

# Applicability -- Preamble

## Subpart B - Applicability

This subpart provides an overview of what has to be certified under the National Organic Program (NOP); describes exemptions and exclusions from certification; addresses use of the term, "organic"; addresses recordkeeping by certified production and handling operations; and addresses allowed and prohibited substances, methods, and ingredients in organic production and handling.

### Description of Regulations

Except for exempt and excluded operations, each production or handling operation or specified portion of a production or handling operation that produces or handles 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 or food group(s))" must be certified. Certified operations must meet all applicable requirements of these regulations.

This final rule becomes effective 60 days after its publication in the Federal Register and will be fully implemented 18 months after its effective date. Eighteen months after the effective date, all agricultural products that are sold, labeled, or represented as "100 percent organic," "organic," or "made with..." must be produced and handled in compliance with these regulations. Products entering the stream of commerce prior to the effective date will not have to be relabeled. The U.S. Department of Agriculture (USDA) seal may not be affixed to any "100 percent organic" or "organic" product until 18 months after the final rule's effective date.

We anticipate that certifying agents and production and handling operations will move as quickly as possible after the effective date of the final rule to begin operating under the national organic standards. Certifying agents must begin certifying organic production and handling operations to the national standards upon receipt of their accreditation from the Administrator. Any production or handling operation or specified portion of a production or handling operation that has been already certified by a certifying agent on the date that the certifying agent receives its accreditation under this part shall be deemed to be certified under the Act until the operation's next anniversary date of certification. We have taken this approach because we believe that such certifying agents will, upon the effective date of the final rule, demonstrate their eligibility for accreditation by applying the national standards to the certification and renewal of certification of their clients. We also believe this approach will provide relief to certified operations which might otherwise have to be certified twice within a 12-month period (prior to their certifying agent's accreditation and again following their certifying agent's accreditation). This relief will only be available to those certified operations certified by a certifying agent that receives its accreditation within 18 months from the effective date of the final rule.

Certifying agents can apply for accreditation anytime after the effective date of the rule. Applications will be processed on a first-come, first-served basis. Those certifying agents who apply for accreditation within the first 6 months after the effective date of the final rule and are determined by the Administrator to meet the requirements for accreditation will be notified of their status approximately 12 months after the final rule's effective date. This approach is being taken because of the market advantage that could be realized by accredited certifying agents if USDA did not announce the accreditations simultaneously.

### Exempt and Excluded Operations

This regulation establishes several categories of exempt or excluded operations. An exempt or excluded operation does not need to be certified. However, operations that qualify as exempt or

excluded operations can voluntarily choose to be certified. A production or handling operation that is exempt or excluded from obtaining certification still must meet other regulatory requirements contained in this rule as explained below.

### **Exempt Operations**

(1) A production or handling operation that has \$5,000 or less in gross annual income from organic sales is exempt from certification. This exemption is primarily designed for those producers who market their product directly to consumers. It will also permit such producers to market their products direct to retail food establishments for resale to consumers. The exemption is not restricted to U.S. producers. However, as a practical matter, we do not envision any significant use of the exemption by foreign producers because: (1) the products from such operations cannot be used as ingredients identified as organic in processed products produced by another handling operation, and (2) it is unlikely that such operations will be selling their products directly to consumers in the United States.

An exempt producer or handler must comply with the labeling requirements of section 205.310 and the organic production and handling requirements applicable to its type of operation. For example, a producer of organic vegetables that performs no handling functions would have to comply with the labeling requirements of section 205.310 and the applicable production requirements in sections 205.202 through 205.207. The labeling and production and handling requirements protect the integrity of organically produced products.

(2) A retail food establishment or portion of a retail food establishment that handles organically produced agricultural products but does not process them is exempt from all of the requirements in these regulations.

(3) A handling operation or portion of a handling operation that handles only agricultural products containing less than 70 percent organic ingredients by total weight of the finished product (excluding water and salt) is exempt from the requirements in these regulations, except the recordkeeping provisions of section 205.101(c); the provisions for prevention of contact of organic products with prohibited substances in section 205.272; and the labeling regulations in sections 205.305 and 205.310. The recordkeeping provisions maintain an audit trail for organic products. The prevention of contact with prohibited substances and the labeling requirements protect the integrity of organically produced products.

