

**OMRI Testimony on Enhancing the TAP Review Process  
NOSB Meeting October 22, 2003  
Washington, D.C.**

**Introduction**

Thank you for inviting Organic Materials Review Institute (OMRI) to present testimony at this NOSB session on enhancing petitions and the Statement of Work. We appreciate this opportunity to offer our perspective as a former TAP contractor from May 1999 to October 2002. In our comments, we would like to present our assessment of the petition process as it directly and indirectly involves the TAP contractor and make recommendations for improvements that will ensure a more transparent process and enable the NOP and NOSB to fulfill their respective statutory responsibilities.

From its inception in 1997, OMRI's mission has been to provide professional, independent, and transparent review of materials and compatible processes allowed in organic production. We are a 501(c)(3) organization that was established by members of the organic industry to provide an objective third-party, materials review service that would ensure uniformity in materials review and guarantee protection of confidential business information submitted by the suppliers of materials inputs to organic production. In conducting our core service of evaluating brand name products used in organic production and handling, OMRI deals with many of the issues that must be addressed in the conduct of transparent TAP reviews. We are also an organization that has a long-established institutional memory that has been built since the earliest beginnings of the organic industry. Our Board is designed to fully represent the breadth of the organic industry with members who are organic farmers, staff of organic certification agencies, organic inspectors, organic processors and handlers, manufacturers of inputs for organic production, and representatives of the public interest. OMRI's Review Panel and Advisory Council, independent bodies of experts that participate respectively in review of brand name products for organic production and policy guidance, also represent a breadth of expertise and experience in organic production. Since 1993, OMRI Board, Advisory Council, and staff have built a broad experience with the specifics of the TAP review process. Our comments are drawn from this institutional memory, experience and expertise. We offer the following assessments and recommendations in an effort to contribute constructively to the enhancement of materials review under the NOP Rule.

**The Petition**

The Organic Food Production Act (OFPA) gives the NOP authority to establish procedures under which petitions can be submitted to add substances to the *National List*. Inherent in the regulatory oversight of the petition process is the need for transparency. In July 2000, NOP published Petition Guidelines to clarify the necessary steps and criteria for petitions submitted to add a substance to or remove one from the *National List*.<sup>1</sup> Because the petition initiates NOP/NOSB review of a substance, it is critical that the guidelines be followed. Deficiencies in information required under the guidelines and/or failure by the petitioner to provide the necessary justifications for the petitioned substance threatens the transparency of the material review from the very beginning. An incomplete petition under the current Petition Guidelines inhibits a fair assessment both at the initial screening stage and during the TAP review. Under the current process, the weakness in the preliminary assessment stage is both with the

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<sup>1</sup> 7 CFR 205.600 – 205.607.

adequacy of petitions relative to the petition criteria and with the thoroughness of the preliminary review. Fail-safe procedures should be implemented to prevent an incomplete petition from completing the TAP review process. At each stage of the preliminary review, including the point at which the TAP contractor begins its review, OMRI recommends that the petition be evaluated for critical deficiencies that must be corrected by the petitioner before the petition can progress to the next step.

### ***Responsibilities of the Petitioner***

The NOP and NOSB may wish to consider revisions to the July 2000 Petition Guidelines. The following recommendations would bring more clarity to the specific categories of substances that can or cannot be petitioned under the statutory and regulatory criteria and specify the responsibility of the petitioner in submitting a complete petition.

1. Statutory and regulatory criteria. Cite the statutory exemptions specified in §6517(c) of OFPA.
2. Specify the criteria established in the final rulemaking for processing substances.<sup>2</sup>
3. Require a justification for nonorganic, non-agricultural substances petitioned for use in handling.
4. Clarify that petitions can be filed in any one of three categories: (a) add a substance, (b) remove a substance, or (c) amend annotations for current listings in the *National List*. For removing a material or amending an annotation, the petitioner may cite existing data and documents already on file with the NOP and NOSB provided that it is adequate for fulfilling the requirements of a complete petition.

An additional document that provides directions and clarification of the following definitions would be of value to petitioners.

1. Differentiate between synthetic and non-synthetic substances used in crops and livestock production and between agricultural and non-agricultural (nonorganic) substances used in handling.
2. Develop examples to enable petitioners to determine if a given substance is agricultural or non-agricultural.
3. State the statutory conditions necessary to exempt synthetic substances as well as the criteria that a petition justification must meet to invoke the statutory exemption. List the substances or categories of substances that are explicitly prohibited by OFPA and the NOP Rule.
4. Routinely publish a list of denied petitions to discourage re-petitions except where new information or statutory interpretation is available.
5. Clarify the limitations placed by claims of Confidential Business Information on a full technical review by the TAP contractor and the NOSB, including the possibilities for delays caused by insufficient information when CBI is claimed.

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<sup>2</sup> 7 CFR 205.600(b). The Petition Guidelines should also establish that the §205.600(b) criteria apply to all nonorganic (non-agricultural) substances used in processing and are not limited to “synthetic processing aids and adjuvants” as currently stated in the July 13, 2000 *Federal Register* notice.

## **Initial Handling and Screening of Petitions**

A successful TAP review begins with a complete petition. OMRI recommends that the NOP and NOSB implement an approval procedure that verifies that the petition has met the criteria that qualify it to move to the TAP review stage. For a petition to progress through this process, the following questions should be answered.

### Step 1: Is the petition complete?

If any of the 12 points specified in the Petition Guidelines are missing and determined to be essential to the review of the petitioned substance, the petition should be returned to the petitioner. A designated time period of 30 days should be allocated to this preliminary assessment. Similarly, the petitioner should be given a designated period within which to resubmit the petition with the required information.

### Step 2: Have the OFPA and NOP Rule criteria been met?

Each petitioned substance submitted should be evaluated for its current statutory and regulatory status under the NOP Rule standards. At this stage, the NOP and NOSB, with possible assistance from the TAP contractor, should jointly evaluate a petitioned substance's status as a synthetic versus non-synthetic and as an agricultural versus non-agricultural substance (processing materials and livestock feed ingredients). This evaluation step would eliminate petitioned substances that are clearly not allowed, thus saving time, effort, and contract funds from unnecessary expense.

OMRI recommends development of procedural steps to permit a preliminary assessment by the TAP contractor, in consultation with the NOP and NOSB. In some cases, there may be reason to withdraw a petition because the substance is identified as an allowed non-synthetic that does not need to appear on the *National List*. On the other hand, the NOP and NOSB may direct the TAP contract to continue to evaluate the petitioned substance as a possible prohibited non-synthetic. These types of situations should follow specific procedural steps.

### Step 3: Have other applicable regulatory authorities been evaluated?

OFPA requires the USDA to consult with the Secretary of Health and Human Services and the Administrator of the Environmental Protection Agency regarding the impact of substances used in organic production on human health and the environment.<sup>3</sup> Substances used in organic production need to comply with other Federal statutes administered by the EPA, FDA, and USDA.<sup>4</sup> An initial NOP screening for compliance of the petitioned substance and use under these statutes should be performed before assigning the petition to TAP contractor stage. There is a dual purpose of this review step: (1) determine the exact regulatory status to avoid unnecessary work if the petition is for a use that is incompatible with these pre-emptive statutes and (2) ensure that the scientific review by

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<sup>3</sup> 7 USC 6517(c) and 6517(d).

<sup>4</sup> 7 USC 6519(f) requires that all substances used must comply with the following authorizing statutes for various programs in the USDA, FDA, and EPA: Federal Meat Inspection Act (21 USC 601 et seq.) the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.), and the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 136 et seq.).

the TAP contractor will take the regulatory status of the petitioned substance into consideration.

Step 4 Public record of a terminated petition.

A mechanism should be established for terminating a petition when the initial screening establishes that the petitioned substance will not meet the statutory and regulatory criteria for potential listing in the *National List*. Depending on the stage at which the petition is terminated, the NOP can publish a public notice of termination on the basis of the agency's assessment or a formal vote can be taken at the NOSB if the petition has reached the stage of preliminary NOSB review.

## **TAP Contractors**

### ***Pool of contractors***

There are a number of factors to consider for improvement in the contractual relationship with the Technical Advisory Panel. To improve overall TAP competence, a bigger pool of contractors with diverse and possibly specialized expertise is warranted. It is difficult for an individual contractor to have expertise in all three categories of food processing, livestock production, and crop production. It is rare when an individual or an organization is fully competent in all three categories of 'materials.' Even universities are structured into separate departments for various disciplines, such as animal science and veterinary medicine for livestock, agronomy and horticulture for crops, food science and nutrition for processing. NOP should consider dividing the TAP work into its three natural pieces and contracting each to an organization or individual with demonstrated expertise in the respective category.

