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NOTE: The columns will calculate automatically. If Col. E's response is something other than annually, i.e., 1/6 years, list as "1/6" & decimal will display.

TITLE OF INFORMATION COLLECTION DOCUMENT
National Organic Program: Strengthening Organic Enforcement (SOE) Final Rule

OMB NO. 0581-0321
DATE PREPARED
 September 1, 2021

IDENTIFICATION OF REPORTING OR RECORDKEEPING REQUIREMENT		ANNUAL BURDEN									
SECTION OF REGS. (A)	DESCRIPTION (B)	FORMS NO (S) (If "none" so state) (C)	REPORTS					RECORDS			
			NO. OF RESPONDENTS (D)	NO OF RESPONSES PER RESPONDENT (E)	TOTAL ANNUAL RESPONSES (Col. D x E) (F)	HOURS PER RESPONSE (G)	TOTAL HOURS (Col. F x G) (H)	NO. OF RECORD-KEEPERS (I)	ANNUAL HOURS PER RECORD-KEEPER (Col. I x J) (J)	TOTAL RECORD-KEEPING HOURS (Col. I x J) (K)	
Producers and Handlers (Operations)											
205.103	Subpart B -- Applicability - certified operators maintain records for not less than 5 years	None			0.00			0.00	47,363.78	0.25	11840.94
Subpart E --Certification											
205.400(b) 205.406(a)(1)(i); 205.201(a)(1) - (6), 205.401d 205.406(a)(3)	New Group of Handlers that were previously excluded from certification must get certified. Traders and brokers of organic products that facilitate the trade of, but do not directly produce, process, or manufacture agricultural products, are now required to be certified as organic and must submit initial Organic System Plan (OSP).		3364	1.00	3364.00	40.00	134,560.00	3,364.00		10.00	33640.00
205.400(b) 205.406(a)(1)(i); 205.201(a)(1) - (6), 205.401d 205.406(a)(3)	New operations that are required to be certified under current rules must now include a description of the new monitoring practices and procedures to verify suppliers in the supply chain and organic status of products received to prevent organic fraud in their initial Organic System Plan (OSP)	None	2639	1.00	2638.78	0.50	1,319.39				
205.400(b) 205.406(a)(1)(i); 205.201(a)(1) - (6), 205.401d 205.406(a)(3)	Currently certified operations (farmers and handlers) must now include a description of the new monitoring practices and procedures to verify suppliers in the supply chain and organic status of products received to prevent organic fraud when they update their OSP	None	44,725	1.00	44725.00	0.50	22,362.50				
205.201(c)	In addition to paragraph (a) of this section, a producer group operation's OSP must describe its internal control system.	None	5,900	1.00	5900.00	2.00	11,800.00				
205.400(g)(5)	In addition to paragraphs (a) through (f) of this section, a producer group operation must: Identify, prevent and address conflicts of interest, and provide training on compliance with organic regulations and ICS procedures to all personnel and members;	None	5,900	1.00	5900.00	5.00	29,500.00				
Subpart D - Labels, Labeling, and Market Information											
205.300(c)	NOP Import Certificates: Organic products produced in a foreign country and exported for sale in the United States must ... arrive in the United States associated with a valid NOP Import Certificate (Form NOP 2110-1, approved under 0581-0191) from a certifying agent. Persons wishing to export organic products to the US must obtain a NOP Import Certificate through their certifying agent.		3856	4.00	15,424.00	0.50	7,712.00				
205.300(c)	(5) Upon receipt of the shipment, the organic importer of record must ensure the shipment is accompanied by a verified NOP Import Certificate,	None	1350	59.34	80109.00	0.10	8,010.90				
205.307	Labeling of bulk nonretail containers - domestic products		29,929	6.53	195,387.00	0.10	19,538.70				
205.507	Labeling of bulk nonretail containers -international products		3856	20.78	80109.00	0.10	8,010.90				
PRODUCERS and HANDLERS SUBTOTAL			50,728		433,556.78		242,814.39	50,728			45,480.94

