

Plant Survey Program Manual

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Notice to External Users

The mission of the USDA, Agricultural Marketing Service (AMS) Dairy Program is to facilitate the efficient marketing of milk and dairy products. We accomplish this mission with a dedicated, courteous, and professional staff. The Plant Survey (PS) Manual is intended to provide clarification and direction to Dairy Grading and Cooperating State survey inspectors, as well as participating dairy stakeholders. The PS Manual is based on the requirements outlined in 7 CFR 58 Subpart B, General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service hereinafter referred to as “General Specifications” and is made available to the general public as a reference. External users should understand the document is not all-inclusive. The absence of specific information or direction does not imply sanction. Participation in the plant survey inspection program is voluntary. A request to participate in the plant survey inspection program will be deemed as acknowledgement the PS Manual, General Specifications, Pasteurized Milk Ordinance (PMO), and 3-A Sanitary Standards and Practices are guiding reference documents.

Changes within the PS Manual include adapting content to a new format which aligns the document with a quality management system (QMS). The goal is to establish uniformity and efficiency in communicating program guidelines.

The PS Manual is intended to include all informational topics related to industry’s participation in the Plant Survey Program. The PS Manual does not include the inspection procedures or the equipment expectations for industry.

The Dairy Program is the author of the PS Manual. Any questions about the PS Manual can be directed to the Dairy Program at:

USDA AMS Dairy Program
1400 Independence Ave., S. W. Room 2530-S
Washington, D.C. 20250-0230
Phone: (630)-437-5073
Email: DairyNFO@usda.gov
<https://www.ams.usda.gov/DairyGrading>

1. Purpose

The PS Manual provides guidance and further clarification to program principles and directives outlined in General Specifications.

2. Scope

Dairy Program's Dairy Grading Branch (DGB) conducts plant survey inspections performed under the authority of the Agricultural Marketing Act of 1946. A plant survey inspection is the basis for determining eligibility for USDA dairy commodity grading and participation in the surveyed and approved dairy plant survey inspection program. The PS Manual provides information that is applicable to the inspection of dairy product and ingredient manufacturers who produce dairy products such as, but not limited to, butter, cheese, ice cream, lactose, whey fractions and dry dairy mixes. The PS Manual does not provide guidance on the inspection of processing facilities that produce composite food products containing dairy, such as cheesecake, cheese filled appetizers or baked goods. Plant status is assigned to a plant by product code. Based on business needs, plant management determines the products desired to have surveyed and approved. Product codes denote products that are manufactured from USDA-approved dairy ingredients at USDA-approved dairy plants through inspection services. Products with USDA standards for grades are eligible for USDA grading.

3. References

- 7 CFR Part 58, General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service (General Specifications)
- 21 CFR part 117, Current Good Manufacturing Practice, Hazard Analysis, And Risk-Based Preventive Controls for Human Food
- 3-A Sanitary Standards and Accepted Practices
- Agricultural Marketing Act of 1946
- Current Volume of USDA-Dairy Accepted Equipment
- Dairy Grading and Inspection Request Form
- Dairy Plants Surveyed and Approved for USDA Grading Service
- Food and Drug Administration (FDA) MOU 225-75-4002
- Interstate Milk Shippers List (IMS)
- Pasteurized Milk Ordinance (PMO)
- Request for Applicant Number Form DA-228
- Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers List
- USDA Guidelines for the Sanitary Design and Fabrication of Dairy Processing Equipment

4. Definitions

- **3-A Sanitary Standards and Accepted Practices:** 3-A SSI maintains an extensive inventory of design criteria for equipment and processing systems,

oversees the 3-A Symbol Authorization program and other voluntary certificates to help affirm the integrity of hygienic processing equipment and systems and provides extensive knowledge resources to support the training and education needs in the rapidly changing food, beverage, and pharmaceutical industries.

- **Approved Status (Plant Status):** The plant satisfactorily meets requirements of the General Specifications. No non-conformances are classified as **Critical** or Major.
- **Critical Non-Conformance:** An imminent health hazard caused by a condition which presents a biological, chemical, or physical food safety or food defense hazard that if not prevented, eliminated, or reduced by a subsequent process, practice, step, or procedure; or that may cause food to be unsafe for consumption or otherwise adulterated.
- **Dairy Products:** Butter, cheese (whether natural or processed), skim milk, cream, whey, or buttermilk (whether dry, evaporated, stabilized, or condensed), frozen desserts and any other food product which is prepared or manufactured in whole or in part from any of the aforesaid products.
- **Grader:** Any employee of the Department (USDA) authorized by the Administrator or any other person to whom a license has been issued by the Administrator to investigate and certify, in accordance with the Agricultural Marketing Act of 1946 and this part, to shippers of products and other interested parties, the class, quality, quantity, and condition of such products.
- **Ineligible Status (Plant Status):** The plant has a **Critical** non-conformance, or two or more Major non-conformance items noted during the inspection for the same product code or systemic connection. The National Field Office has discretion to assign an **Ineligible** status to a plant that exhibits repetitive direct contamination or adulteration non-conformances or has onsite unapproved sources in an approved plant.
- **Inspection or Grading Service:** Means in accordance with this part, the act of (1) drawing samples of any product; (2) determining the class, grade, quality, composition, size, quantity, condition, or wholesomeness of any product by examining each unit or representative samples; (3) determining condition of product containers; (4) identifying any product or packaging material by means of official identification; (5) re-grading or appeal grading of a previously graded product; (6) inspecting dairy plant facilities, equipment, and operations; such as, processing, manufacturing, packaging, repackaging, and quality control; (7) supervision of packaging inspected or graded product; (8) reinspection or appeal inspection; and (9) issuing an inspection or grading certificate or sampling, inspection, or other report related to any of the foregoing.
- **Inspector:** Means any Federal or State employee to whom a license has been issued by the Administrator to perform one or more types of inspections or grading services.
- **Interstate Milk Shippers List (IMS):** Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers List for U.S. based domestic Grade A

producers of bovine dairy products and ingredients with an approved product code list and a rating for each manufacturing facility.

