2013 SUPPORTING STATEMENT
FOR
NATIONAL ORGANIC PROGRAM
REPORTING AND RECORDKEEPING REQUIREMENTS

OMB NO. 0581-0191

A. Justification

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

The Organic Foods Production Act of 1990 (OFPA) as amended (7 U.S.C. 6501 - 6522) mandates that the Secretary develop a National Organic Program (NOP) to accredit eligible State program's governing State officials or private persons as certifying agents who would certify producers or handlers of agricultural products that have been produced using organic methods as provided for in OFPA. As mandated by the OFPA § 6501, the purposes of the NOP regulations are: (1) to establish national standards governing the marketing of certain agricultural products as organically produced products; (2) to assure consumers that organically produced products meet a consistent standard; and (3) to facilitate interstate commerce in fresh and processed food that is organically produced.

The NOP regulation (7 CFR Part 205) fulfills the requirements of the OFPA. It includes comprehensive production and handling standards, labeling provisions, requirements for the certification of producers and handlers, accreditation of certifying agents by USDA, and an administrative subpart for fees, State Programs, National List, appeals, compliance, and pesticide residue testing.

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

Certifying agents, who want to be accredited by USDA to certify organic production and handling operations, will have to submit an application to USDA. Auditors will review the application, perform a site evaluation, and submit reports to USDA. The USDA will make a decision to grant or deny accreditation. Annually, accredited agents have to submit an update of their operations to USDA. Agents also are to notify certified operations, USDA or State officials when they observe noncompliance to the regulations.

Producers, handlers, and certifying agents whose operations are not approved

have the right to mediation and appeal of the decision. This also requires extensive paperwork. Finally, the producers and handlers will store their certification records for 5 years, and certifying agents will store records they create for operators' certification for 10 years, records received from operators for 5 years, and accreditation records for 3 years.

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

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

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

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

States. Upon approval by the Secretary, a State Program's governing State official may operate a State Organic Program with requirements that exceed the NOP. To obtain the Secretary's approval, a State Program's governing State official will have to submit a proposed program that includes statutory authorities, program description, a statement of acceptance of the general requirements for organic programs, and other information required by the Secretary. Any proposed amendments to an existing program also will have to be submitted. If the Secretary does not approve the State program or proposed amendment, a State Program's governing State official may submit revisions. Sections 205.621(a) and 205.621(c) are the sections with reporting requirements for State Organic Programs.

Approved State Organic Programs will have some compliance requirements. States will have to report the findings of non-compliance to the NOP Program Manger and submit results of residue testing to the appropriate officials. These requirements are in §§ 205.668(c) and 205.670(d).

Accredited Certifying Agents. Certifying agents are State government, private, or foreign entities who are accredited by USDA to certify domestic and foreign producers and handlers as organic in accordance with the OFPA and NOP. The regulation imposes a paperwork burden upon certifying agents for certification activities as well as for obtaining USDA accreditation. To become accredited, an agent will have to submit an application to USDA demonstrating that it has policies and procedures in place to perform accurate and impartial certifications.

The following list describes the most significant documents a certifying agent will have to submit for accreditation.

1. A copy of procedures used for making certification decisions, complying with recordkeeping requirements, maintaining confidentiality of client's business-related information, preventing conflicts of interest, sampling and residue testing, training and supervising personnel, and public disclosure of prescribed information concerning operations they have certified and laboratory analyses. Certifying agents may have to create these policies or modify existing policies to conform to the regulation.

2. Documentation on the qualifications of all personnel used in the certification operation, annual performance appraisals for each inspector and personnel involved in the certification, and an annual internal program evaluation. Existing certifying agents may already perform these operations. New certifying agents will have to establish procedures.

3. Documentation on the financial capacity and compliance with other administrative requirements (e.g., fee structure, reasonable security to protect the rights of the certifying agent's clients as provided in the NOP, and business relationships showing absence of conflicts of interest). Some of this information can be compiled from existing records and some may be generated from other sources.

4. An annual report to the Administrator including an update of previously submitted business information, information supporting any requested changes in the areas of accreditation, and steps taken to respond to previously identified concerns of the Administrator regarding the certifying agent's suitability for continued accreditation. The annual report requirement will draw on records created in the normal course of business.