USDA Accredited Domestic Based Certifying Agents with only domestic ops that do not import foreign produced product.	30.00	0.00	0.00	0.50	0.00		
USDA Accredited Domestic Based Certifying Agents with 8% of Foreign Operations certified under USDA	15.00	427.25	6408.72	0.50	3,204.36		
USDA Accredited Foreign Based Certifying Agents with 92% of foreign operations certified under USDA	30.00	1228.34	36850.14	0.50	18,425.07		
Foreign Accredited Foreign Based Certifying Agents with foreign operations that export to the U.S.	30.00	1228.34	36,850.14	0.50	18,425.07		
SUBTOTAL	105.00		131,386.78		68,243.39	75.00	75.00

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OMB NO. 0581-0321
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IDENTIFICATION OF REPORTING OR RECORDKEEPING REQUIREMENT			ANNUAL BURDEN							
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	Inspectors									
205.403(a)(3)	Inspectors - unannounced inspections conducted on 5% of operations - 50% of those will count as full complete annual inspections. 50% are partial inspections focused on following up on specific concerns, so they are over and above the annual inspection. These unannounced inspections include the new requirement for trace back and mass balance audits. The inspections are calculated to take half the time as would be required of a full inspection.		250.00	5.07	1268.19	5.00	6,340.97			
205.501 (a)(4)-(a)(6)	New inspectors (14% of current inspectors - assumes an equal loss of inspectors due to BLS separation rates) must have 40 hours of additional training their first year. Certifiers are already offering at least 10 hours, so new burden hours are 40. Calculated as five (5) 8 hour trainings		35.00	5.00	175.00	8.00	1,400.00			
	SUBTOTAL		250.00		1443.19		7740.97			

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Foreign Governments										
205.511 (a)-(e)	Recognition and Equivalence of foreign governments: AMS establishes arrangements with foreign governments accrediting their certifying agents to facilitate the international trade of organic products per 205.500(c)-(d) and shall conduct peer reviews of each trade arrangement periodically to verify that the foreign government's technical requirements and conformity assessment system, as applicable, continue to be at least equivalent to the requirements of the Act, and will determine whether the arrangement should be continued. Estimating one foreign government peer review per year		8.00	1.00	1.00	60.00	60.00			
205.511 (a)-(e)	Recognition and Equivalence of foreign governments: AMS establishes arrangements with foreign governments accrediting their certifying agents to facilitate the international trade of organic products per 205.500(c)-(d) and shall conduct peer reviews of each trade arrangement periodically to verify that the foreign government's technical requirements and conformity assessment system, as applicable, continue to be at least equivalent to the requirements of the Act, and will determine whether the arrangement should be continued. All foreign governments with whom we have trade arrangements need to maintain records		8.00					8.00	10.00	80.00
SUBTOTAL			8.00	1.00	1.00	60.00	60.00	8.00	10.00	80.00

