Cc: Valerie ROY (E-mail); Viviane NIUAITI (E-mail); Valérie ANTRAS (E-mail); Leopold STEIN (E-mail); Inspection QAAV (E-mail); 'qaav.aeroport@rural.gov.pf'; 'odile.berhonde-mischieri@douane.pf'; 'henri.viel@sante.gov.pf'; 'glenda.melix@sante.gov.pf'; vetea.plichart@rural.gov.pf; bertrand.dubray@agriculture.min.gov.pf

Objet: Importation des produits laitiers des USA ; PJ : 2

N° 943 SDR / QAAV
DÉPART LE 25/08/09

(2ème envoi)

Mesdames, Messieurs,

Suite aux informations reçues de l'autorité compétente américaine, il apparaît que pour pouvoir obtenir le modèle de certificat sanitaire joint qui répond aux exigences de l'arrêté n° 651/CM, les producteurs de produits laitiers doivent figurer sur l'une des trois listes figurant sur les sites internet suivants :

1. AMS list - Dairy Plants Surveyed and Approved for USDA Grading Service : http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRD3641022
2. Plants approved for export to the European Union : https://sanco.ec.europa.eu/traces/output/MMP_US_en.pdf
3. Interstate Milk Shippers List : http://www.cfsan.fda.gov/~acrobat/ims0801.pdf

Ci-joint un document en anglais expliquant l'organisation du contrôle des produits laitiers aux USA et le modèle de certificat délivré par l'AMS (Agricultural Marketing Service de l'USDA).

Les établissements ne figurant pas sur les trois listes ne sont pas régulièrement inspectés par la FDA, ne sont pas autorisés à vendre leurs produits dans un autre état américain que le leur et ne peuvent obtenir de certification de salubrité que de l'autorité locale compétente.

Aucun modèle de certificat n'a été négocié avec ces autorités locales pour l'instant et il faudrait connaître pour chaque état, le programme de contrôle des résidus et containants qui est appliqué. Par ailleurs, il n'est pas sûr que ces autorités locals puissent émettre un certificat zoosanitaire.

Aussi, pour ceux dont les fournisseurs ne s'approvisionnent pas dans les établissements figurant dans les trois listes précitées et qui voudraient poursuivre leurs importations, il sera nécessaire de me fournir les coordonnées du responsable de l'autorité compétente locale pour savoir s'il est possible ou non de négocier un modèle conforme.

Par ailleurs, vous constaterez que sur la liste IMS figurent des établissements situés dans des pays étrangers autres

que les USA.

Avant de commander des produits d'établissements figurant dans ces pays, veuillez d'abord vérifier auprès du département QAAV que leur importation ou transit est bien autorisé en Polynésie française.

Normalement, le modèle VS Form 16-4 est seulement un modèle de certificat zoosanitaire et les mentions d'attestation de salubrité telles l'absence de containants à des taux dangereux ne peuvent pas y être apposées, d'autant plus si l'établissement ne figure pas sur l'une des trois listes.

Aussi, l'autorité américaine va confirmer auprès des inspecteurs de l'USDA de ne plus délivrer ces modèles pour des produits exportés vers la Polynésie française et que les produits doivent être certifiés avec le modèle AMS.

Cordialement,

Le secrétariat QAAV

certificat produits laitiers.p...

Overview of the Regulation - D...

UNITED STATES OF AMERICA

SANITARY CERTIFICATE FOR EXPORTS

Country of Origin: **USA**
Certification Authority: **U.S. Department of Agriculture, Agricultural Marketing Service**
Reference Number of this Certificate:

I. Exporter *(Name and Address)*

II. Identification of the Dairy Products *(Information Supplied by the Manufacturer or Exporter)*
Product Description:
Condition or Kind of Treatment:
Type of Packaging:
Number of Packages:
Total Net Weight:
Required Temperature: Storage and Transportation:
Validity Date (Shelf Life):

III. Origin of the Products: *(Information Supplied by the Manufacturer or Exporter)*

Plant Number:

