

Regulatory Flexibility Act Analysis

Appendix C.--Final Regulatory Flexibility Analysis

The Regulatory Flexibility Act (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.

1. Need for and objectives of the National Organic Rule

Currently, organic certification is voluntary and self-imposed. Members of organic industries across the United States have experienced numerous problems marketing their organically produced and handled agricultural products. Inconsistent and conflicting organic production standards may have been an obstacle to the effective marketing of organic products. There are currently 36 private and 13 State organic certification agencies (certifying agents) in the United States, each with its own standards and identifying marks.

Some existing private certifying agents are concerned that States might impose registration or licensing fees which would limit or prevent private certification activities in those States. Labeling problems have confronted manufacturers of multiingredient organic food products containing ingredients certified by different certifying agents because reciprocity agreements have to be negotiated between certifying agents. Consumer confusion may exist because of the variety of seals, labels, and logos used by certifying agents and State programs. Also, there is no industrywide agreement on an accepted list of substances that should be permitted or prohibited for use in organic production and handling. Finally, a lack of national organic standards may inhibit organic producers and handlers in taking full advantage of international organic markets and may reduce consumer choices in the variety of organic products available in the marketplace.

To address these problems in the late 1980's, the organic industry attempted to establish a national voluntary organic certification program. At that time, the industry could not develop consensus on the standards that should be adopted, so Congress was petitioned by the Organic Trade Association to establish national standards for organic food and fiber products.

In 1990, Congress enacted the Organic Foods Production Act of 1990, as amended (7 U.S.C. 6501 et seq.) (OFPA). The OFPA requires all agricultural products labeled as "organically produced" to originate from farms or handling operations certified by a State or private agency that has been accredited by USDA.

The purposes of the OFPA, set forth in section 2102 (7 U.S.C. 6501), are to: (1) establish national standards governing the marketing of certain agricultural products as organically produced products; (2) assure consumers that organically produced products meet a consistent standard; and (3) facilitate commerce in fresh and processed food that is organically produced. The National Organic Program (NOP) is the result of the OFPA.

Recently, the Organic Trade Association published *American Organic Standards, Guidelines for the Organic Industry* (AOS). However, not all participants in the organic industry elected to participate in developing the AOS. Many certifying agents preferred to wait for implementation of the national standards, and some certifying agents disagree with portions

of the AOS. For these reasons, USDA will implement a regulation for the NOP. .

2. Summary of the significant issues raised by public comments in response to the Initial Regulatory Flexibility Analysis (IRFA), a summary of agency assessment of such issues, and a statement of any changes made in the final rule as a result of such comments.

Although we received many individual comments in reference to the proposed rule's IRFA, they were, for the most part, variations of several form letters. Most of the concern on the part of commenters regarded the fees that small certifying agents would be subject to under the rule.

Comments Accepted:

(1) We received numerous comments to the effect that the fees, recordkeeping, and paperwork requirements for producer and handler certification must be kept as low as possible while still offering a quality certification program. We believe that we have made every effort in this rule to minimize the cost and paperwork burden to certifiers and certified operations as much as possible. We have permitted certifiers and certified operations to develop their own recordkeeping and reporting systems-so long as they conform to the needs of the program. For the most part, the paperwork and recordkeeping requirements for certified operations conform to the requirements that they presently face under existing certification programs. In order to minimize the cost to the industry of transitioning to a system where certifying agents are accredited (assuming that there will be a learning curve as agents familiarize themselves with the requirements of accreditation), we have waived the per-hour cost that USDA will charge to conduct an accreditation review for the first 18 months of the program.

(2) In the proposed rule, we requested comment on the benefits of an exemption for small certifiers similar to that for small producers. We received comments in opposition to such an exemption because commenters wanted to maintain documented verification of standards that is afforded by certification and accreditation. They felt that exemptions weakened the organic system in its ability to assure consumers of products that meet a consistent standard. We concurred with this comment and have not developed an exemption for certifiers in the final rule.