- **Major Non-conformance:** Condition, practice, step, or procedure which, in itself, does not present a food safety, food defense or imminent health hazard yet has the potential to affect food safety or the product's intended use due to loss or lack of verifiable control.
- **Minor Non-conformance:** Condition, practice, step, or procedure that is not in accordance with food safety and defense requirements and does not meet the criteria of a **Critical** or Major Non-Conformance.
- **No Status Assigned (Plant Status):** The plant inspected has no current, approved code for the product and/or process inspected and does not comply with the requirements of the General Specifications
- **Pasteurization (Pasteurized):** Pasteurization shall mean that every particle of product shall have been heated in properly designed and operated equipment to one of the temperatures specified in the table and held continuously at or above that temperature for specified time.

Batch (Vat) Pasteurization	
Temperature	Time
63 °C (145 °F)	30 minutes
Continuous Flow High-Temperature-Short-Time (HTST) and Higher-Heat-Shorter-Time (HHST) Pasteurization	
Temperature	Time
72 °C (161 °F) *	15 Seconds
74 °C (166 °F)- Cream	15 Seconds
85 °C (185°F) **	15 Seconds
89 °C (191 °F)	1.0 Seconds
90 °C (194 °F)	0.5 Seconds
94 °C (201 °F)	0.1 Seconds
96 °C (204 °F)	0.05 Seconds
100 °C (212 °F)	0.01 Seconds

**Per the PMO, if the fat content of the milk product is ten percent (10%) or greater, or a total solids of 18% or greater, or if it contains added sweeteners, the specified temperature shall be increased by 3°C (5°F).*

*** Destruction of pathogenic bacteria (pasteurization) in cream can be achieved by heating to the minimum time/temperature required for cream, however, as indicated in 7 CFR 58.334, cream for butter making shall be pasteurized at a minimum of 185° F for not less than 15 seconds for the HTST method, when the vat method is used, cream for butter making shall be pasteurized at a temperature of not less than 165° F and held continuously for not less than 30 minutes.*

- **Plant Survey:** An appraisal of a plant to determine the extent to which facilities, equipment, method of operation, and raw material being received are in accordance with the provisions of this part. The plant survey shall be used to determine suitability of the plant for USDA inspection or grading service.
- **Plant Survey Quality Assessment Document:** A document used to assess the status of a plant with repetitive **Critical** or Major non-conformances on two consecutive plant surveys.
- **Probationary Status Assignment (Plant Status):** The plant has non-conformances that, if not corrected, would result in the **Ineligible** status being assigned. One (1) Major non-conformance or, multiple Minor non-conformances that in total create conditions that do not meet the requirement of the General Specifications. The length of the *Probationary* Status assigned will be based on the severity of the non-conformance ranging from 10 days to 3 months and will be determined by the National Field Office.
 - If the plant is able to correct any **Critical** or two or more Major non-conformances during the course of the survey, the non-conformances will be documented on the survey; however, the plant will not receive an **Ineligible** status; however, the status will be *Probationary* for affected codes.
- **Quality Control:** The inspection of the quality of the raw material and the conditions relative to the preparation of the product from its raw state through each step in the entire process. It includes the inspection of conditions under which the product is prepared, processed, manufactured, packed, and stored. In addition, assistance and guidance is offered to improve the raw milk quality, processing methods, quality, stability, and packaging and handling of the finished product.
- **Resident Program Cursory Inspection:** The Resident Program Cursory Inspection is a brief review conducted by the Resident Graders to visually identify non-conformances including **Critical**, Major, and Minor non-conformances. The Cursory Inspection Report is issued weekly by the Resident Grader and can include equipment inspected for plants taking part in the Rolling Survey Program.
- **Resident Service:** Inspection or grading service performed at a dairy manufacturing plant or grading station by an inspector or grader assigned to the plant or station on a continuous basis.
- **Rolling Survey (Resident Service Facilities):** An optional inspection of a representative sampling of equipment within the time between the twice-yearly plant survey inspections to determine the eligibility for grading and inspection

services. Inspections of equipment are routinely scheduled and inspected throughout this time period. Recommendations will be included on the final periodic survey report. This type of inspection will decrease the overall downtime and cost to the plant. This survey is only optional at facilities with Resident service.

- **Shall:** Expresses a provision that is mandatory.
- **Should:** Expresses recommended nonmandatory provisions which, when followed, would significantly aid in a quality improvement program.
- **Systemic Connection:** Refers to the interconnectedness between equipment, processes, and operational workflows with each component affecting the others on safety and/or product quality.

5. Confidentiality

Inspectors are instructed to not sign any confidentiality agreements in facilities as the Dairy Program employees obtain and use private information from the facility on the plant survey reports. If a signature is mandatory, the inspector is allowed to cross out any confidentiality agreement statement and sign for the remaining information. If digital signature is required and a paper version is not available, the inspector will contact a supervisor for further instructions.

6. Safety

All Dairy Program staff shall follow the plants GMPs and safety protocols.

Inspectors will take caution when working around and inspecting equipment in the facility. Inspectors are to always conduct themselves in a safe manner and exercise extreme care when working around moving and operating machinery.

7. Supplies and Equipment

Each plant is responsible for providing Personal Protective Equipment (PPE) for inspectors specific to their location. They are to wear protective safety items such as bump caps, protective eyewear, and ear plugs provided by USDA or the plant.

8. General Program Information

The PS Manual was developed by USDA, AMS, Dairy Program as additional guidance and further clarification of the program's principles and directives outlined in the General Specifications. The PS Manual is written to support the dairy industry with guidance to support the facilitation of marketing milk and dairy products.

