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

**Date:** **11/05**/2009 _____

**Subject:** Egg White Lysozyme  Sunset Review _____

**Chair:** __Jeff Moyer_____ _ _____

**Recommendation**

The NOSB hereby recommends to the NOP the following:
    Rulemaking Action: __X__
    Guidance Statement: _____
    Other: ___ ___

**Summary Statement of the Recommendation** (including Recount of Vote)**:**

Egg White Lysozyme was reviewed for sunset by the NOSB at the November 2009 meeting.  A summary of the Handling committee's recommendation is attached.  No comments were received during the meeting that disagreed with the committee's recommendation.

The NOSB voted to recommend relisting of Egg White Lysozyme on §205.605(a) with 13 voting yes, 0 no votes and 2 absent.

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

*Board vote:  Yes - 13    No- 0     Abstain- 0      Absent - 2*

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

**Response by the NOP:**

**National Organic Standards Board**
**Handling Committee Recommendation for §205.605(a)**
*Sunset of Egg White Lysozyme*

August 28, 2009

**I. List:**

**National Organic Program Subpart G: The National List of Allowed and Prohibited Substances. §205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."**

   a. *Nonsynthetics allowed*

**II. Committee Summary:**

Egg white lysozyme was added to the National List (Federal Register Vol. 71, No. 175) §205.605(a) on September 11, 2006. This addition was based on a re-assessment of egg white lysozyme by the NOSB at their May 13-14, 2003 meeting. This is the first time that egg white lysozyme has been reviewed through the sunset process. Egg white lysozyme is a purified enzyme preparation extracted from hen egg white. Lysozyme is a natural anti-microbial. The food applications for egg white lysozyme include cheese and wine.

The April 1, 2003 TAP reviewed "Enzymes, Plant and Fungal" and included these findings: The substance is used in handling and is non-synthetic but is not organically produced (7 USC 6517 (b)(c)(iii)). Enzymes contained in various ingredients have been used to prepare foods since before recorded history. Enzymes have been used in a broad number of applications by organic food processors for as long as organic processed food has been on the market. The TAP did not address any unacceptable risks to the environment, human or animal health resulting specifically from the use or manufacture of egg white lysozyme. The petitioner describes the manufacturing process thusly: "The food-lysozyme that is the subject of the petition is naturally derived from chicken egg whites. A food-grade inert material (a polymer resin) that specifically binds to lysozome is used to extract the enzyme from the egg whites. After the binding process, the lysozyme is stripped from the resin, concentrated, purified, and dried. The extraction process requires the use of the following chemicals: citric acid, salt (NaCl), and hydrochloric acid / sodium hydroxide for pH adjustment. There are no solvents used in the manufacturing of the enzyme and the final dry product is nearly 100% pure egg white lysozyme." Alternatives to this material in food handling are generally considered to be more harsh preservatives such as formaldehyde, nitrate, nisin, or hydrogen peroxide.

The NOSB has received seven public comments in support of, and no public comments opposed to, the relisting of egg white lysozyme in response to the Federal register notice of the sunset of egg white lysozyme (AMS-TM-07-0136). No public comments have been received opposing the continued use of egg white lysozyme in organic handling.

**III. Committee Recommendations**

The Handling Committee recommends the re-listing of egg white lysozyme on §205.605(a).

*Moved: Tracy Miedema        Second: Joe Smillie*

*Committee Vote:  Yes- 5       No- 0       Absent- 1    Abstain-        Recuse- 0*