(4) A handling operation or portion of a handling operation that uses the word, "organic," only on the information panel is exempt from the requirements in these regulations, except the recordkeeping provisions of section 205.101(c); the provisions for prevention of contact of organic products with prohibited substances as provided in section 205.272; and the labeling regulations in sections 205.305 and 205.310. The recordkeeping provisions maintain an audit trail for organic products. The prevention of contact with prohibited substances and labeling requirements protect the integrity of organically produced products.

As noted above, exempt handling operations producing multiingredient products must maintain records as required by section 205.101(c). This would include records sufficient to: (1) prove that ingredients identified as organic were organically produced and handled and (2) verify quantities produced from such ingredients. Such records must be maintained for no less than 3 years, and the operation must allow representatives of the Secretary and the applicable State program's governing State official access to the records during normal business hours for inspection and copying to determine compliance with the applicable regulations.

### **Excluded Operations**

(1) A handling operation or portion of a handling operation that sells organic agricultural products labeled as "100 percent organic," "organic," or "made with..." that are packaged or otherwise enclosed in a container prior to being received or acquired by the operation, remain in the same package or container, and are not otherwise processed while in the control of the handling operation is excluded from the requirements in these regulations, except for the provisions for prevention of commingling and contact of organic products with prohibited substances in section 205.272. The requirements for the prevention of commingling and contact with prohibited substances protect the integrity of organically produced products.

This exclusion will avoid creating an unnecessary barrier for handlers who distribute nonorganic products and who want to offer a selection of organic products.

(2) A retail food establishment or portion of a retail food establishment that processes on the premises of the retail food establishment raw and ready-to-eat food from certified agricultural products labeled as "100 percent organic," "organic," or "made with..." is excluded from the requirements in these regulations, except for the provisions for prevention of contact of organic products with prohibited substances as provided in section 205.272 and the labeling regulations in section 205.310. The prevention of commingling and contact with prohibited substances and labeling requirements protect the integrity of organically produced products.

Excluded retail food establishments include restaurants; delicatessens; bakeries; grocery stores; or any retail outlet with an in-store restaurant, delicatessen, bakery, salad bar, or other eat-in or carry-out service of processed or prepared raw and ready-to-eat food.

There is clearly a great deal of public concern regarding the handling of organic products by retail food establishments. We have not required certification of retail food establishments at this time because of a lack of consensus as to whether retail food establishments should be certified, a lack of consensus on retailer certification standards, and a concern about the capacity of existing certifying agents to certify the sheer volume of such businesses. Retail food establishments, not exempt under the Act, could at some future date be subject to regulation under the NOP. Any such regulation would be preceded by rulemaking with an opportunity for public comment.

No retailer, regardless of this exclusion and the exceptions found in the definitions for "handler" or "handling operation," may sell, label, or provide market information on a product unless such product has been produced and handled in accordance with the Act and these regulations. Any retailer who knowingly sells or labels a product as organic, except in accordance with the Act and these regulations, will be subject to a civil penalty of not more than \$10,000 per violation under this program.

### **Recordkeeping Requirements for Certified Operations**

A certified operation must maintain records concerning the production and handling of agricultural products that are sold, labeled, or represented as "100 percent organic," "organic," or "made with..." sufficient to demonstrate compliance with the Act and regulations. Such records must be adapted to the particular business that the certified operation is conducting, fully disclose all activities and transactions of the certified operation in sufficient detail to be readily understood and audited, be maintained for not less than 5 years beyond their creation, and be sufficient to demonstrate compliance with the Act and regulations. Certified operations must make the records required by this regulation available for inspection by authorized representatives of the Secretary, the applicable State organic program's (SOP) governing State official, and the certifying agent. Access to such records must be provided during normal business hours.

### **Examples of Records**

Each exempt, excluded, and certified operation should maintain the records which demonstrate compliance with the Act and the regulations applicable to it and which it believes establish an audit trail sufficient to prove to the Secretary, the applicable SOP's governing State official, and the certifying agent that the exempt, excluded, or certified operation is and has been in compliance with the Act and regulations.

