USDA POULTRY EXPORT VERIFICATION PROGRAM SPECIFIED PRODUCT REQUIREMENTS FOR THE EUROPEAN UNION

1 Purpose

This document provides the specified product requirements for marketing U.S. Poultry to the European Union (EU) under the USDA Poultry Export Verification (PEV) Program.

2 Scope

These requirements apply to U.S. growers that supply poultry to harvest and processing establishments that are eligible for export to European Union as listed on the Food Safety and Inspection Service (FSIS) website. Growers who wish to supply poultry as meeting the specified product requirements for EU under the PEV Program must meet these requirements through an approved USDA Quality System Assessment (QSA) Program.

3 References

The following reference documents are used 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.

QAD 1000 Procedure: Quality Systems Verification Programs, General Policies and Procedures

QAD 1002 Procedure: USDA Quality System Assessment (OSA) Program

USDA FSIS: Export Library – Requirements by Country\European Union website

USDA AMS: Quality System Assessment Program website

4 Specified Product Requirements

The supplier shall prepare and maintain a Good Manufacturing Practices (GMP) manual that contains requirements for the production farm and production office. The GMP manual must contain the following documentation (at a minimum):

4.1 Production Farm Requirements

- 4.1.1 Standard Operating Procedures (SOPs) for biosecurity (dead bird disposal methods, chlorinator use, farm logs for visitors, type of housing for poultry (screened housing), sanitation stations, footbaths, pest control programs, etc.).
- 4.1.2 Feed Delivery records.
- 4.1.3 Mortality records.
- 4.1.4 Vaccination records (specifics of the type of vaccination program).

- 4.1.5 Medication records (On farm records should have documentation of withdrawal times).
- 4.1.6 Records of antimicrobials used, under the discretion of the veterinarian, for purposes other than growth promotion and/or yield increase; and that those antimicrobials are not reserved for the treatment of certain infections in humans as laid down in Commission Implementing Regulation (EU) 2022/1255. See Appendix 1.
- 4.1.7 Internal audits conducted by service technician on established GMP's and corrective actions taken if deficiencies are observed. A formal audit shall be conducted before starting the EU program and once during the life of the flock. The record of the internal audit shall be sent to a company representative for signature of the EU certificate.
- 4.1.8 Records of regular veterinary visits to the operation. The frequency of these visits should at minimum be annually.
- 4.1.9 All records must be retained for a minimum of three years.

4.2 Production Office Requirements

- 4.2.1 Documented testing program.
- 4.2.2 Specific type of vaccination programs used.
- 4.2.3 The company must maintain an approved suppliers listing. The approved suppliers listing must:
 - a) Identify the supplier's name, address, and approval date;
 - b) Identify the date that suppliers were removed from the suppliers listing; and
 - c) Be available to the USDA for review.
- 4.2.4 Record of Service technicians' internal audits.
- 4.2.5 Record of formulations (to show medications used in feed relate to records of inventory control and feed delivery). Verify that Ractopamine is not part of the feed formulation.
- 4.2.6 Drug inventory control records.
- 4.2.7 Quality Assurance reports for feeding, residue testing, pellets, time, temperature, and microbiological.
- 4.2.8 Records of specifications for ingredients.
- 4.2.9 Records of water quality testing results.
- 4.2.10 Records of housing specifications.
- 4.2.11 Records of housing maintenance requirements.

- 4.2.12 Records of pest control program.
- 4.2.13 Records of feed withdrawal program (for residue and contamination control and representative notified about withdrawal times).
- 4.2.14 Records of residue control program with test results.
- 4.2.15 Records of NPIP breeder flock registration or proof of health program for *S.pullorum*, *S.gallinarum*, *M. gallisepticum*, and *M. synoviae*.
- 4.2.16 Records of hatchery sanitation program or participation in the NPIP Sanitation monitored program.
- 4.2.17 Records of vaccination program.
- 4.2.18 Records for hatchery microbiological results with type of sampling program.
- 4.2.19 Records of feed deliver.
- 4.2.20 <u>Affidavit sent from the production farm to the harvest facility attesting to the following animal health requirements:</u>
 - Production farms do not utilize Canadian born poultry except those imported only as "day-old." "Day-old" chicks are "all poultry less than 72 hours old, not yet fed and Muscovy ducks (*Cairina moschata*) or their crosses, less than 72 hours old whether or not fed".
 - Poultry being delivered to harvest facility are not from flocks that are under quarantine.
 - Flocks are located over 10 km away from the Mexican border.
 - Poultry have not been vaccinated against avian influenza.
 - Ractopamine is not part of the feed formulation.

