

Proposed Rules

Federal Register

Vol. 65, No. 135

Thursday, July 13, 2000

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-00-04]

RIN 0581-AA40

Submission of Petitions for Evaluation of Substances for Inclusion on or Removal From the National List of Substances Allowed and Prohibited in Organic Production and Handling

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of Guidelines and Call for National List Petitions.

SUMMARY: The Organic Foods Production Act of 1990, as amended, (Act) requires the Secretary of Agriculture (Secretary) to establish a National List of Allowed and Prohibited Substances (National List) which identifies the synthetic substances that may be used, and the nonsynthetic substances that cannot be used, in organic production and handling operations. The Act authorizes the National Organic Standards Board (NOSB) to develop and forward to the Secretary a recommended Proposed National List, and subsequent proposed amendments to it. The Act provides that persons may petition the NOSB to evaluate a substance for inclusion on or removal from the National List. This notice explains who can submit a petition, for what substances a petition can be submitted, and the information that should be included in a submitted petition. All submitted petitions will be evaluated by the Department of Agriculture's (USDA) National Organic Program (NOP) for completeness. If there is incomplete information, petitioners will be given a reasonable opportunity to provide the missing information. Petitioners should realize that providing incomplete information may increase the evaluation time or result in no substance evaluation. This notice also provides the name and

address of the person to whom a petition should be submitted.

ADDRESSES: Petitions should be submitted in duplicate to: National Organic Standards Board, c/o Robert Pooler, Agricultural Marketing Specialist, USDA/AMS/TM/NOP, Room 2510-So., Ag Stop 0268, P.O. Box 96456, Washington, D.C. 20090-6456. Phone: 202/720-3252. Fax: 202/205-7808. e-mail: nlpetition@usda.gov. Petitioners are encouraged to submit the required information through one system of submission (mail, fax or e-mail).

FOR FURTHER INFORMATION CONTACT: Keith Jones, Program Manager, National Organic Program, USDA/AMS/TM/NOP, Room 2945-So., Ag Stop 0268, P.O. Box 96456, Washington, D.C. 20090-6456. Phone: 202/720-3252. Fax: 202/690-3924. e-mail: keith.jones@usda.gov.

SUPPLEMENTARY INFORMATION: To help readers better understand the petition process, we have provided answers to some frequently asked questions about the National List and the petition process.

What Is the Purpose and Timing of This Notice?

The NOSB submitted a Proposed National List to the Secretary that was subsequently published on March 13, 2000, as part of the NOP proposed rule, 65 FR 13512-13658, (2000). Based on information supplied to the NOSB by trade associations, certification organizations and other organic industry sources, there are many substances currently used in organic production and handling that have not been evaluated by the NOSB for inclusion on the National List. Evaluations of these materials must be expedited to prevent the disruption of many well-established and accepted production, handling and processing systems. The NOP and the NOSB will be developing a workplan to process the potential evaluation of the numerous substances which may be presented to the NOSB and the NOP. Therefore, the organic industry is encouraged to initiate notification to the NOSB and the NOP on which substances should receive priority for evaluation. Substances that are petitioned and under evaluation by the NOSB will be announced on the NOP website: www.ams.usda.gov/nop. Interested individuals or groups can provide information or commentary to

the NOSB or NOP for any substance being evaluated by the NOSB.

How Are National List Decisions Made?

The NOSB reviews information from various sources in evaluating substances for inclusion on or removal from the National List. Sources include Technical Advisory Panels (TAP), the Environmental Protection Agency, the Food and Drug Administration, the National Institute of Environmental Health Studies, and the testimony of the public.

TAP reviews assist the NOSB in evaluating substances being considered for addition to or removal from the National List. The NOP, on behalf of the NOSB, establishes contracts to conduct the TAP with qualified individuals or organizations who have specialized knowledge of the petitioned substances. These reviewers have expertise in such fields as organic production and handling, veterinary medicine, chemistry, or food handling and preparation. All contractors, whether an individual or an organization, must meet USDA contract requirements including the prevention of conflict of interest. Recent TAP reviews conducted for the NOSB have been performed under contract by the Organic Materials Review Institute (OMRI). However, the NOP on behalf of the NOSB may contract with any individual or organization having the necessary technical expertise to conduct TAP reviews for NOSB substance evaluations.

TAP reports and the NOSB recommendations for each substance are submitted to the Secretary. The Secretary evaluates the recommendations and other documentation regarding each substance for inclusion on or removal from the National List.

The Act requires that the initial Proposed National List and subsequent proposed amendments to it be published in the **Federal Register** for public comment.

How Long Can a Substance Appear on the National List and Will the List Change?