5. A list of producers, wild-crop harvesters, and handlers currently certified. This information can be compiled from existing records. Certifying agents are required to submit annually a list of certified operations.

6. Program information to help certification applicants comply with the regulation. To comply with this requirement, certifying agents may need to modify existing standards and practices.

7. Retention of records created by the certifying agent regarding applicants and certified operations for not less than 10-years, retention of records obtained from applicants and certified operations for not less than 5-years, and retention of other records created or received for USDA accreditation for not less than 3 years. This activity requires records, database management capabilities, and resources (storage space, file cabinets, electronic storage, etc.). In an informal inquiry, AMS found that most existing certifying agents currently retain records for at least 10 years and use both

electronic and paper storage.

8. Issue recommendations that the NOP issue a temporary variance and notify certified operations that would be affected.

9. Submit residue test results to USDA or a Governing State Official. When tests exceed regulatory tolerances, agents will have to notify the appropriate health agencies.

Sections 205.290, 205.501, 205.503, 205.504, 205.505, 205.507 and 205.510 contain the reporting requirements. Testing report requirements are in §§ 205.670 and 205.671.

Accredited agents will determine if a producer or handler is eligible for certification by using detailed information from the operation documenting its specific practices and on-site reports from organic inspectors. The following list describes the most significant activities a certifying agent will have to perform to comply with certification requirements. Certifiers routinely perform these activities. New certifying agents will have to establish procedures.

1. Review applications from producers and handlers for completeness and viability, communicating findings to the applicant, and if appropriated scheduling on-site inspections. The application will include general business information and the Organic System Plan.

2. Provide on-site inspection reports from the previous year and any test results to the inspector.

3. Issue a certificate, if appropriate, after making a decision to certify an operator.

4. Provide written notification to operators of noncompliance when certification is denied, approving corrective actions, and issuing a certificate.

5. Notify applicant if the corrective actions are not sufficient.

6. Submit copies to USDA of all notices that are issued on certification approval, denial, noncompliance, and suspension or revocation of certification. This requirement will be fulfilled simultaneously with sending notices to applicants or clients.

Sections that contain reporting burden include 205.400 - 205.406. The compliance requirements are in §§ 205.642, 205.663, 205.665, and 205.668.

Organic Inspectors. Inspectors are employees of certifying agents or independent contractors that they employ. They conduct on-site inspections of each applicant for certification and annual inspections of each certified operation, and provide a report of their findings to the certifying agent. The inspection is a significant factor in determining whether or not certification should continue. Section § 205.403 is the rule section that requires an inspection report.

Producers and handlers. Producers and handlers will have to determine whether they have to be certified, or if they are exempt or excluded from certification. Producers include farmers, livestock and poultry producers, and wild crop harvesters. Handlers include millers, bulk distributors, food manufacturers, processors, repackagers, or packers. Some handlers may be part of a retail operation that processes organic products in a location other than the premises of the retail outlet. Certified operations include producers or handlers that produce or handle crops, livestock, livestock products, or other

agricultural products that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients)” .

Operations exempt from certification include (1) producers and handlers whose gross agricultural income from organic sales totals $5,000 or less annually; (2) handling operations that are retail food establishments that handle organically produced agricultural products but does not process them, (3) handlers handling agricultural products that contain less than 70 percent organic ingredients by total weight of the finished product; and (4) handlers that handle agricultural products that contain at least 70 percent organic ingredients and choose to use the word "organic" only on the information panel of a packaged product. Exempt operations, described in § 205.101, will be required to maintain records for 3 years to verify that their operations meet the requirements for exemption. This specific recordkeeping requirement is in § 205.101(c).

Operations excluded from certification include: (1) handlers selling only agricultural products labeled as “100% organic” “organic” or “made with organic ingredients” that are enclosed in a container prior to being received, remain in the same container, and are not otherwise processed while in the control of the operation, (2) retail food establishments that process on the premises raw and ready-to-eat food from products that are previously labeled “100% organic”, “organic” or “made with organic ingredients”. Excluded operations, also described in § 205.101, are not subject to a recordkeeping requirement.