IV. Product Destination: *(Information Supplied by the Manufacturer or Exporter)*
Origin:

Destination:
Method of Transport:

V. Sanitary Certification
(1) The United States of America is free from Foot & Mouth Disease and Rinderpest.
(2) The product was manufactured in facilities inspected and approved by the competent authority and subjected to regular audits or inspections aimed at ensuring that the processing is properly and hygienically carried out, to produce a product that is fit for human consumption.
(3) The product was manufactured from milk that received a pasteurization treatment or adequate safeguards have been taken with the aim of avoiding public health hazards arising from pathogenic organisms associated with milk.
(4) To the best of our knowledge, the product contains no harmful levels of contaminants.

[Date]

[Name]
[Title]
United States Department of Agriculture
Agricultural Marketing Service, Dairy Grading

Date Signed

OVERVIEW OF THE REGULATION OF THE SAFETY OF MANUFACTURED DAIRY PRODUCTS IN THE UNITED STATES

I. Introduction

Currently in the United States, milk and milk products are regulated in two different manners, addressing the following two different categories of dairy products:

- "Grade A," which consists of liquid products such as fluid milk, cream, and yogurt, and those condensed and dried dairy products that are used as ingredients in these products.

- "Non-Grade A," which consists of manufactured products such as cheeses, butter, dried milk products, ice cream and other frozen desserts, filled milk and imitation milk products.

The system for ensuring the safety of Grade "A" products is based on State enforcement of State regulations, combined with federal and state audits, under a federal/state cooperative program.[1] The safety of Non-Grade "A" products is ensured through the traditional compliance activities used to enforce the requirements of the Federal Food, Drug, and Cosmetic Act, several other Federal laws, and the Code of Federal Regulations.

The following overview of the U.S. food safety system for non-Grade "A" products includes information applicable to both the Grade "A" system (as it pertains to dairy farms) and the non-Grade "A" system.

II. Regulating the Safety of Grade "A" Raw Milk

More than ninety-five percent of all milk produced in the United States is produced on dairy farms that are regulated under the Grade "A" system. This section describes how that farm milk is regulated.

A Federal-State Alliance:

FDA's participation in the Federal/State Cooperative Milk Safety Program for regulating Grade "A" Products is based on the authority granted to the Secretary of Health and Human Services under the Public Health Service (PHS) Act. The PHS Act directs the

[1] Milk safety is one of three major cooperative programs between FDA and the 50 states. (The other two cooperative programs address retail food protection and shellfish sanitation.)

Secretary to "assist States ... in the prevention and suppression of communicable diseases," "to cooperate with and aid State and local authorities in the enforcement of their...health regulations," "to encourage cooperative activities between the States with respect to...the establishment and maintenance of adequate public health services, and otherwise carrying out the public health activities," and to advise States "on matters relating to the preservation and improvement of the public health."[2] The Secretary of Health and Human Services has delegated this authority to FDA (which is located within the Department of Health and Human Services).

Under the federal/state cooperative program and the authority granted to FDA by the PHS Act, FDA worked together with the States to develop a model ordinance, the "Grade "A" Pasteurized Milk Ordinance" (PMO). (This work was done within the framework of the National Conference on Interstate Milk Shipments (NCIMS), which is described below.) All 50 states and Puerto Rico (a commonwealth associated with the United States) have adopted regulations based on this model ordinance.

The States have the primary responsibility for ensuring compliance with the PMO (by enforcing compliance with the corresponding State regulations). As is described below, both the States and FDA also have additional oversight roles.

FDA also worked with the States (within the framework of the NCIMS) to develop the administrative documents needed to govern the Grade "A" program. These documents include the "Methods of Making Sanitation Ratings," the "Evaluation of Milk Laboratories," and the "Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments".

The 50 States have formed the NCIMS, through which the States and Puerto Rico have agreed to accept Grade "A" raw milk and Grade "A" products from those States/territories/countries that follow the PMO (and related documents) or that have been evaluated by FDA and been determined to have a system that has an equivalent effect on the safety of dairy products. The NCIMS has biennial meetings at which Federal and State officials, along with industry representatives and others, meet to review/revise the PMO and related documents. These meetings are open to all interested parties.

