

**2007 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 (OFPA) of 1990, Title XXI of the Food, Agriculture, Conservation and Trade Act of 1990 (Farm Bill), U.S.C. Title 7 Section 6503 (a), mandates that the Secretary of Agriculture develop a national organic program. In general, the Secretary shall establish an organic certification program for producers and handlers of agricultural products that have been produced using organic methods as provided for in the OFPA. In addition, the OFPA § 6514 requires the Secretary to establish and implement a program to accredit a State Program's governing State official or any private person, who meets the requirements of the OFPA and the regulations, as a certifying agent for the purpose of certifying a production or handling operation as being in compliance with the standards set out in the rule. As mandated by the OFPA § 6501, the purposes of the 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 National Organic Program (NOP) regulation (7CFR 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 back to the certifying agent. The 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 will 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. And, a Peer Review Panel will be established to review USDA's accreditation of certifying agents and compliance with the accreditation guidelines.

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 the OFPA. They serve the Agency mission, program objectives, and management needs in providing information on the efficiency and effectiveness of the program. The information will be used as a basis for evaluating compliance with the OFPA and the regulations, for administering the program, for management decisions and planning, and for establishing the cost of the program. It will also support administrative and regulatory actions in response to non-compliance with the OFPA and the regulations.

In general, the information will be used by USDA, State Program's governing State officials, and certifying agents. It will be created and submitted by State Organic

Program officials, accredited certifying agents, organic inspectors, certified organic producers and handlers, those seeking accreditation or certification, peer review panel members, and parties interested in changing the National List. Additionally, it will necessitate that most 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 sections 205.668 (c) and 205.670 (d).

Estimates: 2 States will operate a State Organic Program. The annual federal paperwork burden for each State to administer the program is estimated to be 55 hours. Calculated at the rate of \$32 per hour, the average estimated cost to each State Organic Program would be \$1,760.

Peer Review Panels. The Peer Review Panel, functions as an unpaid, advisory committee to the Administrator, and consists of three members, each serving a three-year term. Their role will be to annually evaluate the NOP's performance in accreditation decisions and on their adherence to International Organization of Standardization (ISO) guide 61 principles. The panel will present their findings to the Secretary in a report. Section 205.509 addresses the peer review panel report. Estimates: The annual burden for each member of the panel to review documents and create the report is estimated at 4 hours. Calculated at the rate of \$35 per hour, the average estimated cost to each Peer Review Panel member would be \$140.

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 farmers, 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. This would be a new activity for all certifying agents.

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. This would be a new activity for most certifying agents.

Sections 205.290, 205.501, 205.503, 205.504, 205.505, 205.507, 205.509 and 205.510 contain the reporting requirements. Testing report requirements are in sections 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. Existing certifiers routinely perform these activities, except for notifying USDA. 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 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 sections 205.642, 205.663, 205.665, and 205.668.

Estimates: Currently, 95 certifying agents (2 state programs, 53 private entities, and 40 foreign entities). We have estimated that the annual federal paperwork burden is expected to be 1,708 hours, or if calculated at the rate of \$32 per hour, it would be \$54,656 per agent.

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.

Estimates: 293 inspectors will be used. The annual burden for each inspector to prepare required on-site inspection reports for 55 operations will be 218 hours, or if calculated at \$32 per hour, it would be \$6,976.

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 Plan (§ 205.201). Producers and handlers will be required to update their application 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 sections 205.300 - 205.311. Estimates: 19,400 total organic operators (14,253 certified and 5,147 exempt), including 17,150 producers (12,176 certified and 4,974 exempt) and 2,250 handlers (1,977 certified and 273 exempt). We do not have an estimate of the number of foreign producers and handlers that will apply for organic certification. The annual paperwork burden for certification of each domestic producer and handler will be 27 hours, or if calculated at \$32 per hour, \$864. Certified handlers will have an additional burden of 35 hours for labeling requirements, or if calculated at \$32 per hour, \$1,120. Exempt producers and handlers will have a burden of 1 hour, or \$32, for record keeping. Exempt handlers will have an additional burden of 5 hours, or if calculated at \$32 per hour, \$160.