Comments Rejected:

(3) We received comments suggesting that, in order to lower the direct cost of accreditation to smaller certifier applicants, we should eliminate on-site visits during accreditation or extend the time beyond the initial on-site visit for a subsequent visit. Although eliminating the on-site visits would certainly lower the applicant's costs, we have not made the change to reduce or eliminate on-site visits. We did not see how USDA could make an informed decision about whether or not to continue to accredit a certifying agent without complete access to the relevant records documenting the agent's business practices. This can only be efficiently done through a site visit.

(4) We received numerous comments that the fees proposed by USDA will result in certification fees that are excessive for small farming operations. The commenters suggested that USDA impose fees on a sliding scale based on a farmer's income so as not to drive these farmers out of business and deprive consumers of the benefits of these operations. We received a similar comment to the Fees section of the proposed rule, and our response is the same. Although one of our top priorities is assisting the small farmer, AMS is primarily a user-fee-based Federal agency. We are aware that our accreditation fees will figure into the fees that certifiers charge their clients. However, the fee we will charge to accredit an applicant is

based not on earning profits, but on recovery of costs. In addition, our waiver of the hourly service charges for accreditation during the first 18 months of the program should help to keep the cost of accreditation to certifying agents down. We believe the requirements that fees charged by a certifying agent must be reasonable and that certifiers must file a fee schedule for approval by the Administrator will help to keep costs under control. Since certifiers are required to provide their approved fee schedules to applicants for certification, the applicants will be able to base their selection of certifying agent on price if the applicants so choose. In addition, nothing in the regulations precludes certifying agents from pricing their services on a sliding scale so long as their fees are consistent and nondiscriminatory and are approved during the accreditation process.

(5) Other commenters were concerned that in the rule USDA neglects to establish "reasonable fees" annually for farm/site/wild crop production and handling operation certification. Commenters did not believe that a valid Regulatory Flexibility Act analysis could be made without the annual farm and handling operation fee projection. We have not established guidelines for what constitutes a "reasonable fee" in the final rule. Accredited certifying agents will be required to submit a proposed fee schedule as a part of their application. At that time, we will work with applicants for accreditation to ensure that their fees are appropriate. In addition, certifying agents will be required to send a copy of their fee schedule to anyone who requests one. This will allow operations that wish to be certified to shop around and will provide a disincentive for accredited agents to price themselves out of the market.

3. Description of and an estimate of the number of small entities to which the rule will apply.

Small business size standards, Standard Industrial Code (SIC) (13 CFR part 121), are developed by an interagency group, published by the Office of Management and Budget, and used by the Small Business Administration (SBA) to identify small businesses. These standards represent the number of employees or annual receipts constituting the largest size that a for-profit enterprise (together with its affiliates) may be and remain eligible as a small business for various SBA and other Federal Government programs.

There are three categories of operations that contain small business entities that would be affected by this rule: certifying agents, organic producers, and/or organic handlers. The term, "certifying agent," means the chief executive officer of a State or, in the case of a State that provides for the statewide election of an official to be responsible solely for the administration of the agricultural operations of a State, such official and any person (including private entities) who is accredited by the Secretary as a certifying agent for the purpose of certifying a farm or handling operation as a certified organic farm or handling operation.

According to the most complete data available to USDA's Agricultural Marketing Service (AMS), there are 49 certifying agents (36 private and 13 State) in the United States. More than half of the private and State certifying agents certify both producers and handlers, while the others certify only producers. Over three-fourths of private and State certifying agents each certify fewer than 150 producers and 20 handlers. The number of certifying agents has remained fairly stable, between 40 and 50, for some years, with entries and exits tending to offset each other. The NOP staff anticipates that, in addition to the 49 domestic certifying agents, 10 foreign certifying agents may seek accreditation during the initial phase of the program.

Small businesses in the agricultural services sector, such as certifying agents, include firms with average annual revenues of less than \$5 million (SIC Division A Major Group 7). Based on SBA's small business size standards for the agricultural services sector, it is not likely that many, if any, of the 49 domestic certifying agents have annual revenue greater than \$5 million. All private, nonprofit certifying agents would be considered small by SBA's standards.

