

Grade “A” Dairy Equivalence

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What is Equivalence?

- Equivalence is a trade-facilitating mechanism, established in Article 4 of the World Trade Organization SPS Agreement.
- A positive equivalence determination concludes that an exporting Member's sanitary measures achieve an importing Member's appropriate level of public health protection.

U.S. Obligation

- Considering an equivalence request is an obligation of the United States pursuant to Article 4 of the SPS Agreement.
- It is important to note that the obligation is to accept a request and to conduct an assessment, not to reach a positive conclusion.
- The Codex Alimentarius Commission has several guidelines that address equivalence (CXG 26-1997, CXG 34-1999, CXG 53-2003).

Equivalence and U.S. Law

- The Uruguay Round Agreements Act of 1994 (19 U.S.C. §2578a) implements the WTO Agreement into U.S. law.
- "An agency may not determine that a sanitary or phytosanitary measure of a foreign country is equivalent to a sanitary or phytosanitary measure established under the authority of Federal law unless the agency determines that the sanitary or phytosanitary measure of the foreign country provides at least the same level of sanitary or phytosanitary protection as the comparable sanitary or phytosanitary measure established under the authority of Federal law."

Equivalence and the Pasteurized Milk Ordinance (PMO)

- Grade “A” milk-and milk products from a foreign country are not subject to interdiction by states when they are produced under food control systems determined to be in compliance with or equivalent to the provisions of the PMO.
- FDA’s Cooperative Agreement with NCIMS recognizes that FDA has the responsibility for assessing the equivalence of foreign milk safety systems.
- The PMO states that FDA will confer with the NCIMS before finalizing a Grade “A” dairy equivalence determination of a foreign food safety system.

Equivalence Assessment Process

For the purposes of determining equivalence, the sanitary measures associated with a food inspection and certification system can be broadly categorized as:

- **Infrastructure**; including the legislative base (e.g., food and enforcement law), and administrative systems (e.g., organization of national and regional authorities, enforcement systems, etc.);
- **Programme design, implementation and monitoring**; including documentation of systems, monitoring, performance, decision criteria and action, laboratory capability, transportation infrastructure and provisions for certification and audit; and/or
- **Specific requirements**; including requirements applicable to individual facilities (e.g., premises design), equipment (e.g., design of food contact machinery), processes (e.g., HACCP plans), procedures (e.g., ante- and post-mortem inspection), tests (e.g., laboratory tests for microbiological and chemical hazards) and methods of sampling and inspection.

Equivalence Assessment Process

The steps involved in a Grade “A” dairy equivalence assessment include:

- Receive **official request**
- **Review** of the foreign milk safety program against the PMO by a technical team;
- **On-site audits** of laboratories, farms, and processors;
- **Recommendation** of whether **equivalence is objectively demonstrated** by the foreign system; and
- If equivalence is recommended, solicit public comment on proposed determination, draft and implement an arrangement.

Equivalence Assessment Process

- PMO requirements are considered as part of any "Grade A" dairy equivalence assessment, including but not limited to:
 - Milk Plants;
 - Dairy Farms/Raw Milk Transportation and Sampling;
 - Animal Health Laws;
 - Laboratory Support Services;
 - Animal Drug Testing and Residue Requirements for Dairy Animals and Milk/Milk Products;
 - FSMA-Appendix T Preventive Controls for Human Food.

Equivalence Requests

Certain WTO Members requested equivalence assessments for Grade “A” milk and milk products:

- Canada;
- New Zealand;
- European Union Member States (Bulgaria, the Czech Republic, France, Germany, Ireland, the Netherlands, Sweden, and the United Kingdom)

Process

- **Communications:** Inform and confer with NCIMS Executive Board prior to reaching a determination of equivalence.
- **Public Proposal:** The URAA requires that the FDA provide an opportunity for public comment on any proposed determination of equivalence.
- **An Equivalence Agreement:** Agreement containing the understandings reached by the parties.

