

domestic and foreign producers and handlers as organic in accordance with OFPA and NOP. Each entity wanting to be an agent seeks accreditation from USDA, submitting information documenting its business operations and program expertise. Accredited agents determine if a producer or handler meets organic requirements, using detailed information from the operation documenting its specific practices and on-site inspection reports from organic inspectors. Initial estimates were based on 59 entities applying for accreditation (13 State programs, 36 private entities, 10 foreign entities). The initial burden for each State program was an average of 695 hours or if calculated at a rate of \$27 per hour (rounded up to the next dollar) \$18,765. The initial burden for each private or foreign entity was 700 hours or if calculated at a rate of \$27 per hour (rounded up to the next dollar) \$18,900. To date 87 certifying agents (15 State programs, 38 private entities, 34 foreign entities) have been accredited. The AMS anticipates receiving an estimated 10 new applications per year. Accredited certifying agents submit annual updates with an annual burden, for each certifying agent, of an average of 3 hours or if calculated at a rate of \$27 per hour (rounded up to the next dollar) \$81.

Administrative costs for reporting, disclosure of information, and recordkeeping vary among certifying agents. Factors affecting costs include the number and size of clients, the categories of certification provided, and the type of systems maintained.

When an entity applies for accreditation as a certifying agent, it must provide a copy of its procedures for complying with recordkeeping requirements (§ 205.504 (b)(3)). Once certified, agents have to make their records available for inspection and copying by authorized representatives of the Secretary (§ 205.501 (a)(9)). The USDA charges certifying agents for the time required to do these document reviews. Audits require less time when the documents are well organized and centrally located.

Recordkeeping requirements for certifying agents are divided into three categories of records with varying retention periods: (1) Records created by certifying agents regarding applicants for certification and certified operations, maintain 10 years, consistent with OFPA's requirement for maintaining all records concerning activities of certifying agents; (2) records obtained from applicants for certification and certified operations, maintain 5 years, the same as OFPA's requirement for the retention of records by certified

operations; and (3) records created or received by certifying agents regarding accreditation, maintain 5 years, consistent with OFPA's requirement for renewal of agent's accreditation (§ 205.510 (b)).

*Organic inspectors.* Inspectors, on behalf of certifying agents, conduct on-site inspections of certified operations and operations applying for certification. They determine whether or not certification should continue or be granted and report their findings to the certifying agent. Inspectors are the agents themselves, employees of the agents, or individual contractors. We estimate that about half are certifying agents and their employees and half are individual contractors. Individuals who apply for positions as inspectors submit to the agents information documenting their qualifications to conduct such inspections. Estimates: 293 inspectors (147 certifying agents and their employees, 146 individual contractors). The annual burden for each inspector is an average of 48 hours or if calculated at \$27 per hour (rounded up to the next dollar) \$1,296.

*Producers and handlers.* Producers and handlers, domestic and foreign, apply to certifying agents for organic certification, submit detailed information documenting their specific practices, provide annual updates to continue their certification, and report changes in their practices. Producers include farmers, livestock and poultry producers, and wild crop harvesters. Handlers include those who transport or transform food and include millers, bulk distributors, food manufacturers, processors, repackagers, or packers. Some handlers are part of a retail operation that processes organic products in a location other than the premises of the retail outlet.

The OFPA requires certified operators to maintain their records for 5 years. Initial estimates of: 19,400 total operators (14,253 certified and 5,147 exempt), including 17,150 producers (12,176 certified and 4,974 exempt) and 2,150 handlers (1,977 certified and 173 exempt) have not changed. The annual recordkeeping burden for each certified operator is an average of 5 hours or if calculated at \$24 per hour (rounded up to the next dollar) \$120.

The NOP exempts certain operations from certification: (1) Producers and handlers whose gross agricultural income from organic sales totals \$5,000 or less annually; (2) handlers selling only agricultural products that contain less than 70 percent organic ingredients by total weight of the finished product; (3) 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; and (4) handlers that are retail food establishments that handle organic food but do not process it. The NOP also excludes certain operations from certification: (1) Handlers selling only agricultural products labeled as 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; and (2) handlers that are retail food establishments that process or prepare, on the premises, raw and ready-to-eat food from organic agricultural products.

Administrative costs for reporting and recordkeeping vary among certified operators. Factors affecting costs include the type and size of operation, and the type of systems maintained.

Research studies have indicated that operations using product labels containing the term "organic" handle an average of 19.5 labels annually and that there are about 16,000 products with the term organic on the label. An estimate of the time needed to develop labels for products sold, labeled, or represented as "100 percent organic," "organic," "made with organic (specified ingredients)," or which use the term organic to modify an ingredient in the ingredients statement is included. Also included is the time spent deciding about use of the USDA seal, a State emblem, or the seal, logo, or other identifying marks of a private certifying agent (Sec. 205.300–Sec. 205.310). Because the labeling requirements are in addition to Food and Drug Administration and Food Safety and Inspection Service requirements, the burden measurement does not include the hours necessary to develop the entire label. For purposes of calculating the burden, it is estimated that each handler develops 20 labels annually. Estimates: 1,977 certified handlers. The annual burden for each certified handler is an average of 1 hour per product label times 20 product labels per handler or if calculated at a rate of \$27 per hour (rounded up to the next dollar) \$540.

*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. Estimates: 25 interested parties may petition the NOSB. The annual burden for each interested party is an average of 104 hours or if calculated at \$24 per hour (rounded up to the next dollar) \$2,496.