Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 205

[TM–98–00–7]

RIN 0581–AA40

National Organic Program—Issue Papers

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed Rule; request for comments on Issue Papers.

SUMMARY: Agricultural Marketing Service (AMS) is seeking comments on three papers that address certain issues raised in the comments received on the National Organic Program proposed rule published in the **Federal Register** on December 16, 1997. These issue papers which address livestock confinement, livestock health care, and certification termination, and comments received on them will be considered during the development of a revised National Organic Program proposed rule.

DATES: Comments must be submitted on or before December 14, 1998.

ADDRESSES: Interested persons are invited to submit written comments on these issues to: Eileen S. Stommes, Deputy Administrator, USDA-AMS-TM-NOP, Room 4007-S, AG Stop 0275, P.O. Box 96456, Washington, D.C. 20090–6456. Comments may also be sent by fax to (202) 690–4632 or via e-mail to: *NOPIssue Papers@usda.gov*. Additionally, USDA plans to accept comments via the National Organic Program home page at a future date. Notification of acceptance of comments by this form will occur through an additional **Federal Register** notice.

FOR FURTHER INFORMATION CONTACT: T. Keith Jones, Program Manager, USDA-AMS-TM-NOP, Room 2510-S, AG Stop 0275, P.O. Box 96456, Washington, D.C. 20090–6456. Phone (202) 720–3252.

SUPPLEMENTARY INFORMATION: AMS is seeking comments on three papers that address certain issues raised during the National Organic Program's proposed rule comment period. These issue papers which address livestock confinement, livestock health care, and certification termination, and comments received on them will be considered during the development of a revised National Organic Program proposed rule.

The issue papers are: Issue Paper 1. Livestock Confinement in Organic Production Systems; Issue Paper 2. The Use of Antibiotics and Parasiticides in Organic Livestock Production; and Issue Paper 3. Termination of Certification by Private Certifiers. These issue papers are being published in an effort to provide the opportunity for public input. USDA is committed to a process that is open to all interested parties.

All comments, whether mailed, faxed, or submitted via the Internet, will be available for viewing at the USDA–AMS, Transportation and Marketing Programs, Room 2945-South Building, 1400 Independence Ave., S.W., Washington, D.C., from 9:00 a.m. to 1:00 p.m., and from 2:00 p.m. to 4:30 p.m., Monday through Friday (except official Federal holidays). Persons wanting to visit the USDA South Building to view comments received in response to this proposal are requested to make an appointment in advance by calling Gayle Patterson at (202) 720–3252.

The issue papers are published below.

Issue Paper 1. Livestock Confinement in Organic Production Systems

1. Goal

USDA's goal is to establish clear, consistent regulations that stimulate the growth of the organic livestock sector, satisfy consumer expectations and allow organic livestock producers flexibility in making site-specific, real-time management decisions.

2. Issue

Commenters on USDA's proposed rule, published December 16, 1997 (62 FR 65850), assert that the language in the proposed rule,

> if necessary, livestock may be maintained under conditions that restrict the available space for movement or access to the outside,

section 205.15(b), creates a significant loophole for factory farming of livestock despite the other requirements for access to outdoors and space for movement. USDA believes that commenters are concerned that the term if necessary, could be broadly interpreted by public and private certifiers.

3. Background

The Organic Foods Production Act (7 U.S.C. 6501–6522) (OFPA) is silent on livestock confinement. In its proposed rule, USDA specifically requested public comment on the conditions under which animals may be maintained, specifically with regard to the available space for movement and access to the outdoors. Many commenters advocated USDA's adoption of the National Organic Standards Board (NOSB) recommendations on livestock production which recognize that proper livestock management may provide for times when livestock are confined. The NOSB said

> temporary indoor housing may be justified for: 1. inclement weather conditions; 2. health, care, safety and well-being of the livestock; and 3. protection of soil and water quality.

Therefore, commenters who support the NOSB recommendations appear to accept animal confinement as long as the criteria allowing confinement are clearly delineated.

In writing the proposed rule, USDA, like the NOSB, sought to balance animal health issues, such as prevention of exposure to disease and predators, with the concepts that organic management is soil-based, and that animals should be allowed access to the soil. USDA envisioned that the language of section 205.15(b) would allow the flexibility needed for producers to confine animals during critical periods such as farrowing.

In keeping with this intent, USDA chose the term if necessary to capture the spirit of the NOSB recommendation. The terms if necessary or justified, used respectively in the proposed rule and the NOSB recommendation, envisioned guidelines by which a producer or certifier would benchmark the management decision. USDA believed that such guidelines would be formulated during development of a program manual for the National Organic Program. USDA also concluded that the proposed livestock standards, when taken as a whole, serve as a delimiting mechanism to large-scale confined animal feeding operations.