Producers and handlers, domestic and foreign, who seek certification or renewal of certification, will apply for certification to certifying agents. The application will provide agents with detailed information documenting compliance with the regulations including basic business information and an Organic System Plan (OSP) (§ 205.201). Producers and handlers will be required to update their OSP annually. The regulation § 205.401 requires an application and § 205.406 requires an annual update. Section 205.103 requires certified operators to maintain their records for 5 years.

Handlers, including exempt operations, must meet labeling requirements**.** The rule imposes a paperwork burden for an estimate of the time needed to develop labels for products sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" according to the labeling requirements for each category. Handlers will also have to design labels and decide about using the USDA seal, a State emblem, or the seal, logo, or other identifying marks of a private certifying agent. These requirements can be found in §§ 205.300 - 205.311.

Interested parties. Any interested party may petition the NOSB for the purpose of having a substance evaluated for recommendation to the Secretary for inclusion on or deletion from the National List. The reporting burden for petitioning a new substance is derived from requirements found in § 205.607.

Organic ruminant producers. Under the NOP (§ 205.103) each producer of organic ruminant livestock is required to maintain and make available upon request, for 5 years, such records as are necessary to verify compliance with the NOP. Under the final rule, monthly documentation of: (1) feed rations; (2) the daily dry matter demand of each animal; (3) how much dry matter is fed daily to each animal; and (4) the percentage

of dry matter fed daily would become a part of that recordkeeping system. These records will provide the best evidence of compliance with the requirement that for the growing season, producers of organic ruminants provide not more than an average of 70 percent of a ruminant's dry matter demand from dry matter fed. The recordkeeping burden includes the amount of time needed to store and maintain records.

This information collection is only used by the organic ruminant producer; authorized representative of USDA, including AMS, NOP staff; and USDA accredited certifying agents. Organic ruminant producers and USDA accredited certifying agents are the primary users of the information and AMS is the secondary user.

Since the last renewal in 2010, the NOP forms listed below have undergone a few cosmetic changes, such as titles, addresses, the separation of the Paperwork Reduction Act statement, and a distinction in the estimated time required to complete the information collection for an initial application and annual update.

Information is no longer collected in relation to the peer review panel requirements in section 205.509 and the National Organic Program intends to make a policy change to reflect that this requirement is being fulfilled by a different process.

a. **Application For Accreditation – TM-10CG**: This form is used by a private or governmental entity seeking accreditation as a certifying agent to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program established in §§ 205.100 and 205.101, §§ 205.201 through 205.203, §§ 205.300 through 205.303, §§ 205.400 through 406, and §§ 205.661 and 205.662; and its ability to comply with the requirements for accreditation set forth in § 205.501. For applicants for initial accreditation, we estimate this form to take 93.75 hours to complete, and 1 hour to renew for every year thereafter. This form is accessible via the internet at (http://www.ams.usda.gov/nop/CertifyingAgents/AccreditationApp.pdf), respondents can fill out this form on-line, print and sign it for submission to the NOP.

b. **Export Certificate – TM-11** This form is used by an authorized certifying agent to issue an export certificate when required under an export arrangement between the USDA and a foreign government. This form is accessible via the internet at http://www.ams.usda.gov/nop/NOP/TradeIssues/exportcertificate.pdf, respondents can fill out this form on-line, print and sign it for issuance.

c. **National Organic Program Import Certificate (NOP 2110-1)**. This form is used by EU designated certification entities for each shipment of organic product from the EU to the U.S. The NOP Import Certificate is necessary to document that the organic products were certified under the EU organic regulations and meets all the requirements specified in the EU – U.S. organic equivalency arrangement. This form is accessible via the internet at http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5098482, respondents can fill out this form on-line, print and sign it for issuance.