Based on anecdotal information, only a few private, for-profit, certifying agents might be categorized as large businesses. In addition, the 13 State certifying agents, although not exceeding the revenue threshold, would not be considered to be small entities under the Act as only government jurisdictions with populations under 50,000 are considered to be small entities under section 601(5). Therefore, at least 30 certifying agents would qualify as a small business.

The term, "producer," means a person who engages in the business of growing or producing food or feed. It is more difficult to establish the number of organic producers. Organic farming was not distinguished from conventional agriculture in the 1997 Census of Agriculture. There are sources which give insight into the number of producers. The Organic Farming Research Foundation (OFRF), a California-based nonprofit organization, has conducted three nationwide surveys of certified organic producers from lists provided by cooperating certifying agents. The most recent survey applies to the 1997 production year (1). OFRF sent its 1997 survey to 4,638 names and received 1,192 responses. Because OFRF did not obtain lists from all certifying organizations or their chapters (55 out of a total of 64 identified entities provided lists), its list count is likely an understatement of the number of certified organic producers. Note that the estimated number of organic producers includes only certified organic farms. Comments filed in response to the first proposal and studies indicate that the total number of organic farms is higher.

Dunn has estimated the number of certified organic producers in the United States (2, 3) Dunn's 1995 work, a USDA study, estimated the number of certified producers at 4,060 in 1994; this estimate was used in the first proposal. Dunn's 1997 work reported 4,060 certified organic farms in 1994 and 4,856 in 1995.

Data collected by AMS indicate that the number of organic farmers increased about 12 percent per year during the period 1990 to 1994. OFRF survey efforts indicate that growth has continued, although it is not clear whether the growth rate has changed. Similarly, growth in retail sales, the addition of meat and poultry to organic production, and the possibility of increased exports suggest that the number of operations has continued to increase. Lacking an alternative estimate of the growth rate for the number of certified organic producers, we use the average growth rate of about 14 percent from Dunn's 1997 study. The true rate of growth could be higher or lower. Applying the 14-percent growth rate to Dunn's estimate of certified producers in 1995 gives an estimate of 8,200 organic producers for 1999.

An adjustment is needed to account for the number of producers who are practicing organic agriculture but who are not certified and who would be affected by this regulation. We assume that the number of organic but not certified producers in 1999 is about 4,000. This assumption is based on very limited information about the number of registered but not certified organic producers in California in 1995. Thus, the total number of certified organic producers used in assessing the impact of the rule is 12,176.

Producers with crop production (SIC Division A Major Group 1) and annual average revenues under \$500,000 are small businesses. Producers with livestock or animal specialties are also considered small if annual average revenues are under \$500,000 (SIC Division A Major Group 2), with the exception of custom beef cattle feedlots and chicken eggs, which are considered small if annual average revenues are under \$1,500,000.

Based on SBA's small business size standards for producers, it is likely that almost all organic producers would be considered small. The OFRF survey asked for the producer's total gross organic farming income during 1997. Only 35 (less than 3 percent) of the survey respondents reported gross income greater than \$500,000, the SBA's cutoff between small and large businesses. Over 70 percent reported gross income of less than \$50,000. The OFRF survey does caution readers about potential survey "errors." It is particularly important

to emphasize potential "non-response error"; that is, it is unknown if those who responded to the survey accurately represent the entire population of certified organic growers. Also, some producers combine organic and conventional production on the same operation, some with total sales that may exceed \$500,000. However, it is likely that a majority of organic producers would be considered small. We have estimated that there would be 12,176 producers certified in the first year and of those 97 percent, or 11,811, based on OFRF's survey results, would qualify as a small business.

The term, "handler," means any person engaged in the business of handling agricultural products, excluding final retailers of agricultural products that do not process agricultural products. Little information exists on the numbers of handlers and processors. USDA has estimated that there were 600 entities in this category in 1994. In California, there were 208 registered organic processed food firms in 1995 and 376 in 1999, a growth rate of 20 percent (4). We assume that this growth rate is applicable to the U.S. and project 2,077 certified handlers in 2001. This figure includes 100 livestock feed handlers who would become certified organic. Again, the rate of growth could be higher or lower.

