

## **PROPOSED ADVISORY AND ASSISTANCE SERVICES**

### **Statement of Work**

#### **Request for Proposals to Perform Technical Advisory Panel Reviews of Substances Petitioned for Inclusion on or Removal from the National List of Substances Allowed and Prohibited in Organic Production and Handling**

#### **AGENCY NEED**

**See Statement of Work 1.0 Background**

#### **STATEMENT OF WORK**

##### **1.0 Background**

The Organic Foods Production Act of 1990 (OFPA), as amended, 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

The NOSB submitted a Proposed National List to the Secretary that was subsequently published on March 13, 2000, as part of the National Organic Program (NOP) proposed rule, 65 Fed. Reg.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 substances must be expedited to prevent the possible disruption of well-established and accepted production, handling, and processing systems.

Section 2119 of the OFPA (7 U.S.C. 6518 (k)(3)) provides that the NOSB shall convene technical advisory panels (TAP) to provide scientific evaluation of substances for inclusion on or removal from the National List. 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 reviews.

##### **2.0 Mission of USDA/AMS/NOP**

The mission of NOP is to establish national standards governing the marketing of certain agricultural products as organically produced. The NOP is assisted by the NOSB, which provides policy advice in carrying out the program, including advising the Secretary on substances for the inclusion on or removal from the National List.

The NOSB reviews information from various sources in evaluating substances for inclusion on or removal from the National List. Sources include TAP reviews, the Environmental Protection Agency, the Food and Drug Administration, the National Institute of Environmental Health Studies, and public comment. The NOSB submits its recommendations, along with the results of the required evaluation and technical advisory panel review for each substance, to the Secretary for consideration in accordance with the requirements of section 2118(d) of the OFPA (7 U.S.C. 6517(d)).

### **3.0 Specific Task**

The contractor(s) shall furnish technical advisory panel reviews for crop production, livestock production, and processing substances submitted to the NOSB in response to petition notices, such as was published in the Federal Register on July 13, 2000, as well as other substances requiring review as determined by the NOP.

For crop and livestock production substances, the contractor(s) shall use the criteria in Section 2119 of the OFPA (7 U.S.C. 6518 (m)(1-7)). They are: 1) The potential of the substance 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 in the environment; 3) The probability of environmental contamination during manufacture, use, misuse or disposal of the substance; 4) Its effects on human health; 5) The effects of the substance on biological and chemical interactions in the agroecosystem; 6) The alternatives to using the substance; and, 7) The compatibility of the substance with a system of sustainable agriculture.

For processing substances, the contractor(s) shall use the criteria approved at the February 10, 1999, NOSB meeting. They are: 1) That processing aid or adjuvant cannot be produced from a natural source and has no organic ingredients as substitutes; 2) If manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling as described in section 6513 of the OFPA; 3) The nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human health as defined by applicable Federal regulations; 4) Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during processing except in the latter case as required by law; 5) It is Generally Recognized as Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP) and contains no residues of heavy metals or other contaminants in excess of FDA tolerances; 6) Its use is compatible with the principles of organic handling; and, 7) There is no other way to produce a similar product without its use and it is used in the minimum quantity required to achieve the process.

### **4.0 Minimum Skills and Experience Requirements**

Contractor(s) shall utilize qualified individuals or organizations who have specialized knowledge of the petitioned substances. Contractor(s) must have demonstrable expertise in organic production and handling or scientific disciplines such as veterinary medicine, chemistry, food technology, microbiology or toxicology. Contractor(s) must be familiar with the requirement for technical advisory panels described in the Organic Foods Production Act of 1990.

## **5.0 Place of Performance**

Contractor(s) shall perform all task related activity within the United States of America at specific locations determined by contractor(s). During the contract period, the contractor(s) shall travel at contractor(s)'s expense to NOSB meetings for the purpose of disseminating substance review findings to the NOSB and general public.

## **5.0 Government Furnished Equipment and Facility**

None, except that the NOP shall provide Contractor(s), (on a non-routine basis), with substance review petitions, ancillary documents or other applicable information in possession of NOP.

## **6.0 Compensation**

The NOP may award multiple contracts for tasks outlined in this statement of work. Contractor(s) shall be compensated at a firm-fixed price rate not to exceed \$2000.00 per substance reviewed. Total compensation shall not exceed \$100,000.00.

## **8.0 Period of Performance**

September 30, 2000 – September 30, 2001 (262 working days)(Holiday time off is at contractor(s)' discretion.)