Qualified principal investigators and reviewers are essential to the process; their qualifications should be periodically provided and assessed. An individual investigator does the actual work of creating the base TAP Review document and the individual researchers or principal investigators who prepare the original base documents for materials develop competence as they gain experience. A significant contractor issue is employee continuity and competence as well as institutional memory. It takes time to develop competence. A contractor who depends largely on temporary workers, graduate students, or post-doctoral fellows may not be able to provide a consistent and continuous level of expertise without the benefit of a training program. Likewise, a contractor who is new to the TAP process and does not have experienced individuals available to work on TAP contracts lacks the competence and expertise that requires time to build.

In any event, the contractor is responsible for training new TAP Review researchers or hiring individuals with proven competence in order to turn out satisfactory TAP Reviews. It is important that a contractor have an orientation and training program for new materials researchers. NOP may wish to consider developing training options within the framework of the TAP contractor program, which are consistent with the education mission of academic institutions. As currently negotiated, TAP contracts do not fund any training activities.

It is important that individuals hired to be material researchers have adequate professional qualifications as well as good communication skills. Reviewing a material requires practical judgment based on experience and sufficient technical knowledge to winnow out the wheat from

the chaff. OMRI recommends that the NOP and NOSB specify that TAP contractors be able to demonstrate that their personnel have a proven record of expertise and that they can consistently rely on qualified personnel to perform the TAP contract work. In the event that TAP contracts allow provisions for academic training, the use of graduate students and post-doctoral fellows would be appropriate.

Another aspect of competency is finding competent TAP Reviewers who will review the first drafts on which the TAP review is based. . TAP Reviewers who are obligated to do considerable research to locate relevant information that should have been included in the petition documents are placed in a comprising position. Under the current contract system, their hourly rate of pay becomes so low that they cannot afford to spend the time necessary to do a good quality job. The potential pool of TAP reviewers has been reduced because experienced reviewers are now refusing to participate as a consequence of their previous underpaid TAP contract experiences.

### ***Accountability***

The TAP contract requires bi-monthly reporting, which is adequate in principle. However, the issue is adherence to a timeline, and that requires specific supervision, which is best done by NOP. The timeline in the Statement of Work is based on an annual contract award, with 242 days allotted for reviews. A timeline and progress report keyed to the assignment of each petitioned substance is a more realistic way to track progress and manage the workflow. In OMRI's experience, a balance needs to be struck between the needs of the investigator and the needs of the TAP reviewers, with adequate time for both phases. We suggest that a minimum of 120 days be allotted for the period from assignment of each petition to the point when a draft is sent to TAP reviewers, with an additional 30 days for reviewers to respond. This time frame would allow for two rounds of revision without risk of delaying the petition process by a tabling to the petition due to insufficient information to support NOSB recommendations.

### ***Quality***

The Statement of Work should qualify specifications that are basic performance standards. The measure of a TAP review's quality will be "conformance to requirements."

Based on our experience with the NOSB, a TAP review must fulfill two requirements. First, those on the NOSB who have expertise in the area must be confident from reading the review that the review has gone deeply enough into the subject to identify the key issues and the alternatives for the petitioned material. Second, those on the NOSB who are generalists or not scientifically trained in the subject matter must be able to gain sufficient knowledge from the TAP review and supplementary documentation to be able to decide whether the petitioned material fulfills the statutory and regulatory criteria governing potential candidates for the *National List*.

How big does a TAP Review have to be? How many pages does a TAP Review have to contain? At a minimum, the Statement of Work should include specifications that call for a comprehensive literature search, historical references, and a complete regulatory status report. NOSB and NOP should determine whether a standard of "peer review quality" or something less is more appropriate for measuring quality. It would be useful for NOP and NOSB to identify old, exemplary TAP reviews in the three material areas, so that new contractors have a blueprint

for success. It also would be helpful for NOSB to provide feedback on what critical information makes these exemplary TAP reviews most useful, preferably indicated in a version with sidebar annotations.

#### *Research Tools*

As a matter of course, the petitioner should search several standard references for the substance's current uses and its precursors. Key references are the NAL (National Agricultural Library) AGRICOLA database, the U.S. patent database ([www.uspto.gov](http://www.uspto.gov)), the Kirk-Othmer Encyclopedia of Chemical Technology (especially the early editions), and the Merck Index. From these, the petitioner will need to examine the literature, existing patents, and prior methods cited. The TAP Review contractor should examine whether the petitioner properly searched and cited the alternatives identified in these standard references. These and other standard references in the field can be searched to make a reasonably authoritative and complete list of alternatives.

### **Guidance for TAP Contractors**

#### ***Instructions and Templates for Review***

Contractors should be provided templates and detailed instructions for TAP reviews. The existing templates should be reassessed with attention to the need for specifications designed for each of the three *National List* categories of crops, livestock and processing. Regarding livestock materials, application of the OFPA criteria should follow the NOSB recommendations adopted in October, 2002.

OMRI's instructions for TAP reviewers used while it was a TAP contractor offer an example of one approach for designing reviewer guidelines. These instructions and forms (attached as Appendices 1 and 2) are based on the existing TAP review templates as currently provided by NOSB to contractors, with instructions for applying the OFPA criteria. This standardized format allows for collation of individual reviewer responses to the preliminary TAP report as provided by the primary investigator. This model of instructions could be adapted as initial instructions to the contractor as a whole, with instructions specific to the material category under each section of the template.

#### ***Scope of Tap Review Investigation***

The NOP's current Statement of Work requires the contractor to review alternatives to the petitioned substance. The TAP review should identify alternatives noted in the literature, including historical accounts published prior to the invention or conventional adoption of the petitioned substance. Web searches often fail to identify these historical sources. The National Agricultural Library database is a valuable resource that could be better used. Patent searches provide basic manufacturing information and often discuss alternatives and the technology described in the published literature at the time a patent was filed, known in intellectual property law as 'prior art.' Although this may be contrary to the sincere belief of the petitioner, it is rare that there is no alternative to the petitioned material.

The NOSB has often expressed concern about availability or economic feasibility of the identified alternatives. It is very difficult for the TAP contractor to determine if the alternatives reported in the literature are in fact currently available to industry. Cost considerations are not

mentioned in the OFPA criteria and economics is not one of the areas of expertise identified for TAP reviewers. The NOP and NOSB may wish to consider a process, separate from the TAP contract, for assessing these factors.

***TAP Contractor Communications with NOSB Committee Chairs and the Petitioner***

The TAP contractor should be able to communicate directly with NOSB Committee Chairs to clarify the scope of the TAP review (e.g., what uses should be considered). In the event that additional information is required from the petitioner, procedures should be established for authorized contacts between the TAP contractor and petitioner. To avoid unduly burdening the NOP with the role of an intermediary, guidelines should be established for direct written communications by letter or fax. To maintain the transparency of these communications, copies should be provided to the NOP and NOSB Committee Chair for placement in the petition file's records. At no time should telephone communications be allowed between the TAP contractor and the petitioner. In designing procedures for direct communication between the petitioner and the contractor, an arms-length relationship must be maintained.

## **TAP Review and Decision Making**

***Public Review***

An essential element of transparency is public disclosure. Posting of petitions and their associated TAP Reviews for public review and comment is as important as the openness of the NOSB public meetings where votes on petitioned substances determine their eligibility for placement on the *National List*. The opportunity to participate in the NOSB's public hearings should be balanced with sufficient time for public review of the TAP reviews. Similarly, the petitioner should also have access to the TAP review with sufficient time to evaluate the findings and opportunity to prepare a public response. Members of the public should be afforded the opportunity to submit additional information for the NOSB's consideration and to identify information that is incorrect or missing from the TAP reviews. Such information might be obtained from independent experts with specific knowledge and experience in organic production and handling, industry trade associations, or the manufacturers of a competing technology. Petitioned substances often have uses other than those petitioned and, depending on the scope of the TAP contract, it may be difficult for the TAP contractor to fully identify all uses relevant to organic handling or production. Innovative producers and handlers may wish to comment on alternatives that they have developed within the framework of the existing regulations that are not widely known or may be proprietary.

If, through public comment, new information is brought into the record, a procedure should be developed to address these additions as part of the formal evaluation of the petitioned substance. This procedure should incorporate steps for resubmitting the new information to the TAP contractor, with a re-negotiated TAP contract, if necessary. Sufficient time to address issues raised in public comments, as well as amend or revise the TAP review on the basis of new information provided by public comment, should be built into the process for a supplemental TAP review.