Examples of records include: application and supporting documents for certification; organic system plan and supporting documents; purchased inputs, including seeds, transplants, livestock, and substances (fertilizers, pesticides, and veterinary biologics consistent with the livestock provisions of subpart C), cash purchase receipts, receiving manifests (bills of lading), receiving tickets, and purchase invoices; field records (planting, inputs, cultivation, and harvest); storage records (bin register, cooler log); livestock records, including feed (cash purchase receipts, receiving manifests (bills of lading), receiving tickets, purchase invoices, copies of grower certificates), breeding records (calendar, chart, notebook, veterinary documents), purchased animals documentation (cash purchase receipts, receiving manifests (bills of lading), receiving tickets, purchase invoices, copies of grower certificates), herd health records (calendar, notebook, card file, veterinary records), and input records (cash purchase receipts, written records, labels); producer invoice; producer contract; receiving manifests (bills of lading); transaction certificate; producer certificate; handler certificate; weigh tickets, receipts, and tags; receiving tickets; cash purchase receipts; raw product inventory reports and records; finished product inventory reports and records; daily inventories by lot; records as to reconditioning, shrinkage, and dumping; production reports and records; shipping reports; shipping manifests (bills of lading); paid freight and other bills; car manifests; broker's contracts; broker's statements; warehouse receipts; inspection certificates; residue testing reports; soil and water testing reports; cash receipt journals; general ledgers and supporting documents; sales journals; accounts payable journals; accounts receivable journals; cash disbursement journals; purchase invoices; purchase journals; receiving tickets; producer and handler contracts; cash sales receipts; cash purchase journals; sales invoices, statements, journals, tickets, and receipts; account sales invoices; ledgers; financial statements; bank statements; records of deposit; canceled checks; check stubs; cash receipts; tax returns; accountant's or other work papers; agreements; contracts; purchase orders; confirmations and memorandums of sales; computer data; computer printouts; and compilations of data from the foregoing.

### **Allowed and Prohibited Substances**

A certified operation must only use allowed substances, methods, and ingredients for the production and handling of agricultural products that are sold, labeled, or represented as "100 percent organic," "organic," or made with..." for these products to be in compliance with the Act and the NOP regulations. Use of ionizing radiation, sewage sludge, and excluded methods are prohibited in the production and handling of organic agricultural products.

### **Applicability - Changes Based on Comments**

This subpart differs from the proposal in several respects as follows:

(1) Violations of the Act or Regulations. We have amended section 205.100 by adding a new paragraph (c), which addresses violations of the Act and these regulations. A number of commenters advocated for provisions within the final rule describing what legal proceedings USDA would conduct against operations or persons that violate the NOP. We agree that this rule should include provisions addressing violations of the Act and these regulations. Accordingly, we have added at section 205.100 the misuse of label provisions and false statement provisions of section 2120 (7 U.S.C. 6519) of the Act. Specifically, section 205.100(c) provides that persons not in compliance with the labeling requirements of the Act or these regulations are subject to a civil penalty of not more than \$10,000 per violation and that persons making false statements under the Act to the Secretary, a governing State official, or an accredited certifying agent shall

be subject to the provisions of section 1001 of Title 18, United States Code. The provisions of the Act and these regulations apply to all operations or persons that sell, label, or represent their agricultural product as organic.

(2) Prohibition on Use of Excluded Methods. We have moved section 205.600 from subpart G, Administrative, to subpart B, Applicability, and replaced paragraph (d), which referred the reader to section 205.301, with new paragraphs (d) through (g). As amended, this section, redesignated as section 205.105, includes all of the provisions covered under old section 205.600.

The vast majority of commenters strongly supported the prohibition on the use of excluded methods in organic production and handling but raised concerns that they could not point to one provision that prohibited use of excluded methods in all aspects of organic production and handling. To close what they perceived to be "loopholes" in the prohibition, commenters made several suggestions for inclusion of new provisions prohibiting use of excluded methods in particular aspects of organic production and handling that they believed were not covered in the proposed rule. Other commenters pointed to inconsistencies in the way the prohibition on use of excluded methods was described in different sections, raising concerns that these apparent inconsistencies may create confusion for organic operations, certifiers, and consumers.

