

2018 Justification for Change #0581-0191 Q15 Breakout

SUMMARY OF 2017 INFORMATION COLLECTION - Currently Approved (Subparts C - F) Organic System Plan (OSP)			SUMMARY OF 2017 INFORMATION COLLECTION - Revised Burden (Subparts C - F)			
REGS	REG Text	Previously Approved Burden	REGS	REG Text	New Burden & Format	Difference Between New and Previous Burden Type of Change
Subpart C - Production & Handling -- Operators submit initial application or update existing Organic System Plan (OSP)			Subpart C & E - Production & Handling -- Operators submit initial application or update existing Organic System Plan (OSP)			
205.201(a)(1) - (6), 205.400(b), 205.401d, 205.406(a)(1)(i) 205.406(a)(3)	Initial Application: Operators applying for organic certification for the first time 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.	56,800.00	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. Consolidated all Organic System Plan regs for operations applying for certification for the first time attributed with corrected hours.	152,000.00	95,200.00 ADJ
205.201(a)(1) - (6), 205.400(b), 205.401d, 205.406(a)(1)(i) 205.406(a)(3)	Annual Update: Certified operators update lists of 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.	1,286,500.00	205.201(a)(1) - (6), 205.400(b), 205.401d, 205.406(a)(1)(i) 205.406(a)(3)	Annual Update: Operators update lists of 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. Consolidated all Organic System Plan regs for certified operations updating their OSPs annually with corrected hours	1,240,000.00	-46,500.00 ADJ
			Below items are consolidated into the above Subpart C - Production & Handling -- Operators submit initial application or update existing Organic System Plan (OSP)			
205.400(b) 205.406(a)(1)(i), 205.201(a)(1)	Operators list practices & procedures to be performed & maintained (application) Inc.in respondents and hrs per response	32,300.00		Consolidated into above burden for all all new applicants for organic certification with corrected hours	0.00	ADJ
205.201(a)(1)	Operators practices & procedures to be performed & maintained (update). Incr. in hours per response	527,000.00		Consolidated into above burden for all certified operations updating their OSP's annually with corrected hours	0.00	ADJ
205.201(a)(2)	Operators list substances used (application). Inc.in respondents	3,800.00		Consolidated into above burden for all all new applicants for organic certification with corrected hours	0.00	ADJ
205.201(a)(2)	Operators list substances used (update) Inc.in respondents	124,000.00		Consolidated into above burden for all certified operations updating their OSP's annually with corrected hours	0.00	ADJ
205.201(a)(3)	Operators list monitoring practices & procedures to be performed & maintained (application). Inc.in respondents	7,600.00		Consolidated into above burden for all all new applicants for organic certification with corrected hours	0.00	ADJ
205.201(a)(3)	Operators list monitoring practices & procedures performed & maintained (update) Inc.in respondents	217,000.00		Consolidated into above burden for all certified operations updating their OSP's annually with corrected hours	0.00	ADJ
205.201(a)(4)	Operators describe recordkeeping system implemented to comply with 205.103 (initial) Inc.in respondents	3800.00		Consolidated into above burden for all all new applicants for organic certification with corrected hours	0.00	ADJ
205.201(a)(4)	Operators describe recordkeeping system implemented to comply with 205.103 (update) Inc.in respondents	124,000.00		Consolidated into above burden for all certified operations updating their OSP's annually with corrected hours	0.00	ADJ
205.201(a)(5)	Operators list practices & procedures to prevent commingling & contact with prohibited substances (initial). Inc.in respondents	3,800.00		Consolidated into above burden for all all new applicants for organic certification with corrected hours	0.00	ADJ
205.201(a)(5)	Operators list practices & procedures to prevent commingling & contact with prohibited substances (update) Inc.in respondents	124,000.00		Consolidated into above burden for all certified operations updating their OSP's annually with corrected hours	0.00	ADJ
205.201(a)(6)	Operators provide additional information as necessary (initial) Inc.in respondents	3,800.00		Consolidated into above burden for all all new applicants for organic certification with corrected hours	0.00	ADJ
205.201(a)(6)	Operators provide additional information as necessary (update) Inc.in respondents	124,000.00		Consolidated into above burden for all certified operations updating their OSP's annually with corrected hours	0.00	ADJ
Subpart D - Labels and Labeling			Subpart D - Labels and Labeling			

