

**FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)**

Date: 5/8/2007

Subject: Whey Protein Concentrate for addition to National List §205.606

Chair: Andrea Caroe

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: XXX

Guidance Statement:

Other:

Statement of the Recommendation (including Recount of Vote):

The Board recommends adding Whey Protein Concentrate to the National List under §205.606 nonorganically produced agricultural products

NOSB Vote: **Motion:** Julie Weisman **Second:** Steve DeMuri

Board vote: Yes - 8 No - 3 Abstain - 0 Absent – 4 Recuse - 0

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

The National List of Allowed and Prohibited Substances § 205.606

Response by the NOP:

National Organic Standards Board

Final Recommendation for

Date: May 8, 2007

I. List: (*where in FR rule example 205.606*)

National Organic Program Subpart G: The National List of Allowed and Prohibited Substances. §205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food groups(s)).”

II. Committee Summary:

On June 9, 2005 a court final order and judgment arising from *Harvey v. Johanns*, stated that “the Secretary must issue a declaratory judgment that 7 CFR § 205.606 shall not be interpreted to create a blanket exemption to the National List requirements specified in 7. U.S.C. 6517.” These “requirements permit the use of nonorganic agricultural products in or on processed organic products when their organic form is not commercially available.”

Further, “consistent with OFPA, 7 CFR §205.606 shall be interpreted to permit the use of a non-organically produced agricultural product that has been listed in § 205.606 pursuant to National List procedures and when a certifying agent has determined that the organic form of the agricultural product is not commercially available.”

Effort was made through many channels to elicit from manufacturers, petitions for any non-organically produced agricultural materials that had been using on products labeled and sold as “organic.”

In addition, pursuant to the judgment in *Harvey v. Johanns*, the NOSB was instructed to develop criteria for determining commercial availability, an essential tool in evaluating whether or not petitioned materials could be listed on § 205.606. These criteria were finalized in the NOSB “Recommendation for the Establishment of Commercial Availability Criteria National List § 205.606” of October 19, 2006. That recommendation allows for pro-active listing on 205.606 of materials which may currently be available in an organic form, but the supply of which has a history of fragility due to factors such as limited growing regions, weather or trade-related issues. Furthermore, the recommendation reiterates the role of the Accredited Certifying Agent (ACA) in making the ultimate decision as to whether a 606-listed material may be used, on a case by case basis.

Petitions received for non-org agricultural materials contained widely varying amounts information with which to assess the current availability or fragility of current supply of organic forms of the petitioned material. Two petitions were received for whey protein concentrate materials. They were for whey protein concentrate 35% and 80%. Public comment was received to demonstrate that these two materials were produced through identical processes and differed only in the amount of protein from each other and other whey protein concentrates. The Handling Committee recommended, and the Board voted to approve, making a recommendation for Whey Protein Concentrate as a class of materials.

The petitioner for Whey Protein Concentrate made the case that processors capable of manufacturing Whey Protein Concentrate are instead choosing to manufacture whey powder. Most whey is processed into either whey powder, which is used in dry cheese powders, or demineralized whey powder, which is used in organic infant formulas and organic protein bars. The processing yield for whey powder is higher than for Whey Protein Concentrate which is produced through a multiple step process. The process of producing Whey Protein Concentrate results in lactose which can be recovered and sold. Finally, the market for organic Whey Protein Concentrate is still relatively small resulting in proportionately small processing runs for organic Whey Protein Concentrate. The quantity of lactose recovered from processing of organic Whey Protein Concentrate is too small to make recovery economically feasible. This in combination with other losses associated with small processing runs and lower processing yield creates an economic disincentive for processors to produce Whey Protein Concentrate.

The Handling Committee noted that agricultural substances are only required to be evaluated using the criteria specified in the Act (7 U.S.C. 6517 and 6518).

6517(c)(1)(a)

(i) would not be harmful to human health or the environment;

(ii) is necessary to the production or handling of the agricultural product because of unavailability of wholly natural substitute products; and

(iii) is consistent with organic farming and handling;

Agricultural substances do not need to be evaluated against section 205.600 (b). (i.e. essentialness). This additional criteria is only required for any synthetic substance used as a processing aid or adjuvant.

The Handling Committee also considered what constitutes “essential” for organic handling of a finished retail product and how that may be different from that of a material used in crop or livestock production. A number of commenters cited Whey Protein Concentrate as an essential ingredient in the organic consumer products they make for this reason. There were no public comments specifically opposing the listing of Whey Protein Concentrate on § 205.606.

The Handling Committee carefully considered the difference between the availability of a raw agricultural product as organic, and the availability of certified organic handlers to process that raw material. The petitioner for Whey Protein Concentrate acknowledged that organic milk and whey is available organically but that currently no processor with the equipment or technology to process Whey Protein Concentrate is willing to use their equipment to fulfill current organic requirements.

III. Board Recommendation

The Handling Committee recommends the listing of the following substance in this use Category:

Whey Protein Concentrate

Moved: Julie Weisman Second: Steve DeMuri

Board vote: Yes - 8 No - 3 Abstain – 0 Absent – 4 Recuse - 0