

be accredited as a certifying agent, as described in section 2115(b) of the OFPA (7 U.S.C. 6514(b)). States are also preempted under sections 2104 through 2108 of the OFPA (7 U.S.C. 6503 through 7 U.S.C. 6507) from creating certification programs to certify organic farms or handling operations unless the State programs have been submitted to, and approved by, the Secretary as meeting the requirements of the OFPA.

Pursuant to section 2108(b)(2) of the OFPA (7 U.S.C. 6507(b)(2)), a State organic certification program may contain additional requirements for the production and handling of organically produced agricultural products that are produced in the State and for the certification of organic farm and handling operations located within the State under certain circumstances. Such additional requirements must: (a) Further the purposes of the OFPA, (b) not be inconsistent with the OFPA, (c) not be discriminatory toward agricultural commodities organically produced in other States, and (d) not be effective until approved by the Secretary.

Pursuant to section 2120 (f) of the OFPA (7 U.S.C. 6519(f)), this regulation would not alter the authority of the Secretary under the Federal Meat Inspection Act (21 U.S.C. 601 *et seq.*), the Poultry Products Inspections Act (21 U.S.C. 451 *et seq.*), or the Egg Products Inspection Act (21 U.S.C. 1031 *et seq.*), concerning meat, poultry, and egg products, nor any of the authorities of the Secretary of Health and Human Services under the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), nor the authority of the Administrator of the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 *et seq.*).

Section 2121 of the OFPA (7 U.S.C. 6520) provides for the Secretary to establish an expedited administrative appeals procedure under which persons may appeal an action of the Secretary, the applicable governing State official, or a certifying agent under this title that adversely affects such person or is inconsistent with the organic certification program established under this title. The OFPA also provides that the U.S. District Court for the district in which a person is located has jurisdiction to review the Secretary's decision.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) requires agencies to consider the economic impact of each rule on small entities and evaluate alternatives that would accomplish the

objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the market. The purpose is to fit regulatory actions to the scale of businesses subject to the action. Section 605 of the RFA allows an agency to certify a rule, in lieu of preparing an analysis, if the rulemaking is not expected to have a significant economic impact on a substantial number of small entities.

Pursuant to the requirements set forth in the RFA, the Agricultural Marketing Service (AMS) performed an economic impact analysis on small entities in the final rule published in the **Federal Register** on December 21, 2000. AMS has also considered the economic impact of this action on small entities and has determined that this final rule will have an impact on a substantial number of small entities. However, AMS has determined that the impact on entities affected by this rule will not be significant. The effect of this rule will be to allow the use of additional substances in agricultural production and handling. This action relaxes the regulations published in the final rule and provides small entities with more tools to use in day-to-day operations. The AMS concludes that the economic impact of this addition of allowed substances, if any, will be minimal and entirely beneficial to small agricultural service firms. Accordingly, the Administrator of the AMS hereby certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Small agricultural service firms, which include producers, handlers, and accredited certifying agents, have been defined by the Small Business Administration (SBA) (13 CFR 121.201) as those having annual receipts of less than \$750,000 and small agricultural producers are defined as those having annual receipts of less than \$5,000,000.

The U.S. organic industry at the end of 2001 included nearly 6,600 certified crop and livestock operations, including organic production and handling operations, producers, and handlers. These operations reported certified acreage totaling more than 2.34 million acres, 72,209 certified livestock, and 5.01 million certified poultry. Data on the numbers of certified handling operations are not yet available, but likely number in the thousands, as they would include any operation that transforms raw product into processed products using organic ingredients. Growth in the U.S. organic industry has been significant at all levels. From 1997 to 2001, the total organic acreage grew by 74 percent; livestock numbers

certified organic grew by almost 300 percent over the same period, and poultry certified organic increased by 2,118 percent over this time. Sales growth of organic products has been equally significant, growing on average around 20 percent per year. Sales of organic products were approximately \$1 billion in 1993, but are estimated to reach \$13 billion this year, according to the Organic Trade Association (the association that represents the U.S. organic industry). In addition, USDA has accredited 85 certifying agents who have applied to USDA to be accredited in order to provide certification services to producers and handlers. A complete list of names and addresses of accredited certifying agents may be found on the AMS NOP Web site, at <http://www.ams.usda.gov/nop>. AMS believes that most of these entities would be considered small entities under the criteria established by the SBA.

D. Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act of 1995, the existing information collection requirements for the NOP are approved under OMB number 0581-0181. No additional collection or recordkeeping requirements are imposed on the public by this final rule. Accordingly, OMB clearance is not required by section 350 (h) of the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*, or OMB's implementing regulation at 5 CFR part 1320.

E. Comments Received

Altogether, 23 comments were received on these proposed revisions and amendments. Commenters included consumers, producers, processors, the National Organic Standards Board (NOSB), certifying agents, food industry organizations, State governments, and trade organizations.

Section 205.601 Synthetic Substances Allowed for Use in Organic Crop Production

No comments were opposed to the revision of the introductory text concerning use of materials as required in 205.203(c) and 205.206(a)-(d). One commenter, however, questioned whether every substance in 205.601 has to be measured against the criteria in 205.206(a)-(d). The commenter pointed out that algicides should be measured against these criteria in paragraphs 205.206(a)-(d), but that disinfectants, sanitizers, and cleaning materials in irrigation systems should not have to meet the criteria in (a)-(d). The commenter suggests revising paragraph 205.601(b) to include algicides and