The constitution and by-laws of the NCIMS are contained in "Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments." This document also contains the Memorandum of Understanding between the NCIMS and FDA that governs the relationship between the two organizations.

---

[2] 42 USC 243

Inspections and Enforcement:

There are three levels of oversight for Grade "A" raw milk and Grade "A" milk products:

1. State and local regulatory agencies are responsible for inspections and for the enforcement of PMO sanitation requirements on dairy farms (and also in processing plants, dry milk plants, receiving and transfer stations,[3] and laboratories).

2. Every two years, FDA-certified State Milk Sanitation Rating Officers evaluate the sanitation and construction conditions of Grade "A" facilities and the regulatory enforcement vigor of State and local regulatory agencies. Based on this evaluation, the State Milk Sanitation Rating Officers produce Interstate Milk Shipper (IMS) sanitation and enforcement ratings for Grade "A" farms. Those Grade "A" farms that receive acceptable IMS sanitation and enforcement ratings are considered to be acceptable sources of Grade "A"raw milk for interstate shipments. They are listed as acceptable sources in the Interstate Milk Shippers (IMS) List, which is published by FDA.[4]

3. As is described in the next section, FDA provides an additional layer of oversight through "check ratings" (audits of the State IMS listings), laboratory evaluations and certifications, and State Program evaluations.

While each state has jurisdiction over the Grade "A" products within its borders, FDA generally has jurisdiction over Grade "A" products that are in interstate commerce,[5] and FDA can make and enforce regulations[6] affecting these products. For example, FDA requires that all fluid milk in interstate commerce in final package form be pasteurized.[7]

---

[3] Receiving and transfer stations are establishments where raw milk or cream is received for further transport.

[4] The IMS List enables States and industry to know which shippers meet the PMO requirements for sanitary quality of milk. Since States have agreed under the NCIMS to permit the interstate shipment of only those products that meet the PMO requirements, they use the IMS List as a reference that tells them which firms are permitted to market milk in interstate commerce in the United States. (The IMS List also contains lists of acceptable laboratories and other information needed to support this program.)

[5] "Interstate commerce" includes shipments between the States, imports into the United States, and exports from the United States.

[6] U.S. regulations have the force of law.

[7] 21 CFR 1240.61. The pasteurization requirement in section 1240.61 does not apply to milk and milk products that are not in interstate commerce. As a result, there are a number of U.S. firms that market unpasteurized milk within the same State where the milk is produced. (Since "interstate commerce" includes commerce that crosses the borders of the United States, unpasteurized milk in final package form intended for direct human consumption generally may not be imported or exported.)

FDA's Role in the Federal/State Cooperative Program:

In addition to the development of the PMO (which is recognized as the national standard for milk sanitation), FDA's primary functions under the Federal/State Milk Safety Cooperative Program are:

- to provide technical assistance to the States regarding the implementation and enforcement of the PMO, and
- to audit State implementation and enforcement activities.

This technical assistance and monitoring is provided through FDA's regional milk specialists and through the Milk Safety Team (MST) and Laboratory Quality Assurance Team (LQAT) in FDA's Center for Food Safety and Applied Nutrition (CFSAN).

FDA's compliance program entitled " NCIMS Milk Safety Program" provides guidance to FDA's milk specialists in their work with the States. Under this program, the activities of FDA's milk specialists, MST and LQAT include:

(1) Promoting the adoption, implementation, and enforcement of the uniform technical guidelines, administrative procedures, and regulatory standards provided in the PMO and related documents, through: Provision of technical assistance and consultation; meetings with state government officials; and consultation with national, State, and industry organizations.

- FDA's MST works with other members of the NCIMS to produce Memoranda of Interpretation (usually interpretations of NCIMS documents such as the PMO); Memoranda of Information on any subject that may influence the NCIMS program; Memoranda of Equipment Review (FDA reviews equipment for compliance with the requirements of the PMO); and Memoranda of NCIMS Conferences and NCIMS Executive Board Actions. Examples of all these documents are available on FDA's internet site at http://www.cfsan.fda.gov/~ear/prime.html .