OMRI recommends that TAP reviews be posted on the NOP website at least 30 days prior to the NOSB public meeting where the petitioned substance will be presented. To maintain the

transparency inherent in public review, TAP reviews and supplementary information that are not available within this timeframe should be held for the next NOSB public meeting.

Recommendations from the appropriate NOSB Committee on any petitioned substance should also be posted at least two weeks prior to the NOSB meeting. Any supplemental information received and used by the NOSB or its Committees to support its recommendation on a petitioned substance (including supplementary data from the petitioner after the TAP review is completed) should also be publicly available at least two weeks before the NOSB public meeting. If the NOSB and the public have not had adequate time to review supporting studies or evidence submitted by the petitioners and other members of the public after publication of the TAP review, procedures should be established to table the associated petition until the TAP, NOSB and the public has had adequate time to evaluate the studies and evidence.

### ***Decision making protocol***

The NOSB should develop a standard protocol for the steps leading to the NOSB vote on a petitioned substance's eligibility for the *National List*. Adopting a separate decision tree for crop, livestock and processing substances can help guide the NOSB in this process. OMRI's decision-tree models (Appendix 3) which was provided to the NOSB in November 2000, offers an example.

The need for public disclosure is also important at the final stage of NOSB's consideration of a petition. Whether the NOSB recommends (a) to support the petition, (b) to deny the petition, (c) to make a recommendation for an annotation that is counter to the petitioners' request, or (d) to call for more information, it should disclose the reasoning supporting the recommendation. Although the NOP's Petition Material Form thoroughly covers all the statutory and regulatory criteria that must be met, the NOSB does not have an associated method for addressing each of the criteria to support its recommendations. A decision tree that is specific for crops, livestock, and processing would aid the NOSB committees in applying the criteria and thereby justifying their recommendations for NOSB votes on the petitioned substances. This type of process should make it easier to document the outcomes as needed by NOP.

### **Conclusion**

OMRI thanks the NOSB and the NOP for the opportunity to present these recommendations for enhancing the petition process. Our goal is to aid in the design of a smoothly functioning process from arrival of the petition to the final NOSB vote by drawing upon the record that has developed since the beginning of the TAP review process in 1993. The consistent message is that there is a need for more guidance directed at the petitioner and the TAP contractor. In the case of the petition, there are two fundamental areas for improvement: (1) assessment of a petition's adequacy in presentation of the necessary information to progress it to the TAP review stage and (2) fulfillment of the criteria by which a petition's appropriateness for the TAP review process is determined. For the TAP contractor, a successful review that meets the expectations of the NOSB for taking the review through its various steps of decision making depends both on the qualifications of the TAP contractor and how well the contractor has been prepared for its task. OMRI recommends steps to ensure selection of qualified contractors with the appropriate expertise for the TAP review. For the guidance of the TAP contractor, OMRI recommends standardized guidelines and timelines to ensure that the NOSB has the necessary information for reaching informed recommendations in a timely manner. Additionally, it is critical for the

overall transparency of the process that public participation be honored as an integral component that is ensured by guidelines that specify a timeframe and mechanism for contribution to the review.

Regarding specific issues of policy, OMRI recommends that the NOP and NOSB develop clarifications that will guide the petitioners, TAP contractors, and the public on questions that relate to the following points:

- Distinction between agricultural and non-agricultural status for handling substances
- Determination of synthetic or non-synthetic status for crops and livestock substances
- Definition of an antibiotic used in livestock health
- Guidance on how to reach a determination of commercial non-availability
- Policy to clearly define the application of commercial availability to non-organic agricultural commodities used in processing.

These various issues are best addressed and clarified in guidelines available in the preliminary screening stage. Although these issues will play into the investigations of the TAP contractors, they should not be left unresolved with respect to the status of a petitioned substance. It should not be the responsibility of the TAP contractor to make determinations of the status of petitioned substances in any of the above-mentioned categories. With respect to commercial availability, the TAP review is not an appropriate venue for making this determination. Additionally, agricultural commodities should be screened out at the preliminary review stage rather than continued through the process to the TAP review stage. With respect to the synthetic ingredient petitions for the processing category, OMRI recommends that the NOP develop specific guidance to clarify their status under OFPA.

As a service organization dedicated to education and research, OMRI offers its assistance to the NOP and NOSB to develop mechanisms for enhancing the TAP review process. We hope our recommendations will prove useful for strengthening the process and ensuring its transparency.

Respectfully submitted,

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## Appendix 1a

### OMRI's Instructions for TAP Reviewers-Crops and Livestock

Please review the attached document, and provide corrections, comments, suggestions, additions, responses to questions, additional references, and an evaluation of the material according to the criteria in OFPA and the Agreement with TAP Reviewers. OMRI staff acknowledges that the TAP review cannot be exhaustive or comprehensive, but seeks your help to make sure that the information provided to the NOSB is adequate and unbiased. Your job includes the following tasks, and there is a form at the end of this document: NOTE: PLEASE COMPLETE THE FORM (PAGES 4-5). The especially critical parts are included as Question 4 on page 5. You are asked to:

- 1) vote as to whether or not a material is synthetic or non-synthetic
- 2) vote whether or not it should be added to the National List
- 3) Suggest restrictions or annotations for the material, if needed. Annotations must have justification for use.
- 4) An assessment as to the completeness and accuracy of database and evaluation according to criteria. Any significant changes require that OMRI have supporting documentation on file.
- 5) Answer any additional questions that are in the database in "TAP Reviewer Discussion" section.

Please consider the petition, information provided with the petition, enclosed supporting documents, and any information or data you have based upon your expertise in the field of organic agriculture.

#### Background: Description of the TAP Document

##### 1. Database

###### Identification:

Contains basic information about names and identification numbers of the material. This will be completed by OMRI in most instances. If you have a handy cross-reference or know of any common identifiers that are not included, please offer corrections and / or additions.

###### Characterization:

The NOSB needs to be familiar with the nature of the material, thus the Composition and Properties sections should describe the material in terms familiar to a broad audience.

The NOSB requires sufficient information to vote on whether or not a given substance is synthetic as defined by the Organic Foods Production Act and the National Organic Program Final Rule. The OFPA / NOP **defines synthetic** as

"[a] substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes."

Therefore, to be able to make the determination, the NOSB will need to know how a petitioned substance is produced, manufactured, purified, extracted, or otherwise made in the How Made section.

In addition, the OFPA also requires the National List to be itemized by Specific Uses or application [7 USC 6517(b)]. Specific uses, action, and combinations should be comprehensive enough to cover all potential uses that might occur if the item is on the National List.

In addition to classifying the substance in the appropriate category, the information provided under Uses, Actions, and Combinations may help with the development of any annotations that the NOSB and NOP might deem necessary for a substance to be added to the National List.

###### Status:

Historic use includes prior status under certified and non-certified systems, and may include a bit of historical context.

Synthetic substances used in production and non-agricultural substances used in processing must be consistent with the requirements under the Organic Foods Production Act. These are found in the respective sections on Crops (7 USC 6508), Livestock (7 USC 6509) and Processing (7 USC 6510), as well as in the guidelines for prohibitions or exemptions (7 USC 6517). A copy of OFPA is in the back of OMRI's green-covered *Operating Manual*. The substance also has a status under the Final Rule. This will depend on (a) whether or not it is synthetic and used in production, or if it is not an organically produced agricultural product and used in processing, and (b) if it is already on the National List. This section will also note the section of the Final Rule where it would appear.

## Appendix 1a

EPA / NIEHS / Other Sources section. In developing recommendations for the National List, the NOSB is required to “review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and such other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List” [7 USC 6517(l)]. The TAP review should provide information from the appropriate EPA programs, including whether or not the product or its precursors in production and waste stream are considered part of the Toxics Release Inventory. The primary source within NIEHS is the National Toxicology Program (NTP) database. This is usually presented in summary form. Other sources may also be considered, such as the Food and Drug Administration, the USDA’s Food Safety Inspection Service, and the Association of American Plant Food Control Officials.

OMRI endeavors to solicit comments from subscribing certifiers and will consider information provided by any certifier operating anywhere in the world. In the absence of a comprehensive list of USDA accredited certifiers, it is not possible to identify and compare the standards of all certifiers. However, if you are aware of any inaccuracies or differences not identified in the Database, please provide them. Note: OMRI relies on *current written standards* for this section. OMRI assumes that a certifier is following its written standard, and rules for variances made for a specific material (e.g., a phase-out) must be spelled out in the standards to be listed here.

