

August 2, 2006

This is in response to your notification (Log 06-NT 0215-N-A) dated June 9, 2006, requesting approval of Bioshield 75 to be used in any Food Safety Inspection Services (FSIS) establishments as a sanitizing agent.

On July 18, 2006, representatives from Indusco met with the Food Safety and Inspection Service (FSIS) to present their technology and request a letter of “no objection” for the use of BioShield 75 solution on federally inspected establishments as a sanitizing agent.

**BioShield 75 is a stable aqueous solution of Organosilane Quaternary Ammonium that is intended to be applied to food contact and non-food contact materials, e.g., floors, drains, tables, cutting boards, slicers, etc., followed by a wash and rinse. BioShield 75 has strong bonding capabilities upon application to various materials. Thus, the use of BioShield 75 results in a durable coating that is effective in eliminating and preventing the growth of bacteria, mold, and fungi. BioShield 75 is registered with the Environmental Protection Agency (EPA).**

FSIS has completed its review of the information submitted supporting BioShield 75 as a sanitizing agent and has no objection to the use of BioShield 75 as FSIS regulated establishments as a sanitizing agent. This letter should not be considered as validation that BioShield 75 will be effective in any particular FSIS establishment.

On October 20, 1999, USDA published in the Federal Register, a Final Rule entitled “Sanitation Requirements for Official Meat and Poultry Establishment”. This rule consolidates the sanitation regulations into a single part applicable to both official meat and poultry plants, eliminates unnecessary differences between the sanitation requirements for meat and poultry processing, and converts many of the highly prescriptive sanitation requirements to performance standards. Among the prescriptive sanitation requirements that were eliminated was the regulation (Title 9, Code of Federal Regulations (CFR), Section 381.60) requiring the authorization of nonfood compounds by USDA, prior to their use in a Federally inspected meat or poultry establishment. The new sanitation regulations (9 CFR, Section 416.4) state that nonfood compounds and processing aids used by an establishment must be safe and effective under the conditions of use.

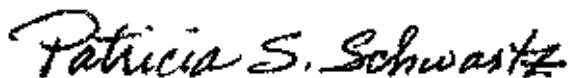
The establishment must have documentation on file substantiating the safety of a chemical's use in a food processing environment and this documentation must be available to FSIS inspection program employees for review. The documentation may be in the form of a manufacturer's or supplier's letter of guaranty or a third party authority's certification that the compound is safe according to some established safety criteria and, as proposed for use will have no deleterious effects on meat and poultry being processed. A manufacturer's or supplier's letter of guaranty should contain the following information: 1) name and address of the supplier; 2) brand name, code name, or other designation; 3) statement of safety and efficacy; 4) statement of compliance with U.S. Federal regulations (if applicable); 5) use directions; and 6) signature of an authorized firm representative.

FSIS does not object to the proposed use of BioShield 75 to treat food contact and non-food contact materials in meat and poultry establishments. Those establishments, who use BioShield 75, are to be supplied with following information:

- Information to support the safety of the product when in contact with BioShield 75 solution in food processing environments.
- Copy of EPS's registration Certificate

If you have any further questions, please contact Dr. Kris Murthy at (202) 690-5646 or [kris.murthy@fsis.usda.gov](mailto:kris.murthy@fsis.usda.gov).

Sincerely,



Patricia S. Schwartz, Ph.D.  
Acting Director New Technology Staff  
Office of Policy, Program, and Employee Development