grower groups. AMS estimates zero cost to certifying agents. Based on AMS experience in conducting regular audits of accredited certifying agents, which include witness inspections of grower group operations, the proposed requirements for grower group certification are consistent with the current guidance for this type of operation. Placing these requirements in the regulations will support the implementation and enforcement of consistent practices for the certification of grower groups. Nearly all grower group operations are located outside of the United States. Therefore, the proposed amendments will not impose any new burden on certifying agents or certified operations in the United States. These clarifications would improve regulatory oversight of organic supply chains and mitigate organic fraud.

For detailed background analysis and proposed regulatory text, see the Strengthening Organic Enforcement proposed rule preamble, Section III, Chapter 16.

<sup>&</sup>lt;sup>97</sup> Organizing a grower group as a single person clarifies the operation as a basic regulatory unit; certification is granted to the group, rather than individual growers within the group.

<sup>&</sup>lt;sup>98</sup> NOP Policy Memorandum 11-13, Grower Group Certification, January 21, 2011: https://www.ams.usda.gov/sites/default/files/media/NOP-11-10-GroupGrowerCert.pdf

<sup>&</sup>lt;sup>99</sup> Grower group operations are prevalent throughout Central and South America, Africa, and Asia. Grower group operations are rarely established in the United States.

#### Calculating the Percentage of Organically Produced Ingredients (§§ 205.302)

#### **Background**

This proposed rule clarifies requirements for calculating the percentage of organically produced ingredients in processed products. The current requirements in the USDA organic regulation may cause inaccurate and inconsistent calculation methods for determining the organic content of a product. The proposal clarifies that organic content must be calculated (by weight or volume) at the time of formulation, regardless of whether further processing occurs.

#### **Cost Analysis**

The proposed rule would affect certifying agents and certified operations. AMS is aware that certifying agents and certified operations are already performing organic percentage calculations that align with these proposed requirements. This proposal will not impose any new burden on industry located in the United States. These clarifications would ensure consistent enforcement of USDA organic regulations. AMS estimates zero cost to certifying agents and certifier operations because of this proposed amendment.

For detailed background analysis and proposed regulatory text, see the Strengthening Organic Enforcement proposed rule preamble, Section III, Chapter 17.

### Supply Chain Traceability and Organic Fraud Prevention (§§ 205.103, 205.201, 205.501, and 205.504)

#### **Background**

This proposed rule specifies regulatory requirements that address organic product traceability and organic fraud prevention. The amendments require certified organic operations to maintain audit trail documentation to facilitate supply chain traceability and to describe monitoring practices and procedures in their organic system plan that prevent fraud. The amendments also require certifying agents to share information with other certifying agents to verify supply chains and conduct investigations. They must also have procedures for identifying high-risk operations and products to conduct risk-based supply chain audits, and procedures for reporting credible evidence of fraud to the USDA.

The amendments span several sections of the regulations, standardizing the procedures and practices used by certifying agents and certified operations to ensure product traceability. These changes work in conjunction with other proposed changes, specifically, requiring certification of additional types of handlers, NOP Import Certificates, and labeling of nonretail containers, to improve organic enforcement capacity, facilitate verification of organic supply chains, and set consistent requirements for all operations in the organic market.

#### **Cost Analysis**

The proposed rule would affect certifying agents and certified operations. Certifying agents would be required to write new procedures for identifying high-risk operations and products to conduct risk-based supply chain audits. Certified operations would be required to describe in their organic system plans the monitoring practices and procedures used to prevent organic fraud and verify suppliers in their supply chain. These changes are necessary to support supply chain traceability, product and supplier verification, and fraud prevention throughout the organic industry.

#### Cost to Certifying Agents

These proposed amendments directly affect 46 USDA-accredited certifying agents headquartered in the United States. AMS estimated that each certifying agent would spend one hour to develop the new procedures required by the proposed rule, at a corresponding labor rate of \$45.91 per hour. <sup>100</sup> This includes the costs to develop criteria to identify high risk operations, conduct supply chain audits and report evidence of fraud to AMS. Therefore, the estimated annual cost of this proposed amendment is \$45.91 per certifying agent (46 domestic labor hours x \$45.91/hour ÷ 46 certifying agents).

#### Cost to Certified Operations

These proposed amendments directly affect 24,933 certified operations located in the United States. AMS estimated that each certified operation would spend 30 minutes to modify their organic system plans with the procedures to verify suppliers and status of organic products

<sup>100</sup> U.S. Bureau of Labor Statistics—Group 13-1041 Compliance Officers: https://www.bls.gov/oes/current/oes131041.htm

received required by this proposed amendment, at a labor rate of \$50.86 per hour.  $^{101}$  Therefore, the estimated annual cost of this proposed amendment is \$25 per certified operation (12,466 domestic labor hours x \$50.86/hour  $\div$  24,933).

#### **Estimated Cost Table**

AMS estimates the following total costs in current dollars: \$45.91 per certifying agent per year, and \$25 per certified operation per year. These dollar estimates represent the first year of the model used to approximate annualized and total costs (to industry and per business). Below is a summary table of the annualized and total costs. Please see Exhibit B for complete cost tables for this section.

		Table 18 Economic Impact: Supply Chain Traceability and Organic Fraud Prevention												
		Cost to Affected Industry Cost Per Business												
Affected Industry	Number Affected	Annualized Cost <sup>a</sup>	Total Cost <sup>b</sup>	Annualized Cost	Total Cost									
Certifying Agents	46	\$2,466 - \$2,518	\$22,458 - \$30,064	\$53.6 - \$54.75	\$488 - \$654									
Certified Operations	24,933	\$740,270 - \$756,072	\$6,742,318 - \$9,025,941	\$29.69 - \$30.32	\$270 - \$362									

<sup>&</sup>lt;sup>a</sup> These are the 15-year annualized domestic costs for affected industry discounted at 3 and 7 percent

For detailed background analysis and proposed regulatory text, see the Strengthening Organic Enforcement proposed rule preamble, Section III, Chapter 18.

<sup>&</sup>lt;sup>b</sup> These are the total domestic costs for affected industry in Net Present Value discounted at 3 and 7 percent, 15 years

<sup>&</sup>lt;sup>101</sup> U.S. Bureau of Labor Statistics—Group 11-9013 Farmers, Ranchers, and Other Agricultural Managers: <a href="https://www.bls.gov/oes/current/oes119013.htm">https://www.bls.gov/oes/current/oes119013.htm</a>

#### **Summary of Costs by Affected Industry**

Table 19 is a summary of estimated first-year costs identified and described above. Each estimated cost is grouped by industry (certifying agents, excluded handlers, and certified operations). Proposed amendments are adjacent to corresponding estimated costs. Costs are categorized in terms of (1) regulatory impact and (2) paperwork and recordkeeping burden. The total cost estimate for each industry appears below each industry group.

Table 19 Economic Impact (RIA) and Paperwork Reduction (PRA) Costs by Affected												
	Industry – Year :	1	·									
Affected	Proposed Amendments	Regulatory Flexibility Estimate Yr-1 Cost per Business										
Industry	·	RIA Cost	PRA Cost									
ted	Imports to the United States	\$0.00	\$2,675.75									
46 Certifying Agents Affected	Certificates of Org. Operations & Cont. of Certification	\$0.00	\$7,104.04									
gent	Personnel Training & Qualifications	\$0.00	\$3,300.81									
ng A	On-Site inspections	\$0.00	\$1,927.18									
ertifyi	Supply Chain Traceability & Organic Fraud Prevention	\$0.00	\$45.91									
46 (	Mediation	\$0.00	\$45.91									
	Total Estimated Annual RIA + PRA Cost per Certifying Agent	\$15,0	99.61									
961 Excluded Handlers Affected	Applicability and Exemptions	\$2,000.00	\$2,543.00									
961 Ex Han Affe	Imports to the United States	\$0.00	\$354.70									
	Total Estimated Annual RIA + PRA Cost per Excluded Handler	\$4,89	97.70									
70												
,933 Certifie Operations Affected	Labeling of Nonretail Containers	\$0.00	\$30.52									
24,933 Certified Operations Affected	Supply Chain Traceability & Organic Fraud Prevention	\$0.00	\$25.43									
	Total Estimated Annual RIA + PRA Cost per Certified Operation	Total Estimated Annual RIA + PRA Cost \$55.95										

#### **ALTERNATIVES**

AMS considered three alternatives to the proposed rulemaking: (1) maintain the status quo and do not conduct rulemaking; (2) require transporters of organic products to be certified in addition to the amendments in the proposed rule; and (3) reduce the number of new requirements for certifying agents. AMS assessed present and future costs and feasibility of each alternative.

#### Alternative 1—No Change to Organic Regulations

The first alternative assessed present and future costs to industry in the absence of additional regulation to strengthen enforcement and improve oversight of the organic supply chain. AMS focused on market failures that stem from the absence of additional regulation, specifically the costs to and adverse effects on the organic supply chain caused by unintentional contamination, asymmetric information, and fraudulent activity. As established in the benefits section of this impact assessment, AMS estimated the net present value (NPV) of these costs at 3 and 7 percent over a 15-year period. AMS estimates the total cost of not implementing the proposed rule to be \$765 million – \$1.04 billion, or approximately \$84 – \$87 million annually. The assessment of the status quo alternative to the proposed rule is characterized by the following welfare loss model.

#### Welfare Loss from Organic Fraud

#### Background

Organic products are considered *credence goods*. <sup>102</sup> The current USDA system of third-party certification and labeling of organic products mitigates supply-side market failures that result from asymmetric information within the organic supply chain. Additionally, the current system serves to safeguard against conventional products that may be fraudulently marketed as organic by businesses seeking economic rents from the premiums normally associated with organic prices.

However, information asymmetry persists in segments of the organic supply chain; these information gaps create uncertainty about the true attributes of organically labeled product. <sup>103</sup> The gaps reduce consumer welfare and may erode demand for organic food products. Thus, the current regulations, which do not have adequate fraud prevention and supply chain traceability requirements, could generate a demand-side market failure. <sup>104</sup>

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<sup>&</sup>lt;sup>102</sup> Credence goods include those with qualities that cannot be readily observed by consumers after purchase, making it difficult to assess utility.

<sup>&</sup>lt;sup>103</sup> Darby, M. and E. Karni. 1973. Free competition and the optimal amount of fraud. Journal of Law and Economics 16: 67B88. <sup>104</sup> Giannakas, K. "Information Asymmetries and Consumption Decisions in Organic Food Product Markets." *Canadian Journal of Agricultural Economics*, 50(2002): 35-50.

Modelling Fraud in the Organic Market

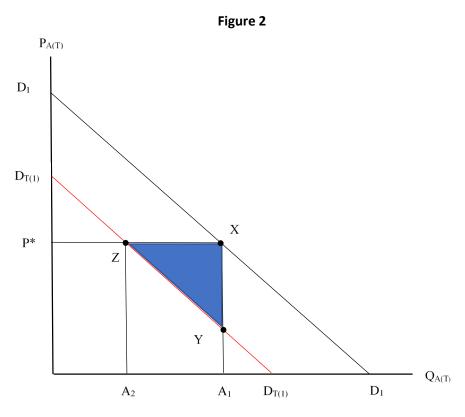
**D**<sub>1</sub>: Consumer's initial demand curve for organic product A based on consumer's subjective evaluation of the attributes of product A in period t.

**D**<sub>T</sub>: Consumer's true demand curve for product A based on perfect information, in this case the accurate organic status of product A.

**P\*:** It is assumed that product A has a constant market price.

**NOTE:** If **D**<sub>1</sub> and **D**<sub>T</sub> are not identical, this indicates a misallocation of the consumer's expenditures and the corresponding losses in welfare and changes in the consumer's surplus.

The presence of organic fraud represents a market with imperfect information because the consumer will overestimate the organic attribute of product A. In this case,  $\mathbf{D}_{T(1)}$  represents the demand curve that would occur if the consumer had perfect information about the fraudulent organic product.



#### Welfare Analysis

In the presence of organic fraud, the consumer will incur a loss in welfare for the additional  $A_1$ - $A_2$  units purchased. While the corresponding purchase amount is represented by  $A_2ZXA_1$ , the actual value of these units revealed by  $D_{T(1)}$  is only  $A_2ZYA_1$ . Therefore, the consumer incurs a welfare loss in period t equal to ZXY.

The expected economic loss (ECL) to a consumer from imperfect information about an organic product in any given time period is defined by the loss incurred from over-evaluating the product weighted by the probability of over-evaluation of the fraudulent organic product.

$$ECL = [Probability of Fraud] \left[\frac{1}{2}(ZX)(XY)\right]$$
 (1)

Aggregation of welfare losses from all consumers results in U.S. total welfare losses from organic fraud.

$$ECL = \sum_{i=0}^{j=m} \sum_{i=0}^{i=n} ECL_i$$
 (2)

In equation (2), n is the universe of U.S. consumers of organic goods and m represents all the different organic products purchased by them. The mathematical derivation of equation (1) can be expressed as

ECL = [Probability of Fraud] [P\*(A<sub>1</sub>-A<sub>2</sub>) - 
$$\int_{A_2}^{A_1} f^1(p) dp$$
] (3)

where demand curves in Figure 2 are expressed by  $D_1=f^0(p)$  and  $D_{T(1)}=f^1(p)$ .