(2) Supporting and training State regulatory officials, including:

(a) standardization of State Milk Sanitation Rating Officers and State Milk Sampling Surveillance Officers and LQAT's standardization of State laboratory officials regarding interpretation of the PMO, laboratory analysis methods, etc.; and

(b) participation in regional seminars, State workshops and other training courses.

- Dairy experts in the State Training Team in FDA's Office of Regulatory Affairs also provide training to the States. The training is based on the NCIMS documents.

(3) Conducting oversight activities through two types of audits: (a) "Check Ratings" of milk shippers and (b) "State Program Evaluations."

(a) Check Ratings

- Under the Federal/State Milk Safety Cooperation Program, there is an auditing feature called "check rating," through which FDA double-checks State evaluations of milk sources that appear on the Interstate Milk Shippers List. These check ratings are made for dairy farms approximately every four years. For milk plants, these check ratings are made approximately every three years.
- To standardize the State evaluations of milk shippers and to provide guidance to FDA staff who carry out check ratings, FDA issued a document entitled "Methods of Making Sanitation Ratings of Milk Supplies".

(b) State Program Evaluations:

- FDA's milk specialists evaluate the State programs to measure their effectiveness in maintaining adequate levels of conformity with the PMO and related documents. In connection with these evaluations, FDA advises State program officials on their program's strengths and weaknesses, and FDA makes recommendations on matters relating to the preservation and improvement of the public health and compliance with the PMO.

In addition to the above-mentioned activities, FDA milk specialists track public health problems, such as those caused by bacterial contamination, to assess the impact of State control programs and the effects of FDA's activities on the public health.

FDA uses its five administrative regions – Northeast, Central, Southeast, Southwest, and Pacific—as geographic sectors for the FDA-State milk safety program, with each FDA region responsible for a cluster of states. Working within these regions, State officials can readily consult with FDA experts about technical problems and training needs. The proximity also facilitates FDA check ratings and state program evaluations.

III. Regulating the Safety of Non-Grade A (Manufactured) Products

FDA has the primary responsibility for regulating the safety of Non-Grade A (manufactured) products. FDA's regulatory and enforcement activities in this area are based on authority given to the agency under the Federal Food, Drug and Cosmetic Act, as well as the Public Health Service Act.

The Federal Food, Drug, and Cosmetic Act prohibits the adulteration and misbranding of all foods in interstate commerce and provides penalties for violations. Sections of the Federal Food Drug, and Cosmetic Act that are particularly relevant to the safety of non-Grade A products include:

- Chapter III: Prohibited Acts and Penalties

This section sets out prohibited acts, enforcement actions, and penalty provisions. Prohibited acts include, for example, the adulteration and misbranding of any food in interstate commerce. Enforcement actions include injunctions and seizures; penalties include imprisonment and fines.

- Section 402: Adulterated Food
  This section describes conditions under which food is deemed adulterated.
- Section 403: Misbranded Food
  This section describes conditions under which food is deemed misbranded.
- Section 406: Tolerances for Poisonous Ingredients in Food
- Section 408: Tolerances and Exemptions for Pesticide Chemical Residues
- Section 409: Food Additives
- Section 414: Maintenance and Inspection of Records
  This section provides authority for accessing and copying company records when there is a reasonable belief that a food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.
- Section 701: Regulations and Hearings
  This section includes the authority to issue regulations.
- Section 703: Records of Interstate Shipment
  This section includes authority to inspect records of interstate shipment by common carriers and recipients.
- Section 704: Factory Inspection
  This section provides authority to carry out inspections and investigations in establishments where products are manufactured, processed, packed, or held.
- Section 721: Color Additives.
- Section 801: Imports and Exports.

The portion of the Public Health Service Act that is particularly relevant to the regulation of Non-Grade A dairy products is Section 264,[8] which provides FDA with authority to make and enforce regulations to prevent the introduction, transmission, or spread of communicable diseases.

