



## **USDA Quality System Assessment (QSA) Program Processed Eggs and Egg Products Export Verification Program**

### **1. GENERAL**

The Processed Eggs and Egg Products Export Verification (PEEPEV) Program services are provided by the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Livestock, Poultry, and Seed Program, Quality Assessment Division, under the authority of the Agricultural Marketing Act (AMA) of 1946, as amended, and the Code of Federal Regulations (CFR) 7, Part 70, in cooperation with the USDA Foreign Agricultural Service (FAS).

This document specifies the verification requirements of the PEEPEV Program. The PEEPEV Program is a voluntary, user-fee service available to the egg processing industry. It includes third-party verification that processed egg products and hard-cooked eggs are wholesome for export.

This Program recognizes the responsibilities related to verification audits and the issuance of export certificates services contribute to the protection of consumers by helping the egg industry fulfill their responsibility to ensure that their products are safe and meet applicable Food and Drug Administration (FDA) Good Manufacturing Practices (GMPs).

All requirements of the PEEPEV Program are generic and are intended to be applicable to all clients, regardless of type, size, and product provided. Any requirement(s) of this Program that cannot be applied due to the nature of the client and its product can be considered for exclusion.

### **2. SCOPE**

The scope of the program includes verification (every 6 months) that product:

1. Produced for export is certified fit for human consumption in accordance with the Food and Drug Administration's [Current Good Manufacturing Practices \(GMPs\)](#),
2. Was produced in accordance with management's conformity to AMS' Quality System Assessment (QSA) Program Requirements, and
3. Meets public health attestations of the respective foreign government.

Foreign government regulations may define whether such products require a public health certificate and whether additional public health requirements exist.

These requirements apply to the auditing and approval of egg products processors and other food processors that export further processed eggs and product containing eggs. FDA-regulated processed eggs and egg products include a variety of cooked products from peeled hard-cooked whole or diced eggs, omelets, and crepes. The product category for composite foods containing components of eggs range from quiche mixes, imitation eggs and egg substitutes, egg extracts, mayonnaise, ice cream, and more.

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### 3. REFERENCES

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

- 3.1 *QAD 1000 Procedure QSVF General Policies and Procedures*
- 3.2 *QAD 1002 Procedure USDA Quality System Assessment (QSA) Program*
- 3.3 *QAD 1002 Checklist USDA Quality System Assessment (QSA) Program*
- 3.4 *QAD 1062 Procedure Processed Eggs and Egg Products Export Verification Program*
- 3.5 *QAD 1062 GMP Checklist*
- 3.6 [FDA PART 110 Current Good manufacturing Practice in Manufacturing, Packing, or Holding Human Food](#)
- 3.7 <http://www.ams.usda.gov/services/business-listings>

### 4. RESPONSIBILITIES

- 4.1 Clients shall meet all applicable policies, procedures, and requirements outlined in this document and the Division's *QSVF General Policies and Procedures*.
- 4.2 Clients shall provide access to all processes and areas, records, and personnel for the purposes of initial audit approval, surveillance, re-approval, and the resolution of complaints.
- 4.3 The Division shall meet all applicable policies, procedures, and requirements outlined in this document and the Division's *QSVF General Policies and Procedures*, and referenced documents as applicable.

### 5. PROGRAM REQUIREMENTS

The client shall submit a documented program that addresses the PEEPEV Program requirements as outlined in the following clauses.

#### 5.1. Quality System Assessment

Clients who wish to meet the specified GMP and foreign country requirements, as applicable, under this Program shall meet these requirements through an approved USDA Quality System Assessment (QSA) Program. To operate an approved USDA-QSA Program, a company must submit a documented program that meets the program requirements. The USDA-QSA Program provides companies that supply agricultural products and services the opportunity to assure customers of their ability to provide consistent quality products or services. It is limited to programs or portions of programs where specified product requirements are supported by a documented quality management system.