In handling operations, a small business has fewer than 500 employees (SIC Division D Major Group 20). It is also likely that the vast majority of handlers would be considered small, based on SBA's small business size standards for handlers. Based on informal conversations with organic certifying agents, currently, about 25 (about 2 percent) of the estimated 1,250 organic handlers in 1999 had more than 500 employees. This includes firms that handle or process both organic and conventional foods. We have estimated that 2,077 handlers would be certified organic in the first year. Based on this information, 98 percent or 2,035 would qualify as a small business.

4. An estimate of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.

The reporting, recordkeeping, and compliance requirements of the rule will directly affect three sectors of the organic industry that contain small business entities: accredited certifying agents, organic producers, and organic handlers. We have examined the requirements of the rule as it pertains to each of these entities, however several requirements to complete this Regulatory Flexibility Analysis (RFA) overlap with the Regulatory Impact Assessment (RIA) and the Paperwork Reduction Act (PRA) section. In order to avoid duplication, we combine some analyses as allowed in section 605(b) of the Act. This RFA provides information specific to small entities, while the RIA or PRA should be referred to for more detail. For example, the RFA requires an analysis of the rule's costs to small entities. The RIA provides an analysis of the benefits and costs of this regulation. This RFA uses the RIA information to estimate the impact on small entities. Likewise, the RFA requires a description of the projected reporting, recordkeeping, and other compliance requirements of the final rule. The PRA section estimates the reporting and recordkeeping (information collection) requirements that would be required by this rule from individuals, businesses, other private institutions, and State and local governments. The burden of these requirements is measured in terms of the amount of time required of program participants and its cost. This RFA uses the PRA information to estimate the burden on small entities.

Certifying Agents

We have identified 36 private certifying agents and 13 State programs providing certification. These 49 domestic entities are considered likely applicants during the first 12 months, as are an estimated 10 foreign certifying agents. An unknown number of new entrants to the certifying business may also apply. However, over the last 10 years, the number of certifying

agents does not appear to have grown significantly, with the net effect of entries and exits maintaining a population of U.S.-based certifying agents at about 40 to 50. Of the 49 domestic certifying agents, based on information discussed previously, we estimate that 30 of the 36 private certifying agents are small businesses.

The recordkeeping and paperwork requirements are outlined in the Paperwork Reduction Act section. The requirements for small and large certifying agents are identical. The recordkeeping and paperwork requirements for accreditation will be a new burden to most agents as the majority of them have not been accredited in the past. However, the actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that would begin their activities only after the national program is implemented. Certifying agents that currently are active in the organic industry already perform most of these required administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices are different from the requirements of the final regulation. Because the rule does not require any particular system or technology, it does not discriminate against small businesses. The ability of an agent to carry out the paperwork and recordkeeping sections of the rule will be more dependant on the administrative skill and capacity of their particular organization than their size. We did not receive significant comments about the paperwork requirements of the proposed rule that would indicate that they will be onerous for small certifying agents.

Certifying agents will be the front line in monitoring and ensuring that certified operations stay in compliance with the Act and the regulations. However, most of the compliance requirements, with the exception of some reporting requirements, are consistent with what certifiers are currently expected to do. Like the paperwork and reporting requirements, the additional costs to an agent will depend on how different their current practices are from the final regulation.

The final, and probably most significant, area in which certifying agents are affected by the rule is in the fees that they must pay for accreditation. Certifying agents will be assessed for the actual time and travel expenses necessary for the NOP to perform accreditation services, including initial accreditations, 5-year renewals of accreditation, review of annual reports, and changes to accreditation. Although the fees have not been set yet, we are using as a starting point the hourly fees that are charged for the voluntary, fee-for-service program provided by AMS to certification bodies requesting conformity assessment to the ISO Guide 65, "General Requirements for Bodies Operating Product Certification Systems." We expect that at the time the NOP's final rule is implemented, the fees will be approximately \$95 per hour with higher overtime and holiday rates. Certifying agents will also be charged for travel, per diem, and other related costs associated with accreditation. To ease the financial burden of accreditation during the 18 month transition period after the NOP has been implemented, USDA will not impose hourly charges on certifying agents. The direct costs for certifying agents to obtain accreditation will be limited to per diem and transportation costs to the site evaluation. Review of the certifying agent's annual report is anticipated to range from 2 to 8 hours at the ISO Guide 65 hourly rate. Also, if certifying agents wish to become accredited in additional areas for which they were not accredited previously, a site evaluation (with associated fees) will be necessary. Detail about the expected costs of accreditation can be found in the RIA.