2021 INFORMATION COLLECTION - Strengthening Organic Enforcement (SOE)
OMB NO. 0581-0321

REGS	REG Text	Previous Approved Burden	Final Burden	Difference Between New and Previous Burden	Reason For Change	Type of Change
205.103	Subpart B -- APPLICABILITY Certified operators document compliance maintain records for not less than 5 years	11,190.00	11840.94	650.94	Change in hours due to industry growth. This shows the new recordkeeping burden due to the proposed changes only - this is not the total recordkeeping burden for currently certified operations.	ADJ
205.400(b) 205.406(a)(1)(i); 205.201(a)(1) - (6), 205.401d 205.406(a)(3)	Previously exempted Handling Operators that facilitate the trade of, but do not directly produce, process, manufacture, or physically store agricultural products, submit initial Organic System Plan (OSP) - Handling operations that conduct any activity that affects the status or ownership of an agricultural product after production as it moves from production source through the supply chain, including, but not limited to: distributing, selling, representing, trading, facilitating sale or trade of, brokering, processing, packaging, repackaging, labeling, combining, containerizing, storing, receiving, or loading. (application) Reporting	76,880.00	134560.00	57,680.00	Change in burden increases due to refinements in NAICS code 425 and the addition of operations from NAICS code 4244 in response to public comment. 2018 Farm Bill mandates traders and brokers must become certified. AMS estimates 855 of the operations in NAICS code 425 which defines a broker, trader or facilitator of transactions of agricultural products domestically plus 1,130 from NAICS code 4244 for domestic Grocery and Related Product Merchant Wholesalers (see RIA) totalling 1985 domestic formerly excluded operations now required to be certified as organic. To estimate the number of foreign operations impacted, AMS estimates the 1985 domestic operations as 59% and 1379 foreign operations as 41%. AMS estimates 3364 new handlers in this category 40 hours to prepare their organic system plan as a new applicant for the first time.	ADJ
205.400(b) 205.406(a)(1)(i); 205.201(a)(1) - (6), 205.401d 205.406(a)(3)	Previously exempted Handling Operators that facilitate the trade of, but do not directly produce, process, manufacture, or physically store agricultural products, submit initial Organic System Plan (OSP) - Handling operations that conduct any activity that affects the status or ownership of an agricultural product after production as it moves from production source through the supply chain, including, but not limited to: distributing, selling, representing, trading, facilitating sale or trade of, brokering, processing, packaging, repackaging, labeling, combining, containerizing, storing, receiving, or loading. (application) Recordkeeping	19,220.00	33640.00	14,420.00	Change in burden increases due to refinements in NAICS code 425 and the addition of operations from NAICS code 4244 in response to public comment. 2018 Farm Bill mandates traders and brokers must become certified. AMS estimates 855 of the operations in NAICS code 425 which defines a broker, trader or facilitator of transactions of agricultural products domestically plus 1,130 from NAICS code 4244 for domestic Grocery and Related Product Merchant Wholesalers (see RIA) totalling 1985 domestic formerly excluded operations now required to be certified as organic. To estimate the number of foreign operations impacted, AMS estimates the 1985 domestic operations as 59% and 1379 foreign operations as 41%. AMS estimates 3364 new handlers in this category 10 hours to store their records annually.	ADJ
	Subpart C & E - Production & Handling -- Operators submit initial application or update existing Organic System Plan (OSP)			0.00		
205.201(a)(1) - (6), 205.400(b), 205.401d, 205.406(a)(1)(i) 205.406(a)(3)	Initial Application consists of: Operators list practices and procedures to be performed and maintained, substances used, monitoring practices & procedures, describe recordkeeping systems, practices to prevent commingling & contact with prohibited substances, and other information as necessary	1,250.50	1319.39	68.89	Change in hours due to industry growth. These are the new operations seeking certification for the first time based on existing rules. Over the next 12 months, AMS expects 2,639 operations will seek organic certification as required under current rules, based on the 5.9% rate of growth in number of operations observed in the last 12 months. The new burden accounts for the one time only new requirement to write their fraud prevention procedures as a part of their Organic System Plan (OSP).	ADJ