#### 5.2. GMP Program

To be eligible for the PEEPEV Program, a client is required to meet current GMPs found in 'FDA PART 110 Current Good manufacturing Practice in Manufacturing, Packing, or Holding Human Food' to the extent that product is prepared, packed, or held under sanitary conditions and therefore found fit for human consumption and not rendered injurious to health. At a minimum, the GMP Program documentation shall cover:

- Personnel
- Buildings and Facilities



- Sanitary Operations
- Equipment
- Production and Process Controls
- Warehousing and Distribution

### 5.3. Foreign Country Requirements

Clients will also need to meet additional public health attestations of the respective foreign government for which products are being exported. The foreign government will define whether such products require a public health certificate and whether additional public health requirements exist, as applicable.

### 5.4 Product List

Approved programs must include a list of all eligible product items intended for shipment to countries requiring a QSA EV Program. In signing FSIS Form 9060-6, the exporter is attesting to, among other things, the eligibility of all the listed products. Products that are not required to be produced under an EV Program shall not be listed on the approved product list.

The product list must:

- Identify all eligible processed egg and egg products intended for shipment;
- Provide the following information for each item on the list:
  - FSIS/FDA Establishment Number
  - Establishment Name
  - Establishment Location (City and State)
  - Product Name
  - Product Code
- Be in the approved Excel format. The approved format is available on the QA Division EV Program website at: [www.ams.usda.gov/LSEVProgram](http://www.ams.usda.gov/LSEVProgram); and
- Be submitted to the QA Division ([ev.export@ams.usda.gov](mailto:ev.export@ams.usda.gov) or 202-354-5207) for initial review and approval and when changes are made.

### 5.5 Company's Consignor/Exporter Listing

Approved programs must include a company consignor/exporter listing if PEEPEV Program product is exported from another location. If another company requests an export certificate to export product on behalf of an approved PEEPEV company, this company must be noted on the company's consignor list in order to be issued the export document.

The company consignor listing must:

- Identify the consignor's name and FSIS establishment number (if applicable);
- Identify the date a consignor is added to the list;
- Identify the date a listed consignor is no longer shipping product; and
- Be submitted to the QA Division ([ev.export@ams.usda.gov](mailto:ev.export@ams.usda.gov) or 202-354-5207) for review when changes are made.

## 6. LISTING OF APPROVED PEEPEV PROGRAMS

**6.1** The Program provides public information about the current status of a client's program in the *Official Listing of Approved PEEPEV Programs*.

**6.2** The *Official Listing* is maintained on the PEEPEV web site and contains information including:



1. Client's name or position title;
2. Client's address;
3. Client's contact information including telephone number, fax number, and email address,
4. when available;
5. Effective date (date originally approved);
6. Renewal date (date approval expires); and
7. Scope, including the type of FDA-regulated egg product or composite food authorized for
8. certification; and
9. Foreign country

**6.3** In addition:

1. If a client is under suspension due to a GMP major non-conformance, the scope of the suspension, the effective date of the suspension and the following statement are included: "Under Suspension – Agricultural products certified under the program prior to suspension remain certified. No additional products may be certified while the suspension is in effect."
2. Suspension is lifted once 1) an acceptable corrective action response is provided, and 2) FDA has evaluated the non-conformance and cleared the facility.
3. If the client has requested to cancel service, the following statement is included: "Requested to Cancel Service – Agricultural products certified under the program are eligible until [date]." The date referenced is the date that cancellation is effective, normally the date that the surveillance or reassessment was to occur.

**7. Audit Findings**

**7.1** GMP Major Non-conformance: Includes evidence in determining whether a product is adulterated, and whereby food has been prepared, packed, or held under insanitary conditions through which it may have become contaminated with filth, or may have been rendered injurious to health thus unfit for human consumption. Sixteen major non-conformances are identified in PAMP 105.0a GMP Checklist.

**7.2** GMP Minor non-conformance: is a GMP non-conformance that does rise to the level of the GMP major non-conformance.