The Act (7 U.S.C. 6517(e)) requires that substances appearing on the National List be reviewed by the NOSB and the Secretary at least once every 5 years following implementation of the NOP. Once a substance evaluation is

completed and a recommendation is forwarded to the Secretary, the NOSB will not reevaluate its decision within the 5 year period unless substantive new information becomes available.

What Criteria Does the NOSB Use to Evaluate Petitioned Substances?

The Act (7 U.S.C. 6518(m)) requires that the NOSB consider the following criteria for each substance evaluated:

- (1) The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;
- (2) The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment;
- (3) The probability of environmental contamination during manufacture, use, misuse or disposal of such substance;
- (4) The effect of the substance on human health;
- (5) The effects of the substance on biological and chemical interactions in the agroecosystem, including the substance's physiological effects on soil organisms (including the salt index and solubility of the soil), crops and livestock;
- (6) The alternatives to using the substance in terms of practices or other materials; and,
- (7) Its compatibility with a system of sustainable agriculture.

How Does the NOSB Evaluate Substances Such as Processing Aids or Adjuvants?

In addition to the criteria cited in the Act, the NOSB developed internal guidelines for evaluating processing substances such as synthetic processing aids or adjuvants for inclusion on or removal from the National List during their February 1999 meeting. For specific information about these guidelines, please refer to the USDA NOP website: www.ams.usda.gov/nop/nosbf99.html, or write the Program Manager, National Organic Program, USDA/AMS/TM/NOP, Room 2945-So, Ag Stop 0268, PO Box 96456, Washington, D.C. 20090-6456. Phone: 202/720-3252. Fax: 202/690-3924. e-mail: keith.jones@usda.gov.

When Can the NOSB be Petitioned?

The NOSB can be petitioned at any time for substances not previously evaluated by the NOSB. For substances receiving a prior recommendation by the NOSB restricting or prohibiting its use, a petition may be filed only when significant new information may alter the established NOSB recommendation. However, the NOSB and the NOP

expects that amending the National List will be a continuous process. For instance, the National List may need to be amended to accommodate development of new substances or technologies in organic production or handling of foods. Recommendations to amend the National List result from the review and deliberation of the TAP reports and other information by the NOSB Committees (Crop, Livestock, Processing or Materials). These committees forward their recommendations to the entire NOSB which considers, then accepts, modifies or rejects these recommendations during scheduled public meetings or conferences conducted periodically, as needed.

Who Can Submit a Petition?

Any person may submit a petition. Each substance to be evaluated must be submitted in a separate petition.

To Whom Should a Petition be Submitted?

Petitions should be submitted in duplicate to: National Organic Standards Board, c/o Robert Pooler, Agricultural Marketing Specialist, USDA/AMS/TM/NOP, Room 2510-So., Ag Stop 0268, P.O. Box 96456, Washington, D.C. 20090-6456. Phone: 202/720-3252. Fax: 202/205-7808. e-mail: nlpetition@usda.gov.

What Are the Substances for Which a Petition May be Submitted?

Only single substances or ingredients may be petitioned for evaluation. Formulated products cannot appear on the National List. Substances that appear on USDA's current Proposed National List, 65 Fed. Reg. 13626-13628 (2000), should not be petitioned for inclusion on the National List.

What Information Has to be Included in the Petition?

A petition seeking evaluation of a substance must indicate within which of the following categories the substance is being petitioned for inclusion on or removal from the National List:

- (1) Synthetic substance's allowed for use in organic crop production;
- (2) Nonsynthetic substances prohibited for use in organic crop production;
- (3) Synthetic substances allowed for use in organic livestock production;
- (4) Nonsynthetic substances prohibited for use in organic livestock production; and
- (5) Nonagricultural (nonorganic) substances allowed in or on processed products labeled as "organic" or "made with organic (specified ingredients)."

The petition must also include, as applicable, the following information:

1. The substance's common name.
2. The manufacturer's name, address and telephone number.
3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant.
4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode of action must be described.
5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information can follow the guidelines in the Instructions for Submitting Confidential Business Information (CBI) listed in #13.
6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance.
7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers.
8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance.
9. The substance's physical properties and chemical mode of action including (a) chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.
10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies.
11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List.
12. A "Petition Justification Statement" which provides justification for one of the following actions requested in the petition:

When petitioning for the inclusion of a synthetic substance on the National List, the petition should state why the synthetic substance is necessary for the production or handling of an organic product. The petition should also describe the nonsynthetic substances or alternative cultural methods that could be used in place of the petitioned synthetic substance. Additionally, the petition should summarize the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support the use of it instead of the use of a nonsynthetic substance or alternative cultural methods.