205.201(a)(1) - (6), 205.400(b), 205.401d, 205.406(a)(1)(i) 205.406(a)(3)	Annual Update: Current certified operators (farmer and handlers) submit updated Organic System Plan (OSP) - current operators must include a description of the new monitoring practices and procedures to verify suppliers in the supply chain and organic status of products received, and to prevent organic fraud, as appropriate to the operation's activities.	21,129.50	22362.50	1,233.00	Change in hours due to industry growth. These are the currently certified operations that will be updating their OSP this year. The new burden accounts for the one time only new requirement to write their fraud prevention procedures as a part of their OSP.	ADJ
205.201(c)	In addition to paragraph (a) of this section, a producer group operation's OSP must describe its internal control system.	0.00	11800.00	11,800.00	Change in burden in response to public comment. Greater producer group Internal Control System (ICS) specificity is required than was originally proposed to ensure the ICS can manage the unique challenges of producer groups.	ADJ
205.400(g)(5)	In addition to paragraphs (a) through (f) of this section, a grower group operation must: Identify, prevent and address conflicts of interest, and provide training on compliance with organic regulations and ICS procedures to all personnel and members;	0.00	29500.00	29,500.00	Change in burden in response to public comment. In response to public comment, greater producer group Internal Control System (ICS) specificity is required than was originally proposed to ensure the ICS can manage the unique challenges of producer groups. Procedures to address conflicts of interest and more training of ICS personnel and producer members requirements are expanded.	ADJ
Subpart D - Labels and Labeling				0.00		
205.300(c)	NOP Import Certificates: Organic products produced in a foreign country and exported for sale in the United States must ... arrive in the United States accompanied by a valid NOP Import Certificate (Form NOP 2110-1, approved under 0581-0191), or equivalent from a certifying agent accredited by a foreign country with whom we have an equivalence agreement. Persons wishing to export organic products to the US must obtain a NOP Import Certificate or equivalent through their certifying agent.	33,511.50	7712.00	-25,799.50	Burden on foreign exporters due to the mandatory use of the NOP Import Certificates (Form NOP 2110-1) is reduced overall even though we are estimating more exporters (final 3856, proposed 961). Certifying agents and foreign governments with whom we have trade arrangements report that 3856 traders and brokers will work with their certifiers to prepare the NOP Import Certificate form to export organic product to the United States. In response to public comments, AMS estimates that NOP Import certificates are issued seasonally (quarterly) rather than with every shipment as proposed. AMS estimates that importers and certifying agents will reconcile multiple shipments associated with a single NOP Import Certificate issued quarterly. AMS estimates 30 minutes for the 3856 foreign traders to work with their certifier to prepare 15,424 NOP Import Certificates (Form NOP 2110-1) calculated on an annual basis .	ADJ
205.300(c)	(5) Upon receipt of the shipment, the organic importer of record must ensure the shipment is accompanied by a verified NOP Import Certificate, and complies with organic regulations.	6,702.30	8010.90	1,308.60	Burden on importers due to the mandatory use of the NOP Import Certificates (Form NOP 2110-1) is increased due to modifications in previously excluded operations that need to be certified and due to industry growth. More importers (1350 final; 961 proposed) will work with their certifiers to reconcile all shipments associated with their respective NOP Import Certificate. The estimate of the number of shipments coming into the United States is derived the same in 2020. Data Source: USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS). Select: Partners, World Total, Product Type, Imports - General, Products: All Aggregates; Product Groups: Organic - Selected: https://apps.fas.usda.gov/gats/default.aspx . The number of annual shipments has increased to 80,109 due to industry growth in 2020 from 67,023 in 2017. In response to public comments, AMS estimates that NOP Import certificates are issued seasonally (quarterly) rather than with every shipment as proposed. AMS estimates that importers and certifying agents reconcile multiple shipments associated with a single NOP Import Certificate issued quarterly. AMS estimates 30 minutes for the 1350 domestic importers to work with their certifier to reconcile the 80,109 annual shipments.	ADJ