Although we intended that use of excluded methods would be prohibited in all aspects of organic production and handling, the structure of the proposed rule may not have made that clear. We also share the concerns that, in attempting to identify all aspects of organic production and handling where excluded methods might be used, we may inadvertently have left out some provisions, creating confusion for organic operations, certifying agents, and consumers and creating doubt as to the scope of the prohibition on use of excluded methods. Similarly, to the extent that the prohibition on excluded methods may have been described differently in various sections of the proposed rule, we also share the concern that these inconsistencies could create confusion.

As a result of these concerns, we have created a new provision in section 205.105 that prohibits the use of excluded methods (and ionizing radiation and sewage sludge) generally. This provision should alleviate perceptions that some areas of organic production may not have been covered by the prohibitions in the proposed rule. It also allows us to eliminate from the regulation most of the individual references to the prohibition on use of these methods, thereby eliminating any potential confusion where these provisions may have appeared inconsistent. These changes do not lift the prohibition on use of these methods in those sections. In fact, the purpose of this new provision is to make clear that use of these methods is prohibited in the production and handling of organic products.

(3) Animal Vaccines. The proposed rule specifically asked for public comment on the potential impact of the prohibition on use of excluded methods as it relates to animal vaccines. A number of commenters raised concerns that there may be some critical vaccines that are only available in forms produced using excluded methods. Several commenters requested that we prohibit use of animal vaccines produced using excluded methods but that we provide for a temporary exemption until such time as vaccines produced without using excluded methods are approved for use on the National List. Other commenters requested that we prohibit use of vaccines produced using excluded methods without exception.

We have concluded that the potential impact of prohibiting vaccines produced using excluded methods on animal production systems is still unknown. We do not know of any critical animal vaccine that is only available in a form produced using excluded methods, but it is unclear whether producers and certifying agents are tracking the possible use of such vaccines. There also appears to be no international consensus on the use in organic production systems of animal vaccines produced using excluded methods, although there is precedent for such an exemption.

European Union regulations, for example, allow for use of animal vaccines produced using excluded methods.

Based on comments received and because the potential impact of the prohibition on use of excluded methods is still uncertain, we have created the possibility at section 205.105(e) for the NOSB to exercise one very narrow exception to allow use of animal vaccines produced using excluded methods but only if they are explicitly approved on the National List. We believe the issue of animal vaccines requires further deliberation and that it is most appropriate to consider it through the National List process, which mandates review by the NOSB and Technical Advisory Panels. Consideration of animal vaccines produced using excluded methods is appropriate for the National List review process because animal vaccines, we believe, are most appropriately considered synthetic materials. That is why the provision is structured so that vaccines produced using excluded methods could only be used in organic production if they are affirmatively included on the National List. We do not believe that a broad-based exemption of the type suggested in some comments, even if only temporary, is appropriate.

The Act allows use of animal vaccines in organic livestock production. Given the general prohibition on the use of excluded methods, however, we believe that animal vaccines produced using excluded methods should not be allowed without an explicit consideration of such materials by the NOSB and without an affirmative determination from the NOSB that they meet the criteria for inclusion on the National List. It is for that reason that we have not granted this request of commenters but, rather, provided an opportunity for review of this narrow range of materials produced using excluded methods through the National List process.

It is important to make clear, however, that this provision does not open all potential applications of excluded methods to a case-by-case review in the context of the National List, nor are we proposing that any particular vaccines be reviewed for inclusion on the National List at this time. The prohibition on use of excluded methods applies across the board to all phases of organic production and handling. We are simply responding to comments suggesting that a narrow exception for animal vaccines may be appropriate and providing for the possibility that such an exception could be invoked upon thorough review and recommendation by the NOSB

### **Applicability - Changes Requested But Not Made**

This subpart retains from the proposed rule regulations on which we received comments as follows:

(1) Exemption of Handling Operations Producing Multiingredient Products. Some commenters asserted that only certified handling operations should be allowed to identify ingredients in multiingredient products as organic. These commenters believe that consumers will be misled if noncertified handling operations are allowed to identify ingredients as organic even if the organic claim is limited to the information panel. We do not agree with these assertions and have retained the proposed rule provisions that do not require handler certification when a product only identifies ingredients as organic within the information panel. Although handling operations only making organic claims on the information panel are exempt from certification, these operations are required to use organic product from certified operations. They are also required to prevent contact of organic products with prohibited substances as set forth in section 205.272, adhere to the labeling provisions of sections 205.305 and 205.310, and maintain records in accordance with section 205.101(c). We believe consumers will understand the distinction between products that have the organic nature of the product stated on the principal display panel and those that merely identify an ingredient as organic on the information panel.