Empirical Estimation of Benefits

Academic literature recognizes the difficulty of accurately measuring the prevalence of food fraud. The number of documented incidents may represent only a fraction of the true scale of the problem because the goal of those deliberately involved in fraud is to avoid detection. <sup>105</sup> In addition, businesses that detect fraud may choose to handle it privately in order to avoid negative publicity or legal exposure. In an early study, Ependitis (1998) posited that the prevalence of fraud amongst organic produce ranged between 15 percent and 40 percent in southern countries of the EU. <sup>106</sup> A subsequent report published in 2013 by the European Parliament ranked products most at risk of food fraud; organic goods ranked third out of the top 10 products most at risk. <sup>107</sup> In the same year (2013) as the European Parliament report, Everstine and Kircher reported that various forms of fraud affect nearly 10 percent of all commercially sold food products. <sup>108</sup> "Often, economic fraud has trickle-down effects that impact businesses and individuals that are not directly involved. As an illustration of the severity of the issue, a 2014 report from the Association of Certified Fraud Examiners estimated that a typical organization loses 5 percent of their [sic] annual revenues to all types of fraud, which results in a global fraud loss of nearly \$3.7 trillion." <sup>109</sup> A 2016 study from the OECD estimated that counterfeit and pirated goods accounted

<sup>&</sup>lt;sup>105</sup> Giannakas, K. "Information Asymmetries and Consumption Decisions in Organic Food Product Markets." *Canadian Journal of Agricultural Economics*, 50(2002): 35-50.

NCFPD, "EMA Frequently Asked Questions" <a href="http://www.ncfpd.umn.edu/">http://www.ncfpd.umn.edu/</a>

Spink, J. and Z.L. Fejes, "A review of the economic impact of counterfeiting and piracy methodologies and assessment of currently utilized estimates," *International Journal of Comparative and Applied Criminal Justice*, September 2012.

<sup>&</sup>lt;sup>106</sup> Ependitis, The. 1998. "Organic?" October 22B24, p. 29 (in Greek).

<sup>&</sup>lt;sup>107</sup> European Parliament, Public Health and Food Safety draft report "on the food crisis, fraud in the food chain and the control thereof," (2013/2091(INI)).

http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A7-2013-0434+0+DOC+PDF+V0//EN

<sup>&</sup>lt;sup>108</sup> Estimated by the Food Standards Agency of the U.K., as reported by K. Everstine and A. Kircher, "The Implications of Food Fraud," *Food Quality & Safety* magazine, June/July 2013.

<sup>&</sup>lt;sup>109</sup> Association of Certified Fraud Examiners. 2014. Report to the Nations on Occupational Fraud and Abuse, 2014, Global Fraud Study. <a href="https://www.acfe.com/rttn/docs/2014-report-to-nations.pdf">https://www.acfe.com/rttn/docs/2014-report-to-nations.pdf</a>

for up to 2.5 percent of world trade. AMS adopted a prudent approach and estimated the probability of fraud to be 2 percent for imported and domestically produced organic products. This rate represents the probability of fraud in equation 3.

To solve equation 3 and calculate the ECL incurred from purchases of fraudulent organic products, ZXY, estimated aggregate organic premiums paid by U.S. producers and consumers are weighted by the probability of fraud.<sup>111</sup>

#### Calculating the Cost of Fraud

AMS estimated the total value of organic premiums for organic products entering the U.S. supply chain using data from the FAS, NASS and ERS. The estimates show the total organic premium for domestic and imported organic products to be \$3.93 billion and \$1.47 billion, respectively (2017). Using a 2 percent rate of fraud occurrence (see Benefits discussion above), AMS calculated the value of fraudulent organic premiums at approximately \$108 million (\$79 million domestically and \$30 million from imports). This valuation served as a baseline for the estimation that fraud is halved to \$54 million as a result of the proposed rule; in the absence of the proposed rule, fraud would remain at an estimated \$108 million. This valuation shows a social welfare loss of between \$765 million and \$1.04 billion over 15-years, discounted at a rate of 3 and 7 percent. Therefore, absent rulemaking, the annualized social welfare loss is approximately \$84 million to \$87 million. 112

In summary, AMS estimates the forgone benefits associated with the status-quo to be a costly alternative to the proposed rule. AMS observes these social costs as a direct result of regulatory inaction. These costs would increase over time, as indicated by the annualized cost range of \$84 million to \$87 million. AMS believes the proposed rule would mitigate social welfare losses by approximately half through the use of practical, risk-based oversight and enforcement.

43

<sup>&</sup>lt;sup>110</sup> OECD/EUIPO (2016), Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact, OECD Publishing, Paris. https://doi.org/10.1787/9789264252653-en

Using organic premium rates reported by USDA-ERS; total premiums are estimated for 2016 organic U.S. farm sales (USDA-NASS) and for U.S. organic imports in 2017 (USDA-FAS). The aggregate estimations are then weighted by the 1 percent and 2 percent probability of risk, respectively.

<sup>&</sup>lt;sup>112</sup> Please see Exhibit A for a complete 15-year cost table.

#### Alternative 2—Imposing Certification Requirements on a Larger Number of Entities

The proposed amendments to §§ 205.100–101 would require the certification of middle-market operations that facilitate the trade of organic products, identified by NAICS category 425, Wholesale Electronic Markets and Agents and Brokers. AMS is proposing certification of these operations because their activities pose a high risk to organic integrity, yet the number of these operations in the supply chain is relatively small. Therefore, the benefits of requiring certification of these operations outweighs the potential costs.

AMS considered further expanding oversight by requiring certification of additional operations that are currently exempt or excluded. This alternative assesses the costs of certifying operations that transport organic products, identified by NAICS categories 48–49, *Transportation and Warehousing*. These operations are currently exempt from certification. Certification of transportation operations is assessed here because their activities pose a moderate risk to organic integrity (although much less risk than the activities of NAICS category 425).

AMS estimates that an additional 10,522 U.S. business would need to become certified as a result of this alternative proposal. This represents about 6 percent of the total businesses classified by NAICS categories 48–49. This benchmark is derived from the 2018 Organic Trade Association Survey of Industry that shows organic products represent 5.5 percent of all retail food sales. <sup>113</sup> In consideration of the OTA study and of supply chain linkages between warehouses and retailers, AMS determined use of a 6 percent benchmark feasible to establish a conservative, low-end estimate of affected businesses within NAICS code 48-49.

AMS anticipates that annual certification fees for transporters would cost approximately \$4,000 per business. AMS officials knowledgeable and experienced in certification confirm this estimate aligns with cost models used by certifying agents for businesses conducting similar activities. AMS also considered the additional labor costs associated with the paperwork and recordkeeping burden to be approximately \$2,500 per business per year. 114 As such, the total annual cost is estimated at \$6,500 per business.

Over a 15-year cost period and at 3 and 7 percent discounts, AMS estimates the total cost to businesses that transport organic products is between \$727 million and \$974 million. Annualized, the total cost is between \$80 million and \$82 million, or roughly \$7,600 per transportation business per year. Note that this is only the estimated cost to businesses that transport organic products; the total costs of this alternative would also include the costs of the proposed rule discussed above.

AMS further noted that this alternative would increase the total number of certified operations in the United States by nearly 39 percent, from approximately 27,000 to 37,500 certified operations. <sup>116</sup> In contrast, the proposed rule will add approximately 961 certified operations, or only 3.54 percent of the current level of certified operations (27,000). AMS expects increasing the number of certified operations by 39 percent would place significant strain through the entire regulatory system, potentially overwhelming the oversight capacity of certifying agents. AMS

<sup>&</sup>lt;sup>113</sup> 2018 Organic Industry Survey. At the time this assessment was written, the 2019 and 2020 surveys were not available.

<sup>114</sup> This cost is consistent with recordkeeping estimates for excluded handling operations established earlier in this analysis.

<sup>&</sup>lt;sup>115</sup> Please see Exhibit C for a complete 15-year cost table.

<sup>&</sup>lt;sup>116</sup> Organic Integrity Database: <a href="https://organic.ams.usda.gov/integrity/">https://organic.ams.usda.gov/integrity/</a>

expects the resulting lapses in oversight would impair certifying agents' ability to ensure compliance with USDA organic regulations.

In summary, AMS determined the second alternative to be costly and inefficient. Requiring additional certification of lower-risk segments of the organic supply chain creates greater cost with limited additional benefit. AMS believes a risk-based approach is the most practical, effective, and cost-sensitive means to address fraud within the organic supply chain. The proposed rule would accomplish this by requiring certification of businesses that pose the greatest risk to organic integrity in the supply chain. Additionally, strengthening organic enforcement through a broad treatment of supply chain threats would inadvertently dilute the capacity of regulatory bodies to administer the NOP in accordance with the Act.

Figure 3

NAICS Category	Number	Risk	]_
<b>425</b> , Wholesale Electronic Markets and Agents and Brokers	Low	High	Proposed Rule Alternative 2
<b>48–49</b> , Transportation and Warehousing	High	Low	

#### Alternative 3—Less Stringent Proposed Requirements for Certifying Agents

AMS also considered a less-stringent alternative to the proposed rule. This alternative was designed to assess whether a lower-cost alternative would be as effective as the proposed rule in increasing oversight of organic supply chains and reducing fraud. Relative to the proposed rule, this alternative would place fewer new requirements on certifying agents, lowering both the cost to certifying agents and the overall cost of the proposed rule. Proposed new requirements, and therefore costs, for other affected entities (e.g., new handlers, producers, and processers) would not change.

This alternative is similar to the proposed rule, except that it would: (1) not include the requirement for certifying agents to issue standardized certificates of organic operation generated in the USDA Organic INTEGRITY Database; and (2) reduce the annual continuing education hours that must be completed by organic inspectors and certification review personnel. See the proposed rule, chapter 5, Certificates of Organic Operation (§ 205.404), and chapter 8, Personnel Training and Qualifications (§ 205.501) for more information.

Chapter 5 of the proposed rule requires that certifying agents must issue all certificates of organic operation in a standardized format generated in the USDA's Organic INTEGRITY Database. This proposed amendment is intended to provide uniform, publicly available data about all certified operations, and facilitate the verification of operations' organic status. This proposed amendment would allow for more efficient and accurate verification of organic status during sales, transactions, and traceability exercises. Removing this requirement, as proposed in this alternative, would remove all cost associated with this requirement, equal to approximately \$7,104 per certifying agent in the first year following implementation of the proposed rule.

Chapter 8 of the proposed rule discusses standardizing education, experience, and training requirements for organic inspectors and certification review personnel. Part of this proposed amendment includes specifying an annual continuing education requirement of 20 hours. This alternative proposes reducing that requirement to 10 hours of annual continuing education. As discussed in the proposed rule and the associated Paperwork Reduction Act, NOP's experience auditing certifying agents indicates that inspectors and certification review personnel currently receive at least 10 hours of annual continuing education. By reducing the proposed rule's continuing education requirement to 10 hours, this alternative brings the requirement in alignment with current industry practice and removes the cost associated with additional continuing education. This would reduce this proposed amendment's estimated first-year cost to each certifying agent from approximately \$3,301 to \$1,470.

By eliminating one proposed requirement and modifying another, this alternative would reduce the estimated total first-year cost to each certifying agent from approximately \$15,100 to \$6,165. The total cost to other affected entities would remain the same. For this scenario, AMS estimates that the annualized costs range from \$7.10 million to \$7.24 million and the total costs would range from \$64.61 million to \$86.49 million. The upper bound of the estimated total cost of the rule would be reduced from \$88 million to \$87.

This alternative was used to assess a lower-cost alternative's effectiveness relative to the proposed rule. AMS determined this alternative would be less effective than the proposed rule and therefore has not chosen to implement it, based on the following discussion.

Standardized certificates of organic operation would increase the consistency of data reported to certifying agents and the NOP. A standardized format would allow certified operations to verify suppliers and products in less time, with greater accuracy and assurance. It would also facilitate the certification and annual inspection of an operation by a certifying agent by providing more consistent records of verification, and simplify trace-back audits conducted by a certifying agent. Traceability and verification of organic products is critical to fraud prevention and product integrity. The cost associated with this proposed amendment is also expected to diminish significantly after the first year, as certifiers would only have to maintain and update data in INTEGRITY after an initial upload. AMS therefore strongly believes that the requirement for standardized certificates of organic operation is necessary to support the overall objectives of the NOP and has chosen to include it in the proposed rule.

Organic inspectors and certification review personnel are the backbone of the organic system. Ensuring these personnel are held to a consistent standard is vital to providing effective and fair oversight of the organic supply chain. Specifying a 20-hour continuing education requirement in the proposed rule would strengthen the inspection and certification activities of certifying agents. This level of continuing education is consistent with similar food-industry professions, and represents only a moderate increase over the established organic industry practice of 10 hours. AMS also anticipates that part of this requirement may be satisfied free of charge via the NOP's online Organic Integrity Learning Center, which is designed to provide relevant training to organic industry professionals. Therefore, AMS determined that any cost savings associated with this alternative are outweighed by the benefits of the 20-hour requirement specified in the proposed rule.

AMS also chose not to pursue this alternative because it would weaken other critical amendments discussed in the proposed rule, which consists of many interrelated amendments. These amendments work together to achieve a common objective: more effective oversight and less fraud. The elimination of any provision affects the effectiveness of the others. For example, removing the provision for standardized certificates of organic operation would reduce the effectiveness of the proposed rule's improvements to traceability and on-site inspections. Similarly, the omission of a specific continuing education requirement for inspectors and certification review personnel would weaken almost every other provision in the proposed rule, including on-site inspections, certification of new handlers and grower groups, issuance of NOP Import Certificates, and supply chain trace-backs. Therefore, AMS chose to reject this alternative because it would significantly reduce the effectiveness of the proposed rule and would not provide the oversight and enforcement necessary to successfully administer the program.

#### REGULATORY FLEXIBILITY ACT

#### Introduction

When an agency is required by 5 U.S.C. 553(b), or any other law, to publish a rulemaking proposal in the Federal Register, the Regulatory Flexibility Act (RFA) requires the agency to "prepare and make available for public comment an initial regulatory flexibility analysis. Such analysis shall describe the impact of the proposed rule on small entities." Under section 605, and when there is a factual basis on which to do so, the RFA also allows for certification by the head of an agency, wherein the "agency shall publish such certification in the Federal Register at the time of the publication of general notice of proposed rulemaking," including "a statement providing the factual basis for such certification." Certification, in lieu of a regulatory flexibility analysis, indicates the proposed rulemaking is not expected to have a significant economic impact on a substantial number of entities.