Several factors will influence the amount of time needed to complete an accreditation audit. An operation in which documents are well organized and that has few nonconformities within the quality system will require less time for an audit than an organization in which documents are scattered and there are many nonconformities (7). Similarly, in a followup audit, operations that lack organization in their documents and that had a large number of nonconformities during previous audits will require a greater amount of time. The scope of a followup audit is to verify the correction of nonconformities and to evaluate the effectiveness

of the corrections. Certifying agents are able to control these cost factors by making certain that documents are well organized and by educating themselves about quality systems.

The complexity of a certification agency's organization also will affect the time needed to complete an audit. An agency with a central office in which all certification activities take place will require less time for document review and site evaluation than a chapter organization or a business structured so that responsibility for making certification decisions is delegated outside of the central office. In the latter cases, the auditors' document review would require additional time and site evaluation that would extend from the central office to one or more of the chapters or to the site to which the certification decision making is delegated.

Other factors determine the amount of time needed to complete an accreditation audit. For an agency with numerous clients, auditors may need to spend more time reviewing client files or examining business operations than they would have to spend for a smaller agency. Audit of an agency with a large number of processor clients may require an extended amount of time to follow audit trails, confirm that organic ingredients remain segregated from nonorganic ingredients, and establish that foreign-produced ingredients originate from approved entities. Finally, the complexity of the agricultural practices certified could influence the amount of time necessary to complete an accreditation audit. An agency whose certification covers only producers who grow and harvest one crop per field per year, such as wheat or sugar beets, could quickly be audited. An agency whose producers grow several different crops per field per year or an agency that certifies producers of crops and livestock as well as handlers would require a greater amount of time.

All of these factors will affect both small and large certifying agents. A small certifying agent could be assumed to have a less complex organization or have fewer clients, and, thus, potentially less time would be necessary for review. However, other factors, such as the degree of paperwork organization or the complexity of the agricultural practices certified, may influence the time needed for review for any size of business.

Currently, relatively few certifying agents have third-party accreditation because accreditation of certifying agents is voluntary. Fetter reports that in a sample of 18 certification programs, selected to include six large, private programs, six smaller private programs, and six State programs, four programs were accredited and one had accreditation pending (8). All of these were large private certifying agents. Three of the certifying agents identified by Fetter as accredited requested ISO Guide 65 assessments by USDA and have been approved for selling organic products into the international market. Those certifying agents currently accredited by third parties will likely pay less for USDA accreditation because their documents are organized and they have fewer nonconformities.

It is expected that all certifying agents will set their fee schedule to recover costs for their certification services, including the costs of accreditation. The larger the number of clients per certifying agent, the more fixed costs can be spread out. It is possible, however, that small certifying agents could be significantly affected by this final rule and may not be able to continue in business from a financial standpoint.

Costs to Producers and Handlers

The OFPA established a small farmer exemption from certification and submission of organic plans for small producers with a maximum of \$5,000 in gross sales of organic products. For purposes of the exemption, the OFPA defines a "small farmer" as those who sell no more than \$5,000 annually in value of agricultural products. In this rule, we have clarified that the exemption applies to producers and handlers who sell no more than \$5,000 annually in value

of organic products (9). In addition, handling operations are exempt if they: are a retail food establishment that handles organically produced agricultural products but does not process them; handles agricultural products that contain less than 70 percent organic ingredients by weight of finished product; or does not use the word, "organic," on any package panel other than the information panel if the agricultural product contains at least 70 percent organic ingredients by weight of finished product.

A handling operation or specific portion of a handling operation is excluded from certification if it handles packaged certified organic products that were enclosed in their packages or containers prior to being acquired and remain in the same package and are not otherwise processed by the handler, or it is a retail food establishment that processes or prepares on its own premises raw and ready-to-eat food from certified organic products.