(2) Retailer Exclusion from Certification. Many commenters objected to the provisions of section 205.101(b)(2) which exclude retail food establishments from certification. These commenters

assert that only final retailers that do not process agricultural products should be excluded from certification. There is clearly a great deal of public concern regarding the handling of organic products by retail food establishments. We have not required certification of retail food establishments at this time because of a lack of consensus as to whether retail food establishments should be certified, a lack of consensus on retailer certification standards, and a concern about the capacity of existing certifying agents to certify the sheer volume of such businesses. In addition, most existing certification programs do not include retail food establishments, and we do not believe there is sufficient consensus to institute such a significant expansion in the scope of certification at this time. However, since a few States have established procedures for certifying retail food establishments, we will assess their experience and continue to seek consensus on this issue of establishing retailer provisions under the NOP. Any such change would be preceded by rulemaking with an opportunity for public comment. The exclusion of nonexempt retail food establishments from this final rule does not prevent a State from developing an organic retail food establishment program as a component of its SOP. However, as with any component of an SOP, the Secretary will review such components on a case-by-case basis.

(3) Producer Exemption Level. Several commenters advocated for an increase in the producer exemption level above the \$5,000 limit. Comments supporting the exemption suggested increasing the statutory limit for qualifying for the exemption to as high as \$75,000. Other commenters stated that all producers should be certified and opposed the exemption even though it is required by the Act. These commenters were concerned about maintaining the integrity of the organic product and about the lack of verification of the exempt operations.

We have not increased or removed the \$5,000 producer exemption because the exemption is mandated by section 2106(d) (7 U.S.C. 6505(d)) of the Act. Our purpose is to limit the financial burdens of certification on such operations but not to exempt them from the standards for organic production and handling. Accordingly, exempt production and handling operations must comply with the applicable organic production and handling requirements of subpart C and the labeling requirements of section 205.310.

Some of the commenters wanting a change in the producer exemption level suggested that the NOP add provisions for restricting these producers to marketing at farmers markets or roadside stands. We disagree with these comments. While we believe that most producers qualifying for the exemption are indeed likely to be small producers who market their products directly to consumers, we do not believe it is in the best interest of these producers to restrict their market opportunity to a specific sales method.

A few comments suggested that we establish a sliding-scale certification fee based upon either the size of the operation or sales of agricultural product instead of the exemption. The NOP does not establish fees for certification. Certifying agents may establish a sliding-scale system as long as their fees are reasonable and applied in a consistent and nondiscriminatory manner.

Finally, some commenters expressed concern that exempt operations were forbidden from certification. This interpretation is not correct. Any production or handling operation, including an exempt operation, which makes application for certification as an organic operation and meets the requirements for organic certification may be certified.

(4) Handler exemption. Many commenters disagreed with the proposed rule provision providing for an exemption of \$5,000 to handlers. These commenters asked the NOP to remove the phrase, "or handlers," from the exemption provision. The commenters argue that the handler exemption is not authorized by the Act. We disagree with the commenters, and we have retained the handler exemption in the final rule. The Act states that the exemption is available to "persons" selling not more than \$5,000 annually in value of agricultural products. The Act's definition of "persons" includes handlers. Thus, handlers grossing \$5,000 or less qualify for the exemption.

(5) Categories of Income to Qualify for an Exemption. Some commenters want the \$5,000 producer/handler exemption to include all sales of agricultural products, not just sales of organic agricultural products. These commenters perceive this provision to be a loophole for large, split operations. We disagree with these commenters, and we have retained the \$5,000 producer/handler exemption based upon total sales of organic agricultural products. We do not believe there is a significant number of split operations which only gross \$5,000 in annual sales of organic products and, therefore, qualify for this exemption. In setting the exemption levels, the Department sought to maximize the benefits to small producers afforded by the Act while setting a threshold level that minimizes the potential of product mislabeling.