## **9.0 Scope of Performance**

### **Phase I ---Data Gathering and Compilation (120 days)**

Phase I is not to exceed 120 days for any one substance. During this phase the contractor(s) provider shall perform the following activities:

- Characterize [the] substance(s) and identify uses and applications
- Determine whether [the] substance(s) are synthetic or non-synthetic (See 7 U.S.C. 6502 (21) for definition of synthetic.)
- Determine [the] substance(s) chemical or biological composition and possible impact on human/animal health and the environment.
- Identify [the] substance(s) relevant toxicological studies, including ensuring substance does not contain residues of heavy metals or other environmental contaminants in excess of Food and Drug Administration Action Level or Environmental Protection Agencies tolerances.
- Determine [the] substance(s) persistence in the environment
- Determine [the] substance(s) effect on soil structure and ecology
- Identify alternatives to the use of the substance(s)
- Determine [the] substance(s) historical use in organic production, processing and handling
- Determine [the] substance(s) status under OFPA and with other government agencies

Additionally, within 45 days of commencement of Phase I, the contractor(s) must notify the NOP in writing of any substance(s) not appropriate for National List review. Other substances for review may be substituted upon agreement between the NOP, the NOSB, and the contractor(s).

**Phase II---Review Against Criteria (100 days)**

Phase II is not to exceed 100 days for any one substance. The contractor(s) shall engage no less than three reviewers for each substance. No current member of the NOSB may serve as a reviewer. Reviewers may use data from all relevant sources. Reviewers shall make recommendations to the contractor(s) as to the substance's status as synthetic or non-synthetic and whether, in either case, the substances should be added to or removed from the National List.

**Phase III---Recommendation (42 days)**

Phase III is not to exceed 42 days for any one substance. Contractor(s) shall provide the NOP with a recommendation regarding each substance's suitability for inclusion on or removal from the National List. All data and analyses collected in Phase I and II will be forwarded to the NOP upon the completion of Phase III in accordance with the reporting requirements stated below.

**EVALUATION FACTORS FOR AWARD**

The NOP may award multiple contracts for tasks outlined in this statement of work. Contractor(s) selection will be based on evaluation of proposals in accordance with the responses received to the criteria outlined in Section 4.0, Minimum Skills and Experience Requirements and Section 9.0, Scope of Tasks. Award will be made to that offeror whose combination of technical experience and cost represents the best value to the Government and is most advantageous, cost and other factors considered, and which is within the available NOP resources.

The NOP also reserves the right to reject any or all proposals received and/or request clarification or modification of proposals. The NOP reserves the right to determine a competitive range for negotiation based upon the technical and cost acceptability of proposals. In addition, the NOP reserves the right to award a contract without discussions.

Cost evaluation will include an analysis of the total cost and cost elements (if applicable) to perform the required work. The total costs supplied by the offeror shall constitute the total firm-fixed unit price for that service or deliverable.

Proposals that are unrealistic in terms of technical commitment or unreasonably low or high in cost or price will be deemed reflective of an inherent lack of technical competence or indicative of failure to comprehend the complexity involved in the contract requirements and may be grounds for rejection of the proposal.

**OTHER EVALUATION FACTORS**

Technical proposals will be initially evaluated with respect to six (6) major factors for determination of the competitive range. Technical factors are listed in descending order of importance. The technical proposal is of greater importance than the cost proposal; when technical proposals are relatively equal in technical merit, cost will increase in importance.

## **Technical Factors**

- Factor 1** Overall Technical Approach; Proposed Methodology; Demonstrated Understanding of the Scope of Work and the Requirements
- Factor 2** Previous Demonstrated Experience and Past Performance
- Factor 3** Quality Control
- Factor 4** Capability and Experience of Key Personnel
- Factor 5** Project Management and Support Capability
- Factor 6** Reasonableness of Cost

## **REPORTING REQUIREMENTS**

Progress reports are due to the NOP each 60 days after the contract award date. A final report is due within 60 days of the end of the contract period. The contractor(s) shall forward five copies of the bi-monthly progress reports and the final report and all deliverables to the NOP in Washington DC. Documents should be addressed to: 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, Attention: Substance Reviews.

The narrative in the progress reports should refer back to the stated objectives and timeline of the original contract proposal. Beneath each objective, the objective's current status should be reported. Any substantive diversion from a stated objective, or any deviation from the proposed timeline should be explained. Only the activities required under the contract should be reported. At a minimum, the progress reports should also include the following: 1) A short summary of the accomplishments for the reporting period; 2) Progress on completing individual project tasks; 3) The planned and actual schedules for task completion; 4) Projected accomplishments for the next reporting period; and, 5) Data on financial expenditures by task category.

Any deliverables required under the contract should be enclosed with the first report following the date the deliverable was due to be produced. A final report will be required upon completion of the contract. NOP is working on developing a standard electronic format for use by contractor(s) in reporting their contract activities.