According to the OFRF survey, 27 percent of currently certified farms that responded to the survey would fall under the producer exemption. This percentage does not take into account those organic farms that are not currently certified by a private or State certifying agent. A study of California organic farms found that, of all organic farms (10) in 1994-95, about 66 percent have revenues less than \$10,000 (11). If California is representative and the distribution within the sub-\$10,000 category is uniform, then a third of the farms would be classified as small for purposes of the statutory exemption with annual sales less than \$5,000. Based on the California study and the OFRF survey results, we estimate that between 25 and 33 percent of organic producers are small and would qualify for exemption from the certification requirements.

We have estimated that there are 4,801 small organic producers and 173 handlers that will be exempt from certification (this figure does not include excluded operations). These operations would be required to comply with the production and handling standards and labeling requirements set forth under the NOP. They do not have to meet the paperwork requirements of certification and they must only keep records that document compliance with the law for 3 years (rather than 5 for certified operations). We anticipate that this exemption will be used primarily by small market gardeners and hobbyists who grow and process produce and other agricultural products for sale at farmers markets and roadside stands to consumers within their communities.

Exempt producers will be allowed to market their products as organically produced without being certified by a certifying agent. Products marketed by exempt producers cannot be represented as certified organic or display the USDA organic seal. Products produced or handled on an exempt operation may be identified as organic ingredients in a multiingredient product produced by the exempt operation, but they may not be identified as organic in a product processed by others. These limitations may discourage some small producers from seeking exemption, who instead may choose to become certified. In this case, the costs of certification would apply. The value associated with having organic certification may outweigh the costs of certification.

As with accredited certifying agents, the regulation will impose administrative costs on certified producers and handlers for reporting, recordkeeping, residue testing, and other compliance requirements. The actual amount of the additional administrative costs that would be imposed by the final rule is expected to be different for those entities that become certified only after the national program is implemented. Producers and handlers who currently are active in the organic industry already perform most of these administrative functions; therefore, the additional costs to them would depend upon the extent to which their current practices differ from the requirements of the final regulation. Projected reporting, recordkeeping, and other compliance requirements of certifying agents are discussed in greater detail in the PRA and the RIA. The only distinction made in the final rule between large and small entities for reporting, recordkeeping, and compliance is for operators who

produce less than \$5000 per year in organic products as stated above.

As with the certifying agents, most of the concern this rule generated for small certified operations revolves around fees. Under this rule, USDA will not impose any direct fees on producers and handlers. Certifying agents will establish a fee schedule for their certification services that will be filed with the Secretary and posted in a place accessible to the public. Certifying agents will provide all persons inquiring about the application process with a copy of their fees. The certifying agent may only charge those fees that it has filed with the Secretary. Furthermore, the certifying agent will provide each applicant with an estimate of the total cost of certification and an estimate of the annual costs of updating the certification.

Currently, supply and demand for certification services determine the fees charged in most areas. Some States charge minimal fees for certification and instead subsidize operating costs from general revenues. According to separate studies by Fetter, and Graf and Lohr, the majority of certifying agents structure their fee schedules on a sliding scale based on a measure of size, usually represented by the client's gross sales of organic products but sometimes based on the acres operated. Some certifying agents charge an hourly rate for inspection and audit services.

Graf and Lohr's study indicates that even small farms require significant time for the certification process, and this time does not increase proportionately as farm size increases. None of the existing certification programs mention costs for residue testing, which the NOP will require in the form of preharvest testing when there is reason to believe that agricultural products have come into contact with prohibited substances. Preharvest testing is expected to be infrequent. Certifiers will recover the costs of preharvest testing through explicit charges to the producer whose crop is tested or through a generally higher fee structure that spreads the expected costs of tests over all clients.

This rule imposes no requirements that would cause certifying agents that are presently using a sliding-scale type fee schedule to abandon their current fee system. Certifying agents could recover their net additional costs by increasing their flat-fee component, their incremental charges, or both. Because accreditations are renewed only every 5 years, certifying agents will have 5 years to recover their net new costs. Certifying agents who become accredited during the first year of the program would have fewer direct costs to recover because they will not be charged the application fee and hourly charges for accreditation services.