3. DESCRIBE WHETHER, AND TO WHAT EXTENT, THE COLLECTION OF INFORMATION INVOLVES THE USE OF AUTOMATED, ELECTRONIC, MECHANICAL, OR OTHER TECHNOLOGICAL COLLECTION

TECHNIQUES OR OTHER FORMS OF INFORMATION TECHNOLOGY, E.G. PERMITTING ELECTRONIC SUBMISSION OF RESPONSES, AND THE BASIS FOR THE DECISION FOR ADOPTING THIS MEANS OF COLLECTION. ALSO DESCRIBE ANY CONSIDERATION OF USING INFORMATION TECHNOLOGY TO REDUCE BURDEN.

The USDA encourages producers, handlers, and certifiers to use any electronic means available to them to create, submit and store records, including keeping database records of products produced on certified operations; maintaining lists of producers and handlers and their location; creating certification or training documents; maintaining business accounting records; and sending documents over the Internet. Research of the industry indicates that many certifiers use electronic data creation, storage and the Internet. Some producers and handlers use computers and word processors for their recordkeeping. Based on this information, we estimated that 25 percent of the collection of information could be performed by automated, electronic, mechanical, or other technological means.

Forms TM-10CG, TM-11, and NOP 2110-1 have been created in a PDF format allowing the respondent to fill out and print a copy from the internet for submission. The URL address for TM-10CG is: http://www.ams.usda.gov/nop/CertifyingAgents/AccreditationApp.pdf; TM-11 is http://www.ams.usda.gov/nop/NOP/TradeIssues/exportcertificate.pdf; and NOP 2110-1 is http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5098482. Minor housekeeping changes were made to the forms.

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

We have made every effort to contact appropriate sources within USDA, other government agencies, and outside sources to ensure that we are not duplicating information collection. Some of the requirements for organic production and handling, certification, accreditation, State Organic Programs, and petitions to add substances to the National List are unique to the organic industry. Other information such as names and addresses are routinely collected for income tax and other purposes. Some Federal and State programs may require operators to provide maps and other information contained in the organic plan. Internal management systems such as HACCP may require schematics of processing plants. It is impossible to determine the number of organic program participants who provide information that can be used on one or more instance.

We encourage participants in the NOP to reduce the paperwork burden by establishing business operating plans and procedures that incorporate the NOP requirements.

5. IF THE COLLECTION OF INFORMATION IMPACTS SMALL BUSINESSES OR OTHER SMALL ENTITIES (ITEM 5 OF THE OMB FORM 83-1), DESCRIBE THE METHODS USED TO MINIMIZE BURDEN.

The Regulatory Impact Analysis (RIA) and the Regulatory Flexibility Analysis (RFA) indicate that many of the businesses in the organic industry are small businesses. Several options have been explored and every effort has been made to mitigate any negative impacts caused by a reporting or recordkeeping burden.

The NOP has made every effort possible to secure information about the smallest segments of the industry, to provide open dialogue with them, to develop performance standards with a range of practices, and to accept the required documents in a reasonable, logical fashion.

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

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

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

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

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

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

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

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

The OFPA § 6511 (d)(1) requires that producers and handlers maintain records concerning the production and handling of agricultural products sold or labeled as organically produced for 5 years. OFPA § 6515 (c)(1) requires any certifying agent to maintain all records concerning its activities for a period of not less than 10 years.

The three categories of records with varying retention periods that are addressed in the NOP regulations are: (1) records created by certifying agents regarding applicants for certification and certified operations to be maintained 10 years; (2) records obtained from applicants for certification and certified operations to be maintained 5 years; and (3) other records created or received by certifying agents to be maintained 5 years.

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

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

- THAT INCLUDES A PLEDGE OF CONFIDENTIALITY THAT IS NOT SUPPORTED BY AUTHORITY ESTABLISHED IN STATUE OR REGULATION, THAT IS NOT SUPPORTED BY DISCLOSURE AND DATA SECURITY POLICIES THAT ARE CONSISTENT WITH THE PLEDGE, OR WHICH UNNECESSARILY IMPEDES SHARING OF DATA WITH OTHER AGENCIES FOR COMPATIBLE CONFIDENTIAL USE; OR

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

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

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

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

On Friday, June 28, 2013, a 60-day notice was published in the Federal Register (78 FR 38913) requesting an extension and a revision of a currently approved information collection and request for comments. AMS received seventy four comments regarding this information collection from certified operations and USDA Accredited Certifying Agents (certifiers), 52 of which contained substantive information. AMS requested comments regarding four specific questions discussed below.

