the issuance of a complaint seeking a civil penalty under the Act may enter into a stipulation with any person, in accordance with the following prescribed conditions:

(1) The Administrator gives notice of an apparent violation of the Act or the regulations issued thereunder by such person and affords such person an opportunity for a hearing regarding the matter as provided by the Act;

(2) Such person expressly waives hearing and agrees to a specified order including an agreement to pay a specified civil penalty within a designated time; and

(3) The Administrator agrees to accept the specified civil penalty in settlement of the particular matter involved if it is paid within the designated time.

(4) If the specified penalty is not paid within the time designated in such stipulation, the amount of the stipulated penalty shall not be relevant in any respect to the penalty that may be assessed after the institution of a formal administrative proceeding pursuant to the Uniform Rules of Practice, Subpart H, Part 1, Title 7, Code of Federal Regulations.

[64 FR 40738, July 28, 1999, as amended at 69 FR 57168, Sept. 24, 2004]

PART 58—GRADING AND INSPECTION, GENERAL SPECIFICATIONS FOR APPROVED PLANTS AND STANDARDS FOR GRADES OF DAIRY PRODUCTS[1]

Subpart A—Regulations Governing the Inspection and Grading Services of Manufactured or Processed Dairy Products

DEFINITIONS

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58.1 Meaning of words.
58.2 Designation of official certificates, memoranda, marks, identifications, and devices for purpose of the Agricultural Marketing Act.

ADMINISTRATION

58.3 Authority.

[1]Compliance with these standards does not excuse failure to comply with the provisions of the Federal Food, Drug and Cosmetic Act.

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58.5 Where service is offered.
58.6 Supervision of service.
58.7 Who may obtain service.
58.8 How to make application.
58.9 Form of application.
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58.11 Approval of application.
58.12 When application may be rejected.
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58.14 Authority of applicant.
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58.19 Issuance of inspection or grading certificates.
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APPEAL INSPECTION OR GRADING AND REINSTATEMENT OF REGRADING

58.22 When appeal inspection or grading may be requested.
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58.24 Record of filing time.
58.25 When an application for appeal inspection or grading may be refused.
58.26 When an application for an appeal inspection or grading may be withdrawn.
58.27 Order in which appeal inspections or gradings are performed.
58.28 Who shall make appeal inspections or gradings.
58.29 Appeal inspection or grading certificate or report.
58.30 Application for reinspection or regrading.
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58.34 Suspension or revocation of license.
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58.38 Payment of fees and charges.
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58.40 Fees for appeal inspection or grading.
58.41 Fees for additional copies of certificates.
58.42 Travel expenses and other charges.
58.43 Fees for inspection, grading, and sampling.
58.45 Fees for continuous resident services.
58.46 Fees for service performed under cooperative agreement.

MARKING, BRANDING, AND IDENTIFYING PRODUCT

58.49 Authority to use official identification.
58.50 Approval and form of official identification.
58.51 Information required on official identification.
58.52 Time limit for packaging inspected or graded products with official identification.

PREREQUISITES TO PACKAGING PRODUCTS WITH OFFICIAL IDENTIFICATION

58.53 Supervisor of packaging required.
58.54 Packing and packaging room and equipment.
58.55 Facilities for keeping quality samples.
58.56 Incubation of product samples.
58.57 Product not eligible for packaging with official identification.

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58.58 Debarment of service.

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58.61 Political activity.
58.62 Report of violations.
58.63 Other applicable regulations.
58.64 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

Subpart B—General Specifications for Dairy Plants Approved for USDA Inspection and Grading Service

DEFINITIONS

58.100 OMB control numbers assigned pursuant to the Paperwork Reduction Act.
58.101 Meaning of words.

PURPOSE

58.122 Approved plants under USDA inspection and grading service.

APPROVED PLANTS

58.123 Survey and approval.
58.124 Denial or suspension of plant approval.

PREMISES, BUILDINGS, FACILITIES, EQUIPMENT AND UTENSILS

58.125 Premises.
58.126 Buildings.
58.127 Facilities.
58.128 Equipment and utensils.

PERSONNEL, CLEANLINESS AND HEALTH

58.129 Cleanliness.
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PROTECTION AND TRANSPORT OF RAW MILK AND CREAM

58.131 Equipment and facilities.

QUALITY SPECIFICATIONS FOR RAW MILK

58.132 Basis for classification.
58.133 Methods for quality and wholesomeness determination.
58.134 Sediment content.
58.135 Bacterial estimate.
58.136 Rejected milk.
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58.138 Quality testing of milk from new producers.
58.139 Record of tests.
58.140 Field service.
58.141 Alternate quality control program.

OPERATIONS AND OPERATING PROCEDURES

58.142 Product quality and stability.
58.143 Raw product storage.
58.144 Pasteurization or ultra-pasteurization.
58.145 Composition and wholesomeness.
58.146 Cleaning and sanitizing treatment.
58.147 Insect and rodent control program.
58.148 Plant records.
58.149 Alternate quality control programs for dairy products.

PACKAGING AND GENERAL IDENTIFICATION

58.150 Containers.
58.151 Packaging and repackaging.
58.152 General identification.

STORAGE OF FINISHED PRODUCT

58.153 Dry storage.
58.154 Refrigerated storage.

INSPECTION, GRADING AND OFFICIAL IDENTIFICATION

58.155 Grading.
58.156 Inspection.
58.157 Inspection or grading certificates.
58.158 Official identification.

EXPLANATION OF TERMS

58.159 Terms.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING NONFAT DRY MILK, INSTANT NONFAT DRY MILK, DRY WHOLE MILK, AND DRY BUTTERMILK

DEFINITIONS

58.205 Meaning of words.

ROOMS AND COMPARTMENTS

58.210 Dry storage of product.
58.211 Packaging room for bulk products.
58.212 Hopper or dump room.
58.213 Repackaging room.