Many commenters indicated opposition to factory farming of livestock. It is unclear how these commenters would define the term factory farming and whether those who oppose factory farming are concerned about animal space requirements, environmental issues, or a particular business structure. Like NOSB and USDA, they believe that routine, continuous confinement of livestock must be prohibited, but some commenters stated that the proposed livestock requirements, which required access to outdoors and space for movement, fall short of consumer expectations for the production of organically grown livestock. Therefore, a more detailed delineation of the criteria for appropriate confinement may be necessary to satisfy the concerns of these commenters.

4. Options

In response to these comments, USDA is considering the following options:

Option 1—Retain the Current Language but Elaborate on Its Intent

Pros: Consistent with NOSB recommendations;
Allows for producer/certifier flexibility;
Allows for various animal space requirements.
Cons: May not meet expectations of some commenters;
Compliance verification could be difficult.

Option 2—Establish Animal Space Requirements in Animal Feeding Operations

Pros: Addresses commenter concerns about animal space requirements.
Simplifies animal space verification.
Cons: An issue not addressed by NOSB or USDA;
Criteria for space requirements could be difficult to establish;
Further reduces producer/certifier flexibility.

Option 3—Establish Requirements for Access to Pasture.

Pros: Would satisfy commenter concerns;
Would address animal safety concerns;
Allows for various animal space requirements;
Cons: An issue not addressed by NOSB or USDA;
Compliance verification could be difficult;
May not be appropriate for all species of livestock;
Further reduces producer/certifier flexibility.

Option 4—Explore Feasibility of Allowing Livestock Products Labeled as Organic To Include Additional Label Claims, Such as Pasture-Raised, Free-Range or Never Confined in a Feedlot

Pros: Provides consumers with more product information;
Allows producers to market to a further defined niche.
Cons: Could cause consumer confusion;
Could devalue the term organic;
Limited verification for label claims.

USDA is interested in exploring other options. Additionally, we are seeking comments on the following questions: Should the rule ban confined animal feeding operations? Would requiring access to pasture satisfy commenters, including those who oppose factory farming? What economic impact would these options have on organic livestock producers? How would additional labeling claims affect the marketing of organic livestock products?

Would annual or semi-annual organic certification site visits be sufficient to ensure that routine, continuous confinement is not occurring? How should certifiers determine that confinement is being employed in accordance with the regulations?

How should access to pasture be defined? Should a species-by-species approach be taken? When permitted by regulation, should the duration and frequency of confinement be resolved on a case-by-case basis between certifier and producer?

Issue Paper 2.—The Use of Antibiotics and Parasiticides in Organic Livestock Production

1. Goal

USDA's goal is to establish clear, consistent regulations that stimulate the growth of the organic livestock sector, satisfy consumer expectations and allow organic livestock producers flexibility in making site-specific, real-time management decisions.

2. Issue

In its proposed rule published December 16, 1997 (62 FR 65850), USDA specifically requested public comment on the use of animal drugs in the production of organic livestock. Many commenters advocated the adoption of the National Organic Standards Board (NOSB) recommendations on both antibiotics and parasiticides. The NOSB recommendations prohibit the use of antibiotics and parasiticides in organic production except under certain clearly delineated animal health conditions.

Many other commenters go beyond the options proposed by USDA and the NOSB by advocating an absolute prohibition on the use of antibiotics in organic livestock production. Further, commenters who specifically mention the use of parasiticides as an area of concern assert that the language in the proposed rule defining the term routine use of parasiticides as administering a parasiticide to an animal without cause is inadequate. These commenters suggest that it would be too easy for producers to find cause to administer a parasiticide, and that they might therefore become reliant on parasiticides rather than on preventative measures. Some commenters would prefer a complete ban on the use of all animal medications, including antibiotics and parasiticides, in organic livestock production.

3. Background

The OFPA prohibits only the use of subtherapeutic doses of antibiotics and of synthetic internal parasiticides on a routine basis. Since young animals are especially vulnerable to disease, USDA believed there was sufficient justification for additional protection in the early days of life. To ensure the health of animals during critical periods, USDA also allowed the therapeutic use of antibiotics in dairy and breeder stock because of the animals' longevity and the potential for infections arising from pregnancy and delivery. USDA attempted to capture the statutory prohibition on routine use of parasiticides by defining such use as, administering a parasiticide to an animal without cause.

4. Options

In light of these comments, USDA is analyzing options to assist in determining the proper role for antibiotics and parasiticides in organic livestock production. Options under consideration, along with USDA's assessment of the pros and cons of each option, are listed below:

Option 1—Prohibit all use of antibiotics and parasiticides.

Pros: Consistent with many comments.
Cons: Animal health could be adversely affected, particularly that of young animals;
Inconsistent with NOSB recommendations;
Compliance verification could be difficult;
Could limit industry growth by preventing the production of some types of livestock in specific geographic areas.