The Dairy Program recognizes it is not possible, or necessary, to check every piece of equipment during each plant survey. The inspector will select a representative number of equipment systems and components on which to base their evaluation of day-to-day operations. The inspector will conduct an opening meeting with the facility staff to review assigned product codes, related equipment that will be opened and inspected during the survey, and the schedule of downtime. The inspection process is in-depth and requires participating plants to commit and invest in the downtime necessary to gain access to equipment. The inspector will work with the facility and accommodate to production schedules to the best of their ability.

8.1. Significance of USDA Approval

The Plant Survey Program is designed to support the dairy industry in quality-oriented dairy processing operations and compliment a plant's existing in-house program while serving as an impartial third-party.

The Plant Survey Program provides reassurances that a facility's consistent production of high-quality dairy products meets the requirements for USDA grading services. The approved facility is then listed in the Dairy Plants Surveyed and Approved for USDA Grading Services List, which provides the dairy industry with an expectation that participating plants meet the criteria detailed in the General Specifications. Plants that have received either an "Approved Status" or a "Probationary Status" can participate fully in dairy product grading certification programs.

9. Application of Services

To apply for services, an account with the Dairy Program is required. To request the establishment of an account, complete the fillable Request for Applicant Number Form DA-228. Completed forms can be emailed to DairyNFO@usda.gov.

**Please note:*

Line 2., Federal Tax ID Number, use only numbers, no dashes.

Line 13., Company Mailing Address, please include the Zip+4 code.

The Dairy Program billing system performs data matches with IRS' entity registered to the Federal tax ID number.

In 2 business days, an account number will be provided and emailed back to the requestor. After an account is established, to request dairy grading services, complete the Dairy Grading and Inspection Request form with the account number.

Participation in the Plant Survey Program is voluntary. DGB is a user-fee organization, and applicants are charged for services provided.

10. Initial Plant Inspection

Initial plant survey inspections are requested and arranged to accommodate the facility. Because there is a high likelihood the conditions at the time of the announced inspection are not typical of day-to-day operations, USDA restricts initial status ratings to a *Probationary Status*. An unannounced inspection will take place in approximately 90 days from the date of the initial inspection to provide the inspector an opportunity to review of day-to-day operations.

Status will not be assigned to plants with **Critical** or multiple Major non-conformances. A commitment addressing corrections will not be sufficient to award status at this time. Status will not be assigned to a plant until it meets the minimum requirements of the General Specifications. Plants found not to meet the criteria outlined for an approved dairy plant will be assigned *No Status Assigned* and can reapply for the program after the **Critical** or Major non-conformances have been corrected.

11. Performance of a Plant Survey Inspection

11.1. Inspection Considerations

The inspection process is in-depth and requires participating plants to commit and invest in the downtime necessary to gain access to equipment for inspection purposes. Plant

survey inspections include the analysis of plant practices and processing equipment through visual examination. Applicants participating in the Plant Survey Program should anticipate the inspector's request to examine product contact surfaces of various equipment and may include the review of supporting production and procedural documentation.

All equipment, processes, practices, and products that are either in actual use or could be used to manufacture a product covered by a product code are subject to inspection. The inspector will select a representative number of equipment pieces and request those pieces be made available for inspection. This will require certain equipment components to be disassembled. A request for access to equipment, even if part of a continuous run, should be anticipated. The inspection will be inclusive of the entire manufacturing process, beginning with product receipt and ending with storage and shipment. To receive product code approval, all aspects of an operation under plant control will be included within the scope of an inspection.

11.2. Use of Product Codes

Plants status is assigned to a plant by product code(s). Based on business needs, plant management can work with the NFO to determine the products they would like to have surveyed and approved. Codes can be found in the Dairy Plants Surveyed and Approved for USDA Grading Service list.

During each consecutive survey, the inspector will discuss with plant management the current codes and plant status assignments to ensure that the facility would like to keep all codes and add/remove codes as needed.

11.3. Inspection Frequency

Plant inspections will be conducted at a minimum of twice a year under the Approved Status Assignment. Inspections may occur more often when the *Probationary* Status is assigned. After each inspection, the plant will be assigned a plant status indicative of the conditions observed and notice of when the next inspection can be anticipated.

11.4. Unannounced Inspections

All plant survey inspections are unannounced insofar as practical to the efficient operation of the Plant Survey Program.

12. Cursory Inspections

A cursory inspection is a visual inspection of production for (drip, drain and/or draw) processing, packaging and warehousing of the plant. It will consist of checking High Temperature Short Time (HTST) seals, building construction, operating procedures, housekeeping, pest control procedures, and a visual inspection of any equipment that is not currently in use.

A cursory inspection shall be made in conjunction with all partial surveys. Partial surveys may include:

- A follow-up survey after a plant has received a *Probationary* or an *Ineligible* status.

- Reviewing only a portion of a multi-product/code facility, where one or more of the codes were not reviewed at the same time due to extenuating circumstances, such as time restrictions, cleaning schedules, etc.

Critical or Major non-conformances noted during a cursory inspection cannot be ignored. If these deficiencies cause an *Ineligible* status to be assigned, the inspector will contact a supervisor to report the observations. Depending on the observations, the inspector will provide applicable recommendations on the cursory inspection report or arrange for a complete survey.

12.1. Unannounced Cursory Survey

A cursory inspection of the plant shall be conducted in conjunction with the scheduled plant survey inspection to evaluate plant conditions during processing periods. The cursory inspection should include inspection of any equipment which may be available. It may be conducted either before or after the scheduled plant survey inspection, provided it is within *two weeks* of the scheduled plant survey inspection. All conditions observed during the cursory inspection is to be included in the official plant survey report and will be considered in the assignment of the plant status.

If serious unsatisfactory conditions are observed during the cursory inspection, the NFO may make an appropriate plant status change (for instance *Ineligible* or *Probationary*) without making a scheduled complete plant survey. Plants which are unable to satisfy the basic minimum requirements for approval during a scheduled plant survey and/or cursory inspections shall be assigned *Ineligible* status.