A checklist is provided for auditors and industry representatives to verify the specified requirements listed above and to document audit findings. The checklist is divided into six sections: item number, verification audit item, measurement/verification, auditor instructions, item conformance, and observations/comments (see Exhibit 1).

5 Listing of Approved Programs

U.S. suppliers that have an approved USDA QSA Program and have demonstrated the ability to produce products in accordance with this procedure will be listed on the <u>Official Listing of Approved Suppliers Under the Poultry Export Verification (PEV) Program for the European Union.</u>

6 Responsibilities

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U.S. suppliers must meet all requirements outlined in this procedure, *Quality Systems Verification Programs, General Policies and Procedures,* and *the QSA Program*.

Jeff Waite, Branch Chief Quality Assessment Division Livestock and Poultry Program

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Appendix 1

(r) Omadacycline

(2) Antivirals

Antimicrobials or groups of antimicrobials reserved for treatment of certain infections in humans per Commission Implementing Regulation (EU) 2022/1255 of 19 July 2022

July 2022
(1) Antibiotics
(a) Carboxypenicillins
(b) Ureidopenicillins
(c) Ceftobiprole
(d) Ceftaroline
(e) Combinations of cephalosporins with beta-lactamase inhibitors
(f) Siderophore cephalosporins
(g) Carbapenems
(h) Penems
(i) Monobactams
(j) Phosphonic acid derivates
(k) Glycopeptides
(l) Lipopeptides
(m) Oxazolidinones
(n) Fidaxomicin
(o) Plazomicin
(p) Glycylcyclines
(q) Eravacycline

- (a) Amantadine
- (b) Baloxavir marboxil
- (c) Celgosivir
- (d) Favipiravir
- (e) Galidesivir
- (f) Lactimidomycin
- (g) Laninamivir
- (h) Methisazone/metisazone
- (i) Molnupiravir
- (j) Nitazoxanide
- (k) Oseltamivir
- (1) Peramivir
- (m) Ribavirin
- (n) Rimantadine
- (o) Tizoxanide
- (p) Triazavirin
- (q) Umifenovir
- (r) Zanamivir
- (3) Antiprotozoals
- (a) Nitazoxanide

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EXHIBIT 1 POULTRY EXPORT VERIFICATION CHECKLIST

Item #	Verification Audit Item	Measurement/Verification	Auditor Instructions	Conformance Yes/No	Observations/Comments	
4.1	ON-FARM PRODUCTION REQUIREMENTS					
4.1.1	SOP's for biosecurity	Written company-approved biosecurity SOPs.	Verify Biosecurity SOPs.			
4.1.2	Feed delivery records	On-farm feed tags for the flock showing batch/lot/mill producing the feed, formulation identifier and date of delivery.	Check for on-farm records as specified.			
4.1.3	Mortality records	Record showing daily mortality.	Verify availability of records.			
4.1.4	Vaccination records	Record of vaccination date and vaccine used.	Verify vaccination records as specified.			
4.1.5	Medication records	Feed tags and/or written logs of any medication used in the water.	Verify medication records as specified.			
4.1.6	Antimicrobial records	Veterinary directives, feed tags and/or written logs of antimicrobial use.	Verify use and purpose of antimicrobial medications and that those listed in Appendix 1 are not used.			
4.1.7	Internal Audits	Performed Quarterly if shipping product, else an initial audit and then yearly. Retain for one year.	Verify internal audits are conducted on a quarterly and yearly basis.			
4.1.8	Veterinary visits	Records of veterinary visits.	Verify visits are conducted at least annually.			
4.1.9	Record Retention	All production records retained for at least 3 years.	Verify records are retained for at least 3 year.			
4.2	PRODUCTION OFFICE REQUIREMENTS					