When petitioning for the removal of a synthetic substance from the National List the petition must state why the synthetic substance is no longer necessary or appropriate for the production or handling of an organic product.

When petitioning for the inclusion on the National List of a nonsynthetic or nonagricultural substance as a prohibited substance the petition must state why the nonsynthetic or nonagricultural substance should not be permitted in the production or handling of an organic product.

When petitioning for the removal from the National List of a nonsynthetic or nonagricultural substance as a prohibited substance the petition must state why the nonsynthetic or nonagricultural substance should be permitted in the production or handling of an organic product.

13. A Commercial Confidential Information Statement which describes the specific required information contained in the petition that is considered to be Confidential Business Information (CBI) or confidential commercial information and the basis for that determination. Petitioners should limit their submission of confidential information to that needed to address the areas for which this notice requests information. Instructions for submitting CBI to the National List Petition process are presented in the instructions below:

(a) Financial or commercial information the applicant does not want disclosed for competitive reasons can be claimed as CBI. Applicants must submit a written justification to support each claim.

(b) "Trade secrets" (information relating to the production process, such as formulas, processes, quality control tests and data, and research methodology) may be claimed as CBI. This information must be (1) commercially valuable, (2) used in the

applicant's business, and (3) maintained in secrecy.

(c) Each page containing CBI material must have "CBI Copy" marked in the upper right corner of the page. In the right margin, mark the CBI information with a bracket and "CBI."

(d) The CBI-deleted copy should be a facsimile of the CBI copy, except for spaces occurring in the text where CBI has been deleted. Be sure that the CBI-deleted copy is paginated the same as the CBI copy. (The CBI-deleted copy of the application should be made from the same copy of the application which originally contained CBI.) Additional material (transitions, paraphrasing, or generic substitutions, etc.) should not be included in the CBI-deleted copy.

(e) Each page with CBI-deletions should be marked "CBI-deleted" at the upper right corner of the page. In the right margin, mark the place where the CBI material has been deleted with a bracket and "CBI-deleted."

(f) If several pages are CBI-deleted, a single page designating the numbers of deleted pages may be substituted for blank pages. (For example, "pages 7 through 10 have been CBI-deleted.")

(g) All published references that appear in the CBI copy should be included in the reference list of the CBI-deleted copy. Published information usually cannot be claimed as confidential.

However, the National List substance evaluations will involve a public and open process. Nonconfidential information will be available for public inspection.

The NOP Program Manager may request additional information from the petitioner following receipt of the petition.

In accordance with the Paperwork Reduction Act of 1980, Public Law 44 U.S.C. 3501 *et seq.*, the information collection requirements contained in this notice have been previously approved by OMB and were assigned OMB control number 0581-0181.

Authority: 7 U.S.C. 6501-6522.

Dated: July 7, 2000.

Sharon Bomer Lauritsen,

Acting Deputy Administrator, Transportation and Marketing.

[FR Doc. 00-17689 Filed 7-12-00; 8:45 am]

BILLING CODE 3410-02-P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 123

Military Reservist Economic Injury Disaster Loans

AGENCY: Small Business Administration (SBA).

ACTION: Notice of proposed rulemaking.

SUMMARY: With this document, SBA proposes to amend its Disaster Loan Program regulations to implement a new program authorized by the Veterans Entrepreneurship and Small Business Development Act of 1999. Under this new program, SBA would make a low interest, fixed rate loan available to a small business employing a military reservist if that reservist is called up to active military duty during a period of military conflict and if he or she is an essential employee critical to the success of the business' daily operation.

DATES: Submit comments on or before August 14, 2000.

ADDRESSES: Written comments should be sent to Bernard Kulik, Associate Administrator, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street, SW, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Herbert Mitchell, Deputy Associate Administrator, Office of Disaster Assistance, 202-205-6734.

SUPPLEMENTARY INFORMATION: SBA proposes adding Disaster Loan Program regulations to implement the Military Reservist Economic Injury Disaster Loan Program ("program"). This rule proposes the program's requirements, application and loan approval process.

The Military Reservist Economic Injury Disaster Loan Program was authorized by Public Law 106-50, enacted on August 17, 1999. The program will allow SBA to make economic injury disaster loans (EIDL) to small businesses employing military reservists if those employees are called up to active duty during a period of military conflict (call-up) and those employees are essential to the success of the small businesses' daily operations.

Under this proposed rule, to qualify for the Military Reservist EIDL, a business would be required to show that the call-up of an essential employee has caused or will cause the business substantial economic injury. The interest rate for a Military Reservist EIDL would be the same as for other EIDL assistance. At the present time the statutory interest rate may not exceed 4 percent. SBA calculates interest rates quarterly, which could result in a lower rate in the future, but SBA proposes that