Whenever extended run plants are encountered, regardless of whether or not advance scheduling is provided, special attention is given to the suitability of the equipment and process for extended runs. The process and equipment shall be evaluated for potential quality or safety issues which may arise from the extended production periods. The NFO Director should consider the plant complexity and the decision making required for the plant survey and, when appropriate, arrange for assistance in conducting the plant survey.

13. Follow-up Surveys after *Ineligible* status assigned

After a *No Status Assigned* or *Ineligible* status has been assigned, plant management may make corrections and request a resurvey. This type of request will be honored as workforce and workload allows. Follow-up surveys are categorized by: Short Term (30 days or less) and Long Term (more than 30 days).

13.1. Short Term Follow Up Plant Survey: Major Non-Conformance(s)

Major non-conformance(s) responsible for an *Ineligible* status being assigned, will necessitate a follow-up plant survey inspection consisting of detailed inspection of all areas of the plant premises, equipment, and operating procedures utilized in the production of the products covered by the code(s) and will also include a summary of the findings and corrections discussed with plant management.

13.2. Long Term Follow-Up Plant Surveys (More than 30 Days)

A plant that has been determined to be *Ineligible* for more than 30 days before requesting a follow-up plant survey shall have a complete plant survey inspection. The highest status that can be assigned at the conclusion of the plant survey shall be *Probationary*.

13.3. Advance Scheduling

Advance scheduling is available at the request of the plant for scheduled maintenance and equipment that is not readily available for inspection. Plant survey inspection scheduling is not universally applied to all dairy plants. DGB will review requests for advanced scheduling and will approve or deny based on availability. Preference will be made to inspect equipment that requires scheduling of maintenance and service providers to dismantle the equipment. Advance scheduling can only be applied with the approval of the National Field Office (NFO) Director.

Reasons for advanced scheduling:

- Dryer Majors – consisting of sock changes, wet washes of chambers and full equipment, etc.
- A third-party company is utilized to breakdown and maintain individual pieces of equipment.

To allow for a progressive survey, an inspector may request the plant's operating schedule to incorporate low production times or down days during the week.

If special scheduling of an inspection is required, it is the plant's responsibility to provide downtime during the normal Monday through Friday work week for the inspection. Weekend or holiday scheduling of plant survey inspections is discouraged. However, at the discretion of the NFO Director, weekend or holiday work may be approved.

When plant survey inspections have been scheduled, all areas of the plant and equipment utilized in the production of products covered by the USDA inspection are to be available for review. Plant employees or contractors shall be available to disassemble equipment for inspection as needed.

Reach out to DairyNFO@usda.gov for further inquiry.

13.4. Arrangements with Management for the Inspection

Upon arrival and prior to starting a plant survey inspection, a designated plant employee will be required to meet and escort the inspector into the facility. A meeting room or office will be required to conduct the opening and closing meetings of the plant survey inspection. In the event a plant survey is declined, the plant is still responsible for the inspector's time and expenses involved. Dairy product code(s) made at the plant will not be eligible for USDA inspection and grading services, and an *Ineligible* status will be assigned to the plant.

14. Alternative Plant Survey Inspection- Resident Grading Service Plant

14.1. Rolling Plant Survey Inspection

As a resident grading service facility, there is an alternative option called the Rolling Plant Survey. This is an optional inspection style that consists of inspecting a representative selection of equipment in-between the twice-yearly plant survey inspection times. A summary of recommendations will be included on the final periodic plant survey report. This type of inspection will decrease the overall downtime and cost to the plant.

Below is a brief overview of the process:

- 1) A plant representative will notify the resident inspector in advance when equipment will be opened and cleaned.
- 2) The resident inspector will inspect the equipment and document any findings.
 - a) **Critical** or multiple Major Food safety deficiencies found will result in an **Ineligible** status assignment.
 - b) Repetitive **Critical** and Major non-conformances will be documented with DGB's Quality Assessment Document (QAD).
- 3) The plant will only receive an intermittent report on individual pieces of equipment if an **Ineligible** status is assigned due to a non-conformance.
- 4) Resident inspectors will continue to issue a Resident Program Cursory Inspection report to plant management at a minimum of once per week.

15. Requirements for Listing

15.1. Section I Plant Codes

Dairy manufacturing operations with an approved status are displayed on the Dairy Plants Surveyed and Approved for USDA Grading Services List. The program uses the following code prefixes to denote products which may be officially graded upon request for facilities in the Plant Survey Program also known as a USDA Approved Plant:

Table 1 Section I Plant Codes

Code	Product
B	Butter products
C	Cheese and cheese products
D	Dry milk products
F	Frozen dessert products
M	Milk and fluid dairy products
S	Specialty products
W	Whey and whey products

15.2. Section II Plant Codes

Grading services can also be provided for packaging and processing operations that utilize dairy ingredients not manufactured at a USDA, Grade A, or IMS listed facility. In these operations, the inspection will include a review of the facilities equipment, sanitation practices, and operating procedures only. Such operations are listed only in the Section II portion of the Dairy Plants Surveyed and Approved for USDA Grading Services list. A "P" code (denoting "packaging and processing") will be the only code available to these facilities. "P" code plants are denied from having the same codes in Section I.

Table 2 Section II Plant Codes

Code	Product
P	Packaging and Processing

Products packaged or processed in “P” code plants are normally not eligible for DGB grading service. Continuous grading service can be provided for short periods or for special orders, only when USDA is satisfied that the dairy ingredients were made by a USDA approved plant (processing and packaging were performed under continuous USDA inspection).

16. Source Ingredient Requirements

All processing facilities requesting USDA approval will be reviewed and classified according to source ingredients. Plants choosing to participate in the Plant Survey program have two options with regards to how the plant sources their ingredients:

1. *Section I Facility*: acquire all dairy products and ingredients from USDA, dairy approved sources or Grade A bovine dairy products and ingredients from U.S. based domestic plants on the Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers List for Grade A Plants with product codes equivalent to USDA DGB product codes; or
2. *Section II Facility*: acquire some or all the plants dairy ingredients from unapproved sources.

