



AUDIT INFORMATION

Applicant Name:	Biova, LLC
Est. Number:	Request #4322
Physical Address:	2325 North Loop Drive, Ames, IA 50010
Mailing Address:	Same as above
Contact & Title:	Tai Misra, Quality and Regulatory Compliance Manager
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Phone Number:	(515) 218-1568
Auditor(s):	Michael Steiskal
Program:	USDA Processed Eggs and Egg Products Export Verification Program (PEEPEV)
Audit Date(s):	July 30, 2019
Audit Identifier:	EP9211MSA
Action Required:	No
Audit Type:	Surveillance audit
Audit Objective:	To verify continuing conformance to the audit criteria.
Audit Criteria:	<ul style="list-style-type: none"> • <i>QAD 1002 Procedure USDA Quality System Assessment (QSA) Program, dated April 1, 2019;</i> • <i>QAD 1062 Procedure Processed Eggs and Egg Products Export Verification Program, dated May 1, 2019;</i> • <i>Export Requirements for Further Processed Egg Products Containing Only Egg – Mexico, dated April 23, 2013;</i> • <i>Export Requirements for Further Processed Egg Products to South Korea;</i> • <i>Further Processed Egg and Egg Products to the European Union;</i> and • <i>Biova Quality Manual Procedure, QA0038-S, dated May 24, 2019.</i>
Audit Scope:	The company’s quality manual including processes, procedures, personnel, facilities, and related records.
Location(s) Audited:	Biova, LLC located in Ames, IA

Biova, LLC (Biova) is a processing plant located in Ames, IA, which utilizes egg membrane materials to produce various protein powders as dietary supplements. The intent of this program is to export product through the USDA Processed Egg and Egg Products Export Verification (PEEPEV) Program to the European Union. On March 29, 2019, Biova submitted a significant change request for the addition of Bahrain, the Dominican Republic, Guatemala, Honduras, Hong Kong, Jordan, Mexico, the Philippines, Puerto Rico, Qatar, Saudi Arabia, Singapore, South Korea, and the United Arab Emirates for export under the USDA Processed Eggs and Egg Products Export Verification (PEEPEV) Program. The significant change was approved on May 10, 2019.



Biova receives egg membrane as the raw material for its products. The membrane is harvested at egg breaking facilities using Biova equipment. The resulting materials are transferred to the Biova plant in totes identified with lot numbers and process dates. Biova receives these materials to process within the plant. Biova's products are processed for human consumption from egg products originating in the United States and processed in a facility under official control of the United States Food and Drug Administration (FDA).

The audit consisted of a review of procedures, processes, documents, records, as well as a tour of the facility, offsite warehouse, and interviews with plant management. Biova has a process for approving suppliers of raw materials. Suppliers have been approved as described in the quality manual and are listed on the company's approved supplier list. Biova maintains identification and traceability of all product components throughout the realization process using lot codes. Unique SKU numbers are used for final product identification. Traceability was demonstrated by using those unique codes and SKU numbers.

Tours of the facility as well as the spray dry facility were conducted with attention to Good Manufacturing Practices (GMP's) of Biova. The facility and employees were observed following all GMP's as described in Biova's GMP and HACCP Programs. The facility and related production, equipment, processing, storage, and employee areas were in good repair, and sanitation and cleaning measures were being conducted as required.

Training procedures and related records were reviewed and found to be adequate for the USDA Processed Egg and Egg Products Export Verification Program. All employees are required to complete GMP and HACCP training annually or refresher training as needed. New employees are required to complete the training prior to working with product. Employee training is recorded on company training logs.

FINDINGS

Observations made, interviews conducted, and procedures and records reviewed verified Biova, LLC is currently operating in conformance to the audit criteria. There were no non-conformances identified during the audit.

RECOMMENDATIONS

Based on the audit findings, the auditor recommends continued approval of Biova, LLC for the USDA Processed Eggs and Egg Products Export Verification (PEEPEV) Program for export to Bahrain, the Dominican Republic, Guatemala, Honduras, Hong Kong, Jordan, Mexico, the Philippines, Puerto Rico, Qatar, Saudi Arabia, Singapore, South Korea, the United Arab Emirates, and to the European Union.



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Quality System Audit Report**

NOTIFICATION OF AUDIT RESULTS

August 20, 2019

The Quality Assessment Division has reviewed the results of the surveillance audit of the Biova, LLC QSA Program that includes the USDA Processed Eggs and Egg Products Export Verification (PEEPEV) Program for export to Bahrain, the Dominican Republic, Guatemala, Honduras, Hong Kong, Jordan, Mexico, the Philippines, Puerto Rico, Qatar, Saudi Arabia, Singapore, South Korea, the United Arab Emirates, and to the European Union. As a result of this review, we have determined that the Program is sufficiently implemented and meets the requirements of the USDA Quality System Assessment (QSA) Program and the Processed Eggs and Egg Products Export Verification (PEEPEV) Program. Information regarding Biova's approval status is posted on the Quality Assessment Division website at <https://www.ams.usda.gov/services/imports-exports/further-processed-egg-products-verification-program>

The findings of the audit did not identify any non-conformances. No actions are necessary by Biova, LLC at this time. However, please note that substantial changes to the approved Program must be submitted in writing to the Quality Assessment Division, at QAD.AuditService@usda.gov, and approved prior to implementation. Depending upon the nature and extent of the changes, a complete or partial on-site audit of the Program may be required prior to approval. Minor changes to the approved Program need not be submitted.

We look forward to working with Biova, LLC to ensure the continued success of Biova's QSA Program. If you or any other persons have questions, concerns, or comments regarding this audit, please contact me directly.

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