OMRI also seeks to incorporate the status of a material under various international organic standards. These include the Codex Alimentarius *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* (CAC/GL 32-1999, as amended); the European Union Council Regulation on Organic Production of Agricultural Products and Indications Referring Thereto on Agricultural Products and Foodstuffs (EU 2092/91, as amended); the IFOAM *Basic Standards*; the Canadian National Standard on organic agriculture; the Japanese Agricultural Standard (JAS), and any other international standard that may differ with any of the standards listed above.

### 2. OFPA Criteria

The NOSB is also required to review materials against criteria specified in OFPA to develop the National List. None of these criteria can be considered in isolation. The NOSB has stated that “no material may be consistent with organic agriculture and appear on the National List in the absence of a strong factual showing in scientific criteria” (NOSB Final Recommendation, Addendum 26). The criteria are in *italics* [7 USC 6517(m)] and OMRI comments in roman:

(1) *the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;*

This includes looking at the interactions with non-synthetic substances or items that are already on the National List used in production.

(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;*

This section relies primarily on environmental fate data and monitoring, as well as toxicology.

(3) *the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;*

Organic agriculture is distinguished from conventional agriculture by its emphasis on maintaining ecological balance for soil and crop management and use of sustainable resources. This section would consider any unintended consequences that would have an environmental impact.

(4) *the effect of the substance on human health;*

OMRI seeks to summarize studies on direct human exposure as the first preference, particularly if they involve exposure through the use(s) to be considered by the NOSB. Animal model studies will also be used, but are given less weight than studies that involve human subjects.

(5) *the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;*

The principle concern here is the impact of a substance on soil organisms--both micro- and macro-. Salt index and solubility are relatively easy to locate, but not all soil amendments have salt indexes published. This section is also important for livestock evaluation, because it is where the effects (beneficial as well as detrimental) on animal welfare are concerned.

(6) *the alternatives to using the substance in terms of practices or other available materials; and*

Alternatives include not only other materials, but also biological, cultural, mechanical, and physical alternatives. OMRI cannot be comprehensive in listing the alternatives. OMRI is not, under this current contract, providing a rigorous economic analysis of the various alternatives, or of the economic impact of either listing or not listing the substance.

## Appendix 1a

However, reviewers should provide any additional information that they are aware of about alternatives, including cost and general availability if known.

*(7) its compatibility with a system of sustainable agriculture.*

OMRI draws upon a number of sources to describe what is sustainable, including early NOSB discussions. The NOSB adopted principles of organic production as of October, 2001, and these should be considered as a baseline for description of system of sustainable agriculture. Comments in this section should reflect a consensus of expert opinion. If you find any statement under this item objectionable, it will be removed without need for documentation. Information contained in this section in the draft review may be moved elsewhere. Individual opinions are more appropriate in the TAP Reviewer Discussion section.

### **TAP Reviewer Discussion Section**

In the version you receive, this section may contain more questions from the OMRI Staff.

This section in the final document is compiled from the complete individual contributions of each TAP reviewer, **based on your response to the form on pages 4-5** and will reflect your professional judgment about the material. Please be professional, courteous, and detached in your responses. Keep your statements credible, and build from the facts presented, along with documentation and data that you provide. Any personal comments that are off-topic, unsupported, or are otherwise deemed inappropriate will be removed. You have been chosen to review this material because OMRI recognizes your expertise in the field. Please honor the fact that reasonable people can be presented with the same facts and still respectfully disagree about the conclusion. Try to objectively examine pros and cons of all arguments, and explain why you feel the evidence leads you to your conclusions.

### **References**

Please review the enclosed literature as well as the TAP review. The references are listed out as ones that are included and ones that are not. If you need one that is not included and don't have access to it, call us. We are relying on you to help identify where we may have misinterpreted a study or inaccurately cited a source. These reviews are complicated and highly technical, so it is often difficult to detect such mistakes. However, such mistakes undermine the credibility of TAP reviews, and it is important that they be caught before the final review is presented to the NOSB and the public and posted on OMRI's web site.

Are there any key studies that are not cited? Are there any studies not included in the references that you think you need to see before completing the review? OMRI may not always be able to provide a copy. OMRI will reimburse you for any documents that you copy and send if you provide the receipt.

**Appendix 1a**  
**TAP REVIEWER RESPONSE FORM – CROPS & LIVESTOCK**

Name \_\_\_\_\_ Date: \_\_\_\_\_

\_\_\_\_\_ I have the following financial interest or conflict related to the use of this substance:

\_\_\_\_\_ I have no interests related to the use of this substance.

Signature \_\_\_\_\_

**1. Database—Check One**

\_\_\_\_\_ I find the database (Characterization and Status) to be reasonably complete and fairly accurate.

\_\_\_\_\_ The following information needs to be corrected or added to the database:

**2. OFPA Criteria Evaluation (check all that apply and supply any additional information)**

Note: if you prefer, you may group your responses to the following subsections together as one narrative. Please do check if you agree overall with each criteria.

*(1) The potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;*

\_\_\_\_\_ I agree with the criteria evaluation. \_\_\_\_\_ Here is additional supporting information or comments.

\_\_\_\_\_ The criteria evaluation needs to be corrected or amended as follows:

*(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;*

\_\_\_\_\_ I agree with the criteria evaluation. \_\_\_\_\_ Here is additional supporting information or comments.

\_\_\_\_\_ The criteria evaluation needs to be corrected or amended as follows:

*(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;*

\_\_\_\_\_ I agree with the criteria evaluation. \_\_\_\_\_ Here is additional supporting information or comments.

\_\_\_\_\_ The criteria evaluation needs to be corrected or amended as follows:

*(4) the effect of the substance on human health;*

\_\_\_\_\_ I agree with the criteria evaluation. \_\_\_\_\_ Here is additional supporting information or comments.

## Appendix 1a

\_\_\_\_\_ The criteria evaluation needs to be corrected or amended as follows:

*(5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;*

\_\_\_\_\_ I agree with the criteria evaluation. \_\_\_\_\_ Here is additional supporting information or comments.

\_\_\_\_\_ The criteria evaluation needs to be corrected or amended as follows:

*(6) the alternatives to using the substance in terms of practices or other available materials; and*

\_\_\_\_\_ I agree with the criteria evaluation. \_\_\_\_\_ Here is additional supporting information or comments.

⋮

\_\_\_\_\_ The criteria evaluation needs to be corrected or amended as follows:

*(7) its compatibility with a system of sustainable agriculture.*

\_\_\_\_\_ I agree with the criteria evaluation. \_\_\_\_\_ Here is additional supporting information or comments.

\_\_\_\_\_ The criteria evaluation needs to be corrected or amended as follows:

### **3. Conclusion – Summarize why it should be allowed or prohibited for use in organic systems.**

#### **REQUIRED INFORMATION**

#### **4. Recommendation Advised to the NOSB:**

a. The substance is

\_\_\_\_\_ Synthetic                      \_\_\_\_\_ Not Synthetic

b. For Crops and Livestock, the substance should be

\_\_\_\_\_ Added to the National List without annotation. (Circle one) as Synthetic allowed    as Nonsynthetic Prohibited

\_\_\_\_\_ Not Added to the National List.

\_\_\_\_\_ Added to the National List only with an annotation that restricts use. (Circle one) allowed as Synthetic, restricted

List as Prohibited non-synthetic, restricted

(Note: Synthetic materials are added to the National List of Allowed Synthetics. Non-synthetic materials are added to the National List of Prohibited Non-synthetics. Non-synthetics may be added to the Prohibited list with a restriction that permits some uses.)

c. Suggested Annotation, including justification:

## Appendix 1a

### 5. Additional Attachments

(check all that are appropriate)

Reviewer Commentary     References     Articles

# Appendix 1b

## Name of Material

### Crops or Livestock

1

2 **Executive Summary**

3 (xxxx to be completed after TAP reviewer comments are returned. TAP Reviewers will see the next version to “sign off”  
4 on it.)