Plants are approved and listed by product code and source ingredients. Plants using approved source ingredients are classified as ‘Section I’ facilities; plants using unapproved source ingredients are classified as ‘Section II’ facilities.

Regardless of source ingredient selection, the plant will undergo the same detailed review of the facility, equipment, and Good Manufacturing Practices.

Note: *A plant may request Source Ingredients derived from domestic Grade A products without an IMS listed product code be reviewed on a case-by-case basis for acceptance by the National Field Director or designee as an approved source.*

16.1. Section I Facilities

A plant surveyed and approved as a Section I facility is required to source all dairy ingredients from approved sources to maintain an eligible Section I status. A plant receiving dairy products from unapproved sources for any purpose is not eligible to receive official grading services. When unapproved ingredients are found at a Section I facility, a **Major** non-conformance will be noted, and an **Ineligible** status will be assigned to product codes that represent or could contain the unapproved dairy ingredient. At the discretion of plant management and the National Field Office, the plant may be reassigned an appropriate Section II product code.

Exception: *At the time of this update (2024), casein and caseinates from non-domestic sources are allowed for use in a Section I plant without impact to status. The exception is based on the lack of U.S. sourced casein and caseinate products. Should production shift*

within the U.S., DGB will review the adequacy of U.S. supplies and drop the exception if availability is deemed sufficient to support market needs.

Note: *Casein or caseinate that is imported and repackaged within the U.S., without the addition of other ingredients, will be classified under a Section II listing. The exception is intended to apply to casein and caseinate used as an ingredient in relatively small batch quantities. In accordance with the PMO, a total of all such ingredients shall not exceed 10% by weight of the finished blend.*

16.2. Section II Facilities

A plant surveyed and approved as a Section II facility may source dairy products and ingredients from unapproved sources. All products emanating from Section II facilities shall comply with wholesomeness requirements. Plant Survey inspections of Section II facilities are conducted to include the same process scope as a Section I facility.

Approval of a plant process is reflected by an approved product code including all aspects the plant has direct control and oversight.

17. Storage of Unapproved Dairy Products

17.1. Central Distribution

A facility can serve as a central staging location for trucking and distribution of dairy products. Dairy products from unapproved sources can be stored on site for future distribution if those stored products are not similar to the USDA Surveyed and Approved Section I products produced by the plant. Similarly, dairy products that could be used in the manufacture of USDA Surveyed and Approved in-house products cannot be stored without impact to approved status.

For example, unapproved cream could not be stored at an approved butter plant, because:

- It limits the potential for misuse of unapproved source ingredients in approved operations.
- It avoids the appearance of blanket approval of similar products stored and shipped from a USDA Surveyed and Approved location.

17.2. Facility Retail Stores

Some facilities house a retail store that sells cheese, butter and other dairy products. To expand the available inventory of the retail store, the facility may bring in additional dairy products not manufactured by the plant and may be from unapproved dairy sources. Dairy products not similar to the USDA Surveyed and Approved Section I products produced by the plant may be stored on site for the purposes of the retail store.

As an example, a plant that is approved for cheddar cheese may wish to sell Swiss cheese from an unapproved source. This is not a conflict since the cheese make process for Swiss is quite different from that used to make cheddar.

17.3. Multi-Product Plant with Different Statuses for One or More Codes

When a plant has multiple codes, each portion of the plant will be plant surveyed at the frequency indicated by its previous status. In these instances, the plant survey shall concentrate on the equipment and procedures affecting the code(s) presently due for a plant survey. Other areas of the plant shall receive a cursory inspection. Multi-product

plants are permitted to the utilization of all approved products.

There may be instances where plant management will prefer that all operations be surveyed during each visit. Plant management requests will be accommodated in this regard as much as practical. In any event, only the codes included in the plant survey or for which status has changed should be listed in the status on the plant survey report.

18. Food Defense Plan Review

The Food Defense Plan Review (FDPR) is a prerequisite for all vendors selling products by means of the USDA Commodity Procurement (CP) Program. Implementation of the FDPR is to verify the alignment with CP contractual requirements outlined in the Master Solicitation and the applicable Commodity Requirements Document (CRD). The Qualified Buyers List (QBL) denotes plants who are in good standing by participating in a plant survey inspection and food defense plan review. The plant shall produce records to verify the product was manufactured in accordance with the contract specifications. The FDPR shall be performed during a plant survey inspection and at a minimum of once per year on all plants that intend to sell product by means of a CP Program. The FDPR Checklist is used to complete the FDPR. Plants that do not sell products by means of a CP Program can sign a FDPR Waiver form requesting to not have their food defense plan reviewed.

19. Food and Drug Administration (FDA)/USDA Salmonella Surveillance Program

Dairy plants producing dry dairy products with approved D, W, and S codes asterisked in the Dairy Plants Surveyed and Approved for USDA Grading Service will be participating in the Salmonella Surveillance Program. Quarterly sampling of dry products and environmental samples are required per FDA MOU 225-75-4002. Drying operations rated *Approved* or *Probationary* will be plant surveyed at the appropriate intervals based on plant survey status, and Salmonella samples will be collected during each plant survey inspection. Remaining quarterly visits, if required, will be for the purpose of taking samples for Salmonella testing. During a salmonella sampling visit, it will be necessary to work around the dryer filters, product sifter, and the vacuum cleaner, as well as the warehouse. If serious non-conformances are noted through visual evaluation of the equipment or environment while taking the samples, all findings will be recorded.

20. Grandfather Exemption for Equipment

A grandfather exemption for plant equipment is provided in certain instances for equipment technology that is obsolete due to advances in equipment design or processing techniques. This procedure allows the processor to continue using a piece of equipment which, when it was installed, complied with all existing requirements. However, through advances in design or technology, or modification of regulations, no longer complies with current standards or requirements. A grandfather exemption does not sanction improper sanitation or poor maintenance of equipment. All grandfather exempted equipment will eventually become worn or may reach a state of disrepair making it no longer acceptable. At that time, the equipment is to be treated as any other piece of equipment in similar condition and appropriate recommendations for repair or replacement will be made.