Option 2—Prohibit the Use of All Animal Medications, Other Than Vaccinations, Including Antibiotics and Parasiticides.

Pros: Consistent with some comments.

Cons: Animal health could be adversely affected, particularly that of young animals;

Inconsistent with NOSB recommendations;

Compliance verification could be difficult;

Could limit industry growth by preventing the production of some types of livestock in specific geographic areas.

Option 3—Allow the Therapeutic Use of Antibiotics and the Non-Routine use of Parasiticides Under Specific Animal Health Conditions.

Pros: Consistent with NOSB recommendations;

Allows for the protection of animal health;

Animal production could be enhanced;

Provides producer/certifier flexibility to respond to rapidly changing animal health conditions.

Cons: Compliance verification could be difficult.

USDA is interested in exploring other options. Additionally, we are seeking comments on the following questions: What economic impact would the prohibition of all medication, including antibiotics and parasiticides, have on organic livestock producers?

Under what conditions, if any, could an animal for slaughter receive a synthetic internal parasiticide? An external parasiticide? What about breeding stock or dairy animals?

Should we make provisions for the use of synthetic parasiticides where other measures has proven ineffective?

Would annual or semi-annual organic certification site visits be sufficient to ensure that preventative measures are being carried out and that antibiotics and parasiticides are being administered in accordance with the Act and its regulations? When permitted by regulation, should the use of antibiotics and parasiticides be resolved on a case-by-case basis between certifier and producer?

Issue Paper 3. Termination of Certification by Private Certifiers

1. Goal

USDA's goal is to implement the Organic Foods Production Act (OFPA) at the local level, while utilizing, to the extent possible, the existing infrastructure of organic certification.

2. Issue

Many commenters on USDA's proposed rule, published December 16, 1997 (62 FR 65850), assert that the proposed process for termination of certification would be unduly bureaucratic and would complicate local certifiers' efforts to ensure the integrity of the organic label.

3. Background

In the proposed rule, USDA sought to balance the public policy goal of withdrawing certification from a farmer or handler who violates the Act against the constitutional protections afforded to entities certified under the OFPA. The National Organic Standards Board did not make any specific recommendation on this issue. Under the OFPA, accredited certifiers are agents of the Secretary in carrying out their responsibilities under the Act. Certifiers' authority is derived from their accreditation under the OFPA.

USDA, acting directly or through accredited certifiers, cannot suspend or revoke a certification once granted without providing due process of law, which requires providing an opportunity to be heard before the suspension or revocation of certification.

A certified entity must be afforded the opportunity for a hearing before certification can be suspended or revoked. Although private certifiers have expressed considerable dissatisfaction with this process, there is no legal mechanism to allow private certifiers to suspend or revoke certifications. Thus, section 205.219(b) of our proposed rule, stated that if a certifying agent had reason to believe that a certified operation had violated the Act, the certifying agent would recommend that USDA terminate certification. After review of the recommendation, the Administrator of the Agricultural Marketing Service could institute proceedings to terminate certification.

4. Options

USDA continues to review comments on this issue and to consider various alternatives that would achieve the objectives expressed in the comments. Options under consideration, along with USDA's assessment of the pros and cons of each option, are listed below. USDA welcomes alternative suggestions.

Option 1—Create a Uniform and Efficient Information System To Inform the Public of USDA Actions To Suspend or Revoke Certification

Pros: Would provide timely information concerning the compliance status of certified entities;

Provides necessary and timely information about the compliance status of a certified entity during the pendency of an enforcement action.

Cons: Does not fulfill commenters' desire for revocation authority at the certifier level;

Does not fulfill commenters' desire for immediate revocation, since certification would remain in full effect pending case resolution.

Option 2—Provide for an Expedited Process, Including Special Rules of Practice and Shortened Time Frames, To Review Certifier Recommendations and Make Determinations

Pros: Would provide due process;

Could result in quicker resolution of enforcement issues;

Might reduce enforcement costs for all parties to the dispute.

Cons: Does not fulfill commenters' desire for revocation authority at the certifier level;

Does not fulfill commenters' desire for immediate revocation, since certification would remain in full effect pending case resolution.

Option 3—Design an Informal Alternative Procedure To Resolve Enforcement Issues on an Expedited Basis Short of an Adjudicatory Hearing

Pros: Would provide due process;

Could result in quicker resolution of enforcement issues;

Might reduce enforcement costs for all parties to the dispute.

Cons: Does not fulfill commenters' desire for revocation authority at the certifier level;

Does not fulfill commenters' desire for immediate revocation, since certification would remain in full effect pending case resolution.

A 45-day comment period is provided for interested persons to provide comment. This period is deemed appropriate because any comments received will be considered in the development of a revised National Organic Program proposed rule.

Authority: 7 U.S.C. 6501–6522.

Dated: October 23, 1998.

Eileen S. Stommes,

Deputy Administrator Transportation and Marketing.

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