To help enforce the above-mentioned laws and to assure the safety of Non-Grade A Products, FDA has published and enforces the following regulations:

- 21 CFR 1240.61: Control of Communicable Diseases
  The requirement for pasteurization of milk and milk products in final package form in interstate commerce.
- 21 CFR Part 133: Cheese and Related Cheese Product Standards
  Standards include pasteurization and cheese aging requirements.
- 21 CFR Part 135: Frozen Dessert Standards

[8] 42 USC 264

- 21 CFR Part 110: Current Good Manufacturing Practices
- 21 CFR Parts 108 and 113: Aseptically Processed Milk and Milk Products; Thermally processed low-acid foods packaged in hermetically sealed containers.
- 21 CFR Parts 106-107: Infant Formula
- 21 CFR Part 556: Tolerance for Residues of New Animal Drugs in Foods
- 21 CFR Parts 172-173: Direct food additives approved for food use
- 21 CFR Parts 174-178: Indirect food additives approved for food use

- 21 CFR Parts 70-82: Color Additives approved for food use
- 21 CFR Parts 510-520: New Animal Drugs *Approvals for use in animals, including food animals*
- 21 CFR Part 184: Direct Food Additives Generally Recognized as Safe

In addition, the Environmental Protection Agency has issued regulations on pesticide tolerances (40 CFR Part 180) that apply to non Grade A products. These requirements are enforced by FDA.

Inspections and Enforcement:

FDA is responsible for inspectional coverage of all Non-grade A products shipped in interstate commerce. In addition, each State has laws and regulations covering non-Grade A products and regularly inspects raw milk producers and processing facilities within its jurisdiction.

FDA has a number of ongoing "compliance programs" that provide guidance to the Agency's field staff who carry out investigations, inspections, sample collections, sample analyses, and enforcement activities related to dairy products.[9] These compliance programs are:

- NCIMS Milk Safety Program (Compliance Program 7318.003)
- Domestic and Imported Cheese and Cheese Products (Compliance Program 7303.037)
- Domestic Food Safety Program (Compliance Program 7303.803)
- Pesticides and Industrial Chemicals in Domestic Foods (Compliance Program 7304.004)
- Domestic Acidified and Low Acid Canned Foods (Compliance Program 7303.803A)
- Mycotoxins in Domestic Foods (Compliance Program 7307.001)

[9] Compliance programs are usually issued for 3-year periods and are renewed, updated, and re-issued after each 3-year period.

FDA's inspections are carried out to enforce the Federal laws and regulations (delineated above) that apply to Non-Grade A dairy products.. Although the PMO does not directly apply to non-Grade A products, they provide procedures and standards of general applicability that are acceptable to FDA. FDA investigators and inspectors can cite deviations from the PMO as objectionable conditions, if the procedures and standards in use at a firm are violative of federal law, such as the Federal Food, Drug, and Cosmetic Act.

FDA has also issued the following documents to provide guidance and help assure uniformity among its investigators, inspectors, and compliance officers:

- Investigations Operations Manual
  Provides standard operation procedures for FDA investigators. The inspectional methods cover sanitation, micro problems, labeling, standards, and Good Manufacturing Practices.
- Guide to Inspections of Dairy Product Manufacturers
- Investigational Training Manual
- Regulatory Procedures Manual
- Foods – Adulteration Involving Hard or Sharp Foreign Objects
- Defect Action Levels for Poisonous or Deleterious Substances in Human Food and Feed
- Frozen Dessert Processing Guidelines
- Compliance Policy Guide 7106.01 Malted Milk
- Compliance Policy Guide 7106.02 Eggnog: Eggnog Flavored Milk – Common or Usual Names
- Compliance Policy Guide 7106.03 Milk and Milk Products Containing Penicillin
- Compliance Policy Guide 7106.04 Use of DDVP (dichlorvos) Strips in Milkhouses and Milkrooms
- Compliance Policy Guide 7106.05 Butter-Adulteration Involving Insufficient Fat Content
- Compliance Policy Guide 7106.06 Cheese-Misbranding due to Moisture and Fat
- Compliance Policy Guide 7106.07 Cheese and Cheese Products – Adulteration with Filth
- Compliance Policy Guide 7106.08 Pathogens in Dairy Products
- Compliance Policy Guide 7106.09 Cheese and Cheese Products – Misbranding Involving Net Contents
- Compliance Policy Guide 7106.10 Whole Milk, Low Fat Milk, Skim Milk-Aflatoxin M1