A change in ownership of a plant which does not interrupt the cycle of unannounced plant survey inspections would not alter the grandfather exemption status of items at that plant. A grandfather exemption, as it is used by DGB, is specific to the equipment or plant

location and may assume two slightly different applications depending upon the circumstances encountered.

20.1. Grandfather Application I

Plant status will be assigned consistent with plant conditions and sanitation. If an acceptable alternative piece of equipment is developed and becomes readily available, DGB will determine when all the remaining items would revert to Grandfather Application II status.

20.2. Grandfather Application II

The policy is specific to an identified piece of equipment located at a specific plant.

Since the grandfather exemption is intended to accomplish the phased withdrawal or replacement of the equipment, movement of the items is prohibited. There is no mandatory maximum time period restriction for a grandfather exemption. However, DGB may announce the end of a grandfather exemption following notification to the industry and provision of a specific phase out period to accomplish replacement of the equipment.

Plant status assignments will be made consistent with plant conditions and sanitation. A piece of equipment exempted by Application II is not free to move between locations. If the item is moved from the identified plant to another approved plant, the item shall be upgraded to meet all current standards, requirements, and regulations.

In addition, under this application, if the plant withdraws from the Plant Survey Program for a period equal to or exceeding one year, all grandfather exempted equipment shall be upgraded to current standards, requirements, or regulations for the plant to be reinstated as an approved plant.

Withdrawal from the Plant Survey Program is not interpreted to include temporary losses of approved status during which the plant is actively working to regain approval.

21. Plant Survey Status Determinations

A plant survey inspection is a 'snapshot' of day-to-day operations. When conducting a plant survey inspection, the inspector will determine how effective plant procedures and controls are in assuring the production of safe and high-quality dairy products. The status determination will be based on manufacturing practices and cleaning procedures, as well as examining equipment after cleaning.

21.1. Prioritization of Non-conformances

To help communicate the severity of observations to plant management, a:

- **Critical** non-conformance results in an *Ineligible* status;
- Major non-conformance(s) may result in an *Ineligible* or/ and;
- Minor non-conformance results from all other observations and recommendations.

***Note:** Minor non-conformances, at the time of the inspection, could deteriorate and contribute to a future compromise in either product wholesomeness, safety, or quality. All identified items should be addressed in a timely manner.*

21.1.1. Critical Non-Conformance

A **Critical** non-conformance is assigned to those items requiring immediate attention. Status is dependent on the plant's correction and therefore, addressing **Critical** non-conformances should be the highest priority. Ratings are assigned to conditions having a direct impact on the plant's ability to qualify as a USDA approved plant. Typically, the finding of a single **Critical** non-conformance will result in the assignment of an **Ineligible** status. **Critical** non-conformances will include observations of direct product contamination, conditions that compromise wholesomeness or quality, or a plant's failure to meet specific General Specifications criteria. Examples include, but are not limited to:

- Infestation of insects, rodents, and other vermin.
- Adulteration of product with chemicals, metal fragments, paint chips or other foreign material.
- Use of scrap or salvage materials collected from unsanitary surfaces in food for human consumption.
- Failure to comply with "shall" items in the General Specifications.
- Heavily soiled equipment such as plugged evaporator tubes or fouled membrane modules.
- Cracked equipment or torn boots drawing unfiltered air.

***Note:** If a **Critical** non-conformance will be noted on the report and the plant has not resolved the **Critical** non-conformance before the end of the plant survey inspection, the plant will receive an **Ineligible** status. Prior to completing the plant survey inspection, the inspector will need to thoroughly evaluate the corrective action to amend the initial **Ineligible** status to the appropriate "Approved" status.*

21.1.2. Major Non-Conformance

A Major non-conformance results in the change of plant status. Major non-conformance(s) should be addressed in a timely manner to avoid elevation to a **Critical** non-conformance rating. Ratings are assigned to conditions that will require immediate correction to avoid direct contamination of the product. The finding of two (2) or more Major non-conformances will result in the assignment of an **Ineligible** status. A single (1) Major non-conformance would warrant the assignment of a "Probationary" status. Major non-conformance(s) include observations related to significant equipment cleaning concerns, deteriorated equipment construction and condition, and compromised facility construction that could lead to failed protection of product. Examples include, but are not limited to:

- A definite product build-up on product contact surfaces of equipment.
- A small roof leak in close proximity to processing areas.
- Peeling paint on ceiling or support beams in close proximity to exposed product.
- Areas of floating floor where water is visibly seeping out from under floor grout and tiles.

- Unsanitary conditions or practices, that if not corrected, could be detrimental to the wholesomeness or quality of the final product.
- While a Major non-conformance will be noted on the report, if the plant has resolved the Major non-conformances before to the end of the survey, the plant will not receive an *Ineligible* Status. Prior to completing the plant survey inspection, the inspector will need to thoroughly evaluate the corrective action to amend the initial *Ineligible* status to the appropriate “Approved” status.

21.1.3. Minor Non-Conformance

A Minor non-conformance is applicable to sanitation, equipment, and facility non-conformances that may contaminate finished products if left uncorrected. Minor non-conformances may require some time to correct, but contamination of product will not likely occur during this period. These deficiencies are of minor significance and each by itself may have a minimal effect on a plant’s status, however, Minor non-conformances could cause a plant’s status to be reduced. Examples include, but are not limited to:

- Unsatisfactory conditions or practices noted at a level such that product wholesomeness is not threatened.
- Contamination, if it occurs, is not a public health concern but will affect product quality such as shelf life and grade.
- Corrective measures that can be verified during the next survey without threatening product safety or wholesomeness.

22. Plant Status Assignments

Plants that are inspected will be assigned one of the following status assignments; *Approved*, *Probationary*, *Ineligible*, or *No Status Assigned*. The inspector will use non-conformance descriptions as a guide to determine a final status assignment

Codes shall be listed to reflect products or processes for which the plant is being approved. If a code is to be added or deleted from the plant record, a special notation in the remarks section of the survey report will reflect the change.