(6) Limiting Handler Exclusions. Many commenters argued that brokers, distributors, warehousemen, and transporters should not be excluded from certification. We do not agree with these commenters. Brokers, distributors, warehousemen and transporters do not alter the product and, in many cases, do not take title to the product. Certifying these handlers would be an unnecessary burden on the industry. Traditionally, distributors and trucking companies have been excluded from State and private certification requirements.

(7) Recordkeeping Requirements for Excluded Operations. Several commenters argued that excluded operations should be required to comply with the same recordkeeping requirements as exempt operations. Some commenters expressed concern over the inability to verify compliance for either exempt or excluded operations and asked that exempt or excluded operations be subject to additional recordkeeping requirements. We disagree with these commenters and have retained the provisions from the proposed rule on recordkeeping for excluded operations. Given the nature of these excluded operations, for example, operations that only sell prepackaged organic products, we believe that extensive recordkeeping requirements would be an unwarranted regulatory burden.

(8) Recordkeeping Burden on Small Certified Operations. Some commenters questioned whether small certified operations have the ability to implement a recordkeeping system which complies with the provisions of section 205.103. These commenters argue that recordkeeping requirements must be tailored to the scale of the operation. We do not believe that the recordkeeping requirements as described in section 205.103 conflict with the suggestions of the commenters. The recordkeeping requirements provide that the records must be adapted to the particular business that the certified operation is conducting and be sufficient to demonstrate compliance with the Act and regulations. It is USDA's intent that each production and handling operation decide for itself what recordkeeping scheme is appropriate, given the complexity and scope of the individual business. These provisions provide considerable latitude for each production and handling operation to decide what records are necessary to demonstrate its compliance with the Act and the NOP regulations.

(9) Public Access to Records. Several commenters asked that the public have full access to any certifying agent record on organic production and/or handling operations. Other commenters expressed concerns about certifying agents divulging confidential business information and asked that records containing confidential business information not be taken from the business' physical location.

We have not changed this provision. The recordkeeping requirements are designed to seek a balance between the public's right to know and a business's right to retain confidential business information. Certifying agents must have access to certain records during their review of the operation to determine the operation's compliance with the NOP. However, certifying agents are required to protect an operation's confidential business information. Requiring full public access could compromise a business' competitive position and place an unfair burden on the organic industry.

(10) Fair Labor Practices on Organic Farms. Many commenters asked the NOP to

develop fair labor practice standards as a part of the final rule. We have not adopted these comments. Other statutes cover labor and worker safety standards. The Act does not provide the authority to include them in these regulations. However, these regulations do not prohibit certifying agents from developing a voluntary certification program, separate from organic certification, that address fair labor and worker safety standards.

(11) "Transitional Organic" Label. Several commenters requested that the NOP adopt regulations on the conversion of operations to organic production and create a "transitional organic" label. We have not included provisions within the final rule that provide for "transitional organic" labeling. Although many commenters requested that we provide for transition labeling, there does not appear to be sufficient consensus to establish such a standard at this time. Given this lack of consensus, it is unclear what marketplace value such a label might have, and we are concerned that allowing such a label at this point might lead to greater consumer confusion rather than providing clarity.

### **Applicability - Clarifications**

Clarification is given on the following issues raised by commenters as follows:

(1) "Genetic" drift. Many commenters raised issues regarding drift of the products of excluded methods onto organic farms. These commenters were concerned that pollen drifting from near-by farms would contaminate crops on organic operations and that, as a result, organic farmers could lose the premium for their organic products through no fault of their own. Many commenters argued that we should use this rule to somehow shift the burden to the technology providers who market the products of excluded methods or the nonorganic farming operations that use their products. Some, for example, suggested that this regulation should require that the nonorganic operations using genetically engineered varieties plant buffer strips or take other steps to avoid drift onto organic farms. Others suggested that the regulation could provide for citizens' right to sue in cases of drift.

While we understand the concerns that commenters have raised, the kind of remedies they suggested are outside the scope of the Act and this regulation. The Act only provides for the regulation of organic operations. We cannot use this regulation to impose restrictions, such as requiring buffer strips or other measures, on operations that are not covered by the Act. Similarly, while citizens may have the ability to bring suit under other laws, the Act itself does not provide for the right to bring suit as a Federal cause of action, and we could not grant it through this regulation.