Below, the Regulatory Flexibility Threshold Assessment discusses each of the four industry types affected by the proposed rule and the Administrator's certification statement. Sections 1 and 3 assess the anticipated cost to excluded handlers and certifying agents. Section 2 assesses the anticipated costs to certified farms and certified food manufacturers.

#### Background of Industry and Industry Threshold Assessment (Sections 1–3)

This proposed rule directly affects four (4) types of businesses in the organic supply chain. Table 20 identifies the number of affected businesses, as well as their respective NAICS codes and U.S. Small Business Administration (SBA) small business size standards. These types of businesses include excluded handlers, USDA-certified handlers and processers, USDA-certified farmers, and certifying agents. Though the proposed rule would expand the number of the handlers required to obtain certification, for the purposes of this analysis, AMS separated excluded handlers from USDA-certified handlers and processers.

Sm	TABLE 20 Small Businesses Affected by Proposed Rule and Size Standard												
Business	Affected Businesses	NAICS Code and Subsector Title <sup>M</sup>	SBA Size Standard <sup>P</sup>										
Excluded Handler	961*	425 - Wholesale Electronic Markets and Agents and Brokers	100										
Certified Handler & Processer	10,167**	311 - Food Manufacturing	500 - 1,250										
Certified Farmer	19,484**	111 - Crop Production / 112 - Animal Production and Aquaculture	\$0.75										
Certifying Agent	46***	54199 - All Other Professional, Scientific, and Technical Services	\$15.00										

<sup>\*</sup>Source: See Regulatory Impact Analysis "Applicability and Exemptions from Certification."

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<sup>\*\*</sup>Source: AMS INTEGRITY Database circa Q1 2019 represents certified operations based in the United States.

<sup>\*\*\*</sup>Source: AMS INTEGRITY Database circa Q1 2019 represents the 46 certifying agents headquartered in United States.

<sup>&</sup>lt;sup>M</sup> North American Industry Classification System

PSBA size standards are expressed either in number of employees or annual receipts in millions of dollars.

<sup>&</sup>lt;sup>117</sup> 5 U.S.C. 603(a)

<sup>&</sup>lt;sup>118</sup> 5 U.S.C. 605(b)

AMS estimated the economic impact for each type of business by assessing industry data and the affected business community. The sections below summarize assessments of each regulated business.

#### Section 1: Excluded Handlers—961 Businesses Affected

As explained in the proposed rule (see "Applicability and Exemptions from Certification") and earlier in this impact analysis, the current USDA organic regulations exempt or exclude certain handler operations from the requirement to obtain organic certification. The proposed rule would limit the types of businesses that may continue to claim exemption. This change will improve regulatory oversight of organic supply chains and provide greater information symmetry in the marketplace between buyers and sellers of organic product. 119

AMS identified the handler operations that would be directly affected by this proposed rule as closely aligned with those businesses identified by NAICS code 425, *Wholesale Electronic Markets and Agents and Brokers*. As such, AMS determined regulatory changes associated with the proposed rule would directly impact this business community.<sup>120</sup>

AMS estimates 961 excluded handlers will be affected by this proposed rule; <sup>121</sup> this figure represents approximately 2.25% of total businesses classified by NAICS code 425. Details of this calculation are available in the Regulatory Impact Analysis. The SBA categorizes businesses in NAICS category 425 with less than 100 employees as small businesses. <sup>122</sup> Based on AMS knowledge and experience, AMS expects that all excluded handlers affected by this proposed rule would meet these criteria and therefore be categorized as small businesses.

The results of AMS' threshold assessment are summarized in Table 21. This table depicts estimated cost relative to the average annual gross revenue for each business. The costs are associated with organic certification fees that excluded handler operations would be required to pay, as well as costs associated with reporting and recordkeeping described in the PRA analysis of this proposed rule.

#### **Section 2: USDA-Certified Operations**

For the purposes of this threshold assessment, AMS separated USDA-certified producers from USDA-certified handlers and processers because each conduct different activities as defined by NAICS industry categories. Although all USDA-certified operations will be subject to the same requirements identified in the proposed rule, this separation is necessary for the threshold assessment.

USDA-Certified Handlers and Processers—10,167 Businesses Affected

The proposed rule also includes several clarifications of the existing regulatory text that will strengthen oversight of USDA-certified organic handlers and processers. <sup>123</sup> Generally, the

<sup>&</sup>lt;sup>119</sup> As indicated in the Proposed Rule, operations that that would be affected include, but are not limited to, brokers, importers, traders, and exporters of organic products.

<sup>&</sup>lt;sup>120</sup> Source: North American Industry Classification System (NAICS). <a href="https://www.census.gov/eos/www/naics/">https://www.census.gov/eos/www/naics/</a>

<sup>&</sup>lt;sup>121</sup> Source: 2016 SUSB Annual Data Tables by Established Industry. <a href="https://www.census.gov/data/tables/2016/econ/susb/2016-susb-annual.html">https://www.census.gov/data/tables/2016/econ/susb/2016-susb-annual.html</a>

<sup>&</sup>lt;sup>122</sup> See 7 CFR 121.201 at <a href="https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=13%3A1.0.1.1.17#se13.1.121\_1201">https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=13%3A1.0.1.1.17#se13.1.121\_1201</a>

<sup>&</sup>lt;sup>123</sup> Clarifications appear in multiple locations of the proposed rule, including but not limited to the topics of NOP Import Certificates, nonretail container labeling, grower group operations, and paperwork submission.

changes of the proposed rule standardize the internal controls and risk-management system for preventing or detecting organic fraud. These changes would improve regulatory consistency of internal oversight and reinforce the integrity of organic supply chains.

The community of USDA-certified organic handlers and processers directly affected by this proposed rule is approximately 10,167 according to the INTEGRITY Database. <sup>124</sup> This business community operates similarly to businesses identified by NAICS code 311, *Food Manufacturing*, <sup>125</sup> for which the SBA small business size standard is 500 or fewer employees. <sup>126</sup> AMS considers all domestic, organic-certified handlers and processers of this community to be small businesses in accordance with this SBA size standard. All costs affecting this business population are associated with reporting and recordkeeping burden. AMS considers these costs to be minimal. See Table 21 for the estimated average cost per firm for this business community.

USDA-Certified Producers (Crops and Livestock)—19,484 Businesses Affected

The economic impact of the proposed rule also extends to USDA-certified producer operations. The impact is associated with regulatory clarifications that strengthen operational oversight and standardize internal controls and risk-management systems. These proposed changes would help improve regulatory consistency at the farm level and prevent and detect organic fraud.

Data from the INTEGRITY Database show that approximately 19,484 certified organic producer operations would be directly affected by this proposed rule.<sup>124</sup> NAICS parses agricultural operations into either code 111 (*Crop Production*) or code 112 (*Animal Production and Aquaculture*). The SBA small-business size standard for each code is defined as a business generating \$750,000 or less in annual receipts.<sup>127</sup> However, the USDA NASS identifies small (family) farms as those earning less than \$350,000 in annual gross cash farm income (GCFI). NASS size standards<sup>128</sup> include the following tiers, each measured in GCFI:

- Small family farms: less than \$350,000
- Midsize family farms: between \$350,000 and \$999,999
- Large-scale family farms: greater than \$1,000,000

Of the two size standards presented here, the SBA standard (\$750,000 or less) is broader and more reflective of the producer population impacted by the proposed rule. USDA's standard (\$350,000 or less) is lower and reflective of a smaller farmer population. AMS determined that using the SBA size standard would provide greater inclusiveness of the organic farmer population and provide a more comprehensive cost estimate of the affected business community.

AMS acknowledges that producers with lower annual income bear a higher cost-to-income ratio than producers of higher annual income levels, given the same fixed costs incurred by each operation type. Because the first-year cost to certified operations is estimated at \$55.95, AMS considers this a nominal cost regardless of farm revenues. See Table 21 for estimated costs of the

<sup>&</sup>lt;sup>124</sup> Source: AMS INTEGRITY Database. https://organic.ams.usda.gov/Integrity/Default.aspx (February 2019)

<sup>&</sup>lt;sup>125</sup> NAICS Code 311 shows approximately 22,386 firms as of March 2019.

<sup>&</sup>lt;sup>126</sup> See 13 CFR 121.201 at <a href="https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=13%3A1.0.1.1.17#se13.1.121">https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=13%3A1.0.1.1.17#se13.1.121</a> 1201; some subclassifications include a size standard up to 1,250 employees.

<sup>&</sup>lt;sup>127</sup> See 7 CFR 121.201 at https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=13%3A1.0.1.1.17#se13.1.121 1201

<sup>&</sup>lt;sup>128</sup> Source: 2012 Census of Agriculture Farm Typology: <a href="https://www.ers.usda.gov/topics/farm-economy/farm-structure-and-organization/farm-structure/">https://www.ers.usda.gov/topics/farm-economy/farm-structure-and-organization/farm-structure/</a>

proposed rule relative to average annual income per business for USDA-certified organic producers. These costs correspond to reporting and recordkeeping burdens.

#### Section 3: Certifying Agents—46 Businesses Affected

The final business community directly affected by the proposed rule includes USDA-accredited certifying agents. This business community is comprised of 78 accredited bodies, including private, foreign, and state organizations. 129 However, AMS assessed only certifying agents headquartered in the United States—a total of 46. Each certifying agent is responsible for making sure USDA-organic certified products meet all organic regulations.

The activities and processes of certifying agents align with businesses identified by NAICS code 54199, All Other Professional, Scientific, and Technical Services. The SBA size standard categorizes businesses generating \$15,000,000 or less (annually) as small. 130 Reviews of available annual revenue and certification fees reported by certifying agents show the average annual income per certifying agent at approximately \$2.38 million, or 15.8 percent of the small business revenue threshold established by the SBA. Therefore, all 46 certifying agents headquartered in the United States are considered small businesses.

As part of this assessment, AMS differentiated domestic and foreign costs that result from the proposed rule; this was necessary to accurately estimate the cost to domestic industry. AMS accomplished this by adjusting wage rates and labor hours (the primary cost variables) to reflect the country of certifying agents' headquarters, the relative wage rate, and certification activities. This decision acknowledges cost variances between different labor markets, which are integrated with one another through organic supply chains. <sup>131</sup> Differentiation also provides a more accurate cost for the creation and validation of NOP Import Certificates. This specific activity is most often conducted by certifying agents operating outside the United States. In short, domestic and foreign cost differentiation provides a more precise assessment of the relative level of economic impact on U.S.-based certifying agents, given the requirements of the proposed rule.

All estimated costs to certifying agents associated with this proposed rule correspond to reporting and recordkeeping burdens—See Table 21.

<sup>129</sup> Source: AMS INTEGRITY Database. <a href="https://organic.ams.usda.gov/Integrity/Default.aspx">https://organic.ams.usda.gov/Integrity/Default.aspx</a> (March 2019)
130 See 7 CFR 121.201 at: <a href="https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=13%3A1.0.1.1.17#se13.1.121">https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5;node=13%3A1.0.1.1.17#se13.1.121</a> 1201

<sup>&</sup>lt;sup>131</sup> Wages include hourly labor rates plus social benefits paid by the employer.

	Table 21 Regulatory Flexibility Threshold Assessment (RFTA)														
Common Name of Affected Industry	Estimated # of Affected Businesses	NAICS Code	Estimated RFTA Yr-1 Annual Cost per Business	Estimated Yr-1 Annual Gross Revenue per Business	Estimated Cost per Business (RFTA Yr-1 Cost ÷ Annual Revenue)										
Domestic Certifying Agent	46	54199	\$15,099.61	\$2,375,913.00	0.6355%**										
Excluded Handler	961	425	\$4,897.70	\$15,390,046.00	0.0318%										
Certified Processer	10,167*	311	\$55.95	\$31,483,150.00	0.0002%										
Certified Farmer	19,484*	111 & 112	\$55.95	\$541,341.00	0.0103%										

<sup>\*</sup> The estimated # of affected businesses (Certified Processers and Farmers) varies due to real-time data updates to INTEGIRTY by certifying agents. AMS relied on Q1-2019 data for the Regulatory Flexibility Threshold Assessment to establish these estimate levels. Elsewhere throughout the RIA and PRA, AMS used a benchmark of 0.59 (or 59%) to reflect the average historical proportion of domestic-based certified operations (both farmers and processers).

The column furthest to the right in Table 21 indicates the percentage of approximate cost-to-revenue for each affected industry in the first year of implementation of the proposed rule. AMS estimates the cost for each affected industry to be less than 1% of the annual revenues.

To determine cost per business for each industry above, AMS estimated the number of small businesses affected and their corresponding annual revenues. AMS was not able to obtain data from the same year for each industry. However, AMS did achieve same-year comparison of cost-to-revenue per business through data adjustments. The most current excluded handler data available to AMS were from 2016. For this industry, AMS adjusted 2012 gross annual sales per business to account for inflation between 2012 and 2016. For USDA-certified processers, AMS estimated per-business 2018 revenues by similarly adjusting for inflation between 2012 and 2018. The most current population data available to AMS for USDA-certified processers were for Q1 of 2019. For USDA-certified farmers, AMS relied upon the most recent Census of Agriculture (2017) to determine estimated revenue for the current population of organic-certified farmers listed in INTEGRITY for Q1 of 2019. The 2017 revenues are the most current farm-gate data on organic revenue available to AMS. AMS did not consider population changes significant and preferred to make an assessment on the most two current data points.