Approved Status	
The plant shall comply with each subgrouping. No Critical or Major non-conformances are noted during the inspection.	
Construction Requirements as specified in the General Specifications	The General Specifications detail the construction requirements for plants that can be listed as USDA surveyed and approved. Approved plants are required to comply with the “shall” items outlined in the General Specifications.

Building Maintenance	The plant is found in good condition. A few routine maintenance items may exist that will require correction. None of the observed non-conformances have a direct and immediate impact on product safety, wholesomeness, or quality.
Equipment Design, Fabrication and Condition	Equipment is found to comply with either the 3-A Sanitary Standards or the USDA Guidelines for the Sanitary Design and Fabrication of Dairy Processing Equipment. If equipment is not in compliance with either of these guidelines, the non-conformances are determined to not directly lead to the contamination of product. The overall condition of the equipment is found to be more often satisfactory, with few Minor non-conformances.
Sanitation	Overall, equipment is predominantly found to be clean, absent of product residues or staining. No single piece of equipment is found to be heavily soiled. An incidence of an isolated cleaning failure, as evidenced by a single piece that is moderately soiled, may still be assigned an Approved status, provided the majority of associated equipment is found to be clean.
Sanitary Practices	Product handling and storage practices are found to protect the product from contamination and quality deterioration. Product that is not suitable for human consumption is properly labeled and handled.
Raw Product Quality	All milk received shall be sampled and tested prior to processing, for beta lactam drug residue. <i>Note: Section I plants - All dairy ingredients are from approved sources.</i>
Pasteurization	Pasteurization, when required by a product standard of identity or FDA best practice, is carried out in appropriately designed, timed, and sealed piece of equipment at the recommended times and temperatures. Legal pasteurization occurs at the plant of manufacture.

Probationary Status

If a plant meets the description of any single aspect of a subgrouping identified below, the *Probationary* status will be assigned provided:

- No **Critical** non-conformances are noted at the time of the inspection,
- No more than one Major non-conformance is observed at the time of the inspection.
- If the plant is able to correct any **Critical** or two or more Major non-conformances during the course of the survey, the non-conformances will be documented on the survey; however, the plant will not receive an **Ineligible** status; however, the status will be *Probationary* for affected codes.

Construction Requirements as specified in the General Specifications	<p>The General Specifications detail the construction requirements for plants that can be listed as USDA surveyed and approved. <i>Probationary</i> facilities shall comply with the “shall” items outlined in the General Specifications. At the discretion of the NFO Director, a <i>Probationary Status</i> may be assigned to a facility that has provided a written commitment to bring its plant into compliance with the General Specifications.</p>
Building Maintenance	<p>The plant is generally in good condition. A number of routine maintenance items may exist that will require correction. Some of these maintenance items may be significant (but not critical) in extent and require a greater capital investment. None of the observed non-conformances have a direct and immediate impact on product safety, wholesomeness, or quality. Failure to address the items could result in a rapid deterioration of processing conditions and negatively impact the product safety and quality.</p>
Equipment Design, Fabrication and Condition	<p>Equipment is found to comply with either the 3-A Sanitary Standards or the USDA Guidelines for the Sanitary Design and Fabrication of Dairy Processing Equipment. If equipment is not in compliance with either of these guidelines, the non-conformances are such that they do not directly lead to the contamination of product.</p>

Sanitation	Cleaning issues are noted at frequencies that suggest a systemic problem with plant sanitation practices. These observations may indicate only slight residues; however, the unsatisfactory findings surpass the satisfactory findings. Alternatively, sanitation concerns may be limited to a small number of equipment components, but the findings reveal moderate product build-ups.
Sanitary Practices	In general, product handling and storage practices are found to protect the product from contamination and quality deterioration. The inspector may observe an isolated unsatisfactory practice that can be corrected with specific employee instruction or training. Product that is not suitable for human consumption is properly labeled and handled.
Raw Product Quality	All milk received shall be sampled and tested prior to processing, for beta lactam drug residue. <i>Note: Section I Plants: All dairy ingredients are from approved sources.</i>
Pasteurization	Pasteurization, when required by a product standard of identity or FDA best practice, is carried out in appropriately designed, timed, and sealed equipment at the recommended times and temperatures. Legal pasteurization occurs at the plant of manufacture.

Ineligible Status

If a plant meets the description of any single aspect of a subgrouping identified below, the *Ineligible* status will be assigned provided:

- One **Critical** non-conformance was noted, or
- Two or more Major non-conformances are observed.

Note: If the plant is able to correct any **Critical** or two or more Major non-conformances during the course of the survey, the non-conformances will be documented on the survey; however, the plant will not receive an *Ineligible* status.

Products manufactured by the plant since the last USDA Plant Survey will receive an *Ineligible* status.

Note: If the plant is able to provide documents that identifies a date after the last survey that provides sufficient evidence indicating safe and quality conformance with the General Specifications with supporting preventive maintenance, the *Ineligible* will be limited to the date identified in the documents.

Construction Requirements as specified in the General Specifications	The construction of the plant does not comply with the General Specifications. Correction of the noted non-conformance will typically require additional construction and possibly a process redesign.
Building Maintenance	A non-conformance is observed that has a direct and immediate impact on product safety, wholesomeness, or quality.
Equipment Design, Fabrication and Condition	Equipment is not in compliance with either the 3-A Sanitary Standards or the USDA Guidelines for the Sanitary Design and Fabrication of Dairy Processing Equipment. Non-conformances are extensive and will likely require redesign. A single non-conformance may have been found that has led to the contamination of product.
Sanitation	Cleaning issues are noted at frequencies that suggest a systemic problem with plant sanitation practices. These observations indicate moderate to heavy residues in a number of components or pieces of equipment. A single observation of heavy product soil may be sufficient to warrant an <i>Ineligible</i> status, depending on the scope and location of the build-up.