1) Is the proposed collection of information necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility? A few commenters stated that the annual paperwork submitted to certifiers was duplicative and burdensome. The NOP supports certifiers, handlers and producers in their efforts to create, submit and store records electronically. The NOP has communicated to the ACAs and AMS auditors that electronic records are an acceptable form of recordkeeping and that the maintenance and provision of records in electronic format should be accommodated.

2) *What is 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?* Over 40 commenters stated that the NOP has underestimated the time for recordkeeping and reporting time and fee burdens. Upon review of the Federal Register Notice (78 FR 38913, June 28, 2013) that requested an extension of the NOP's currently approved information collection, the NOP discovered that the estimated number of annual burden hours for certifying agents, producers, and handlers to provide information was reported incorrectly. NOP agrees with these comments, however due to the wide variance in estimated burdens, NOP calculated the median of these estimates and made adjustments as appropriate as follows:

- Annual record-keeping hours are estimated at 80 hours.
- Annual burden hours for producers and handlers to submit annual updates under the NOP regulations are estimated at 40 hours.
- Annual burden hours for certifiers to review applications for certification are estimated at 6 hours.
- Annual burden hours for on-site inspections and the writing of inspection reports are estimated at 10 hours.
- Annual burden hours for certifiers to submit annual reports to NOP are estimated at 9 hours.
- Annual burden hours for petitioners to submit petitions to amend the National List are estimated at 30 hours.

These numbers are more aligned to the estimated burden hours suggested by commenters.

3) *Ways to enhance the quality, utility and clarity of the information to be collected?* One commenter, the International Organic Inspectors Association (IOIA),

stated that there is a wide range in inspection reporting requirements between certifiers. IOIA stated that the resulting time spent writing reports is widely variable. This statement is supported by the 14 comments submitted by inspectors in response to this collection. NOP understands that the expense for the time writing reports can be partially or fully born by the operation, however while NOP may provide guidance to certifiers for the establishment of uniform qualification requirements for inspectors; certifiers are responsible for establishing the format and method of submission for inspection reports. NOP has provided written communication to all ACAs and AMS auditors that electronic records are acceptable.

4) *Ways to minimize the burden of the collection of information on those who are to respond, including the appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology?* Several commenters suggested that forms required to continue certification such as organic system plans updates are repetitive and could be condensed. Some commenters stated that their certifiers are switching to electronic OSP and inspection report submission and that they either have experienced or expect to see a reduction in time spent submitting required paperwork. NOP has provided written communication to all ACAs and AMS auditors that electronic records are acceptable.

DESCRIBE EFFORTS TO CONSULT WITH PERSONS OUTSIDE THE AGENCY TO OBTAIN THEIR VIEWS ON THE AVAILABILITY OF DATA, FREQUENCY OF COLLECTION, THE CLARITY OF INSTRUCTIONS AND RECORDKEEPING, DISCLOSURE, OR REPORTING FORMAT (IF ANY), AND ON THE DATA ELEMENTS TO BE RECORDED, DISCLOSED, OR REPORTED.

The AMS maintains a working relationship with affected regulatory agencies to ensure compliances with existing laws and regulations. The National Organic Standards Board hold public meetings to discuss and make recommendations to the Secretary on materials to be added or deleted from the National List of Allowed and Prohibited Substances, and also to receive public comment on issues of concern to the industry.

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

The regulation is a synthesis of existing organic standards and certification programs. We have done extensive outreach to the industry including meetings of the NOSB with public input at each meeting; yearly certifier training to discuss accreditation

issues; attendance of NOP staff members at organic inspector meetings; and numerous speaking engagements of the NOP staff to discuss specific issues surrounding organic production, handling, inspection, and certification. In addition, we have worked closely with affected regulatory agencies to ensure compliance with existing laws and regulations.