In addition, FDA uses the Bacteriological Analytical Manual as a guidance document applicable to laboratories. This manual, produced by the Association of Analytical Communities (AOAC), provides quantitative and qualitative bacteriological testing procedures for detecting microbiological contamination

The frequency of FDA inspections of Non-Grade A manufacturing facilities is based on risk considerations. Plants producing soft cheeses are currently considered to be high-risk and are inspected every year. Plants producing other Non-Grade A products are inspected less frequently by FDA. (It should be noted that both high-risk and lower-risk facilities are also inspected by the States, which enforce their own requirements and provide an additional layer of oversight. These State programs are described in more detail in a section below.)

In some instances FDA contracts with State inspectors to carry out FDA inspections of Non-Grade A manufacturing facilities. Under these contracts, the States carry out inspections to assure compliance with the federal standards. This work is also done through partnership arrangements with certain states.

USDA's Programs for Manufacturing Grade Milk

Under the authority of the Agricultural Marketing Act of 1946, the U.S. Department of Agriculture assists State regulatory agencies in the development and administration of State laws addressing milk production and processing requirements. In an effort to promote national uniformity, States are encouraged to adopt standards and requirements developed by the Agricultural Marketing Service (AMS), United States Department of Agriculture (USDA). These recommended requirements are included in an AMS document entitled "Milk for Manufacturing Purposes and its Production and Processing." This document is available on the internet at www.ams.usda.gov/dairy/manufmlk.pdf .

To promote national uniformity, AMS conducts periodic reviews to determine the degree to which individual States have adopted these requirements. These reviews include periodic on-site evaluation of manufacturing grade milk farms during which an AMS representative selects and evaluates on-farm conditions for compliance with the recommended requirements. AMS works closely with State regulatory officials to promote national uniformity and keep the requirements current.

Also, under the authority of the Agricultural Marketing Act of 1946, USDA is directed to carry out certain voluntary service functions to aid in the efficient marketing of American agricultural products, including both Grade A and Non-Grade A dairy products. These services include developing quality grade standards and specifications, furnishing inspection and grading services, and recommending standards to encourage uniformity and consistency in commercial practices. These activities are carried out by USDA/AMS on a voluntary, fee-for-service basis.

Approximately 450 manufacturing facilities participate in the USDA dairy plant survey program. Under this program, USDA plant approval is determined by unannounced inspections, conducted at least twice yearly and covering more than 100 items, including milk supply, plant facilities, condition of equipment, sanitary practices, and processing procedures. The inspection and grading criteria are outlined in "General Specifications

for Dairy Plants Approved for USDA Inspection and Grading Service of Manufactured or Processed Dairy Products",[10] administered by the Dairy Division of USDA/AMS.

As part of its voluntary program, USDA/AMS carries out inspections of non-Grade A dairy manufacturing plants. Only after an inspection shows that the plant has met the requirements in the "General Specifications for Approved Plants" (which focuses on both safety and quality) can that plant qualify for the other USDA/AMS services of grading, sampling, testing and certification of products. Although AMS cannot require that a plant change its operations, USDA/AMS declines to approve and provide grading services to plants that do not pass USDA/AMS inspections. Therefore, if a plant wishes to maintain its approved status, it must make the corrections needed to pass the inspections. Furthermore, under a Memorandum of Understanding with FDA, AMS notifies FDA when a dairy plant is not given an approved status because of sanitation and food safety issues.

The USDA/AMS publishes a quarterly list of Dairy Plants Surveyed and Approved for USDA Grading Service. All dairy plants listed in this publication are inspected and approved for participation in the grading programs offered by AMS.