205.307	labeling of bulk nonretail containers - domestic products	28,009.20	19538.70	-8,470.50	New burden is reduced to a narrowing in new requirements (who and what shipments) in response to public comments. 29,929 (existing and new domestic operations and traders) certified operations will be modifying how they label 195,387 nonretail shipments AMS assumes information added to each nonretail label will take .1 hours (6 minutes).	ADJ
205.307	labeling of bulk nonretail containers -international products	6,702.30	8010.90	1,308.60	New burden is reduced to a narrowing in new requirements (who and what shipments) in response to public comments. 3856 (existing, new, and domestic traders) certified operations will be modifying how they label 80,109 nonretail shipments exported to the US AMS assumes information added to each nonretail label will take .1 hours (6 minutes).	ADJ
	Review of Application			0.00		
205.404(b) 205.406(d)	Agents upload all data for each operation into Organic Integrity Database using federated organic certificate template in Integrity for the first time.	23,341.00	25363.89	2,022.89	Change in burden due to industry growth. AMS assumes that certifiers will need 30 minutes on average to upload remaining data pertaining to certified operations into INTEGRITY for the first time.	ADJ
	Subpart F - Accreditation of Certifying Agents Application, Evidence of Expertise, and Annual Updates			0.00		
205.501 (a)(2-4), (6-7), (11)(v), (15) & (20-21); 205.503 (a -b), (d)(1-2) & (c-e); 205.504(a -e); 205.510(a)(1-2), and 205.642	Accreditation of Certifying Agents - Form TM-10CG - Provide Policies, Procedures, Evidence of Expertise and Ability, describe organizational units, primary location, areas of certification (crops, livestock, & handling), States & foreign countries where they operate, lists of currently certified operations, conduct & provide results of performance evaluations of personnel & inspectors, conduct program evaluations of their certification activities, provide procedures for residue testing, and other information that will assist in evaluating their application, and comply with any other requirements. Consolidated Accreditation application activities & 100% annual updating activity common to all certifying agents	78.00	75.00	-3.00	Change in burden due to a net loss of 3 certifying agents from 2017. This provides for new annual recordkeeping burden for certifying agents addressing new procedures and requirements in this proposed rule.	ADJ
205.501(a)(10-13)	Certifying agents develop fraud prevention and reporting procedures	78.00	150.00	72.00	Changes in burden due to a recognition that these procedures should be comprehensive. AMS assumes two hours to draft fraud and reporting procedures in response to comments.	ADJ
205.501 (a)(4)-(a)(6)	Certifying agents develop procedures to demonstrate that they are sufficiently staffed and that all persons who perform certification review activities and on-site inspections (inspectors) are qualified.	78.00	75.00	-3.00	Change in burden due to a net loss of 3 certifying agents from 2017. AMS assumes one hour to draft staff qualification evaluation procedures.	ADJ
205.663	Certifying agents develop mediation procedures as per §205.504(b)	78.00	75.00	-3.00	Change in burden due to a net loss of 3 certifying agents from 2017. AMS assumes one hour to draft mediation procedures	ADJ
205.501 (a)(4)-(a)(6)	Certifying agents must demonstrate that all persons who perform on-site inspections (inspectors) are observed performing on-site inspections at least once every three years	2,340.00	1125.00	-1,215.00	Burden is reduced due to narrowed requirements. Required certifying agents to observe 2 inspections on average annually rather than 4. Each observation is expected to require 7.5 hours to observe the actual inspection, debrief the inspector, and draft the report.	ADJ
205.501 (a)(4)-(a)(6)	New certifying agent reviewing staff (14% or 35 of current certifying agent review staff - assumes an equal loss of personnel due to BLS separation rates for ag inspectors) must have 40 hours of additional training their first year. Certifiers are already offering at least 10 hours, so new burden hours are 40. Calculated as five (5) 8 hour trainings	2,500.00	1400.00	-1,100.00	Burden is reduced to tiered training requirements targeting new certifying agent reviewing staff.	ADJ
205.500(c)(2)	An NOP Import Certificate, NOP 2110-1, or equivalent, must be associated with all imports entering the US. NOP accredited domestic and foreign certifying agents (46) or foreign accredited certifiers (32), must verify the quantities of product being exported to and imported into the US. The NOP Import Certificate is electronic and generated on Customs and Border				See below	ADJ