Regarding costs to domestic certifying agents, AMS anticipates a cost reduction into future years that is not reflected in Table 21. In particular, the cost reduction is due to a non-recurring, first-year cost estimated at \$7,104.04 in the RIA. This cost is associated with data entry to create standardized certificates of organic operation. This cost appears in Table 21 but occurs only in the first year following implementation of the proposed rule. Therefore, AMS estimates this cost will drop to zero following implementation of the proposed rule and maintain zero cost

<sup>\*\*</sup> Decreases from 0.63(in year-1) to 0.33% in years 2–15 due to a non-recurring cost only experienced in year-1

<sup>&</sup>lt;sup>132</sup>Source: Federal Reserve Bank of Minneapolis Consumer Price Index 1913https://www.minneapolisfed.org/community/financial-and-economic-education/cpi-calculator-information/consumer-price-index-and-inflation-rates-1913

thereafter. AMS estimates the cost-to-revenue for certifying agents would decrease from 0.64 percent (Year-1 showing in Table 21) to approximately 0.33 percent per year (years 2–15).

#### Costs for Reading and Comprehension of Rule

AMS estimated the cost associated with reading and comprehending the proposed rule. This estimated cost is based on the length of the proposed rule document, a reading rate of 250 words per minute, industry wage rates, and additional time for comprehension. AMS calculated the cost for both USDA-accredited certifying agents and certified organic operations.

The proposed rule is approximately 38,000 words, including preamble and regulatory text. In addition to time spent reading the proposed rule, AMS estimates certifying agents would spend an additional 2 hours to comprehend the proposed rule. AMS assigned a wage rate of \$45.91 per hour, including benefits, to certifying agents for reading the proposed rule. <sup>134</sup> Therefore, AMS estimates that to read and comprehend the proposed rule, each certifying agent would need to spend approximately 4.54 hours (4 hours and 32 minutes), or \$212.66. The estimated total cost for all 46 domestic certifying agents to read and comprehend the proposed rule is \$9,782.30.

AMS estimates that certified organic operations and excluded handlers would read half of the proposed rule at most (i.e., only the portions that apply to their scope of operation), or approximately 16,000 words, and spend an additional 30 minutes to comprehend the proposed rule. AMS assigned a wage rate of \$50.86, including benefits, to certified operations and excluded handlers for reading the proposed rule. <sup>135</sup> Therefore, AMS estimates that to read and comprehend the proposed rule, each operation would need to spend approximately 1.57 hours (1 hour and 34 minutes), or \$79.69.

These costs would not affect the conclusion of the Regulatory Flexibility Analysis because the costs are minimal. The total costs as a percentage of annual revenue remain under 1% for operations and under 2% for certifying agents.

#### **Conclusion and Certification Statement**

AMS does not expect the relative levels of costs for each category to cause significant financial harm to operations located in the United States. The additional costs depicted above represent only one element of the production functions within a larger agricultural supply chain. As such, the marginal costs associated with this proposed rule, though passed through to consumers, will be mitigated by the distribution of those costs along organic supply chains. Any change to the final cost of organic retail product as a result of this proposed rule is expected to be minimal and insignificant to the consumer.

As discussed in the PRA analysis, this proposed rule would impose additional paperwork requirements for certifying agents, certified operations, and excluded handlers. The amendments in the proposed rule work in conjunction to support supply chain traceability and robust oversight and fulfill the mandates included in the Agricultural Improvement Act of 2018.

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<sup>&</sup>lt;sup>133</sup> Words per minute:

https://www.researchgate.net/publication/332380784 How many words do we read per minute A review and metaanalysis of reading rate

<sup>&</sup>lt;sup>134</sup> U.S. Bureau of Labor Statistics National Compensation Survey, Occupational Employment and Wages, May 2018. Group 13-1041 Compliance Officers. https://www.bls.gov/oes/current/oes\_nat.htm

<sup>&</sup>lt;sup>135</sup> Group 11-9013 Farmers, Ranchers, and Other Agricultural Managers.

Accordingly, the Administrator of the AMS hereby certifies that this rule will not have a significant economic impact. Based on the data available, AMS estimates that this rule will affect a substantial number of small entities because most or all of the entities impacted are likely to be small businesses. AMS invites comment from members of the public who believe there will be a significant impact either on industry or on consumers.

### Exhibit A

Baseline / Estimated Fraud—Alternative # 1

Total cost to society of not implementing the proposed rule—estimated reduction of organic fraud from 2% to 1%.

Alternative # 1 to Propo	sed Rule /	<b>Estimate</b>	ed Fraud	Baseline	!												
Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
timated Organic Market Annual Growth Rate	-	6%	6%	6%	6%	6%	6%	5%	5%	5%	5%	5%	4%	4%	4%	4%	4%
Period	-	Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Y11	Y12	Y13	Y14	Y15
U.S. Gross Sales (millions)	\$49,360	\$52,322	\$55,461	\$58,789	\$62,316	\$66,055	\$70,018	\$73,519	\$77,195	\$81,055	\$85,107	\$89,363	\$92,937	\$96,655	\$100,521	\$104,542	\$108,724
1% Cost (Imported)	\$14,735,959	\$15,620,117	\$16,557,324	\$17,550,763	\$18,603,809	\$19,720,037	\$20,903,240	\$21,948,402	\$23,045,822	\$24,198,113	\$25,408,018	\$26,678,419	\$27,745,556	\$28,855,378	\$30,009,593	\$31,209,977	\$32,458,376
1% Cost (Domestic)	\$39,280,620	\$41,637,457	\$44,135,705	\$46,783,847	\$49,590,878	\$52,566,330	\$55,720,310	\$58,506,326	\$61,431,642	\$64,503,224	\$67,728,385	\$71,114,805	\$73,959,397	\$76,917,773	\$79,994,484	\$83,194,263	\$86,522,033
1% Total Cost	\$54,016,579	\$57,257,574	\$60,693,028	\$64,334,610	\$68,194,687	\$72,286,368	\$76,623,550	\$80,454,727	\$84,477,464	\$88,701,337	\$93,136,404	\$97,793,224	\$101,704,953	\$105,773,151	\$110,004,077	\$114,404,240	\$118,980,410
Discounted At:	3%	\$55,589,878	\$58,925,270	\$60,641,540	\$62,407,799	\$64,225,502	\$66,096,147	\$67,379,568	\$68,687,909	\$70,021,654	\$71,381,298	\$72,767,343	\$73,473,822	\$74,187,160	\$74,907,424	\$75,634,680	\$76,368,997
Discounted At.	7%	\$53,511,751	\$56,722,456	\$56,192,340	\$55,667,178	\$55,146,924	\$54,631,532	\$53,610,382	\$52,608,319	\$51,624,986	\$50,660,033	\$49,713,116	\$48,319,290	\$46,964,544	\$45,647,781	\$44,367,937	\$43,123,976
Fraud reduction at 3% discount rate																	
Step 1 Net Present Value (NPV) of the																	
stream of future benefits																	
\$1,037,106,112																	
Step 2 Annualized benefits from present																	
value - spreading benefits equally over the																	

\$86,874,833

Fraud reduction at 7% discount rate

Step 1 Net Present Value (NPV) of the stream of future benefits

years while taking into account the discount

\$765,000,79

Step 2 Annualized benefits from present value - spreading benefits equally over the years while taking into account the discount

\$83,992,975

CONCLUSION: The estimated total COST to society of not implementing this rule ranges from \$765 million and \$1,037 million for the 15-year period. CONCLUSION: The estimated annual COST to society of not implementing this rule ranges from \$84 million and \$87 million for the 15-year period.

## **Exhibit B**Proposed Rule Amendments

### Affected Business Type: Certifying Agent Number of Affected Domestic Businesses: 46

Proposed Amendme	Proposed Amendment: Imports to the United States (§ 205.273)																
Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Inflation Rate			-	2%	2%	2%	2%	3%	3%	3%	3%	3%	4%	4%	4%	4%	4%
Period	-	Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Y11	Y12	Y13	Y14	Y15
Total Annual Cost to Certifying Agents	-	-	\$123,085	\$125,546	\$128,057	\$130,618	\$133,231	\$137,228	\$141,344	\$145,585	\$149,952	\$154,451	\$160,629	\$167,054	\$173,736	\$180,686	\$187,913
Estimated Yearly Cost per Certifying Agent	-	-	\$2,676	\$2,729	\$2,784	\$2,840	\$2,896	\$2,983	\$3,073	\$3,165	\$3,260	\$3,358	\$3,492	\$3,632	\$3,777	\$3,928	\$4,085
•	Discounted At:	3%	\$119,500	\$118,339	\$117,190	\$116,053	\$114,926	\$114,926	\$114,926	\$114,926	\$114,926	\$114,926	\$116,042	\$117,168	\$118,306	\$119,454	\$120,614
	Discounted At.	7%	\$115,032	\$109,657	\$104,533	\$99,648	\$94,992	\$91,441	\$88,022	\$84,732	\$81,564	\$78,515	\$76,314	\$74,174	\$72,094	\$70,073	\$68,108
COSTS at 3% discount rate			•			•	-			-		-	•				

COSTS at 3% discount rate	
Step 1 Net Present Value (NPV) of the	Cost Per Affected
stream of future costs	Business
\$1,752,221.84	\$38,091.78
Step 2 Annualized costs from present value - spreading costs equally over the years while	
taking into account the discount rate	
\$146,777.63	\$3,190.82
COSTS at 7% discount rate	
Step 1 Net Present Value (NPV) of the	
stream of future costs	
\$1,308,898.08	\$28,454.31
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$143,709.97	\$3,124.13

# of Affected Businesses

CONCLUSION: The estimated total COST of this amendment to certifying agents, discounted at 3 and 7 percent, will range between \$1.3 million and \$1.8 million for the 15-year period. CONCLUSION: The estimated total annual COST of this amendment to certifying agents, discounted at 3 and 7 percent, will range between \$143,710 and \$146,778 for the 15-year period.

#### Proposed Amendment: Certificates of Organic Operation (§ 205.404) and Continuation of Certification (§ 205.406)

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Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Inflation Rate			-	2%	2%	2%	2%	3%	3%	3%	3%	3%	4%	4%	4%	4%	4%
Period		Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Y11	Y12	Y13	Y14	Y15
Total Annual Cost to Certifying Agents	-	-	\$326,786	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Estimated yearly cost per Certifying Agent	,	-	\$7,104	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
	Discounted At:	3%	\$317,268	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
	Discounted At:	7%	\$305,407	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0

COSTS at 3% discount rate	
Step 1 Net Present Value (NPV) of the	Cost Per Affected
stream of future costs	Business
\$317,267.80	\$6,897.13
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$26,576.44	\$577.75
COSTS at 7% discount rate	
Step 1 Net Present Value (NPV) of the	
stream of future costs	
\$305,407.32	\$6,639.29
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$33,532.08	\$728.96

# of Affected
Businesses

CONCLUSION: The estimated total COST of this amendment to certifying agents, discounted at 3 and 7 percent, will range between \$305,407 and \$317,268 for the 15-year period.
CONCLUSION: The estimated total annual COST of this amendment to certifying agents, discounted at 3 and 7 percent, will range between \$26,576 and \$33,532 for the 15-year period.

<b>Proposed Amendment:</b>	Proposed Amendment: Personnel Training and Qualifications (§ 205.501)																
Year 2017 2018 2019 2020 2021 2022 2023 2024 2025 2026 2027 2028 2029 2030 2031 2032 2033														2033			
Inflation Rate			-	2%	2%	2%	2%	3%	3%	3%	3%	3%	4%	4%	4%	4%	4%
Period	-	Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Y11	Y12	Y13	Y14	Y15
Total Annual Costs to Certifying Agents	-	-	\$151,837	\$154,874	\$157,972	\$161,131	\$164,354	\$169,284	\$174,363	\$179,594	\$184,982	\$190,531	\$198,152	\$206,078	\$214,321	\$222,894	\$231,810
Estimated yearly cost per Certifying Agent	-	-	\$3,301	\$3,367	\$3,434	\$3,503	\$3,573	\$3,680	\$3,790	\$3,904	\$4,021	\$4,142	\$4,308	\$4,480	\$4,659	\$4,846	\$5,039
•	Discounted At:	3%	\$147,415	\$145,984	\$144,566	\$143,163	\$141,773	\$141,773	\$141,773	\$141,773	\$141,773	\$141,773	\$143,149	\$144,539	\$145,942	\$147,359	\$148,790
	Discounted At:	7%	\$141,904	\$135,273	\$128,952	\$122,926	\$117,182	\$112,801	\$108,584	\$104,525	\$100,618	\$96,856	\$94,141	\$91,501	\$88,936	\$86,442	\$84,019

COSTS at 3% discount rate	
Step 1 Net Present Value (NPV) of the	Cost Per Affected
stream of future costs	Business
\$2,161,546.42	\$46,990.14
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$181,065.35	\$3,936.20
COSTS at 7% discount rate	
Step 1 Net Present Value (NPV) of the	
stream of future costs	
\$1,614,660.82	\$35,101.32
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$177,281.08	\$3,853.94

# of Affected Businesses 46

CONCLUSION: The estimated total COST of this amendment to certifying agents, discounted at 3 and 7 percent, will range between \$1.6 million and \$2.2 million for the 15-year period. CONCLUSION: The estimated total annual COST of this amendment to certifying agents, discounted at 3 and 7 percent, will range between \$177,281 and \$181,065 for the 15-year period.