Drift has been a difficult issue for organic producers from the beginning. Organic operations have always had to worry about the potential for drift from neighboring operations, particularly drift of synthetic chemical pesticides. As the number of organic farms increases, so does the potential for conflict between organic and nonorganic operations.

It has always been the responsibility of organic operations to manage potential contact of organic products with other substances not approved for use in organic production systems, whether from the nonorganic portion of a split operation or from neighboring farms. The organic system plan must outline steps that an organic operation will take to avoid this kind of unintentional contact.

When we are considering drift issues, it is particularly important to remember that organic standards are process based. Certifying agents attest to the ability of organic operations to follow a set of production standards and practices that meet the requirements of the Act and the regulations. This regulation prohibits the use of excluded methods in organic operations. The presence of a detectable residue of a product of excluded methods alone does not necessarily constitute a violation of this regulation. As long as an organic operation has not used excluded

methods and takes reasonable steps to avoid contact with the products of excluded methods as detailed in their approved organic system plan, the unintentional presence of the products of excluded methods should not affect the status of an organic product or operation.

Issues of pollen drift are also not confined to the world of organic agriculture. For example, plant breeders and seed companies must ensure genetic identity of plant varieties by minimizing any cross-pollination that might result from pollen drift. Under research conditions, small-scale field tests of genetically engineered plants incorporate various degrees of biological containment to limit the possibility of gene flow to other sexually compatible plants. Federal regulatory agencies might impose specific planting requirements to limit pollen drift in certain situations. Farmers planting nonbiotechnology-derived varieties may face similar kinds of questions if cross-pollination by biotechnology-derived varieties alters the marketability of their crop. These discussions within the broader agricultural community may lead to new approaches to addressing these issues. They are, however, outside the scope of this regulation by definition.

(2) Additional NOP Standards for Specific Production Categories. Many commenters asked that the NOP include in the final rule certification standards for apiculture, greenhouses, mushrooms, aquatic species, culinary herbs, pet food, and minor animal species (e.g., rabbits) food. The NOP intends to provide standards for categories where the Act provides the authority to promulgate standards. During the 18-month implementation period, the NOP intends to publish for comment certification standards for apiculture, mushrooms, greenhouses and aquatic animals. These standards will build upon the existing final rule and will address only the unique requirements necessary to certify these specialized operations.

Some of the other questions raised by commenters are already addressed in the final rule. For example, feed for minor species is covered by livestock feed provisions within subpart C and the livestock feed labeling provisions within subpart D. The production and utilization of culinary herbs, including herbal teas, is covered by the provisions of the final rule. We do not envision needing to do additional rulemaking on these two categories.

Other requests by commenters have not been addressed. We have not addressed the labeling of pet food within this final rule because of the extensive consultation that will be required between USDA, the NOSB, and the pet food industry before any standards on this category could be considered.

(3) Standards for Cosmetics, Body Care Products, and Dietary Supplements. A few commenters asked that the NOP include in the final rule certification standards for cosmetics, body care products, and dietary supplements. Producers and handlers of agricultural products used as ingredients in cosmetics, body care products, and dietary supplements could be certified under these regulations. Producers and handlers of these ingredients might find an increased market value for their products because of the additional assurance afforded by certification. The ultimate labeling of cosmetics, body care products, and dietary supplements, however, is outside the scope of these regulations.

(4) Private Label Products. Many commenters asked about the certification status of

so-called "private label products." Private label products are items for which a retailer contracts with a processor to produce the product to the retailer's specifications and to be sold under the retailer's name. Commenters believe the proposed rule was unclear on the certification requirements for these products. Any product labeled as "100 organic," "organic," or "made with..." must be certified regardless of the business arrangements under which the product was produced. When a retail operation contracts for the production, packaging, or labeling of organic product, it is the certified production or handling operation that is responsible for complying with the applicable organic production or handling regulations.

(5) State Oversight of Exempt and Excluded Operations. Many commenters asked for clarification on the State's enforcement responsibility for exempt and excluded operations. The NOP is ultimately responsible for the oversight and enforcement of the program, including oversight of exempt and excluded operations and cases of fraudulent or misleading labeling. We expect, however, that States would want to monitor for false claims or misleading labeling under these regulations and would forward any complaints to the NOP. States that have an approved SOP which includes regulation of operations excluded under the NOP would be required to enforce those provisions.