- 5 (1.) Describe the use of the material that was requested by the petitioner.  
6 (2.) Describe the nature of the material, its source or manufacturing process, and range of uses.  
7 (3.) Describe if applicable any history of past NOSB recommendations.  
8 (4.) Summarize reviewer’s conclusions.  
9 (5.) Describe any further investigation if needed regarding availability of proposed alternatives, or feasibility of  
10 proposed annotations.  
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13 **Summary of TAP Reviewer’s Analyses<sup>1</sup>**

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16 **Note: the Reviewers are asked to vote whether a material is synthetic or nonsynthetic (natural). They also should**  
17 **decide whether a material should be allowed without restrictions (no annotations), allowed only with certain**  
18 **restrictions (annotation) or prohibited for all uses. Reviewer recommendation for annotations should be listed**  
19 **separately under each reviewers report, and summarized in the Conclusion.**  
20

<i>Synthetic/ Nonsynthetic</i>	<i>Allow without restrictions?</i>	<i>Allow only with restrictions?</i>	<i>Prohibit for all uses</i>
Synthetic (list votes)	Yes (list votes) No (list votes)	Yes (list votes) No (list votes)	Yes (list votes) No (list votes)
Nonsynthetic (list votes)			

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22 **Identification**

- |                            |                        |
|----------------------------|------------------------|
| 23 <b>Chemical Names:</b>  | 31                     |
| 24 List all chemical names | 32 <b>CAS Numbers:</b> |
| 25                         | 33 List CAS numbers    |
| 26 <b>Other Name:</b>      | 34                     |
| 27 List other names        | 35                     |
| 28                         | 36 <b>Other Codes:</b> |
| 29 <b>Trade Names:</b>     | 37 List other codes    |
| 30 List Trade Names        |                        |

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39 **Characterization**

40 **Composition:**  
41 Describe Composition

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<sup>1</sup> This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the investigator’s ability, and has been reviewed by experts on the TAP. The substance is evaluated against the criteria found in section 2119(m) of the OFPA [7 USC 6517(m)]. The information and advice presented to the NOSB is based on the technical evaluation against that criteria, and does not incorporate commercial availability, socio-economic impact, or other factors that the NOSB and the USDA may want to consider in making decisions.

## Appendix 1b

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### **Properties:**

Describe Properties

### **How Made:**

Describe How Made:

### **Specific Uses:**

Describe Specific Uses

### **Action:**

Describe Action

### **Combinations:**

Describe Combinations

## **Status**

### **Historic Use:**

Describe Historic Use

### **OFPA, USDA Final Rule:**

Describe if listed anywhere in OFPA or Final Rule

### **Regulatory: EPA/NIEHS/Other Sources**

Describe other regulatory status

### **Status Among U.S. Certifiers**

Describe status among U.S. Certifiers

### **International**

Describe status among International Organizations

## **Section 2119 OFPA U.S.C. 6518(m)(1-7) Criteria**

1. *The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems.*  
Xxx
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.*  
Xxx
3. *The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*  
Xxx
4. *The effects of the substance on human health.*  
Xxx
5. *The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock.*  
Xxx
6. *The alternatives to using the substance in terms of practices or other available materials.*  
Xxx
7. *Its compatibility with a system of sustainable agriculture.*  
Xxx

## **TAP Reviewer Discussion**

**Note: Contractor to explain to reviewers that they must focus on technical advise versus personal opinions.**

## Appendix 1b

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Reviewer 1 [Describe reviewer's expertise, scientific discipline (i.e. Veterinary medicine – see #4 in Statement of Work),  
Geographical Location of reviewer (ie. West coast, Midwest, etc.)

Provide the Reviewers' analysis of substance according to each OFPA Criteria Point

Provide Reviewer's vote on synthetic or nonsynthetic.

Provide Reviewer's vote to allow or Prohibit.

Provide Reviewers suggested annotation, if made.

Provide the Reviewer's Conclusion: that summarizes their reasoning to support their decisions.

Reviewer 2 [Describe reviewer's expertise, scientific discipline (i.e. Veterinary medicine – see #4 in Statement of Work),  
Geographical Location of reviewer (ie. West coast, Midwest, etc.)

Provide the Reviewers' analysis of substance according to each OFPA Criteria Point

Provide Reviewer's vote on synthetic or nonsynthetic.

Provide Reviewer's vote to allow or Prohibit.

Provide Reviewers suggested annotation, if made.

Provide the Reviewer's Conclusion: that summarizes their reasoning to support their decisions.

Reviewer #3 [Describe reviewer's expertise, scientific discipline (i.e. Veterinary medicine – see #4 in Statement of Work),  
Geographical Location of reviewer (ie. West coast, Midwest, etc.)

Provide the Reviewers' analysis of substance according to each OFPA Criteria Point

Provide Reviewer's vote on synthetic or nonsynthetic.

Provide Reviewer's vote to allow or Prohibit.

Provide Reviewers suggested annotation, if made.

Provide the Reviewer's Conclusion: that summarizes their reasoning to support their decisions.

### **The TAP Reviewers were also asked the following questions:**

*List any additional questions that were asked of the reviewers*

#### **Conclusion:**

TAP contractor should provide a synthesis of reviewers' recommendations. If alternative annotations are proposed, provide suggested options for NOSB to consider.

### **References**

\*= included in packet

\*\*= personal discussion

This TAP review was completed pursuant to United States Department of Agriculture Purchase Order # 43-6395-2900A.

## Appendix 2a

### OMRI's Instructions for TAP Reviewers

Please review the attached document, and provide corrections, comments, suggestions, additions, responses to questions, additional references, and an evaluation of the material according to the criteria in OFPA and the Agreement with TAP Reviewers. OMRI staff acknowledges that the TAP review cannot be exhaustive or comprehensive, but seeks your help to make sure that the information provided to the NOSB is adequate and unbiased. Your job includes the following tasks, and there is a form at the end of this document: NOTE: PLEASE COMPLETE THE FORM (PAGES 4-5). The especially critical parts are included as Question 4 on page 5. You are asked to:

- 1) vote as to whether or not a material is synthetic or non-synthetic
- 2) vote whether or not it should be added to the National List
- 3) Suggest restrictions or annotations for the material, if needed. Annotations must have justification for use.
- 4) An assessment as to the completeness and accuracy of database and evaluation. Any significant changes require that OMRI have supporting documentation on file.
- 5) Answer questions that are in the database in "TAP Reviewer Discussion" section.

Please consider the petition, information provided with the petition, enclosed supporting documents, and any information or data you have based upon your expertise in the field of organic agriculture.

#### Background: Description of the TAP Document

##### 1. Database

###### Identification:

Contains basic information about names and identification numbers of the material. This will be completed by OMRI in most instances. If you have a handy cross-reference or know of any common identifiers that are not included, please offer corrections and / or additions.

###### Characterization:

The NOSB needs to be familiar with the nature of the material, thus the Composition and Properties sections should describe the material in terms familiar to a broad audience.

The NOSB requires sufficient information to vote on whether or not a given substance is synthetic as defined by the Organic Foods Production Act and the National Organic Program Final Rule. The OFPA / NOP **defines synthetic** as "[a] substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes." Therefore, to be able to make the determination, the NOSB will need to know how a petitioned substance is produced, manufactured, purified, extracted, or otherwise made in the How Made section. Both synthetic or nonsynthetic processing substances must appear on the National List in order to be used in organic products. Processing substance must be characterized as **agricultural or non-agricultural** to determine where it belongs on the National List. If determined to be agricultural, it may be listed as approved subject to a determination that it is not commercially available in organic form.

In addition, the OFPA also requires the National List to be itemized by Specific Uses or application [7 USC 6517(b)]. Specific uses, action, and combinations should be comprehensive enough to cover all potential uses that might occur if the item is on the National List. In addition to classifying the substance in the appropriate category, the information provided under Uses, Actions, and Combinations may help with the development of any annotations that the NOSB and NOP might deem necessary for a substance to be added to the National List.

###### Status:

Historic use includes prior status under certified and non-certified systems, and may include a bit of historical context.

Synthetic substances used in production and non-agricultural substances used in processing must be consistent with the requirements under the Organic Foods Production Act. These are found in the respective sections on Crops (7 USC 6508), Livestock (7 USC 6509) and Processing (7 USC 6510), as well as in the guidelines for prohibitions or exemptions (7 USC 6517). A copy of OFPA is in the back of OMRI's green-covered *Operating Manual*. The substance also has a status under the Final Rule. This will depend on (a) whether or not it is synthetic and used in production, or if it is not an organically produced agricultural product and used in processing, and (b) if it is already on the National List. This section will also note the section of the Final Rule where it would appear.