#### Proposed Amendment: On-Site Inspections (§ 205.403)

r roposca Amenament.	On Site in	spection	3 (3 2031	1001																				
Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033							
Inflation Rate			-	2%	2%	2%	2%	3%	3%	3%	3%	3%	4%	4%	4%	4%	4%							
Period	-	Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Y11	Y12	Y13	Y14	Y15							
Total Annual Cost to Certifying Agents	-	-	\$88,650	\$90,423	\$92,232	\$94,076	\$95,958	\$98,837	\$101,802	\$104,856	\$108,001	\$111,241	\$115,691	\$120,319	\$125,131	\$130,137	\$135,342							
Estimated yearly cost per Certifying Agent	-	-	\$1,927	\$1,966	\$2,005	\$2,045	\$2,086	\$2,149	\$2,213	\$2,279	\$2,348	\$2,418	\$2,515	\$2,616	\$2,720	\$2,829	\$2,942							
	Discounted At:	3%	\$86,068	\$85,233	\$84,405	\$83,586	\$82,774	\$82,774	\$82,774	\$82,774	\$82,774	\$82,774	\$83,578	\$84,389	\$85,208	\$86,036	\$86,871							
	Discounted At:	7%	\$82,851	\$78,979	\$75,289	\$71,770	\$68,417	\$65,859	\$63,397	\$61,027	\$58,746	\$56,549	\$54,964	\$53,423	\$51,925	\$50,469	\$49,054							

COSTS at 3% discount rate	
Step 1 Net Present Value (NPV) of the	Cost Per Affected
stream of future costs	Business
\$1,262,017.69	\$27,435.17
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$105,714.91	\$2,298.15
COSTS at 7% discount rate	
Step 1 Net Present Value (NPV) of the	
stream of future costs	
\$942,718.83	\$20,493.89
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$103,505.46	\$2,250.12



CONCLUSION: The estimated total COST of this amendment to all certifying agents, discounted at 3 and 7 percent, will range between \$942,719 and \$1,262,018 for the 15-year period. CONCLUSION: The estimated total annual COST of this amendment to certifying agents, discounted at 3 and 7 percent, will range between \$103,505 and \$105,715 for the 15-year period.

<b>Proposed Amendment:</b>	Supply Cha	ain Trace	<mark>ability a</mark> ı	nd Organ	ic Fraud Pr	evention	(§§ 205	. <mark>103, 205</mark>	. <mark>201, 20</mark> !	5.501, an	d 205.50	4)					
Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Inflation Rate			-	2%	2%	2%	2%	3%	3%	3%	3%	3%	4%	4%	4%	4%	4%
Period	-	Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Y11	Y12	Y13	Y14	Y15
Total Annual Cost to Certifying Agents	-	-	\$2,112	\$2,154	\$2,197	\$2,241	\$2,286	\$2,355	\$2,425	\$2,498	\$2,573	\$2,650	\$2,756	\$2,866	\$2,981	\$3,100	\$3,224
Estimated yearly cost per Certifying Agent	-	-	\$46	\$47	\$48	\$49	\$50	\$51	\$53	\$54	\$56	\$58	\$60	\$62	\$65	\$67	\$70
	Discounted At:	3%	\$2,050	\$2,030	\$2,011	\$1,991	\$1,972	\$1,972	\$1,972	\$1,972	\$1,972	\$1,972	\$1,991	\$2,010	\$2,030	\$2,050	\$2,069
	Discounted At:	7%	\$1,974	\$1,881	\$1,794	\$1,710	\$1,630	\$1,569	\$1,510	\$1,454	\$1,399	\$1,347	\$1,309	\$1,273	\$1,237	\$1,202	\$1,169

COSTS at 3% discount rate	
Step 1 Net Present Value (NPV) of the	Cost Per Affected
stream of future costs	Business
\$30,064.28	\$653.57
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$2,518.38	\$54.75
COSTS at 7% discount rate	
Step 1 Net Present Value (NPV) of the	
stream of future costs	
\$22,457.82	\$488.21
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$2,465.75	\$53.60

# of Affected
Businesses
46

CONCLUSION: The estimated total COST of this amendment to certifying agents, discounted at 3 and 7 percent, will range between \$22,458 and \$30,064 for the 15-year period.

CONCLUSION: The estimated total annual COST of this amendment to certifying agents, discounted at 3 and 7 percent, will range between \$2,466 and \$2,518 for the 15-year period.

#### **Proposed Amendment: Mediation (§ 205.663)**

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Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Inflation Rate			-	2%	2%	2%	2%	3%	3%	3%	3%	3%	4%	4%	4%	4%	4%
Period	-	Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Y11	Y12	Y13	Y14	Y15
Total Annual Cost to Certifying Agents	-	-	\$2,112	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Estimated yearly cost per Certifying Agent	-	\$0	\$46	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
	Discounted At:	3%	\$2,050	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
	Discounted At:	7%	\$1,974	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0

COSTS at 3% discount rate	
Step 1 Net Present Value (NPV) of the	Cost Per Affected
stream of future costs	Business
\$2,050.35	\$44.57
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$171.75	\$3.73
	·
COSTS at 7% discount rate	
Step 1 Net Present Value (NPV) of the	
stream of future costs	
\$1,973.70	\$42.91
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$216.70	\$4.71



CONCLUSION: The estimated total COST of this amendment to certifying agents, discounted at 3 and 7 percent, will range between \$1,974 and \$2,050 for the 15-year period. CONCLUSION: The estimated total annual COST of this amendment to certifying agents, discounted at 3 and 7 percent, will range between \$172 and \$217 for the 15-year period.

Affected Business Type: Excluded Handler Number of Affected Domestic Businesses: 961

#### Proposed Amendment: Applicability and Exemptions from Certification (§§ 205.100–101)

Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Inflation Rate			-	2%	2%	2%	2%	3%	3%	3%	3%	3%	4%	4%	4%	4%	4%
Period	-	Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Y11	Y12	Y13	Y14	Y15
Total Annual Cost to Excluded Handlers	-	-	\$4,365,823	\$4,453,139	\$4,542,202	\$4,633,046	\$4,725,707	\$4,867,478	\$5,013,503	\$5,163,908	\$5,318,825	\$5,478,390	\$5,697,525	\$5,925,426	\$6,162,444	\$6,408,941	\$6,665,299
Estimated yearly cost per Excluder Handler	-	-	\$4,543	\$4,634	\$4,727	\$4,821	\$4,917	\$5,065	\$5,217	\$5,373	\$5,535	\$5,701	\$5,929	\$6,166	\$6,413	\$6,669	\$6,936
	Discounted At:	3%	\$4,238,663	\$4,197,511	\$4,156,759	\$4,116,402	\$4,076,437	\$4,076,437	\$4,076,437	\$4,076,437	\$4,076,437	\$4,076,437	\$4,116,014	\$4,155,975	\$4,196,324	\$4,237,065	\$4,278,202
	Discounted At:	7%	\$4,080,208	\$3,889,544	\$3,707,790	\$3,534,529	\$3,369,364	\$3,243,406	\$3,122,158	\$3,005,441	\$2,893,088	\$2,784,936	\$2,706,853	\$2,630,960	\$2,557,195	\$2,485,498	\$2,415,811

COSTS at 3% discount rate	
Step 1 Net Present Value (NPV) of the	Cost Per Affected
stream of future costs	Business
\$62,151,533.29	\$64,673.81
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$5,206,221.41	\$5,417.50
COSTS at 7% discount rate	
Step 1 Net Present Value (NPV) of the	
stream of future costs	
\$46,426,782.62	\$48,310.91
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$5,097,411.17	\$5,304.28

# of Affected Businesses

CONCLUSION: The estimated total COST of this amendment to excluded handlers, discounted at 3 and 7 percent, will range between \$46.4 million and \$62.2 million for the 15-year period. CONCLUSION: The estimated total annual COST of this amendment to excluded handlers, discounted at 3 and 7 percent, will range between \$5.1 million and \$5.2 million for the 15-year period.

#### Proposed Amendment: Imports to the United States - Importers (§ 205.273)

T Toposca Amename	it. iiiipoi t	S to the	Officea	Juccs	importers	13 203.	2131										
Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Inflation Rate			-	2%	296	296	2%	3%	3%	3%	3%	3%	4%	496	496	496	496
Period	-	YO	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Y11	Y12	Y13	Y14	Y15
Total Annual Cost to Importers	-	-	\$16,316	\$16,643	\$16,975	\$17,315	\$17,661	\$18,191	\$18,737	\$19,299	\$19,878	\$20,474	\$21,293	\$22,145	\$23,031	\$23,952	\$24,910
Estimated Yearly Cost per Importer	-	-	\$355	\$362	\$369	\$3.76	\$384	\$395	\$407	\$420	\$432	\$445	\$463	\$481	\$501	\$521	\$542
	Discounted At:	3%	\$15,841	\$15,687	\$15,535	\$15,384	\$15,235	\$15,235	\$15,235	\$15,235	\$15,235	\$15,235	\$15,383	\$15,532	\$15,683	\$15,835	\$15,989
	Discounted At.	7%	\$15,249	\$14,536	\$13,857	\$13,209	\$12,592	\$12,121	\$11,668	\$11,232	\$10,812	\$10,408	\$10,116	\$9,833	\$9,557	\$9,289	\$9,029

COSTS at 3% discount rate	
Step 1 Net Present Value (NPV) of the	Cost Per Affected
stream of future costs	Business
\$232,276.22	\$241.70
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$19,456.98	\$20.25
COSTS at 7% discount rate	
stream of future costs	
\$173,508.79	\$180.55
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$19,050.33	\$19.82

# of Affected Businesses

CONCLUSION: The estimated total COST of this amendment to certifying agents, discounted at 3 and 7 percent, will range between \$173,509 and \$232,276 for the 15-year period. CONCLUSION: The estimated total annual COST of this amendment to certifying agents, discounted at 3 and 7 percent, will range between \$19,050 and \$19,457 for the 15-year period

Affected Business Type: **Certified Operation** Number of Affected Domestic Businesses: 24,933

<b>Proposed Amendment:</b>	Labeling o	f Nonret	ail Conta	iners (§ 2	205.307)												
Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Inflation Rate			-	2%	2%	2%	2%	3%	3%	3%	3%	3%	4%	4%	4%	4%	4%
Period	-	Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Y11	Y12	Y13	Y14	Y15
Total Annual Cost to Certified Operations	-	-	\$760,871	\$776,089	\$791,611	\$807,443	\$823,592	\$848,299	\$873,748	\$899,961	\$926,960	\$954,768	\$992,959	\$1,032,678	\$1,073,985	\$1,116,944	\$1,161,622
Estimated yearly cost per Certified Operation	-	-	\$31	\$31	\$32	\$32	\$33	\$34	\$35	\$36	\$37	\$38	\$40	\$41	\$43	\$45	\$47
	Discounted At:	3%	\$738,710	\$731,538	\$724,436	\$717,402	\$710,437	\$710,437	\$710,437	\$710,437	\$710,437	\$710,437	\$717,335	\$724,299	\$731,331	\$738,432	\$745,601
	Discounted At:	7%	\$711,095	\$677,866	\$646,190	\$615,994	\$587,209	\$565,258	\$544,127	\$523,785	\$504,205	\$485,356	\$471,748	\$458,521	\$445,665	\$433,170	\$421,025
COSTS at 3% discount rate																	

COSTS at 3% discount rate	
Step 1 Net Present Value (NPV) of the	Cost Per Affected
stream of future costs	Business
\$10,831,708.94	\$434.43
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$907,335.22	\$36.39
COSTS at 7% discount rate	
Step 1 Net Present Value (NPV) of the	
stream of future costs	
\$8,091,214.65	\$324.52
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$888,371.88	\$35.63

# of Affected 24933

CONCLUSION: The total estimated COST of this amendment to certified operations, discounted at 3 and 7 percent, will range between \$8.1 million and \$10.8 million for the 15-year period. CONCLUSION: The total estimated annual COST of this amendment to certified operations, discounted at 3 and 7 percent, will range between \$888,372 and \$907,335 for the 15-year period.

Proposed Amendment: Supply Chain Traceability and Organic Fraud Prevention (§§ 205.103, 205.201, 205.501, and 205.504)																	
Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Inflation Rate			-	2%	2%	2%	2%	3%	3%	3%	3%	3%	4%	4%	4%	4%	4%
Period	-	Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Y11	Y12	Y13	Y14	Y15
Total Annual Cost to Certified Operations	-	-	\$634,026	\$646,706	\$659,640	\$672,833	\$686,290	\$706,878	\$728,085	\$749,927	\$772,425	\$795,598	\$827,422	\$860,519	\$894,939	\$930,737	\$967,966
Estimated yearly cost per Certified Operation		-	\$25	\$26	\$26	\$27	\$28	\$28	\$29	\$30	\$31	\$32	\$33	\$35	\$36	\$37	\$39
	Discounted At:	3%	\$615,559	\$609,583	\$603,664	\$597,803	\$592,000	\$592,000	\$592,000	\$592,000	\$592,000	\$592,000	\$597,747	\$603,550	\$609,410	\$615,327	\$621,301
	Discounted At.	7%	\$592,547	\$564,858	\$538,463	\$513,301	\$489,315	\$471,023	\$453,415	\$436,465	\$420,148	\$404,442	\$393,102	\$382,081	\$371,368	\$360,956	\$350,836

COSTS at 3% discount rate	
Step 1 Net Present Value (NPV) of the	Cost Per Affected
stream of future costs	Business
\$9,025,941.42	\$362.01
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$756,072.25	\$30.32
COSTS at 7% discount rate	
Step 1 Net Present Value (NPV) of the	
stream of future costs	
\$6,742,318.30	\$270.42
Step 2 Annualized costs from present value -	
spreading costs equally over the years while	
taking into account the discount rate	
\$740,270.31	\$29.69

# of Affected 24933

CONCLUSION: The estimated total COST of this amendment to certified operations, discounted at 3 and 7 percent, will range between \$6.7 million and \$9 million for the 15-year period. CONCLUSION: The estimated total annual COST of this amendment to certified operations, discounted at 3 and 7 percent, will range between \$740,270 and \$756,072 for the 15-year period.

## **Exhibit C**Alternative # 2

Additional estimated cost of the proposed rule if additional supply chain businesses are required to obtain organic certification—Transportation and Warehousing.

Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Inflation Rate			-	2%	2%	2%	2%	3%	3%	3%	3%	3%	4%	4%	4%	4%	4%
Period	-	Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Y11	Y12	Y13	Y14	Y15
Total Annual Costs to TW	-	-	\$68,393,000	\$69,760,860	\$71,156,077	\$72,579,199	\$74,030,783	\$76,251,706	\$78,539,257	\$80,895,435	\$83,322,298	\$85,821,967	\$89,254,846	\$92,825,040	\$96,538,041	\$100,399,563	\$104,415,
Estimated yearly cost per TW	-	-	\$6,500	\$6,630	\$6,763	\$6,898	\$7,036	\$7,247	\$7,464	\$7,688	\$7,919	\$8,156	\$8,483	\$8,822	\$9,175	\$9,542	\$9,924
	Discounted At:	3%	\$66,400,971	\$65,756,301	\$65,117,891	\$64,485,678	\$63,859,603	\$63,859,603	\$63,859,603	\$63,859,603	\$63,859,603	\$63,859,603	\$64,479,600	\$65,105,615	\$65,737,709	\$66,375,939	\$67,020,3
	Discounted Att	7%	\$63,918,692	\$60,931,837	\$58,084,555	\$55,370,323	\$52,782,925	\$50,809,731	\$48,910,302	\$47,081,880	\$45,321,809	\$43,627,536	\$42,404,334	\$41,215,428	\$40,059,855	\$38,936,681	\$37,844,9
STS at 3% discount rate																	
p 1 Net Present Value (NPV) of the	Cost Per Affected				# of Affected												
eam of future costs	Business				Businesses												
\$973,637,688.97	\$92,533.52				10522												
p 2 Annualized costs from present value -				•													
eading costs equally over the years while																	
ing into account the discount rate																	
\$81,558,299.81	\$7,751.22																
STS at 7% discount rate																	
p 1 Net Present Value (NPV) of the																	
eam of future costs																	
\$727,300,887.76	\$69,121.92																
ep 2 Annualized costs from present value -																	
eading costs equally over the years while																	
ring into account the discount rate																	
\$79,853,728.02	\$7,589.22																

## **Exhibit D**Alternative # 3

Lower cost than the proposed rule due to less stringent requirements for certifying agents—no requirement for standardized certificates of organic operation and reduced requirements for annual inspector training.

Alternative # 3 to Propo	osed Rule: I	No stand	dardized	certificat	es and redu	iced ann	ual inspe	ctor trai	ning								
Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	2032	2033
Inflation Rate			-	2%	2%	2%	2%	3%	3%	3%	3%	3%	4%	4%	4%	4%	4%
Period	-	Y0	Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Y11	Y12	Y13	Y14	Y15
Total Annual Costs to Certifying Agents	-	-	\$84,212	\$85,896	\$87,614	\$89,367	\$91,154	\$93,889	\$96,705	\$99,606	\$102,595	\$105,672	\$109,899	\$114,295	\$118,867	\$123,622	\$128,567
Estimated yearly cost per Certifying Agent	-	-	\$1,831	\$1,867	\$1,905	\$1,943	\$1,982	\$2,041	\$2,102	\$2,165	\$2,230	\$2,297	\$2,389	\$2,485	\$2,584	\$2,687	\$2,795
	Discounted At:	3%	\$81,759	\$80,966	\$80,180	\$79,401	\$78,630	\$78,630	\$78,630	\$78,630	\$78,630	\$78,630	\$79,394	\$80,164	\$80,943	\$81,729	\$82,522
	Discounted At.	7%	\$78,703	\$75,025	\$71,519	\$68,177	\$64,992	\$62,562	\$60,223	\$57,972	\$55,805	\$53,719	\$52,212	\$50,748	\$49,326	\$47,943	\$46,598
COSTS at 3% discount rate						-											
Step 1 Net Present Value (NPV) of the	Cost Per Affected				# of Affected												
stream of future costs	Business				Businesses												
\$1,198,838.65	\$26,061.71				46												
						-'											
Step 2 Annualized costs from present value -																	
spreading costs equally over the years while																	
taking into account the discount rate																	
\$100,422.61	\$2,183.10																
•																	

CONCLUSION: The estimated total cost of this alternative, discounted at 3 and 7 percent, will be between \$895,525 and \$1,198,839 less than the proposed rule for the 15-year period.

CONCLUSION: The estimated total annual cost of this alternative to certifying agents, discounted at 3 and 7 percent, will be between \$98,324 and \$100,423 less than the proposed rule for the 15-year period.

COSTS at 7% discount rate
Step 1 Net Present Value (NPV) of the stream of future costs

Step 2 Annualized costs from present value spreading costs equally over the years while taking into account the discount rate
\$98,323.78

\$19,467.92

# **Exhibit E**Paperwork Reduction Act

#### **Paperwork Reduction Act**

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (PRA), AMS is requesting OMB approval for a new information collection totaling 275,417 hours for the reporting and recordkeeping requirements contained in this proposed rule. OMB previously approved information collection requirements associated with the NOP and assigned OMB control number 0581-0191. AMS intends to merge this new information collection, upon OMB approval, into the approved 0581-0191 collection. Below, AMS has described and estimated the annual burden, i.e., the amount of time and cost of labor, for entities to prepare and maintain information to participate in this proposed voluntary labeling program. The Organic Foods Production Act of 1990 (OFPA), as amended, provides authority for this action. <sup>136</sup>

Title: National Organic Program.

OMB Control Number: 0581-NEW.

Expiration Date of Approval: 3 years from OMB date of approval.

Type of Request: New collection.

#### Abstract

Information collection and recordkeeping are necessary to implement reporting and recordkeeping necessitated by amendments to §§ 205.2, 205.100, 205.101, 205.103, 205.201, 205.273, 205.300–205.302, 205.307, 205.310, 205.400, 205.403–205.404, 205.406, 205.500–501, 205.504, 205.511, 205.660–205.663, 205.665, 205.680, and 205.681 of the USDA organic regulations to protect organic product integrity and build consumer and industry trust in the USDA organic label. The proposed rule would strengthen organic control systems, improve organic import oversight, clarify organic certification standards, and enhance farm to market traceability, using a risk-based approach to oversight to assure consumers that organically produced products meet a consistent standard.

This proposed rule would amend several sections of the USDA organic regulations, 7 CFR Part 205, to strengthen the NOP's ability to oversee and enforce the production, handling, marketing, and sale of organic agricultural products as established by the OFPA. This proposed rule would improve organic integrity throughout the organic supply chain and benefit stakeholders at all levels of the organic industry. The proposed amendments would close gaps in the current regulations to build consistent certification practices, deter organic fraud, and improve transparency and product traceability. The NOP identified the need for many of the proposed amendments as part of its direct experience in administering this program, particularly via complaint investigation and audits of certifying agents. Other proposed amendments are based on recent amendments to the OFPA included in the Agriculture Improvement Act of 2018;<sup>137</sup> the recommendations of a 2017 Office of Inspector General audit;<sup>138</sup> the

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<sup>&</sup>lt;sup>136</sup> The Organic Foods Production Act of 1990, 7 U.S.C. 6501–6524, is the statute from which the Agricultural Marketing Service derives authority to administer the NOP, and authority to amend the regulations as described in this proposed rule. This document is available at: <a href="https://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter94&edition=prelim">https://uscode.house.gov/view.xhtml?path=/prelim@title7/chapter94&edition=prelim</a>

<sup>137</sup> The Agriculture Improvement Act of 2018 (Public Law No: 115-334), commonly known as the "2018 farm bill" is available at

<sup>&</sup>lt;sup>137</sup> The Agriculture Improvement Act of 2018 (Public Law No: 115-334), commonly known as the "2018 farm bill," is available at <a href="https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf">https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf</a>. Organic certification is discussed in Title X, Section 10104.

<sup>&</sup>lt;sup>138</sup> The National Organic Program International Trade Arrangements and Agreements Audit Report 01601-0001-21, September 2017: <a href="https://www.usda.gov/oig/webdocs/01601-0001-21.pdf">https://www.usda.gov/oig/webdocs/01601-0001-21.pdf</a>

recommendations of the federal advisory committee to the NOP, the National Organic Standards Board (NOSB); and industry stakeholder feedback.

This proposed rule will strengthen enforcement with amendments to the USDA organic regulations and will modify the reporting and recordkeeping burdens as summarized below.

- 1. Reduces the types of uncertified handling operations in the organic supply chain that operate without USDA oversight. <sup>139</sup> The proposed amendments would require certification of operations that facilitate the sale or trade of organic products, including but not limited to, brokers, importers, and traders. These handlers would be required to obtain organic certification by developing an organic system plan (OSP) to describe the practices and procedures used in their operations. Certifying agents customize the format of the OSP to cover standards applicable to the operations seeking certification. Because traders and brokers do not farm or manufacture organic products, the OSPs for traders and brokers would address fewer sections of the current rule than OSPs for operations that farm or manufacture organic products. Therefore, reporting impacts for traders and brokers are estimated at 40 hours for each uncertified handling operation to prepare its 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 (§§ 205.2, 205.100, 205. 101, and 205.103).
- 2. Requires all currently certified organic operations and new applicants to describe their procedures for monitoring, verifying, and demonstrating the organic status of their suppliers and the products received to prevent organic fraud. This information would be part of the OSP. AMS estimates that each currently certified operation and applicant seeking certification would need 30 minutes to describe the supply chain verification procedures and monitoring practices proposed by this regulation (§§ 205.103 and 205.201).
- 3. Requires that each shipment of organic products imported into the United States through U.S. Ports of Entry must be declared as organic to U.S. Customs and Border Protection (CBP) and associated with an NOP Import Certificate (NOP 2110-1)<sup>140</sup> or an equivalent data source. <sup>141</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 proposed rule would expand and make compulsory the use of NOP Import Certificates, regardless of an imported product's country of origin. AMS estimates that exporters and certifying agents would need 30 minutes to report mandatory data, and prepare and review the NOP Import Certificate, respectively. AMS estimates that importers would need an average of one-tenth (0.1) of an hour, or 6 minutes, to compare the shipping manifest with the NOP Import Certificate to verify the accuracy and organic compliance of each shipment (§§ 205.273 and 205.300).

<sup>&</sup>lt;sup>139</sup> Mandated by the Agriculture Improvement Act of 2018. See section 10104(a).

<sup>&</sup>lt;sup>140</sup> Office of Management and Budget (OMB)-approved form NOP 2110-1 NOP Import Certificate: https://www.ams.usda.gov/resources/nop-2110-1

<sup>&</sup>lt;sup>141</sup> Mandated by The Organic Foods Production Act of 1990 (OFPA), as amended by the Agriculture Improvement Act of 2018. See sections 10104(b)–(c).

- 4. Clarifies that previously optional information must now 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 would need: (1) the word "organic" to identify the product as organic; and (2) the name of the certifying agent that certified the product. These changes would 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. AMS estimates that producers and/or processers would need one-tenth (0.1) of an hour, or 6 minutes, to add the word "organic" and the name of the certifying agent to the labels that are displayed on nonretail containers (§ 205.307).
- 5. Codifies current practices for the certification of groups of crop producers as a single operation. The proposed rule describes the criteria to qualify as a grower group, how grower group operations can comply with the existing USDA organic regulations, and how certifying agents should inspect these operations. It also sets a risk-based benchmark to determine how many grower group members in an operation need to be inspected annually. AMS expects that these requirements would not add to current paperwork impacts for grower group operations to prepare an OSP and maintain their certification, or for certifying agents and inspectors auditing and inspecting these operations for compliance with organic standards (§§ 204.400 and 204.403).
- 6. Requires certifying agents to create fraud prevention procedures to: (1) identify high-risk operations, supply chains, and agricultural products, (2) conduct risk-based unannounced inspections and supply chain trace-back and mass-balance 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. AMS estimates each certifying agent would spend one hour documenting these procedures (§§ 205.403, 205.501 and 205.504).
- 7. Requires that certifying agents conduct unannounced inspections on at least 5% of the operations they certify, which is the current recommended practice in NOP Instruction 2609. For the purposes of estimating paperwork impacts, AMS expects that half of the unannounced inspections (2.5% of total inspections) would meet the requirement for a full annual inspection and would not impact current paperwork burden. The remaining half of the unannounced inspections (2.5% of total inspections) would target high-risk operations and supply chains and would 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 would average inspectors 5 hours per inspection; half of the estimated 10 hours for a full annual inspection (§ 205.403).

<sup>&</sup>lt;sup>142</sup> NOP Policy Memo 11-10, Grower Group Certification, October 31, 2011:

https://www.ams.usda.gov/sites/default/files/media/NOP-11-10-GroupGrowerCert.pdf

<sup>&</sup>lt;sup>143</sup> NOP 2609, Instruction, Unannounced Inspections. September 12, 2012. Available in the NOP Program Handbook: <a href="https://www.ams.usda.gov/sites/default/files/media/2609.pdf">https://www.ams.usda.gov/sites/default/files/media/2609.pdf</a>

8. Requires certifying agents to issue standardized certificates of organic operation generated from the USDA's publicly available Organic Integrity Database (INTEGRITY). 144 This would require an initial upload of mandatory data for each operation and maintenance, at least annually, to ensure that data in INTEGRITY are current and accurate. Currently, all certifying agents have voluntarily uploaded and maintain 50% or more data on all certified operations per the recommendations found in the NOP's Data Quality Best Practices. 145 The proposed amendments would require a new, one-time burden of reporting hours for certifying agents to upload remaining data pertaining to currently certified operations into INTEGRITY for the first time. It is estimated that uploading these data into INTEGRITY would require 30 minutes for each operation and would be performed by administrative support personnel who have a lower wage rate than review and compliance staff.

The proposed amendments would simultaneously eliminate the requirement to physically mail the Administrator or State Organic Program paper copies of: (1) the list of operations certified annually; (2) notifications of proposed adverse actions, approvals, or denials of corrective actions; and (3) notifications of executions of adverse actions regarding certified operations or operations applying for certification (§§ 205.404 and 205.501). AMS is not seeking to modify the estimate of paperwork burden associated with these changes in requirements because any change would be trivial and these activities and tasks are still occurring electronically as a part of maintaining the data on all operations over time.