(6) Nonedible Fibers Products in the NOP. Some commenters asked the NOP to clarify the certification status of fibers such as cotton and flax. The final rule allows for certification of organically produced fibers such as cotton and flax. However, the processing of these fibers is not covered by the final rule. Therefore, goods that utilize organic fibers in their manufacture may only be labeled as a "made with..." product; e.g., a cotton shirt labeled "made with organic cotton."

(7) Recordkeeping for Operations That Produce Organic and Nonorganic Product. Several commenters recommended that "split operations," which are operations producing organic and nonorganic agricultural products, be required to maintain separate records. These commenters believe that the proposed rule did not provide adequate provision for the maintenance of separate recordkeeping. The provisions within section 205.103(b)(1) and (b)(2) do indicate that operations which produce both organic and nonorganic agricultural products must maintain a recordkeeping system that differentiates the organic portion of the operations from the records related to other portions of operations.

(8) NOP Program Manual. A few commenters, particularly States, noted that the proposed rule made several references to program manuals as a mechanism for further clarifying certain portions of the rule. These commenters asked whether certifying agents should consider information contained in these manuals as enforceable regulations. NOP program manuals cannot be and are not intended to be the equivalent of regulations. Rather, the NOP envisions development of a program manual to serve as guidance for certifying agents regarding implementation- and certification-related issues. Material contained within the program manual will be designed to address the organic agriculture principles of each final rule section, as appropriate, and to offer information that certifying agents should consider in making certification decisions that will be reliably uniform throughout the country. The use of program manuals as guidance to assist in developing uniform certification decisions is a standard industry practice, and the NOP has compiled examples of program manuals from both large and small certifiers. Because the NOP intends to use the examples it has acquired as the basis for any NOP guidance manual, we believe that most certifying agents will find such NOP manual, when developed, familiar and useful. Additionally, we will use the NOSB public meeting process to seek guidance from industry and the public on what information would be useful in a program manual and to provide input on the program manual as it is developed. Of course, if in developing program guidance, it appears that modifications or changes in the NOP final rule are required, such modifications would be made through notice and comment rulemaking.

(9) Use of Products from Exempt Operations as Organic Ingredients. A few commenters responded to the question in the proposed rule in which we asked whether handlers should be allowed to identify organically produced products produced by exempt production operations as organic ingredients. The proposed rule provided that all ingredients identified as organic in a multiingredient product must have been produced by a production or handling operation certified by an accredited certifying agent.

The commenters supported this position. These commenters believe that the potential for mislabeling outweighed any financial benefit that might accrue to exempt producers through

expanded market opportunities. We concur, and, therefore, have retained the prohibition on using products produced by an exempt production or handling operation as organic ingredients

(10) Exemption of Handling Operations Producing Multiingredient Products. We have amended section 205.101(a)(3) by changing "50 percent" to "70 percent" to make it consistent with the amendments to the labeling provisions. We have also edited section 205.101(a)(4) for clarification purposes. Additionally, we amended sections 205.101(a)(3) and 205.101(a)(4) by citing the labeling requirements of section 205.305. These amendments have been made to clarify that handling operations exempted under these sections are subject to the labeling requirements of section 205.305.

(11) Production and Handling in Compliance with Federal Statutes. We have amended section 205.102 by removing paragraph (c). This paragraph provided that any agricultural product that is sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients)" must be produced and handled in compliance with applicable Federal statutes and their implementing regulations. We have taken this action because the provision is an identical restatement of section 2120(f) (7 U.S.C. 6519(f)) of the Act. The Act makes clear that all production and handling operations are to comply with all applicable Federal statutes and their implementing regulations. Therefore, it is unnecessary to repeat the requirement in these regulations.

(12) Foreign Applicants. We have removed section 205.104, which provided that the regulations in this part, as applicable, apply equally to domestic and foreign applicants for accreditation, accredited certifying agents, domestic and foreign applicants for certification as organic production or handling operations, and certified organic production and handling operations unless otherwise specified. These regulations, as written, apply equally to all applicants for accreditation, accredited certifying agents, applicants for organic certification, and certified organic operations. Accordingly, we have determined that section 205.104 is not necessary.