## Appendix 2a

EPA / NIEHS / Other Sources section. In developing recommendations for the National List, the NOSB is required to “review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and such other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List” [7 USC 6517(l)]. The TAP review should provide information from the appropriate EPA programs, including whether or not the product or its precursors in production and waste stream are considered part of the Toxics Release Inventory. The primary source within NIEHS is the National Toxicology Program (NTP) database. This is usually presented in summary form. Other sources may also be considered, such as the Food and Drug Administration, the USDA’s Food Safety Inspection Service, and the Association of American Plant Food Control Officials.

OMRI endeavors to solicit comments from subscribing certifiers and will consider information provided by any certifier operating anywhere in the world. In the absence of a comprehensive list of USDA accredited certifiers, it is not possible to identify and compare the standards of all certifiers. However, if you are aware of any inaccuracies or differences not identified in the Database, please provide them. Note: OMRI relies on *current written standards* for this section. OMRI assumes that a certifier is following its written standard, and rules for variances made for a specific material (e.g., a phase-out) must be spelled out in the standards to be listed here.

OMRI also seeks to incorporate the status of a material under various international organic standards. These include the Codex Alimentarius *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods* (CAC/GL 32-1999, as amended); the European Union Council Regulation on Organic Production of Agricultural Products and Indications Referring Thereto on Agricultural Products and Foodstuffs (EU 2092/91, as amended); the IFOAM *Basic Standards*; the Canadian National Standard on organic agriculture, the Japanese Agricultural Standard (JAS); and any other international standard that may differ with any of the standards listed above

### 2. OFPA Criteria

The NOSB is also required to review materials against criteria specified in OFPA to develop the National List. None of these criteria can be considered in isolation. The NOSB has stated that “no material may be consistent with organic agriculture and appear on the National List in the absence of a strong factual showing in scientific criteria” (NOSB Final Recommendation, Addendum 26). The criteria are in *italics* [7 USC 6517(m)] and OMRI comments in roman:

*(1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems;*

This includes looking at the interactions with non-synthetic substances or items that are already on the National List used in production.

*(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;*

This section relies primarily on environmental fate data and monitoring, as well as toxicology.

*(3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance;*

Organic agriculture is distinguished from conventional agriculture by its emphasis maintaining ecological balances for soil and crop management. This section would consider any unintended consequences that would have an environmental impact.

*(4) the effect of the substance on human health;*

OMRI seeks to summarize studies on direct human exposure as the first preference, particularly if they involve exposure through the use(s) to be considered by the NOSB. Animal model studies will also be used, but are given less weight than studies that involve human subjects.

*(5) the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;*

The principle concern here is the impact of a substance on soil organisms--both micro- and macro-. Salt index and solubility are relatively easy to locate, but not all soil amendments have salt indexes published. This section is also important for livestock evaluation, because it is where the effects (beneficial as well as detrimental) on animal welfare are concerned.

*(6) the alternatives to using the substance in terms of practices or other available materials; and*

Alternatives include not only other materials, but also biological, cultural, mechanical, and physical alternatives. OMRI cannot be comprehensive in listing the alternatives. OMRI is not, under this current contract, providing a rigorous economic analysis of the various alternatives, or of the economic impact of either listing or not listing the substance.

## Appendix 2a

However, reviewers should provide any additional information that they are aware of about alternatives, including cost and general availability if known.

*(7) its compatibility with a system of sustainable agriculture.*

OMRI draws upon a number of sources to describe what is sustainable, including early NOSB discussions. Comments should reflect a consensus of expert opinion. If you find any statement under this item objectionable, it will be removed without need for documentation. Information contained in this section in the draft review may be moved elsewhere. Individual opinions are more appropriate in the TAP Reviewer Discussion section.

*In addition, the NOSB added the following criteria to be considered for processing:*

- 1. It cannot be produced from a natural source and has no organic ingredients as substitutes.*  
This requires specific knowledge of various recipes on the part of TAP reviewers.
- 2. Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling.*  
This addresses any concerns described in the “How Made” section as well as disposal and manner of use.
- 3. If 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.*  
Additives may be safe, but still may have an adverse effect on human health if they degrade rather than maintain the nutritional properties of a food.
- 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.*  
This requires the review to establish the primary purpose of an additive. While a given additive may serve these functions and still be added to the National List, the review needs to determine whether this is the main reason an additive is used.
- 5. 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.*  
OMRI is taking this to mean ‘Affirmed GRAS’—that is, published in 21 CFR by FDA, as opposed to ‘Self-affirmed GRAS’ by the private sector. The NOSB may want to discuss whether the contamination levels allowed by Food Chemicals Codex are consistent with organic principles. [How do FC Codex levels compare to FDA tolerances? They are not the same? What are you getting at?]
- 6. Its use is compatible with the principles of organic handling.*  
OMRI will seek more guidance from NOSB on this criterion. NOSB is in process of adopting principles for production and handling. OMRI has based the response in past to general goals of preventing contamination, using environmentally sound production methods, natural ingredients and processes when possible.
- 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.*  
This is also considered the “essential-ness” of substance.

### **TAP Reviewer Discussion Section**

In the version you receive, this section may contain more questions from the OMRI Staff.

This section in the final document is compiled from the complete individual contributions of each TAP reviewer, **based on your response to the form on pages 4-5** and will reflect your professional judgment about the material. Please be professional, courteous, and detached in your responses. Keep your statements credible, and build from the facts presented, along with documentation and data that you provide. Any personal comments that are off-topic, unsupported, or are otherwise deemed inappropriate will be removed. You have been chosen to review this material because OMRI recognizes your expertise in the field. Please honor the fact that reasonable people can be presented with the same facts and still respectfully disagree about the conclusion. Try to objectively examine pros and cons of all arguments, and explain why you feel the evidence leads you to your conclusions.

### **References**

Please review the enclosed literature as well as the TAP review. The references are listed out as ones that are included and ones that are not. If you need one that is not included and don't have access to it, call us. We are relying on you to help identify where we may have misinterpreted a study or inaccurately cited a source. These reviews are complicated and highly

## Appendix 2a

technical, so it is often difficult to detect such mistakes. However, such mistakes undermine the credibility of TAP reviews, and it is important that they be caught before the final review is presented to the NOSB and the public and posted on OMRI's web site.

Are there any key studies that are not cited? Are there any studies not included in the references that you think you need to see before completing the review? OMRI may not always be able to provide a copy. OMRI will reimburse you for any documents that you copy and send if you provide the receipt.

## Appendix 2a

### TAP REVIEWER RESPONSE FORM – PROCESSING

Name \_\_\_\_\_ Date: \_\_\_\_\_

\_\_\_\_\_ I have the following financial interest or conflict related to the use of this substance:

\_\_\_\_\_ I have no interests related to the use of this substance.

Signature \_\_\_\_\_

#### **1. Database—Check One**

\_\_\_\_\_ I find the database (Characterization and Status) to be reasonably complete and fairly accurate.

\_\_\_\_\_ The following information needs to be corrected or added to the database:

#### **2. NOSB Processing Criteria Evaluation (check all that apply and supply any additional info)**

Note: if you prefer, you may group your responses to the following subsections together as one narrative. Please do check if you agree overall with each criterium.

1. *It cannot be produced from a natural source and has no organic ingredients as substitutes.*

\_\_\_\_\_ I agree with the criteria evaluation. \_\_\_\_\_ Here is additional supporting information or comments.

\_\_\_\_\_ The criteria evaluation needs to be corrected or amended as follows:

2. *Its 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.*

\_\_\_\_\_ I agree with the criteria evaluation. \_\_\_\_\_ Here is additional supporting information or comments.

\_\_\_\_\_ The criteria evaluation needs to be corrected or amended as follows:

3. *If 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.*

\_\_\_\_\_ I agree with the criteria evaluation. \_\_\_\_\_ Here is additional supporting information or comments.

\_\_\_\_\_ The criteria evaluation needs to be corrected or amended as follows:

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.*

\_\_\_\_\_ I agree with the criteria evaluation. \_\_\_\_\_ Here is additional supporting information or comments.

## Appendix 2a

\_\_\_\_\_ The criteria evaluation needs to be corrected or amended as follows:

5. *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.*

\_\_\_\_\_ I agree with the criteria evaluation. \_\_\_\_\_ Here is additional supporting information or comments.

\_\_\_\_\_ The criteria evaluation needs to be corrected or amended as follows:

6. *Its use is compatible with the principles of organic handling.*

\_\_\_\_\_ I agree with the criteria evaluation. \_\_\_\_\_ Here is additional supporting information or comments.

\_\_\_\_\_ The criteria evaluation needs to be corrected or amended as follows:

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.*

\_\_\_\_\_ I agree with the criteria evaluation. \_\_\_\_\_ Here is additional supporting information or comments.