- 9. 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 would spend one hour documenting these procedures that they are already implementing.
- 10. Clarifies how certified operations may submit annual updates to their OSP. This includes practices or procedures that have changed since their last approved OSP, rather than submitting an OSP in its entirety. This would reduce unnecessary paperwork without compromising oversight because operations would 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).
- 11. Requires certifying agents to establish inspection oversight procedures and demonstrate that they are sufficiently staffed with qualified personnel and that all inspectors, certification reviewers, and in-field evaluators meet knowledge, skills, and experience qualifications. AMS estimates that each certifying agent would 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. AMS estimates each certifying agent would conduct an average of four inspector field evaluations per year and that this activity would require 7.5 hours per evaluation (§§ 205.2 and 205.501).

<sup>145</sup> Data Quality Best Practices: <a href="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</a>

<sup>&</sup>lt;sup>144</sup> Organic Integrity Database: <a href="https://organic.ams.usda.gov/integrity/">https://organic.ams.usda.gov/integrity/</a>

- 12. Requires inspectors and certification review staff to complete an additional 10 hours of training annually. <sup>146</sup> Through two audits every 5 years, AMS estimates that inspectors and certification review staff currently receive at least 10 hours of training per year from certifying agents on topics related to the USDA organic regulations. Inspectors and certification review personnel 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. Certification review personnel may also serve as inspectors. AMS is proposing an additional 10 hours of training annually, calculated as two (2) five-hour trainings. 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 total of 20 hours of required training (§§ 205.2 and 205.501).
- 13. Clarifies AMS responsibilities for equivalent organic conformity with foreign governments. <sup>147</sup> The OFPA at § 6505(b), and the current USDA organic regulations at § 205.500(c), provide the authority to establish organic equivalency. The proposed 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 peer review audits of trade arrangements would occur twice within a five-year period and would result in new periodic paperwork impacts for foreign governments. AMS estimates the paperwork impacts for foreign governments when USDA reviews the applicable trade arrangement to be 60 hours per year, which is comparable to the estimated paperwork impacts for AMS audits of certifying agents (§ 205.511).

### Respondents

AMS has identified four primary types of entities (respondents) that would need to submit and maintain information as a result of this proposed 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 a 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>148</sup> This adds new types of handlers as a subcategory of certified operations and foreign governments as a new type of respondent.

To more precisely understand the paperwork impacts of this proposed rule, AMS has divided the categories of respondents into domestic and foreign, as appropriate, to show the potential impacts on domestic-based versus foreign-based USDA-accredited certifying agents, inspectors, and certified operations, along with foreign-accredited certifying agents, and foreign-governments serving as accrediting bodies. For each type of respondent, we describe the general paperwork submission and

<sup>&</sup>lt;sup>146</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 the implementation of this rule, the specific hours of training offered by our 78 certifying agents will be documented.

 <sup>147</sup> Currently, the United States has established organic trade arrangements with Canada, the European Union, the United Kingdom (effective January 2021), India, Israel, Japan, New Zealand, South Korea, Taiwan, and Switzerland.
 148 See Section 10104(a) of the Agriculture Improvement Act of 2018, Public Law No: 115-334, available at: <a href="https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf">https://www.congress.gov/115/plaws/publ334/PLAW-115publ334.pdf</a>.

recordkeeping activities and estimate: (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 and foreign wages and benefits.

1. Certifying agents. Certifying agents are State, private, or foreign entities accredited by the USDA, or by accreditation bodies of foreign governments with whom USDA has equivalency, 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. Currently, there are 78 USDA-accredited certifying agents (46 are based in the United States and 32 are 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 would be subject to the reporting and recordkeeping burdens of the proposed amendments. In addition, AMS assumes there are 32 foreign government-accredited foreign-based certifying agents that certify handlers to the USDA organic regulations and that would issue NOP Import Certificates, or their equivalent, for organic product shipments to the United States. 149

Certifying agents of operations that export to the United States would need to issue import certificates for all shipments of imported organic products. The USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS) showed 67,023 shipments of organic product coming into the U.S. in 2017. Thirty-two (32) USDA-accredited certifying agents based in foreign countries certify 92% of the foreign operations certified under USDA organic standards. Of the 46 domestic-based USDA accredited certifying agents, 16 certifying agents certify 8% of the foreign operations certified under USDA. 151 This means that 30 domestic-based USDA-accredited certify agents only certify domestic-based operations that do not import foreign organic products or ingredients. AMS estimates 32 foreign-accredited certifying agents that certify foreign operations under trade agreements. 152 AMS would review documents regarding imports during the accreditation audits of USDA-accredited certifying agents. AMS estimates 30 minutes for: (1) USDA-accredited domestic-based certifying agents to work with their foreign-based operations to prepare the NOP Import Certificate (Form NOP 2110-1) for 8% of 67,023 annual shipments; (2) USDA-accredited foreign-based certifying agents to work with their foreign-based operations to prepare the NOP Import Certificate for 46% of 67,023 annual shipments; and (3) foreignaccredited certifying agents to work with their foreign-based operations to prepare the NOP Import Certificate for 46% of 67,023 annual shipments.

AMS is proposing amendments that would reduce the current paperwork burden of accredited certifying agents by eliminating the need to provide notices of approval or denial of certification to the Administrator following the issuance of a notice of noncompliance or adverse action to an applicant for

<sup>&</sup>lt;sup>149</sup> An estimate based on the number of foreign-based USDA accredited certifying agents.

<sup>&</sup>lt;sup>150</sup> 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: <a href="https://apps.fas.usda.gov/gats/default.aspx">https://apps.fas.usda.gov/gats/default.aspx</a>

<sup>&</sup>lt;sup>151</sup> Organic Integrity Database: <a href="https://organic.ams.usda.gov/integrity/">https://organic.ams.usda.gov/integrity/</a>

<sup>&</sup>lt;sup>152</sup> An estimate based on the number of foreign-based USDA-accredited certifying agents.

certification. Also, the proposed rule removes the annual requirement for certifying agents to submit by January 2 an annual list of operations certified. Certifying agents would instead be required to update data in INTEGRITY for each operation they certify. AMS is not seeking to modify the estimate of paperwork burden with these changes in requirements because any change would be trivial. These activities and tasks are still occurring electronically as a part of maintaining the data on all operations over time. In addition, all USDA-accredited certifying agents would need to write procedures to identify high-risk operations and products they certify and procedures to conduct supply-chain audits of those high-risk products. Certifying agents would also be required to issue organic certificates generated by INTEGRITY. Certifying agents would be required to write procedures to demonstrate how they are sufficiently staffed and that all persons who perform certification review activities and on-site inspections (inspectors) are qualified and complying with annual training requirements increased from 10 hours to 20 hours per year. Certifying agents would also be required to write mediation procedures as per §205.504(b).

AMS projects that the proposed changes would increase the overall reporting and recordkeeping burden for certifying agents (See Summary Table 1: *Certifying Agents*). AMS estimates the annual collection cost per domestic-based USDA-accredited certifying agents would be \$12,788.95.<sup>153</sup> This cost is based on an estimated 123.36 labor hours per certifying agent per year for staff with certification review responsibilities at \$45.91 per labor hour, including 31.7% benefits, for a total salary component of \$5,663.55 per year.<sup>154</sup> The estimated cost for domestic certifying agents also includes 300.24 labor hours per certifying agent per year for administrative support staff to upload data about certified operations to INTEGRITY at \$23.73 per labor hour, including 31.7% benefits, for a total salary component of \$7,125.40 per year.<sup>155</sup>

In addition, AMS estimates the annual collection cost for all domestic-based USDA-accredited certifying agents would be \$589,458.85. This cost is based on a total of 5,720.60 hours for all staff with certification review responsibilities at \$45.91 per labor hour, including 31.1% benefits, for a total salary component of \$262,636.29 for all staff with certification review and procedure writing responsibilities of all domestic-based USDA-accredited certifying agents. The estimated cost for all domestic-based certifying agents also includes 13,771.19 hours total hours for administrative support staff uploading data about certified operations to INTEGRITY at \$23.73 per labor hour, including 31.7% benefits for a total salary component of \$326,822.56.

<sup>&</sup>lt;sup>153</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 2018: <a href="https://www.bls.gov/oes/current/oes\_nat.htm">https://www.bls.gov/oes/current/oes\_nat.htm</a>. 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 14, 2018: <a href="https://www.bls.gov/news.release/ecec.nr0.htm">https://www.bls.gov/news.release/ecec.nr0.htm</a>

<sup>&</sup>lt;sup>154</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.

<sup>&</sup>lt;sup>155</sup> 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.

SUMMARY TABLE 1: Certifying Agents						
Respondent Categories	Number of Respondents	Wages + Benefits	Hours per respondent	Cost/ respondent type	Total All Hours	Total All Costs
U.SBased USDA Certifying Agents	46	\$45.91	124.36	\$5,709.37	5,720.60	\$262,636.29
U.SBased USDA Certifying Agents—data entry	46	\$23.73	300.24	\$7,124.70	13,771.19	\$326,822.56
Subtotal U.S Based USDA Certifying Agents	46			\$12,834.06	19,491.79	\$589,458.85
Foreign-Based USDA Certifying Agents	32	\$24.59	547.74	\$13,468.93	17,527.63	\$430,181.78
Foreign-Based USDA Certifying Agents—data entry	32	\$12.71	300.24	\$3,816.05	9,569.81	\$121,633.35
Subtotal Foreign-Based USDA Certifying Agents	32			\$17,286.98	27,097.44	\$551,815.13
Total USDA- Accredited Certifying Agents	78			\$30,119.04	46,589.23	\$1,141,273.98
Foreign- Accredited Certifying Agents	32	\$24.59	481.73	\$11,844.69	15,415.29	\$379,030.04
Total All Certifying Agents	110				62,004.52	\$1,520,304.02

For foreign-based USDA-accredited certifying agents, AMS estimates the annual cost per certifying agent would be \$17,527.63 per year. This cost is based on an estimated 547.74 labor hours for staff with certification review and procedure writing responsibilities at \$24.59 per labor hour, including 35.92% benefits, for a total salary component of \$13,468.93 per foreign-based USDA-accredited certifying agent per year. These estimated costs primarily pertain to the issuance and review of NOP Import Certificates. The estimated cost for foreign-based USDA-accredited certifying agents also includes 300.24 labor hours per certifying agent per year for administrative support staff to upload data about certified operations to INTEGRITY at \$12.71 per labor hour, including 35.92% benefits, for a total salary component of \$3,816.08 per year. 156

AMS estimates the annual collection cost for all foreign-based USDA accredited certifying agents would total \$551,815.13. This cost is based on a total of 17,527.63 hours for all staff with certification review responsibilities at \$24.59 per labor hour, including 35.92% benefits, for a total salary component of \$430,181.78 for staff with certification review and procedure writing responsibilities of all foreign-based USDA-accredited certifying agents. The estimated cost for all foreign-based USDA-accredited certifying agents also includes 9,569.81 hours total hours for administrative support staff uploading data about certified operations to INTEGRITY at \$12.71 per labor hour, including 35.92% benefits, for a total salary component of \$121,633.35.

For foreign-accredited certifying agents, AMS estimates the annual cost will be \$11,844.69 per certifying agent. This cost is based on an estimated 481.73 labor hours per year for staff to issue and review NOP Import Certificates, or an equivalent data source, at \$24.59 per labor hour plus 35.92% benefits. The total for all foreign-accredited certifying agents is estimated to be \$379,030.04. The cost is based on an estimated 15,415.29 total hours for all staff involved in the issuance and review of NOP Import Certificates, or an equivalent data source, at \$24.59 per labor hour plus 35.92% benefits.

The total cost for all certifying agents as a whole includes all costs for all 78 USDA-accredited certifying agents, domestic- and foreign-based, and all costs for the 32 foreign-accredited certifying agents who certify operations that export products to the U.S. The total costs for all certifying agents is \$1,520,304.02. This cost is based on 62,004.52 total hours at their respective wage rates and benefits to comply with the proposed requirements.

2. <u>Organic Inspectors</u>. 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, and a certifying agent may call for additional inspections or unannounced inspections on an as-needed basis (§ 205.403(a)). Any individuals who apply to conduct inspections of operations would need to submit information documenting their qualifications to the certifying agent (§ 205.504(a)(3)). Inspectors must also complete 20 hours of standardized organic training every year. AMS estimates that 10 hours per year for each inspector is a new paperwork burden associated with the proposed rule.

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<sup>156</sup> In this assessment, all foreign labor rates are based on a review of World Bank data, which indicates that labor rates in foreign countries with USDA-accredited certifying agents are approximately 52% of equivalent U.S. labor rates: <a href="https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD">https://data.worldbank.org/indicator/NY.GDP.PCAP.PP.CD</a>. Benefits are based on a review of data from the Organisation for Economic Co-Operation and Development (OECD), which indicates that benefits account for 35.92% of total compensation in foreign countries with USDA-accredited certifying agents: <a href="https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP">https://stats.oecd.org/Index.aspx?DataSetCode=AWCOMP</a>

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. The additional unannounced inspections that would be newly required by this proposed rule are likely to be more limited in scope (such as pasture or dairy surveillance, or mass-balance and traceback audits). AMS projects, on average, that inspectors would spend 5 hours to complete an inspection report for the unannounced targeted scope inspection. AMS Inspectors do not have recordkeeping obligations; certifying agents maintain the records of inspection reports (see Summary Table 2: Inspectors).

SUMMARY TABLE 2: Inspectors						
Respondent Categories	Number of Respondents	Wages + Benefits	Hours per respondent	Cost per Respondent Type	Total All Hours	Total All Costs
USDA U.Sbased Inspectors	148	\$28.45	33.34	\$948.43	4917.80	\$139,897.57
USDA Foreign- based inspectors	102	\$15.27	33.34	\$508.99	3417.45	\$52,172.66
All USDA Inspectors	250				8335.25	\$192,070.23

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. AMS estimates that 148 inspectors are working for USDA-accredited certifying agents in the U.S. For the additional training and unannounced targeted-scope inspections, AMS estimates the annual paperwork impact cost per domestic-based inspector to be \$948.43. This is based on an estimated 33.34 labor hours per year at \$28.45 per labor hour, including 31.7% benefits. The total annual cost for all domestic-based inspectors is \$139,897.57. This cost is based on 3,417 total hours for all domestic based inspectors at \$28.45 per labor hour, including 31.7% benefits.