	USDA Accredited Domestic Based Certifying Agents with only domestic ops that do not import certificates	0.00	0.00	0.00		
	USDA Accredited Domestic Based Certifying Agents that handle 8% of Foreign Operations certified under USDA	2,680.92	3204.36	523.44	Change in burden due to industry growth. Estimate of number of organic imports coming into the United States in 2020: 80,109. Data Source: USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS). Select: Partners, World Total, Product Type, Imports - General, Products: All Aggregates; Product Groups: Organic - Selected: https://apps.fas.usda.gov/gats/default.aspx . AMS estimates 30 minutes for certifiers to work with their foreign based operations to prepare the NOP Import Certificate (Form NOP 2110-1) for 8% of 80,109 annual shipments.	ADJ
	USDA Accredited Foreign Based Certifying Agents with 92% of foreign operations certified under USDA	15,415.29	18425.07	3,009.78	Change in burden due to industry growth. Estimate of number of organic imports coming into the United States in 2020: 80,109. Data Source: USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS). Select: Partners, World Total, Product Type, Imports - General, Products: All Aggregates; Product Groups: Organic - Selected: https://apps.fas.usda.gov/gats/default.aspx . AMS estimates 30 minutes for foreign-based USDA certifiers to work with their foreign based operations to prepare the NOP Import Certificate (Form NOP 2110-1) for 46% of 80,109 annual shipments.	ADJ
	Foreign Accredited Foreign Based Certifying Agents with foreign operations that export to the U.S.	15,415.29	18425.07	3,009.78	Change in burden due to industry growth. Estimate of number of organic imports coming into the United States in 2020: 80,109. Data Source: USDA Foreign Agricultural Service (FAS) Global Agricultural Trade System (GATS). Select: Partners, World Total, Product Type, Imports - General, Products: All Aggregates; Product Groups: Organic - Selected: https://apps.fas.usda.gov/gats/default.aspx . AMS estimates 30 minutes for foreign accredited certifiers to work with their foreign based operations to prepare the NOP Import Certificate (Form NOP 2110-1) for 46% of 80,109 annual shipments.	ADJ
205.403(a)(3)	Inspectors - unannounced inspections conducted on 5% of operations - 50% of those will count as full complete annual inspections. 50% are partial inspections focused on following up on specific concerns, so they are over and above the annual inspection. These unannounced inspections include the new requirement for trace back and mass balance audits. The inspections are calculated to take half the time as would be required of a full inspection.	5835.25	6340.97	505.72	Change due to industry growth	ADJ
205.501 (a)(4)-(a)(6)	New inspectors (14% of current inspectors - assumes an equal loss of inspectors due to BLS separation rates) must have 40 hours of additional training their first year. Certifiers are already offering at least 10 hours, so new burden hours are 40. Calculated as five (5) 8 hour trainings	2500	1400.00	-1,100.00	Burden is reduced to a tiered training requirements targeting new inspectors.	ADJ

205.511 (a)-(e)	<p>Recognition and Equivalence of foreign governments: AMS establishes arrangements with foreign governments accrediting their certifying agents to facilitate the international trade of organic products per 205.500(c)-(d) and shall conduct peer reviews of each trade arrangement periodically to verify that the foreign government's technical requirements and conformity assessment system, as applicable, continue to be at least equivalent to the requirements of the Act, and will determine whether the arrangement should be continued. Recognition and Equivalence of foreign governments: AMS establishes arrangements with foreign governments accrediting their certifying agents to facilitate the international trade of organic products per 205.500(c)-(d) and shall conduct peer reviews of each trade arrangement periodically to verify that the foreign government's technical requirements and conformity assessment system, as applicable, continue to be at least equivalent to the requirements of the Act, and will determine whether the arrangement should be continued. Estimating one foreign government peer review per year.</p>	480.00	60.00	-420.00	<p>Burden is reduced because AMS is estimating the review of one foreign government peer review per year, not all will be reviewed in a single year.</p>	ADJ
205.511 (a)-(e)	<p>Recognition and Equivalence of foreign governments: AMS establishes arrangements with foreign governments accrediting their certifying agents to facilitate the international trade of organic products per 205.500(c)-(d) and shall conduct peer reviews of each trade arrangement on a two-year cycle, beginning at the close of the prior review, to assess the effectiveness of the other government's organic control system. AMS will reassess arrangements every five years to verify that the foreign government's technical requirements and conformity assessment system, as applicable, continue to be at least equivalent to the requirements of the Act, and will determine whether the arrangement should be continued. All foreign governments with whom we have trade arrangements need to maintain records</p>	80.00	80.00	0.00	<p>No change in burden</p>	
TOTAL		266,599.80	364494.69	88,999.64		