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 section 205.607. Estimates: 25 interested parties may petition the NOSB. The estimated annual burden for each interested party will be an average of 10 hours or if calculated at \$35 per hour, it will be \$350.

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; 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 10 percent of the collection of information could be performed by automated, electronic, mechanical, or other technological means.

Forms TM-10CG and TM-11 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>; and TM-11 is

<http://www.ams.usda.gov/nop/NOP/TradeIssues/exportcertificate.pdf>.

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, peer review panels, 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 RIA and the Regulatory Flexibility Analysis indicate that all 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 October 17, 2006, Federal Register Vol. 71 No. 200, pages 61014 to 61015, the agency published the notice requesting an extension of and revision to a currently approved information collection and request for comments. No comments were received regarding this information collection.

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; five public hearings focused on organic livestock production; review of existing industry standards and management practices; consideration of the NOSB recommendations and position papers which were presented to the Secretary only after extensive public comment and debate; presentations at national health food shows, each with question and answer sessions; official meetings between NOP staff members and private and State certification organizations to become familiar with their procedures; a national certifiers meeting to discuss accreditation issues; a meeting of State officials to discuss the relationship of States to the USDA and States to private certification organizations; attendance of NOP staff members at organic inspector meetings and training sessions; 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. Some of the contacts include: Cathy Greene, Economist, Food and Consumer Economics Division, USDA/ERS, author of the Regulatory Impact Assessment, (202-594-5775);

Bob Anderson, Former Chairman, NOSB, (814) 574-1063; and Caren Wilcox, Executive Director of the Organic Trade Association, (413) 774-7511.

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.

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 of the burden of collection of information have been summarized in the AMS Form 71. The respondents' estimated annual cost in providing the information is \$20,336,640. This total has been estimated by multiplying the 635,520 burden hours incurred by certified and exempt producers and handlers by \$32, the hourly rate of GS-12/01. The 118,176.5 burden hours incurred by certifying agents, inspectors, State Programs, peer review panels, and parties submitting substances for inclusion on the National List have been multiplied by \$35, the hourly rate of a GS-12/05.

We chose the Federal employee ratings, GS-12/01 and GS-12/05, because the responsibilities required by the final regulation are similar to the responsibilities of persons working at these ratings. Producers and handlers plan their own work according to established standards, keep records and submit information to the certifying agent.

These activities closely resemble the responsibilities of a GS-12/01 employee who works under a set of standards and elements with little responsibility for making or interpreting policy. A GS-12/01 must retain records of activities and submit work to their supervisor. A GS-12/05, however, has some responsibility for interpreting policy and making decisions that affect the operation of the program. A GS-12/05 can be a supervisor, and they are often responsible for developing procedures, initiating training, establishing recordkeeping systems, and facilitating advisory boards. These activities resemble those of an accredited certifying agent.

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	800.00
Supplies (paper)	400.00
Postage	50.00
Telephone	<u>250.00</u>
	\$1,500.00

(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 that it would cost on a yearly basis approximately \$1,000,000 to operate the NOP when it is initially implemented. These costs would include salaries and benefits; travel and transportation; rent, communications, utilities; printing; contractual services; supplies; and equipment.

The NOP currently operates on appropriated funds. When it is fully implemented, it may rely on a combination of appropriated funds and fees charged for services. The regulation, in §§ 205.640 - 205.642 of subpart G, provides for USDA the opportunity to collect fees from certifiers for accreditation services. The OFPA provides that the fees collected be deposited into an account maintained for NOP use.

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 41,997 burden hours from the last submission. This adjustment increase is a result of an increase in respondents. See “Summary of 2006 Information Collection Attachment 1” for an explanation of differences.

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 is seeking approval to not display the OMB expiration date on the forms associated with this information collection.

The Transportation and Marketing Programs (T&MP) orders forms well in advance, so forms are mailed to the requester in a timely manner. The T&MP office attempts to order forms in quantities large enough to get a price break. If the T&MP office needs to order more forms prior to an OMB submission for extension of approval, there is no guarantee that OMB will use a requested expiration date. 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.