205.303- 205.311	Certified handlers for food design labels in accordance with requirements for products to be labeled. Inc.in respondents	2,626,800.00	205.303- 205.311	Certified handlers, including livestock feed handlers, design labels in accordance with requirements for products to be labeled. Changed to reflect labeling design attributed to organic compliance only - not the entire label design process which is already responsive to FDA and other USDA rules	526,360.00	-2,101,440.00	ADJ
205.306	livestock feed handlers design labels in accordance with requirements for products to be labeled	1,000.00					
Subpart E - Appli. for Cert. of Operations Annual Update as Appropriate							
			Below items are consolidated into the above Subpart C & E - Production & Handling -- Operators submit initial application or update existing Organic System Plan (OSP)				
205.406(a)(2), 205.401(b)	Operators submit names, business names, addresses, & phone numbers of cert. applicants & persons authorized to act on appli. behalf. Inc.in respondents (All)	15,500.00		Function is part of both Initial application and update so consolidated and corrected into Intial & Update above	0.00		ADJ
205.401d 205.406(a)(3)	Operators submit other information as needed for certification, annual (initial). Inc.in respondents	1,700.00		Consolidated into above burden for all all new applicants for organic certification with corrected hours	0.00		ADJ
205.401(d) 205.406(a)(3)	Operators submit other information as needed for certification (update) Inc.in respondents	31,000.00		Consolidated into above burden for all certified operations updating their OSP's annually with corrected hours	0.00		ADJ
Review of Application			Review of Application				
205.402	Agents review applications; communicate findings; sched. on-site inspec. Decr. in respondents	141252.00	205.402, 205.402(b) (2)	Agents review applications; communicate findings; sched. on-site inspec. ; Corrected to reflect the annual application review and update processing of the paperwork of 100% operations annually. The 141,252 hours for certifying agent desk review of new organic applications and annual updates received from operations were inaccurately calculated at 75% of total operations when it should have been 100%. In addition, these certifying agent reporting hours were calculated with the total reporting hours of operations' incorrectly in previously reported burden.	205,400.00	58,262.50	ADJ
205.402(b)(2)	Agents provide copy of on-site inspec. reports. Dec. in respondents	5,885.50		Consolidated into above and corrected to reflect the inspection of 100% of operations annually	0.00		ADJ
205.403 205.406(b)	Inspectors provide on-site inspection reports to certifying agent, (annual). Inc. in respondents	267,500.00	205.403 205.406(b)	Inspectors provide on-site inspection reports to certifying agent, (annual). Corrected to reflect the inspection of 100% of operations annually	329,000.00	61,500.00	ADJ
205.404(b), 205.406(d)	Agents issue certificates of operation; annual & updated certificates. Decr. in respondents	11,755.20	205.404(b), 205.406(d)	Agents issue certificates of operation; annual & updated certificates. Corrected to reflect the inspection of 100% of operations annually	16,450.00	4,694.80	ADJ
Denial of Certification of Operators			Denial of Certification of Operators				
205.405(c)(1)(ii)	Agents deny certification when applicants noncompliance is not corrected; notification of applicants rights. Dec. in respondents.	19.75	205.405(c)(1)(ii) 205.405(c)(2)	Agents deny certification when applicants noncompliance is not corrected or if applicants fail to respond. Notification of applicants rights. Consolidated with below and corrected to all certifying agents	79.00	39.50	ADJ
205.405(c)(2)	Agents deny certification if applicants fail to respond. Dec. in respondents.	19.75	205.405(c)(2)	Consolidated with above and corrected to all certifying agents	0.00		ADJ
Subpart F - Accreditation of Certifying Agents			Subpart F - Accreditation of Certifying Agents Application, Evidence of Expertise, and Annual Updates				
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	4,684.50	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	4,740.00	55.50	ADJ
			Below items are consolidated into the above Subpart F - Accreditation of Certifying Agents Application, Evidence of Expertise, and Annual Updates				
205.501(a)(2) & (a) (3)	Agents demonstrate ability to comply with & implement requirmts. for accreditation. Dec. in respondents.	790.00			0.00		ADJ