\_\_\_\_\_ The criteria evaluation needs to be corrected or amended as follows:

### **3. Conclusion – Summarize why this material should be allowed or prohibited for use in organic systems.**

#### **REQUIRED INFORMATION**

##### **4. Recommendation Advised to the NOSB:**

- a. The substance is: \_\_\_\_\_ Synthetic                      \_\_\_\_\_ Not Synthetic  
                                 \_\_\_\_\_ Agricultural                      \_\_\_\_\_ Non-Agricultural

- b. in a product labeled 95% organic

The substance should be \_\_\_\_\_ Allowed without restriction  
   \_\_\_\_\_ Allowed only with restrictions (annotation)  
   \_\_\_\_\_ Prohibited (do not add to National List)

Suggested annotation: \_\_\_\_\_

- c. in a product labeled “made with organic (specified ingredients)”

The substances should be \_\_\_\_\_ Allowed without further restriction  
   \_\_\_\_\_ Allowed only with additional restrictions (annotation)  
   \_\_\_\_\_ Prohibited (do not add to National List)

Suggested annotation: \_\_\_\_\_

##### **5. Additional attachments**

(check all that are appropriate)

- Reviewer Commentary  
 References  
 Articles

# Appendix 2b

## Name of Material

### Processing

#### Executive Summary

(xxxx to be completed after TAP reviewer comments are returned. TAP Reviewers will see the next version to "sign off" on it.)

- (1.) Describe the use of the material that was requested by the petitioner.
- (2.) Describe the nature of the material, its source or manufacturing process, and range of uses.
- (3.) Describe if applicable any history of past NOSB recommendations.
- (4.) Summarize reviewer's conclusions.
- (5.) Describe any further investigation if needed regarding availability of proposed alternatives, or feasibility of proposed annotations.

#### Summary of TAP Reviewer Analysis<sup>1</sup>

**Note: the Reviewers are asked to vote whether a material is synthetic or nonsynthetic (natural). They also should decide whether a material should be allowed without restrictions (no annotations), allowed only with certain restrictions (annotation) or prohibited for all uses. Reviewer recommendation for annotations should be listed separately under each reviewers report, and summarized in the Conclusion.**

#### **95% organic**

<b>Form</b>	<b>Synthetic / Non-Synthetic:</b>	<b>Allowed or Prohibited:</b>	<b>Suggested Annotation:</b>
Section of National List & recommendation of how it should read	List reviewers recommendation	Yes (list votes) No (list votes)	Describe annotations and summarize if all reviewers agree or disagree with annotation

#### **Made with organic (70% or more organic ingredients)**

<b>Form</b>	<b>Synthetic / Non-Synthetic:</b>	<b>Allowed or Prohibited:</b>	<b>Suggested Annotation:</b>
Section of National List & recommendation of how it should read	List reviewers recommendation	Yes (list votes) No (list votes)	Describe annotations and summarize if all reviewers agree or disagree with annotation

#### **Identification**

##### **Chemical Names:**

List all chemical names

31 List other names

32

##### **Other Name:**

33 **Trade Names:**

34 List Trade Names

<sup>1</sup> This Technical Advisory Panel (TAP) review is based on the information available as of the date of this review. This review addresses the requirements of the Organic Foods Production Act to the best of the investigator's ability, and has been reviewed by experts on the TAP. The substance is evaluated against the criteria found in section 2119(m) of the OFPA [7 USC 6517(m)]. The information and advice presented to the NOSB is based on the technical evaluation against that criteria, and does not incorporate commercial availability, socio-economic impact, or other factors that the NOSB and the USDA may want to consider in making decisions.

## Appendix 2b

35  
36 **CAS Numbers:**  
37 List CAS numbers  
38

39  
40 **Other Codes:**  
41 List other codes

42

### 43 **Characterization**

44 **Composition:**  
45 Describe Composition

46  
47 **Properties:**  
48 Describe Properties

49  
50 **How Made:**  
51 Describe How Made:

52  
53 **Specific Uses:**  
54 Describe Specific Uses

55  
56 **Action:**  
57 Describe Action

58  
59 **Combinations:**  
60 Describe Combinations

61

### 62 **Status**

63 **Historic Use:**  
64 Describe Historic Use

65  
66 **OFPA, USDA Final Rule:**  
67 Describe if listed anywhere in OFPA or Final Rule

68  
69 **Regulatory: EPA/NIEHS/Other Sources**  
70 Describe other regulatory status

71  
72 **Status Among U.S. Certifiers**  
73 Describe status among U.S. Certifiers

74  
75 **International**  
76 Describe status among International Organizations

77

### 78 **Section 2119 OFPA U.S.C. 6518(m)(1-7) Criteria**

79 1. *The potential of the substance for detrimental chemical interactions with other materials used in organic farming systems.*

80 Xx

81  
82 2. *The toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of*

83 *concentration in the environment.*

84 Xx

85  
86 3. *The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.*

87 Xx

88  
89 4. *The effects of the substance on human health.*

90 Xx

91  
92 5. *The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on*

93 *soil organisms (including the salt index and solubility of the soil), crops and livestock.*

94 Xx

95  
96 6. *The alternatives to using the substance in terms of practices or other available materials.*

- 97 Xx  
 98  
 99 7. *Its compatibility with a system of sustainable agriculture.*  
 100 Xx  
 101

### **Criteria From the February 10, 1999 NOSB Meeting**

A PROCESSING AID OR ADJUVANT may be used if:

- 104 1. *It cannot be produced from a natural source and has no organic ingredients as substitutes.*  
 105 Xx  
 106  
 107 2. *Its manufacture, use, and disposal do not have adverse effects on the environment and are done in a manner compatible with organic*  
 108 *handling as described in section 6510 of the OFPA.*  
 109 Xx  
 110  
 111 3. *If the nutritional quality of the food is maintained and the material itself or its breakdown products do not have adverse effects on human*  
 112 *health as defined by applicable Federal regulations.*  
 113 Xx  
 114  
 115 4. *Its primary purpose is not as a preservative or used only to recreate/improve flavors, colors, textures, or nutritive value lost during*  
 116 *processing except in the latter case as required by law.*  
 117 Xx  
 118  
 119 5. *Is Generally Recognized As Safe (GRAS) by FDA when used in accordance with Good Manufacturing Practices (GMP), and contains*  
 120 *no residues of heavy metals or other contaminants in excess of FDA tolerances.*  
 121 Xx  
 122  
 123 6. *Its use is compatible with the principles of organic handling.*  
 124 Xx  
 125  
 126 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.*  
 127 Xx  
 128

### **TAP Reviewer Discussion**

131 **Note: Contractor to explain to reviewers that they must focus on technical advise versus personal opinions.**

133 **Reviewer 1** [Describe reviewer's expertise, scientific discipline (i.e. Veterinary medicine – see #4 in Statement of Work),  
 134 Geographical Location of reviewer (ie. West coast, Midwest, etc.)  
 135

136 Provide the Reviewers' analysis of substance according to each OFPA Criteria Point  
 137

138 Provide Reviewer's vote on synthetic or nonsynthetic.  
 139

140 Provide Reviewer's vote to allow or Prohibit.  
 141

142 Provide Reviewers suggested annotation, if made.  
 143

144 Provide the Reviewer's Conclusion: that summarizes their reasoning to support their decisions.  
 145  
 146

147 **Reviewer 2** [Describe reviewer's expertise, scientific discipline (i.e. Veterinary medicine – see #4 in Statement of Work),  
 148 Geographical Location of reviewer (ie. West coast, Midwest, etc.)  
 149

150 Provide the Reviewers' analysis of substance according to each OFPA Criteria Point  
 151

152 Provide Reviewer's vote on synthetic or nonsynthetic.  
 153

154 Provide Reviewer's vote to allow or Prohibit.  
 155

156 Provide Reviewers suggested annotation, if made.  
157  
158 Provide the Reviewer's Conclusion: that summarizes their reasoning to support their decisions.  
159 Reviewer #3 [Describe reviewer's expertise, scientific discipline (i.e. Veterinary medicine – see #4 in Statement of Work),  
160 Geographical Location of reviewer (ie. West coast, Midwest, etc.)  
161  
162 Provide the Reviewers' analysis of substance according to each OFPA Criteria Point  
163  
164 Provide Reviewer's vote on synthetic or nonsynthetic.  
165  
166 Provide Reviewer's vote to allow or Prohibit.  
167  
168 Provide Reviewers suggested annotation, if made.  
169  
170 Provide the Reviewer's Conclusion: that summarizes their reasoning to support their decisions.  
171  
172 **The TAP Reviewers were also asked the following questions:**  
173  
174 *List any additional questions that were asked of the reviewers*  
175  
176 **Conclusion:**  
177 TAP contractor should provide a synthesis of reviewers' recommendations. If alternative annotations are proposed,  
178 provide suggested options for NOSB to consider.  
179  
180 **References**  
181 \* = *included in packet*  
182 \*\*= *personal discussion*  
183  
184  
185 This TAP review was completed pursuant to United States Department of Agriculture Purchase Order # 43-6395-0-2900A.

