Introduction

The final recommendation below is a work product of a task force of the National Organic Standards Board, which is an advisory board to the USDA’s National Organic Program. The language does not represent new regulation or guidance from the USDA.

The National Organic Program Final Rule contains a provision allowing for use of non-organic agricultural ingredients in processed food products labeled as “organic”, subject to the provisions of 205.201(a)(2) and 205.301(b) and (f). At the time of publication of the Final Rule, AMS requested public comment on implementation of this provision. At this time, the NOSB has formed a task force to provide input to the NOP in order to facilitate development of the necessary guidance for implementation of the “commercial availability” provision.

The USDA National Organic Program and the National Organic Standards Board’s 606 Task Force solicited voluntary information from accredited certifying agents (ACAs) on the procedures used to determine if agricultural ingredients used in processed food products are commercially available in an organic form. We also requested information on any agricultural ingredients that ACAs have determined are not commercially available in an organic form.

The objective of the NOP and NOSB is to establish acceptable practices to be followed by all certification applicants, certified operators, and ACAs for consistent, transparent, and predictable determinations of commercial availability that provide regulatory certainty.

This document provides background information and contains a 4-part recommendation, in which the Task Force recommends that 205.606 be amended; currently listed and recommended items be reviewed; a new section 205.607 be created; and that 205.606 be further amended to contain standardized procedures to be implemented by certification applicants, certified operators, and accredited certifying agents for the determination of commercial availability.

Note that the task force’s work applies only agricultural ingredients used in processed food. We anticipate a future effort to develop guidance on commercial availability as applied to seed and planting stock used in crop production, consistent with this recommendation.
Background

§205.2 of the Final Rule defines “commercially available” as, “the ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling as determined by the certifying agent in the course of reviewing the organic plan.”

§205.201(a)(2) states, “The producer or handler of a production or handling operation, except as exempt or excluded under §205.101, intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:
(2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of commercial availability, as applicable;”

§205.301(b) states, in part, “Products sold, labeled, or represented as “organic.” A raw or processed agricultural product sold, labeled, or represented as “organic” must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form,”

§205.301(f)(6) states, “All products labeled as “100 percent organic” or “organic” and all ingredients identified as "organic" in the ingredient statement of any product must not:
(6) Be produced using nonorganic ingredients when organic ingredients are available;”

In the Preamble to the Final Rule, on page 80563, AMS stated, “While recognizing the potential benefits of applying the commercial availability standard to all agricultural ingredients in a processed product, we are concerned that enforcing this provision could impose an excessive burden on handlers. Although many commenters stated that some existing certifying agents apply a commercial availability standard, we do not have complete information on the criteria used by these certifying agents, and we are unsure whether a consensus exists on criteria for commercial availability within the organic community. Additionally, we are concerned that, unless the standard is clearly articulated and consistently interpreted and enforced, it will not be effective. Disagreement among certifying agents regarding when and under what circumstances an ingredient is commercially available would undermine our intent to create an equitable and enforceable standard.”
“AMS is soliciting additional comment and information on a number of issues concerning the development of standards for the commercial availability of organically produced agricultural commodities used in processed products labeled as "organic." On the basis of these comments and information and additional recommendations that the NOSB may develop, AMS will develop a commercial availability standard for use in implementing the final rule. AMS intends to develop the commercial availability standard and incorporate it within the final rule prior to the commencement of certification activities by accredited certifying agents. This approach will provide organic handlers and certifying agents the standard necessary to incorporate the consideration of commercial availability of ingredients in an organic system plan at the time that the USDA organic standard comes into use.”