Those currently receiving voluntary certification will likely see a modest increase as the certifying agent passes on its cost incurred under the NOP. Those not currently receiving certification and producing over \$5,000 annually in organic products will be required to become certified, and they will incur the actual costs of certification.

Some States, such as Texas and Washington, charge producers and handlers nominal fees for certification, and it is possible that more States might provide certification services as the NOP is implemented. Other States, such as Minnesota, have cost-share programs to help offset costs for organic producers.

Conclusion

This rule will primarily affect small businesses. We have, therefore, attempted to make the paperwork, recordkeeping, and compliance provisions as flexible as possible without sacrificing the integrity of the program. We are not requiring specific technologies or practices and with the 18-month phase-in of the program we are attempting to give both certifying agents and certified operators an opportunity to adapt their current practices to conform with

the rule. Because we have attempted to make the rule conform with existing industry standards, including ISO guide 65 for certification and ISO guide 61 for accreditation, the changes for most organizations and operations should be relatively straightforward.

The fees required for accreditation will be the most significant change faced by most operations-and this was apparent in the comments received. While we understand the concerns of the affected organizations, in order to administer an accreditation program, it is necessary that we recover our costs. We are hoping that the elimination of the hourly charges in the first round of accreditation will help to alleviate some of this burden.

1. Organic Farming Research Foundation. 1999. *Final Results of the Third Biennial National Organic Farmers' Survey*. Santa Cruz, CA.

2. Dunn, Julie Anton. 1995. *Organic Food and Fiber: An Analysis of 1994 Certified Production in the United States*. U.S. Department of Agriculture, Agricultural Marketing Service.

3. Dunn, Julie Anton. 1997. *AgriSystems International Reports Certified Organic Production in the United States: Half a Decade of Growth*. AgriSystems International: Wind Gap, PA.

4. California Department of Health Services (DHS). 1995. *Report on the Registration of California Organic Processed Food Firms*. Sacramento: State of California. September 1999 figures obtained via personal communication with California DHS.

5. Graf, Anita and Luanne Lohr. 1999. *Analysis of certification program costs*. Working Paper, Fund for Rural America project, Market Development for Organic Agriculture Products, Grant No. 97-36200-5.

6. During the first 18 months, site evaluation for initial accreditation will be conducted jointly by two reviewers. Two reviewers offers: (1) anticipated faster turn-around; (2) different areas of expertise - one reviewer would come from the Quality Systems Certification Program audit staff and would be familiar with ISO Guide 65 verification, while the other reviewer would come from the NOP staff and would be familiar with the requirements of the program; and (3) consistency with the organic industry's desire to have reviewers from both areas of expertise during ISO Guide 65 assessments. AMS would consider sending one reviewer, rather than two, for the site evaluation of small certification agents if an individual possessing both reviewing skill and knowledge of the NOP is available. We anticipate only one reviewer would be required after the 18-month transition period.

7. Adequate advance notice will be given to certifying agents to allow them the opportunity to organize their records prior to the audit and minimize the costs of accreditation.

8. Fetter, Robert T. 1999. *Economic Impacts of Alternative Scenarios of Organic Products Regulation*. Senior Honors Thesis. University of Massachusetts, Amherst, MA.

9. We asked for comments on the first proposal as to whether the current statutory limitation of \$5,000 for exemption from certification should be raised to \$10,000 or to another amount and why such an increased monetary limitation for exemption from certification would be appropriate. Few commenters offered recommendations as to a maximum sales volume to exempt producers. Amounts ranged from \$2,000 to \$50,000, with a few suggesting \$10,000 and \$20,000 exemptions. These proposed exemption levels and justifications in comments received are not sufficiently consistent enough for us to recommend changing the statute

requirement of the \$5,000 maximum sales volume exemption.

10. California State law requires organic farmers to register with the State. Certification is voluntary at the current time.

11. Klonsky, Karen, and Laura Tourte. 1998. *Statistical Review of California's Organic Agriculture, 1992-95*. Report prepared for the California Department of Food and Agriculture Organic Program. Cooperative Extension, Department of Agricultural Economics, University of California, Davis.