Sanitary Practices	The inspector has observed unsatisfactory practices that will require process modification and employee training. Product that is not suitable for human consumption is not properly labeled and/or handled.
Raw Product Quality	Not all milk received is being sampled and tested prior to processing, for beta lactam drug residue. <i>Note: Section I Plants- All dairy ingredients are not from approved sources.</i>
Pasteurization	Legal pasteurization is not provided when required by standard of identity, legal definition or process.
Pest Control	The inspector finds evidence of pests, indicating a failure of the Pest Control program.
Access to Facilities and Equipment	The plant has denied access to equipment or specific rooms that apply to a requested product code. The National Field Director shall be contacted to determine status.

23. Quality Assessment Document (QAD)

The QAD will be used for repetitive **Critical** and Major non-conformances. The document will identify the deficiencies that have been notated on consecutive plant surveys document any corrective actions that have been implemented and document the plant's preventive action plan to mitigate any future occurrences. The plant will need to provide:

- The Corrective Actions taken when the non-conformance issue(s) were identified.
- A Preventive Action Plan covering what will be changed in the plant's process control program to prevent the issue from reoccurring.

The QAD will be reviewed with the plant at the next plant survey to ensure the preventive action was successful and can be reinspected by the resident inspector.

23.1. Plants with Previous Ineligible Status

If a plant has a non-conformance serious enough to warrant the **Ineligible** rating, the status assigned on the following survey will not be higher than *Probationary* status. A plant in this situation has a serious problem and closer surveillance is necessary for assurance that corrections are adequate, and operations are satisfactory on a continuing basis.

There may be exceptions to this general policy when the reinstating survey clearly reveals correction of the non-conformance as well as correction of the underlying cause(s). In such instances, an *Approved* Status may be assigned as applicable.

23.2. Consecutive Probationary Plant Status Assignments

Plants participating in the DGB plant survey inspection program should be diligent in monitoring and maintaining conditions that qualify for the *Approved* status. However, a *Probationary* status rating should not be the norm. Plants that, based upon observed conditions, would warrant back-to-back *Probationary* status ratings may not have the necessary controls to maintain acceptable operating conditions without prompting from DGB. It is the responsibility of plant management to ensure conditions meet the ongoing requirements needed for the production of a safe, wholesome and high-quality product. DGB will not assign consecutive *Probationary* status ratings to a manufacturing plant without good cause. Examples of conditions under which a consecutive rating would be considered include:

- Overall sanitation practices are found to meet the criteria of an *Approved* status plant.
- Major non-conformance items from the previous inspection have been addressed.
- The plant has defined, in writing, a specific course of action to address the areas of concern.
- The NFO Director has been consulted and concurs with the assignment of a consecutive *Probationary* status.

24. Final Plant Status Review and Approval

Each plant survey report will include the inspector's recommended status assignment. The NFO Director, or a designated representative, will review the inspection report and may, at their discretion, alter the final status assignment. The NFO Director will communicate any change to a final status to plant management in writing.

24.1. Plant Status Designations

A surveyed plant shall be assigned one of the following status designations:

Approved: The plant satisfactorily meets requirements of the General Specifications. If non-conformances exist, they are of relatively minor significance. None of these non-conformances are classified as **Critical or Major non-conformance**.

Probationary: When very serious non-conformances are observed that, if not corrected immediately, would result in the **Ineligible** status being assigned. Plant management provides a corrective action plan that assures prompt attention to the serious non-conformance(s), consideration may be given to an alternative status of *Probationary* under the following circumstances:

- The serious non-conformance(s) are of such character and extent that correction can be made immediately.
- Plant management commits to make corrections immediately.
- The arrangement is approved by the NFO Director.

The NFO Director may ask to speak with the plant management to become familiar with details of the corrective action plan. If approved, the plant manager will be informed that a resurvey will be performed. In the event an inspector is unable to contact a supervisor or the NFO when a question comes up about the *Probationary* status, an **Ineligible** status will be assigned and the NFO Director will be contacted on the next business day.

Ineligible: The plant has a **Critical** non-conformance or two or more Major non-conformances which may affect product safety. This status assignment is also applicable when raw material source plants are not approved or when no significant improvement has been made in plant operations following assignment of *Probationary* status. When the plant conditions are such that an **Ineligible** status is determined, written notification of the **Ineligible** status, codes affected, date of action, and the inspector will document the how the equipment does not meet the General Specifications. The supervisor and NFO shall also be notified promptly. Products made by plants with the **Ineligible** status shall not be officially graded or inspected. Assistance with plant upgrading or a resurvey for reinstatement will be available upon request.

Discontinued: *Discontinued* status will be assigned if a plant decides to drop a product code and the equipment associated exclusively with the code will not be included in future surveys.

No Status Assigned: There are instances of inspection activity where assignment of a plant status is not applicable. Examples of instances when the *No Status Assigned* designation should be used include:

- After an initial survey in which the plant did not meet the requirements of the General Specifications.
- Management requests a survey of a portion of the plant that was not included in previous surveys and this portion of the plant does not meet the requirements of the General Specifications.
- A plant decides to change or eliminate one or more product codes, and all the equipment remains included in the survey. For example, a plant producing Nonfat Dry Milk (NDM) and Dry Whey on the same dryer decides to stop drying the whey and ship it as condensed whey. They retain the NDM code, add the Condensed Whey code and receive *No Status Assigned* for Dry Whey.
- Management requests a review of operations under construction in order to learn what changes are needed to meet the General Specifications requirements.

Note: *If the plant had dropped all dry codes the Discontinued status would apply because the dryer would no longer be included in the survey.*

25. Background

DGB PS Manual is a guideline for the Plant Survey Program. The PS Manual is based on the requirements outlined in General Specifications. The intended audience is the dairy industry in addition to Dairy Program employees. The Plant Survey Program determines the extent to which plants, raw material, equipment, and methods of operation are in accordance with General Specifications. Approved plants will be listed as either Section I or Section II plants based on their needs.