## Appendix 3a

### Proposal for NOSB Materials Decision CROPS

Date: Nov. 13, 2000  
From: OMRI  
To: NOSB Materials Committee

#### Crops Decision Documentation

1. a) Is it an agricultural substance?

b) Is it non-agricultural? proceed to step 2.

2. Synthetic or Non-Synthetic?

(a) Is it synthetic?:

- Formulated or manufactured by a chemical process.
- Chemical changes of substances from plants, animals, or mineral sources.

If Yes, describe reasons for considering synthetic and continue to Step 2.

---

(b) Is it non-synthetic?

Extracted from a naturally occurring from a plant, animal, or mineral source.  
Created by a naturally occurring biological process.

If Yes, describe reasons for considering non- synthetic and continue to step X.

---

(i) If non-synthetic, should it be reviewed as a potentially prohibited non-synthetic?  
If so proceed to 2.

If vote fails: considered an Allowed -Non-Synthetic, (does not appear on National list.)

3. a. Standing in OFPA: is it prohibited by statute?

---

b. Is there a specific category for exemption under §2118(b)(1)(C)(i)?

---

### Appendix 3a

c. . Is it consistent with requirements of Proposed Rule? (or implemented rule) Identify subsection it will be added to.

---

c. If not clear whether specified in OFPA, is there a precedent established in regulation or National List?

---

**IF Yes to (a) or No to (b) – decide whether to vote, or continue through step 3-7.**

Vote to include on National List inclusion as allowed synthetic.

(a negative vote will prohibit)

---

4. How does it fare under OFPA criteria – go through all seven.

List objections or reservations under each heading and continue to step 4.

- (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 and areas of concentration in the environment.
- (3) The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.
- (4) The effects of the substance on human health.
- (5) The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance 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 available materials.
- (7) Its compatibility with a system of sustainable agriculture.

**Appendix 3a**

5. Any other regulatory limitations or concerns? (International, Codex, FDA, EPA, other).

---

6. Recommend annotations : based on any concerns discussed in steps 3-5

---

---

7. Consider combined evaluation of steps 3-6 as basis for vote.

Voting procedure as established by Board.

a. Vote to determine as Synthetic

- by roll call vote and decided by simple majority

b. Vote to list as Prohibited Non-Synthetic:

- by roll call vote requiring 2/3 majority of those present at vote. (abstentions noted, but registered as no votes)

c. Vote to be on the National List of Allowed Synthetics without annotation.

If this vote is negative, then proceed to vote with annotation.

d. Vote to approve language of annotation

\_use restrictions\_ to be voted by hand rising and decided by simple majority

e. Vote to be on the National List of Allowed Synthetics with annotation.

## Appendix 3b

### Proposal for NOSB Materials Decision LIVESTOCK

Date: Nov. 13, 2000

From: OMRI

To: NOSB Materials Committee

#### Livestock Decision Documentation

1. a) Is it an agricultural substance?

b) Is it non-agricultural? proceed to step 2.

2. Synthetic or Non-Synthetic?

(a) Is it synthetic?:

- Formulated or manufactured by a chemical process.
- Chemical changes of substances from plants, animals, or mineral sources.

If Yes, describe reasons for considering synthetic and continue to Step 2.

---

(b) Is it non-synthetic?

Extracted from a naturally occurring from a plant, animal, or mineral source.  
Created by a naturally occurring biological process.

If Yes, describe reasons for considering non- synthetic and continue to step 2.

---

(i) If non-synthetic, should it be reviewed as a potentially prohibited non-synthetic?  
If so proceed to 2.

---

If vote fails: considered an Allowed -Non-Synthetic, (does not appear on National list.)

3. a. Standing in OFPA: is it prohibited by statute?

---

b. Is there a specific category for exemption under §2118(b)(1)(C)(i)?

---

## Appendix 3b

c. Is it consistent with requirements of Proposed Rule? (or implemented rule) Identify subsection it will be added to.

---

c. If not clear whether specified in OFPA, is there a precedent established in regulation or National List?

---

**IF Yes to (a) or No to (b) – decide whether to vote, or continue through step 3-7.**  
**Vote to include on National List inclusion as allowed synthetic.**  
**(a negative vote will prohibit)**

---

4. How does it fare under OFPA criteria – go through all seven.  
List objections or reservations under each heading and continue to step 4.
- (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 and areas of concentration in the environment.
  - (3) The probability of environmental contamination during manufacture, use, misuse, or disposal of the substance.
  - (4) The effects of the substance on human health.
  - (5) The effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance 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 available materials.
  - (7) Its compatibility with a system of sustainable agriculture.

**Appendix 3b**

5. Any other regulatory limitations or concerns? (International, Codex, FDA, EPA, other).

\_\_\_\_\_

Is the substance allowed by FDA regulation or by AAFCO as a feed ingredient for livestock?

\_\_\_\_\_

6. Recommend annotations : based on any concerns discussed in steps 3-5

\_\_\_\_\_

\_\_\_\_\_

7. Consider combined evaluation of steps 3-6 as basis for vote.

Voting procedure as established by Board.

a. Vote to determine as Synthetic \_\_\_\_\_  
(by roll call vote and decided by simple majority)

b. Vote to list as Prohibited Non-Synthetic: \_\_\_\_\_  
by roll call vote requiring 2/3 majority of those present at vote. (abstentions noted,  
but registered as no votes)

c. Vote to be on the National List of Allowed Synthetics without annotation. \_\_\_\_\_

If this vote is negative, then proceed to vote with annotation.

d. Vote to approve language of annotation  
use restrictions to be voted by hand rising and decided by simple majority

e. Vote to be on the National List of Allowed Synthetics with annotation. \_\_\_\_\_

## Appendix 3c

### Proposal for NOSB Materials Decision PROCESSING

Date: Nov. 13, 2000  
From: OMRI  
To: NOSB Materials Committee

#### Processing Decision Documentation

1. a) Is it an agricultural substance?

b) Is it non-agricultural? proceed to step 2. If agricultural, not necessary to put on National List. (unless it is desired to permit it from a non-organic source)

2. (a) Is it synthetic?:

(i) If Yes, describe reasons for considering, including necessity and unavailability of wholly natural substitutes and continue to Step 3.

---

(b) Is it non-synthetic?

If Yes, describe unavailability of organic sources continue to step 3.

---

2. a. Standing in OFPA: is it prohibited by statute?

---

b. . Is it consistent with requirements of Proposed Rule? (or implemented rule) Identify subsection it will be added to.

---

3. How does it fare under criteria specified in 205.600(b) and (c)? Go through all seven. List objections or reservations under each heading and continue to step 4.

**Appendix 3c**

*(1) It cannot be produced from a natural source and has no organic ingredients as substitutes.*

---

*(2) Its 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) If 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) 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.*

---

*(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. Any other regulatory limitations or concerns? (International, Codex, FDA, EPA, other).

---

### Appendix 3c

5. Recommend annotations : based on any concerns discussed in steps 3-4.

---

---

6. Consider combined evaluation of steps 1-4 as basis for vote.

7. Voting procedure as established by Board.

- a. As allowed non-organic ingredient in foods and animal feed labeled “organic” (95% or greater), with no annotation: if No, then also go to next vote: \_\_\_\_\_

(by roll call vote requiring 2/3 majority of those present at vote. (abstentions noted, but registered as no votes)

- b. As allowed non-organic ingredient in foods and animal feed labeled “organic” (95% or greater), with annotation. If no go to next vote.: \_\_\_\_\_

(by roll call vote requiring 2/3 majority of those present at vote. (abstentions noted, but registered as no votes)

- c. As prohibited as a non-organic ingredient in foods labeled “made with specified organic ingredients” (50% organic or greater). .: \_\_\_\_\_

- d. As a processing aid that appears in a food in only incidental amounts. \_\_\_\_\_

(Subject to structure of final rule, or could vote this as annotation)