



United States  
Department of  
Agriculture

Agricultural  
Marketing  
Service

1400 Independence Ave. SW  
Washington, DC  
20250-0258

Poultry Programs

April 1, 2010

Richard Litman  
Vice President of Engineering & Service  
Diamond-Moba Americas  
23400 Haggerty Road  
Farmington Hills, MI 48335

Dear Mr. Litman,

This is in response to your company's request for the use of ultraviolet (UV) irradiation to disinfect the surface of shell eggs processed in plants operating under the Regulations Governing the Voluntary Grading of Shell Eggs (7 CFR 56). Additionally, if acceptable, the UV irradiation would be utilized as an alternate to the application of an approved chemical sanitizer solution. You stated that the UV disinfection system, designed as a component of the Moba Omnia egg grading and packaging system, is being used in international locations for the processing of shell eggs. Submitted for review with your correspondence was detailed engineering design information, specifications relative to the low pressure mercury UV lamps, and scientific research demonstrating the destruction of various types of microorganisms commonly isolated from the surface of processed shell eggs.

As discussed, all processes and chemical sanitizing compounds used to disinfect the surface of the shell of an egg must be accepted for that intended use by the Federal Food and Drug Administration (FDA). The codified FDA regulations stated in 21 CFR 179.39 defining the use of UV irradiation is limited and does not include the disinfection of the surface of the shell of an egg. The referenced FDA regulation states that UV radiation may be safely used to treat food, water, and juices when the source of the radiation consists of low pressure mercury lamps emitting 90 percent of emissions at a wavelength of 253.7 nanometers (2,537 angstroms equivalent). For interpretation of the FDA regulations, the Agricultural Marketing Service (AMS) contacted FDA officials at the Division of Biotechnology and GRAS Notice Review for interpretation of the regulation as it applies to the proposed use.

Upon review of the information submitted, FDA officials have accepted the proposed use of UV irradiation to disinfect the surface of the shell of an egg in accordance with the above referenced requirements stated in the regulations. Based upon the interpretation of the applicable food additive regulation promulgated under the authority of FDA, the AMS Poultry Programs is approving the application of UV radiation to disinfect the surface of the shell of eggs processed in official plants. This approval is subject to the following provisions:

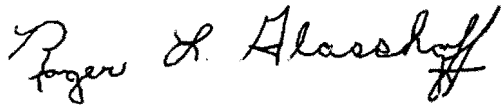
1. Each shell egg processor electing to install the UV disinfection system is responsible for providing technical information and certification (letter of guarantee from the manufacturer) stating that the low pressure mercury lamp bulb used provides 90 percent emissions at a wavelength of 253.7 nanometers (2,537 angstroms equivalent). Proper disposal of the low pressure mercury lamp bulbs in accordance with applicable environmental laws is the responsibility of each processor utilizing UV irradiation.
2. The UV lamp bulb must be replaced based upon the recommended expected duration of function (life expectancy) stated in the manufacturer's specifications. Each processor must maintain a maintenance log for the UV disinfection system identifying the rotation of the UV lamp bulbs. In the event of a UV lamp bulb failure prior to reaching the recommended duration period, to prevent replacement of each bulb in the system at the end of the established duration period, a processor may elect to maintain the dates of installation of each bulb in the UV disinfection system by recording the recommended life expectancy of each lamp bulb. The maintenance records for the UV disinfection system will be subject to review upon request from a USDA representative.
3. Only UV lamp bulbs coated to prevent potential contamination in the event of breakage of the low pressure mercury lamp may be used in the disinfection system.
4. To prevent optical damage to personnel working in plants utilizing the UV disinfection system, the safety procedures incorporated by your company requiring the unit be locked down in operating position prior to function must be maintained at all times. Any malfunction of these incorporated safety measures must be addressed immediately by the egg processor or use of the UV disinfection system in the official plant will be discontinued.
5. Recognizing that the UV emissions area is directly exposed to the product, the sanitation of the disinfection unit (both interior and exterior) must be maintained in an acceptable condition and is subject to preoperative inspection by the USDA grader assigned to the egg processing plant.
6. When used as an alternate for the application of a chemical sanitizer solution, the UV disinfection system must be installed downstream from the wash and rinse cycle chamber on the egg grading and packaging system. Additionally, the eggs must be reasonably dry when entering the UV disinfection system. Shell eggs treated with UV radiation as stated in the applicable FDA regulation and these provisions are eligible to be identified with the USDA grade shield.

Failure by processing plant management to comply with the above provisions may result in the termination of authorization for use of the UV disinfection system in an official USDA egg processing plant.

Please provide a copy of this letter to each U.S. egg processor that purchases a UV disinfection system from Diamond-Moba Americas. For information purposes, copies of this letter are being sent to our supervisory field staff.

Richard, we appreciate your company's patience in the completion of the review of the application of UV irradiation for the processing of shell eggs and your continued cooperation. If you have any additional questions, please contact this office.

Sincerely,

A handwritten signature in cursive script that reads "Roger L. Glasshoff". The signature is written in black ink and is positioned to the right of the word "Sincerely,".

Roger L. Glasshoff  
Nation Supervisor, Shell Eggs  
Poultry Programs, Grading Branch