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

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

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

Evaluators reviewing private certifiers' confidential records would be Federal employees representing the USDA. The OFPA § 6515 (g) states "that any certifying agent shall maintain strict confidentiality with respect to its clients under the applicable organic certification program and may not disclose to third parties (with the exception of the Secretary or the applicable State Program's governing State official) any business related information concerning such client obtained while implementing this chapter." Section 205.504 (b)(4) of the rule further states that a private certifying agent shall establish policies for protecting the confidentiality of client records. In addition to those provisions, the National List petition procedures, published in the Federal Register on January 18, 2007 (72 FR 2167), provides instructions for submitting Confidential Business Information.

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

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

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

INFORMATION.

Estimates of the hour burden of collection of information have been summarized on the enclosed AMS Form 71.

ESTIMATED ANNUALIZED COST TO RESPONDENTS FOR THE HOUR BURDENS FOR COLLECTIONS OF INFORMATION USING APPROPRIATE WAGE RATE CATEGORIES.

Estimates for the burden of collecting information have been summarized in the AMS-71. The respondents' estimated annual cost in providing the information is $141,236,172. This total has been estimated by multiplying the 3,923,227 burden hours incurred by certified and exempt producers and handlers by $36, the mean hourly rate (Bureau of Labor Statistics http://www.bls.gov/oes/current/oes119013.htm).

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

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

- **IF COST ESTIMATES ARE EXPECTED TO VARY WIDELY, AGENCIES SHOULD PRESENT RANGES OF COST BURDENS AND EXPLAIN THE REASONS FOR THE VARIANCE. THE COST OF PURCHASING OR CONTRACTING OUT INFORMATION COLLECTION SERVICES SHOULD BE A PART OF THIS COST BURDEN ESTIMATE. IN DEVELOPING COST BURDEN ESTIMATES, AGENCIES MAY CONSULT WITH A SAMPLE OF**

RESPONDENTS (FEWER THAN 10), UTILIZE THE 60-DAY PRE-OMB SUBMISSION PUBLIC COMMENT PROCESS AND USE EXISTING ECONOMIC OR REGULATORY IMPACT ANALYSIS ASSOCIATED WITH THE RULEMAKING CONTAINING THE INFORMATION COLLECTION, AS APPROPRIATE.

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

(a) Capital and Start-up Costs

There are no capital and start-up costs.

(b) Total Operation and Maintenance Costs for each Certifying Agent

Filing cabinets and storage	1,500.00
Supplies (paper)	750.00
Postage	1,500.00
Telephone	400.00
	$4,150.00

(c) The operation and maintenance costs are based on our best estimate of the additional expenses a certifying agent might incur as a result of compliance with the OFPA and the regulations.

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

We estimate the annual cost to operate the NOP at approximately $6.9 million. These costs include salaries and benefits; travel and transportation; rent, communications, utilities; printing; contractual services; supplies; and equipment. The NOP currently operates on appropriated funds.

15. EXPLAIN THE REASON FOR ANY PROGRAM CHANGES OR ADJUSTMENTS REPORTED IN ITEMS 13 OR 14 OF THE OMB FORM 83-1.

There is an overall increase of 2,595,625 burden hours from the last submission. This adjustment increase is in the reporting and recordkeeping burden due to comments received.

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

No publication of data obtained through the regulation is planned.

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

The Agency requests approval not to display the expiration date for OMB approval of the information collection. This requirement significantly affects mandatory programs by having to destroy otherwise usable forms when the date expires. Such needless actions are counter-productive to the Administration's goal of increasing program efficiency, as well as the effect that an expiration date could have on the Agency. The impact of the expiration date requirement on administrative and regulatory forms for the programs can adversely affect the operation and enforcement of statutes. Inadvertent use of a form with an expired expiration date poses an opportunity for those looking for a means of disruption to challenge paying for services rendered, the validity of the collection of information, or legal requirement imposed by regulations or statutes.

There is also some confusion by respondents thinking their annual applications are good for the length of time noted in the expiration date rather than expiring at the end of the application period. Therefore, we are seeking approval to not display the OMB expiration date on these forms.

18. EXPLAIN EACH EXCEPTION TO THE CERTIFICATION STATEMENT IDENTIFIED IN ITEM 19, "CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS," OF OMB FORM 83-1.

This information collection does not employ statistical methods.