AMS estimates that 102 inspectors are working for USDA-accredited certifying agents in foreign countries. AMS estimates the annual paperwork impact cost per foreign-based inspector to be \$508.99. This estimate is based on an estimated 33.34 labor hours per year at \$15.27 labor hour, including 35.92% benefits for attending 10 hours of training and conducting 4.67 unannounced targeted scope inspections. There are no recordkeeping costs for inspectors. The total annual cost for all foreign-based inspectors is \$52,172.66 at \$15.27 per labor hour, including 35.92% benefits. The total annual cost for all inspectors working for USDA-accredited certifying agents is \$192,070.23, at their respective wage rates and benefits.

3. <u>Producers and handlers</u>. 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.

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<sup>&</sup>lt;sup>157</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.

a) Uncertified Handlers. This proposed rule would require that operations that facilitate the sale or trade of organic products—including, but not limited to, brokers, importers, and traders—obtain certification and submit and maintain an OSP. AMS estimates that 961 domestic, 158 and an equal number of foreignbased, operations would need to become certified as a result of this rule. As stated previously, the OSPs for these handling operations would address fewer sections of the current rule than OSPs for operations that farm or manufacture organic products. Traders and brokers do not farm or manufacture organic products so the OSPs for traders and brokers would address fewer sections of the current rule than OSPs for operations that produce or manufacture organic products. Certifying agents customize the format of the OSP to cover standards applicable to the operations seeking certification. Therefore, AMS estimates that preparation of an initial OSP would require 40 reporting hours, plus 10 hours of annual recordkeeping. The estimated annual reporting burden for each entity to update its OSP in future years is 20 hours (See Summary Table 3a: *Uncertified Handlers*).

All operations that export organic products to the United States would need to request an 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 would need to verify that each shipment is associated with and matches the data on an NOP Import Certificate, and that organic integrity was maintained throughout the import process. In addition, domestic and foreign handlers that would be required to obtain organic certification as a result of this proposed rule may also need to comply with the proposed requirements for labeling nonretail containers.

SUMMARY TABLE 3a: Uncertified Handlers						
Respondent Categories	Number of Respondents	Wages + Benefits	Total hours per respondent	Total cost per respondent type	Total All Hours	Total All Costs
Formerly						
Excluded	961	\$50.86	56.97	\$2,897.49	54,752.30	\$2,784,701.98
Handlers—	301	<b>730.80</b>	30.37	72,637. <del>4</del> 3	34,732.30	72,704,701.30
Domestic						
Formerly						
Excluded	961	\$27.13	84.87	\$2,302.56	81,561.50	\$2,212,763.50
Handlers—	301	<b>γ27.13</b>	04.07	72,302.30	81,301.30	72,212,703.30
Foreign						
All Formerly						
Uncertified	1922				136,313.80	\$4,997,465.47
Handlers						

AMS estimates the annual paperwork impact for each domestic handler to prepare their initial organic system plan and to verify that imported shipments match their respective NOP Import Certificates is

158 These businesses are identified by NAICS Category 425: Wholesale Electronic Markets and Agents and Brokers. These businesses 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 wholesale trade. Please refer to the "Applicability and Exemptions from Certification (§§ 205.100-101)" chapter in the Regulatory Impact Analysis (RIA) for an explanation of how previously excluded domestic handlers were estimated.

\$2,897.71. This is based on an estimated 56.97 labor hours at \$50.86 per labor hour, including 31.7% benefits. The total cost to all previously uncertified domestic handlers is \$2,784,701.98. This cost is based on 55,752.30 total labor hours at \$50.86 per labor hour, including 31.7% benefits. 159

AMS estimates the annual paperwork impact for each foreign-based handler to prepare their initial organic system plan and to work with their certifying agent to prepare their NOP Import Certificates for the products they export is \$2,302.56. This is based on an estimated 84.87 labor hours per year at \$27.13 per labor hour, which includes 35.92% for benefits. The total cost to all previously uncertified foreign handlers is \$2,784,701.98. This cost is based on 55,752.30 total labor hours at \$27.13 per labor hour, which includes 35.92% for benefits. Total costs to the 1922 previously uncertified handlers, domestic and foreign, is \$4,997,465.47, based on 136,313.80 total labor hours at their respective domestic and foreign wage rates and benefits to prepare and keep their initial OSP and related records, and to prepare and review NOP Import Certificates for compliance.

b) *Certified Operations and New Applicants under Current Rules*. There currently are 42,259 organic operations worldwide that are certified to the USDA organic standards. Over the next 12 months, AMS expects 2,501 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>160</sup> Therefore, AMS estimates that 26,408 operations based in the United States, and 18,352 operations based in foreign countries, including the respective applicants for certification, will be impacted by this proposed rule.

All currently certified organic operations and projected new applicants would need to describe their procedures for monitoring, verifying and demonstrating the organic status of their suppliers and products received to prevent organic fraud as part of their initial or updated OSP. All certified organic operations would need to comply with the proposed nonretail labeling requirements, and would be required to keep all records about their organic production and/or handling for five years (§ 205.103(b)(3)). See Summary Table 3b: Certified Organic Operations and New Applicants.

SUMMARY TABLE 3b: Certified Organic Operations and New Applicants						
Respondent Categories	Number of Respondents	Wages + Benefits	Total hours/ respondent	Total cost/ respondent type	Total All Hours	Total All Costs
Certified Producers & Handlers—New and Existing Domestic	26,408	\$50.86	1.54	\$78.33	47,815.50	\$2,432,017.86
Certified Producers & Handlers—New and Existing Foreign	18,352	\$27.13	1.54	\$41.78	20,466.00	\$555,242.58

<sup>&</sup>lt;sup>159</sup> 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*.

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<sup>&</sup>lt;sup>160</sup> Organic Integrity Database: https://organic.ams.usda.gov/integrity/. Calculated on April 3, 2019.

All New and			
Existing	44.760	60 201 EN	\$2.097.260.44
Producers &	44,760	08,281.50	\$2,987,260.44
Handlers			

AMS estimates that the average annual paperwork impact for domestic certified organic producers and handlers to create a fraud prevention procedure and to comply with nonretail labeling requirements is \$78.33. This is based on an estimated 1.54 labor hours at \$50.86 per labor hour, including 31.7% benefits. The total cost for all domestic certified organic producers and handlers to comply with these new requirements is \$2,432,017.86. This cost is based on 47,815.50 labor hours at \$50.86 per labor hour, including 31.7% benefits.<sup>161</sup>

AMS estimates the average annual paperwork impact for foreign-based USDA-certified organic producers and handers to create a fraud prevention procedure and to comply with nonretail labeling requirements to be \$41.78. This is based on an estimated 1.54 labor hours per year at \$27.13 per labor hour, including 35.92% benefits. The total cost for all foreign producers and handlers certified to the USDA organic standards is \$555,242.58. This cost is based on 20,446 labor hours year at \$27.13 per labor hour, including 35.92% benefits. The total cost for the 44,760 current certified organic and projected new producers and handlers under current rules, both domestic and foreign, is \$2,987,260. This cost is based on 68,281.50 labor hours at their respective domestic and foreign wages and benefits, to create their new fraud prevention procedures and comply with new nonretail label requirements.

4. Foreign Governments. The USDA has arrangements with 10 foreign governments to facilitate the international trade of organic products. <sup>162</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 proposed rule describes equivalency determinations in more detail; this creates a new type of PRA respondent category. The proposed 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 proposed rule would also require periodic assessment.

AMS expects these periodic peer review assessments would 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 per foreign government would be \$1,721.15. This cost is based on an estimated 60 reporting labor hours and an estimated 10 hours of recordkeeping per foreign government per year at \$24.59 per labor hour, including 35.92% benefits, for a total salary component of \$1,721.15 per year. The total cost for all foreign governments, with whom AMS has negotiated trade arrangements, to allow AMS to determine whether their foreign products labeled as

<sup>162</sup> Canada, the European Union, the United Kingdom (effective January 2021), India, Israel, Japan, New Zealand, South Korea, Taiwan, and Switzerland. Taiwan is not included in this assessment because costs were calculated prior to May 2020, when the United States–Taiwan equivalency arrangement became effective.

<sup>&</sup>lt;sup>161</sup> The labor rate for producers and handlers is based on Occupational Employment Statistics group 11-9013, *Farmers, Ranchers, and Other Agricultural Managers*, who plan, direct, or coordinate the management or operation of farms, ranches, or other agricultural establishments.

organic are produced and handled are at least equivalent to the requirements of the OFPA and the USDA organic regulations is \$13,768.24. This cost is based on 560 total labor hours for all foreign governments at \$24.59 per labor hour, including 35.92% benefits. 163

Total (Domestic and Foreign) Information Collection Cost (Reporting and Recordkeeping) of Proposed Rule: \$9,711,656 (Also, see Summary Table 4: *All Reporting and Recordkeeping Hours and Costs, and All Domestic Reporting and Recordkeeping Hours and Costs)* 

Total All Reporting Burden Cost: \$8,497,036

*Estimate of Burden*: Public reporting burden for the collection of information is estimated to average .38 hours per year per response

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

Estimated Number of Reporting Respondents: 47,050

Estimated Number of Reporting Responses: 644,269

Estimated Total Annual Burden on Reporting Respondents: 244,927 hours

Estimated Total Annual Reporting Responses per Reporting Respondents: 13.69 reporting responses per reporting respondents

## Total All Recordkeeping Burden Cost: \$1,214,620

Estimate of Burden: Public recordkeeping burden is estimated to be an annual total of 0.65 hours per year per respondent.

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

Estimated Number of Recordkeeping Respondents: 46,768

Estimated Total Recordkeeping Burden on Respondents: 30,568 hours.

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

# Total Domestic Only Information Collection Cost (Reporting and Recordkeeping) of Proposed Rule: \$5,946,076

### Total Domestic Only Reporting Burden Cost: \$5,119,399

Estimate of Burden: Public domestic only reporting burden is estimated to be an annual total .29 hours per year per domestic respondent

Respondents: Certifying agents, certified operations, and inspectors.

Estimated Number of Domestic Reporting Respondents: 27,563

<sup>&</sup>lt;sup>163</sup> The labor rate for foreign governments is estimated at 52% of the labor rate for Occupational Employment Statistics group 13-1041, *Compliance Officers*.

Estimated Number of Domestic Reporting Responses: 380,119

Estimated Total Annual Reporting Burden on Domestic Respondents: 110,719 hours

Estimated Total Domestic Reporting Responses per Reporting Respondents: 13.79 reporting response per reporting respondents

## **Total Domestic Only Recordkeeping Burden Cost:** \$826,677

*Estimate of Burden*: Public domestic only recordkeeping burden is estimated to be an annual total of 0.59 hours per year per respondent.

Respondents: Certifying agents and certified operations.

Estimated Number of Domestic Recordkeeping Respondents: 27,415

Estimated Total Annual Recordkeeping Burden on Domestic Respondents: 16,288 hours.

Estimated Number of Domestic Recordkeeping Responses: 27,542

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

Summary Table 4: All Reporting and Recordkeeping Hours and Costs and All Domestic Reporting and Recordkeeping Hours and Costs						
	Hours	Costs	Number of Respondents	Respondent Types		
Total Reporting & Recordkeeping	275,495	\$9,711,656	47,050	Certifying agents, certified operations, inspectors, and foreign governments		
All Reporting	244,927	\$8,494,137	47,050	Certifying agents, certified operations, inspectors, and foreign governments		
All Recordkeeping	30,568	\$1,214,620	46,768	Certifying agents, certified operations, and foreign governments.		
Reporting & Recordkeeping— Domestic	126,977	\$5,946,076	27,563	Certifying agents, certified operations, and inspectors		
Domestic Reporting	110,719	\$5,119,399	27,563	Certifying agents, certified operations, and inspectors		
Domestic Recordkeeping	16,258	\$826,677	27,415	Certifying agents and certified operations		

#### **Comments**

AMS is inviting comments from all interested parties concerning the information collection and recordkeeping required as a result of the proposed amendments to 7 CFR Part 205. AMS seeks comment on the following subjects:

- 1. Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information would have practical utility.
- 2. The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.
- 3. Ways to enhance the quality, utility, and clarity of the information to be collected.
- 4. Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.
- 5. AMS estimates that the total number of certified organic operations will grow by 5.6% annually, based on the increase in operations recorded in INTEGRITY during the last 12 months. Is this a reasonable and accurate projection of future growth, given the additional burdens imposed by this proposed rulemaking?<sup>164</sup>

Comments that specifically pertain to the information collection and recordkeeping requirements of this proposed rule may be sent to the Federal eRulemaking Portal at <a href="https://www.regulations.gov/">https://www.regulations.gov/</a>. You can access this proposed rule and instructions for submitting public comments by searching for document number, AMS-NOP-17-0065. Comments may also be sent to Valeria Frances, Agricultural Marketing Specialist, National Organic Program, USDA-AMS-NOP, Room 2642-So., Ag Stop 0268, 1400 Independence Ave., SW., Washington, DC 20250-0268 and to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, 725 17<sup>th</sup> Street, NW., Room 725, Washington, D.C. 20503. Comments on the information collection and recordkeeping requirements should reference the date and page number of this issue of the *Federal Register*. All responses to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. The comment period for the information collection and recordkeeping requirements contained in this proposed rule is 60 days.

<sup>&</sup>lt;sup>164</sup> Organic Integrity Database: <a href="https://organic.ams.usda.gov/integrity/">https://organic.ams.usda.gov/integrity/</a>. Calculated on April 3, 2019.