USDA/AMS develops quality grade standards and specifications for dairy products to facilitate fair trade between buyers and sellers. These standards are the basis for assigning official U.S. grades to such products.

The Dairy Grading Branch of the USDA/AMS Dairy Programs also provides service under its resident grading and quality control service. Plants using this service are shown with an asterisk in the publication "Dairy Plants Surveyed and Approved for USDA Grading Service." This full-time program offers on-the-spot official grading of the plant's manufactured products, laboratory testing and quality control, and plant inspection services. The resident program also makes available to the plant manager the technical know-how and experience of the Dairy Grading Branch's supervisory staff for help in solving product quality problems.

In addition, the USDA/AMS Dairy Grading Branch reviews the sanitary design and construction of processing equipment used in the dairy industry. The Branch participates in the development of 3-A equipment standards and accepted practices and utilizes 3-A Sanitary Standards and 3-A Accepted Practices (developed by 3-A Sanitary Standards Inc.). When equipment or systems are presented for USDA review, the Dairy Grading Branch uses the 3-A standard or practice as the sanitary criterion (if a 3-A standard or practice has been developed for that equipment or system). When USDA review of equipment is requested and there are no relevant 3-A standards or practices, the Dairy Grading Branch uses the general criteria found in their publication entitled "USDA Guidelines for Dairy Equipment Design and Fabrication. " These guidelines are available on the internet at www.ams.usda.gov/dairy/dyproceq.pdf and are consistent with the sanitary criteria found in the 3-A Sanitary Standards. Compliance with this sanitary design is required in USDA approved dairy plants as detailed in regulations at

[10] 7 CFR Part 58

7 CFR Part 58.

State Programs for Non-Grade A Dairy Products

As explained previously, States have enacted safety and quality regulations for non-Grade A products that are based on model regulations developed by USDA/AMS that relate to the sanitation and quality aspects of producing and handling Non-Grade A products.

The National Association of State Departments of Agriculture has endorsed the USDA/AMS Recommended Requirements as the minimum acceptable standards for all raw milk produced for manufacturing purposes. As is the case with Grade A standards, States can develop stricter regulations when they believe appropriate. When this occurs, the State applies the more restrictive requirements.

The enforcement of the State regulations is the responsibility of the State's health or agriculture officials. The States operate inspection programs to enforce the State regulations.

The States look to the FDA for guidance on many issues (for example, on equipment for which there are no 3-A standards), and FDA issues memoranda on selected issues from time to time.

IV. Regulating the Import of Grade A and Non-Grade A Milk and Milk Products

FDA (rather than the States) is responsible for regulating the importation of food – including milk and milk products -- into the United States. Imported products are subject to inspection at the time of entry through U.S. Customs. Shipments found not to comply with U.S. laws and regulations are subject to refusal of entry. Where appropriate, they may be brought into compliance or re-exported. In addition, FDA conducts a limited number of inspections of foreign firms that ship product to the United States.

FDA's detailed procedures on import operations are contained in the Regulatory Procedures Manual, chapter 9. In addition, FDA has a number of ongoing "compliance programs" that provide guidance to the Agency's staff involved in regulating dairy imports:

- Domestic and Imported Cheese and Cheese Products (Compliance Program 7303.037)
- Pesticides and Industrial Chemicals in Imported Foods (Compliance Program 7304.016A)
- Import Acidified and Low-Acid Canned Foods Program (Compliance Program 7303.003)
- Imported Foods – General Program (Compliance Program 7303.819)
- Mycotoxins in Imported Foods (Compliance Program 7307.002)
- Imported Foods – Food and Color Additives (Compliance Program 7309.006)

FDA has also published a guidance document (M-I-00-4) regarding Grade A products entitled "Importation of PMO Defined Dairy Products (April 11, 2000)."

In addition, The Import Milk Act provides that milk and cream may be imported only if the importer holds a valid permit; FDA has provided related guidance for the Agency's staff entitled "Imported Milk and Cream – Import Milk Act" (Compliance Policy Guide 7119.05).