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Item #	Verification Audit Item	Measurement/Verification	Auditor Instructions	Conformance Yes/No	Observations/Comments
4.2.1	Poultry and breeder vaccination program	Poultry vaccination program (application method, age, type of vaccine) with range of dates of use, vaccines, records of vaccine purchases. More than one program may be in use at any time. In such a case, the farms under each program should be specified.	Review program as specified.		
4.2.2	Type of vaccination programs used.	Program states the type of vaccination programs maintained.	Review the type of programs.		
4.2.3	Approved supplier listing.	List of suppliers must be maintained.	Review list of suppliers		
4.2.4	Service technician internal audits.	Record of audit performed by the service technician for each flock reviewing compliance with Good Manufacturing Review Program.	Verify servicemen internal audit records?		
4.2.5	Formulations.	Feed formulations showing drugs used, amount and range of dates in use. Ractopamine shall not be used in formulation.	Verify formulations contain the required information. Verify that ractopamine is not part of the feed formulation.		
4.2.6	Drug inventory control.	Records of drug inventory providing purchase and use information.	Verify inventory records as specified.		
4.2.7	Quality Assurance for feed: residue testing and pellet quality (time, temperature, and microbiological.	Feed ingredient residue test protocol and reports. Pellet quality testing protocol and reports for time, temperature and microbes.	Verify records as specified.		



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Item #	Verification Audit Item	Measurement/Verification	Auditor Instructions	Conformance Yes/No	Observations/Comments
4.2.8	Specifications for ingredients.	Written specifications used for purchase of ingredients.	Verify records of specifications for ingredients and that ingredients match specifications.		
4.2.9	Water quality testing.	Water quality testing records.	Verify records for water testing.		
4.2.10	Contractual housing specifications.	Language in current grower contract relating to housing specifications.	Verify records for housing specifications.		
4.2.11	Contractual requirements for housing maintenance.	Language in current grower contract relating to housing maintenance.	Verify records for housing maintenance.		
4.2.12	Pest control program	Rodent control program. Records for purchase of rodent control supplies.	Verify records for pest control program.		
4.2.13	Feed withdrawal program	Feed withdrawal protocol.	Verify records of feed withdrawal program.		
4.2.14	Residue control program (test results)	Log with sampling and testing records. Protocol for sampling and testing. Medicated feed withdrawal records.	Verify records that a residue testing program is in place.		
4.2.15	NPIP breeder flock registration or proof of health program for S. pullorum, S.gallinarum, M. gallisepticum, and M. synoviae.		Verify records are in compliance with NPIP breeder flock registration and health program for <i>S. Pullorum, S. gallinarum, M. gallisepticum, and M. synoviae.</i>		
4.2.16	Hatchery sanitation program or participation in the NPIP sanitation monitored program	Status in NPIP Sanitation- monitored Program or protocol for sanitation program. NOTE-IF THE HATCHERY IS IN THIS PROGRAM, YOU	Verify records are in compliance with NPIP sanitation monitored program. Or review protocol and records verifying program is in practice.		



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Item #	Verification Audit Item	Measurement/Verification	Auditor Instructions	Conformance Yes/No	Observations/Comments
		WON'T NEED TO DO 4.2.18.			
4.2.17	Records of vaccination program	Vaccination program and vaccination records.	Verify records that a vaccination program is in place.		
4.2.18	Records for hatchery microbiological results. (Type of sampling)	Sampling protocol and testing records or logs.	Verify records for hatchery microbiological test results and sampling protocol.		
4.2.19	Control of feed delivery	Records of delivery showing batch/farm/date/drug.	Verify feed delivery records as specified.		
4.2.20	Affidavit sent from the production farm to the harvest facility attesting to the following animal health requirements: • Production farms do not utilize Canadian born poultry except those imported only as "day-old". "Day-old" chicks are "all poultry less than 72 hours old, not yet fed and muscovy ducks (Cairina moschata) or their crosses, less than 72 hours old whether or not fed". • Poultry being delivered to harvest facility are not from flocks that are under quarantine. • Flocks are located over 10 km away from the Mexican border. • Poultry have not been vaccinated against avian influenza.	Affidavit and additional records verifying conformance.	Verify affidavit and any other records confirming that theses animal health requirements are bein met.		



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Item #	Verification Audit Item	Measurement/Verification	Auditor Instructions	Conformance Yes/No	Observations/Comments
	Ractopamine is not part of the feed formulation.				