205.501(a)(4), 205.501(a)(6)	Agents conduct & provide results of performance evaluations of inspectors & other personnel Dec. in respondents.	1,264.00		0.00			ADJ
205.501(a)(7)	Agents have prog. Evaluations conducted of certification activities (annual). Dec. in respondents.	632.00		0.00			ADJ
205.501(a)(11)(v) 205.504(c)(2)	Agents provide procedures to prevent conflict of interes & req. emp. To complete conflict of interest disclosure repts. (annual) Dec. in respondents.	197.50		0.00			ADJ
205.501(a)(15)(ii) 205.504(d)(1)	Agents provide & send lists of currently certified operations w/application (annual) Dec. in respondents.	158.00		0.00			ADJ
205.501(a)(21)	Agents comply with other terms & conditions. Decrease in respondents; inc. in responses per respondent; inc. in response time	632.00		0.00			ADJ
205.503(a), 205.510(a)(1-2)	Agents provide info about their primary location. Dec. in respondents. TM-10CG	19.75		0.00			ADJ
205.503(b)	Agents provide info about their organization units. Dec. in respondents.	79.00		0.00			ADJ
205.503(c), 205.501(a)(15), 205.642	Agents identify areas of certification (crops, livestock, handling) & file certification fee sched. w/Secretary. Dec. in respondents.	79.00		0.00			ADJ
205.503(d)(1)	State agents document their official authority	4.00		0.00			ADJ
205.503(d)(2)	Private agents identify their organizational purpose. Dec. in respondents.	19.50		0.00			ADJ
205.503(e)	Agents list States/foreign countries where they operate or intend to operate. Dec. in respondents.	19.75		0.00			ADJ
	Evidence of Expertise and Ability						ADJ
205.504(a)(1)	Agents list personnel policies & procedures. Dec. in respondents.	39.50		0.00			ADJ
205.504(a)(2)	Agents list names & position descriptions of personnel they intend to use. Dec. in respondents.	79.00		0.00			ADJ
205.504(a)(3)	Agents list qualifications of insp. & emp. Who review/evaluate applications. Dec. in respondents.	79.00		0.00			ADJ
205.504(a)(4)	Agents list training provided to personnel. Dec. in respondents.	158.00		0.00			ADJ
205.504(b)(1)	Agents provide procedures to evaluate applicants, make decisions, issue certificates. Dec. in respondents.	79.00		0.00			ADJ
205.504(b)(2)	Agents provide procedures to rev. compliance & report violations. Dec. in respondents.	39.50		0.00			ADJ
205.504(b)(3)	Agents provide procedures to comply w/recordkeeping requirements. Dec. in respondents.	39.50		0.00			ADJ
205.504(b)(4)	Agents provide procedures to maintain confidentiality. Dec. in respondents.	39.50		0.00			ADJ
205.504(b)(5)	Agents provide procedures to make inf. Available to the public & provide the info. Dec. in respondents.	79.00		0.00			ADJ
205.504(b)(6)	Agents provide procedures to sample & do residue testing. Dec. in respondents.	39.50		0.00			ADJ
205.504(c)(1)	Agents provide procedures to prevent conflicts of interest. Dec. in respondents.	39.50		0.00			ADJ
205.504(e)	agents provide other info they feel will assist in evaluating application. Dec. in respondents.	79.00		0.00			ADJ
205.501(a)(18)	Agents notify insp. Of certifying agents decision - granting or denying certification of operation that an inspector evaluated. Dec. in respondents.	3,950.00	205.501(a)(18)	Agents notify inspectors of 100% of certifying agents decisions - granting or denying certification of operation that an inspector evaluated. Corrected to reflect the inspection of 100% of operations annually	8,225.00	4,275.00	ADJ
205.504(d)(2)	Agents provide inspec. Repts. & evaluation documents for operations certified - prev. yr. Dec. In respondents	23510.40	205.504(d)(2)	Agents provide inspec. Repts. & evaluation documents for operations certified. Agents only provide examples of 3 inspection reports each year, not all operations.	237.00	-23,273.40	ADJ

Export Certificates			Import/Export Certificates				
205.505(b)	private agents provide additional assurances with statements of agreement. Dec. in respondents..	19.50	205.505(b)	private agents provide additional assurances with statements of agreement. Corrected so calculation is based on the number of private agents that are not state programs	15.75	-3.75	ADJ
205.621(c)	State Programs: States submit revised or amended State organic certification program to the Secretary.	15.00	205.621(c)	State Programs: States submit revised or amended State organic certification program to the Secretary. Corrected for actual number of state programs	16.00	1.00	ADJ
205.670(d)	Testing State officials or agents submit results of residue testing to Administrator or Governing State officials	150.00	205.670(d-e))	Testing State officials or agents submit results of residue testing to Administrator or Governing State officials	296.25	-150.00	ADJ
205.670 (e)	State officials or agents submit lab results to residue testing to the AMS Administrator or Governing State Officials	296.25		Corrected duplicate interpretation of regulations & Consolidated into above	0		ADJ
TOTAL		4430157.85	TOTAL		2,482,819.00	-1,947,338.85	