“Specifically, AMS requests comments and information addressing the following questions:
What factors, such as quantity, quality, consistency of supply, and expense of different sources of an ingredient, should be factored into the consideration of commercial availability? What relative importance should each of these factors possess, and are there circumstances under which the relative importance can change?
What activities and documentation are sufficient to demonstrate that a handler has taken appropriate and adequate measures to ascertain whether an ingredient is commercially available?
How can AMS ensure the greatest possible degree of consistency in the application of the commercial availability standard among multiple certifying agents?
Could potentially adverse effects of a commercial availability standard, such as uncertainty over the cost and availability of essential ingredients, impact or impede the development of markets for organically processed products?
What economic and administrative burdens are imposed by the commercial availability standards found in existing organic certification programs?
How would producers benefit from market incentives to increase use of organic ingredients that result from a commercial availability standard?
Would lack of a commercial availability standard provide a disincentive for handlers of products labeled "organic" to seek out additional organic minor ingredients? What impacts could this have on producers of minor ingredients?”

“AMS welcomes any new or unpublished research results or information that exists concerning a commercial availability standard. AMS specifically invites comment from establishments which currently operate using commercial availability or a comparable provision in the conduct of their business.”

In response to the AMS' request for comments, comments were submitted by the following: ForesTrade; Horizon Organic Dairy; Organic Materials Review Institute; Organic Trade Association; Small Planet Foods; Quality Assurance
International; Wood Prairie Farm; and the NOSB. Comments are reflected in recommendation # 2 below.

All comments are posted at www.ams.usda.gov/nop/archive/CommercialAvailability.htm

§205.606 currently reads, “Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

The following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

Any nonorganically produced agricultural product may be used in accordance with the restrictions specified in this section and when the product is not commercially available in organic form.

(a) Cornstarch (native).
(b) Gums—water extracted only (arabic, guar, locust bean, carob bean).
(c) Kelp—for use only as a thickener and dietary supplement.
(d) Lecithin—unbleached.
(e) Pectin (high-methoxy).”

In June, 2001, the NOSB recommended that the words “as ingredients” be deleted from 205.605 and 205.606. The rationale for deleting "as ingredients" from the title and text of 205.605 and 205.606 was a technical correction to make the language of 205.605 and 205.606 consistent with 205.105 (c) and (d), which do not mention the phrase "as ingredients". The intent was not to remove "ingredients" from inclusion or consideration. Rather, the intent was to clarify that the phrase "in or on" includes both ingredients and processing aids.

In May, 2002, the NOSB made a recommendation to amend Section 205.606 of the National List to change the text and re-assign or delete the listed items. The justification for this recommendation was that industry was starting to rely on section 205.606 as a list of agricultural ingredients that are not available in an organic form. The NOSB indicated that once an item is specifically listed on 205.606, the industry no longer has an incentive to develop organic forms of the substance.

**Recommendation # 1a**

The 606 Task Force recommends replacement of the current section 205.606 with a new section 205.606, entitled, “Nonorganically produced agricultural substances prohibited or restricted for use in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”
Any nonorganically produced agricultural product may be used in products labeled “organic” in accordance with restrictions specified in this section and when the product is not commercially available in organic form.

Any nonorganically produced agricultural product may be used in products labeled “made with organic (specified ingredients or food group(s))” in accordance with restrictions specified in this section.

Rationale - If the materials currently under 205.606 (those that include a restrictive annotation) were recommended to remain on the National List, then they would be better identified under a “restricted” or “annotated” listing on a “prohibited agricultural” category, because the items may not fit under 205.605, since it lists “nonagricultural” substances.

Only prohibited and annotated agricultural ingredients would appear on the new section 205.606. Since they have been determined to be agricultural, all items on 205.606 would still be subject to commercial availability requirements, as administered by operators and accredited certifying agents. All other agricultural ingredients used in processed products would not appear on the National List, as they would fall under commercial availability requirements.

Recommendation # 1b

The 606 Task Force recommends that the current materials located under 205.606 be reviewed by the NOSB prior to deletion or movement to another section. In order to be consistent and transparent with the material review process, each substance currently located in 205.606 shall be reviewed for reclassification by the Handling Committee to determine if the substance is:

a) nonagricultural and nonsynthetic, and therefore should be moved to 205.605(a);

b) nonagricultural and synthetic, and therefore should be moved to 205.605(b);

c) agricultural and prohibited or restricted, and therefore should be added to a new section 205.606 “Nonorganically produced agricultural substances prohibited or restricted for use in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)),” or

d) agricultural and allowed subject to commercial availability, and therefore should be removed from the National List.

The following materials currently located on 205.606 shall go through the material review process described above:

Cornstarch (native), Lecithin – unbleached, Pectin (high methoxy), Gums – water extracted only (arabic, guar, locust bean, carob bean) and Kelp – for use as a thickener and dietary supplement.
The following materials previously recommended to be added to section 205.606 by the NOSB shall also go through the review process described above: Gelatin and Shellac

**Recommendation # 2**

The NOSB 606 Task Force recommends that the definition and procedures contained below be used by certification applicants, certified operators, and accredited certifying agents to determine the commercial availability of agricultural ingredients used in processed food products labeled “organic”.

**Commercially available definition**

The Final Rule defines “commercially available” as, “the ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling as determined by the certifying agent in the course of reviewing the organic plan.”

**Commercial availability determination procedures (to be added to Subpart E Certification)**

In order to assure consistency, the Task Force recommends that Subpart E Certification be amended to contain the following commercial availability determination procedures:

A. For a non-organic agricultural ingredient used in a processed product labeled as “organic” to be determined as not commercially available, the applicant or certified operator must submit a written report to the certifying agent as part of the organic system plan or organic system plan update that provides:

1. Description of the ingredient and the required technical specifications of the ingredient (including form and quality);  
2. Estimate of the quantity of the ingredient needed within a specified time period, if this is a factor in the requested allowance of a non-organic ingredient. (Quantity, quality, form, and function may be considered for individual product requirements and not for total business requirements for all potential product lines.); and  
3. Explanation of how the ingredient is used to fulfill an essential function.  
4. During the certification evaluation, the applicant or certified operator must provide information concerning known sources of the ingredient, and organic status thereof; and  
5. Provide written evidence of efforts to locate sources of organic ingredients that meet form, quality and quantity requirements, including the dates when potential suppliers of applicable organic ingredients were contacted. Written evidence may include letters, faxes, email correspondence, ingredient evaluation reports, or phone logs of discussions with potential
suppliers. A minimum of three potential suppliers shall have been contacted during the previous 12 months.

B. The accredited certifying agent, in granting a determination that an agricultural ingredient used in a processed food product is not commercially available in an organic form, shall:

1. Evaluate the applicant or certified operator’s claim that no organic substitutes are commercially available in the form, quality, or quantity needed by the operation to fulfill the required function;
2. Validate that the applicant or operator has documented that the ingredient is not commercially available in an organic form by reviewing the best available information listing known sources of organic ingredients;
3. Notify the certification applicant or certified operator of sources of information which list available organic ingredients, if the certifying agents finds that such ingredients exist;
4. Maintain and annually submit to the National Organic Program an up-to-date list of ingredients that have been granted allowances in non-organic form. (The list shall maintain the confidentiality of ingredient suppliers and parties granted allowances. The reporting requirement shall be implemented through the accreditation process by providing ACAs ample notification and time to adapt data management systems.);
5. Require certified operators to update commercial availability information in each organic system plan update;
6. Acknowledge all complaints concerning allowances granted and provide rationale for determinations. If the investigation of a complaint provides significant new information, then the certifying agent must revisit the allowance; and
7. Require that products without sufficient documentation not be labeled “organic”. Such products may be labeled “made with organic ingredients” if they meet all applicable labeling and product content requirements for that category.

Postscript

The 606 Task Force acknowledges that this recommendation does not apply to organic seed determinations. The task force recommends that the Crops Committee and/or Policy Development Committee develop a draft organic seed recommendation which is consistent with this recommendation.

Conclusion

Based on comments received, the NOSB recommends that 205.606 be amended; currently listed and recommended items be reviewed; and that Subpart E Certification be amended to contain standardized procedures to be implemented by certification applicants, certified operators, and accredited
certifying agents for the determination of commercial availability. A comparable and consistent recommendation is needed to address organic seed issues.