EQUIPMENT AND UTENSILS

58.214 General construction, repair and installation.
58.215 Pre-heaters.
58.216 Hotwells.

58.217 Evaporators and/or vacuum pans.
58.218 Surge tanks.
58.219 High pressure pumps and lines.
58.220 Drying systems.
58.221 Collectors and conveyors.
58.222 Dry dairy product cooling equipment.
58.223 Special treatment equipment.
58.224 Sifters.
58.225 Clothing and shoe covers.
58.226 Portable and stationary bulk bins.
58.227 Sampling device.
58.228 Dump hoppers, screens, mixers and conveyors.
58.229 Filler and packaging equipment.
58.230 Heavy duty vacuum cleaners.

QUALITY SPECIFICATIONS FOR RAW MATERIALS

58.231 General.
58.232 Milk.
58.233 Skim milk.
58.234 Buttermilk.
58.235 Modified dry milk products.

OPERATIONS AND OPERATING PROCEDURES

58.236 Pasteurization and heat treatment.
58.237 Condensed surge supply.
58.238 Condensed storage tanks.
58.239 Drying.
58.240 Cooling dry products.
58.241 Packaging, repackaging and storage.
58.242 Product adulteration.
58.243 Checking quality.
58.244 Number of samples.
58.245 Method of sample analysis.
58.246 Cleaning of dryers, collectors, conveyors, ducts, sifters and storage bins.
58.247 Insect and rodent control program.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

58.248 Nonfat dry milk.
58.249 Instant nonfat dry milk.
58.250 Dry whole milk.
58.251 Dry buttermilk and dry buttermilk product.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING BUTTER AND RELATED PRODUCTS

DEFINITIONS

58.305 Meaning of words.

ROOMS AND COMPARTMENTS

58.311 Coolers and freezers.
58.312 Churn rooms.
58.313 Print and bulk packaging rooms.

EQUIPMENT AND UTENSILS

58.314 General construction, repair and installation.
58.315 Continuous churns.
58.316 Conventional churns.
58.317 Bulk butter trucks, boats, texturizers, and packers.
58.318 Butter, frozen or plastic cream melting machines.
58.319 Printing equipment.
58.320 Brine tanks.
58.321 Cream storage tanks.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

58.322 Cream.
58.323 [Reserved]
58.324 Butteroil.
58.325 Anhydrous milkfat.
58.326 Plastic cream.
58.327 Frozen cream.
58.328 Salt.
58.329 Color.
58.330 Butter starter cultures.
58.331 Starter distillate.

OPERATIONS AND OPERATING PROCEDURES

58.332 Segregation of raw material.
58.334 Pasteurization.
58.335 Quality control tests.
58.336 Frequency of sampling for quality control of cream, butter and related products.
58.337 Official test methods.
58.338 Composition and wholesomeness.
58.339 Containers.
58.340 Printing and packaging.
58.341 Repackaging.
58.342 General identification.
58.343 Storage of finished product in coolers.
58.344 Storage of finished product in freezer.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

58.345 Butter.
58.346 Whipped butter.
58.347 Butteroil or anhydrous milkfat.
58.348 Plastic cream.
58.349 Frozen cream.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING AND PACKAGING CHEESE

DEFINITIONS

58.405 Meaning of words.

ROOMS AND COMPARTMENTS

58.406 Starter facility.
58.407 Make room.
58.408 Brine room.
58.409 Drying room.
58.410 Paraffining room.
58.411 Rindless cheese wrapping area.
58.412 Coolers or curing rooms.
58.413 Cutting and packaging rooms.

EQUIPMENT AND UTENSILS

58.414 General construction, repair and installation.
58.415 Starter vats.
58.416 Cheese vats, tanks and drain tables.
58.417 Mechanical agitators.
58.418 Automatic cheese making equipment.

58.419 Curd mill and miscellaneous equipment.
58.420 Hoops, forms and followers.
58.421 Press.
58.422 Brine tank.
58.423 Cheese vacuumizing chamber.
58.424 Monorail.
58.425 Conveyor for moving and draining block or barrel cheese.
58.426 Rindless cheese wrapping equipment.
58.427 Paraffin tanks.
58.428 Specialty equipment.
58.429 Washing machine.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

58.430 Milk.
58.431 Hydrogen peroxide.
58.432 Catalase.
58.433 Cheese cultures.
58.434 Calcium chloride.
58.435 Color.
58.436 Rennet, pepsin, or other milk clotting enzymes and flavor enzymes.
58.437 Salt.

OPERATIONS AND OPERATING PROCEDURES

58.438 Cheese from pasteurized milk.
58.439 Cheese from unpasteurized milk.
58.440 Make schedule.
58.441 Records.
58.442 Laboratory and quality control tests.
58.443 Whey handling.
58.444 Packaging and repackaging.
58.445 General identification.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

58.446 Quality requirements.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING AND PACKAGING COTTAGE CHEESE

DEFINITIONS

58.505 Meaning of words.

ROOMS AND COMPARTMENTS

58.510 Rooms and compartments.

EQUIPMENT AND UTENSILS

58.511 General construction, repair and installation.
58.512 Cheese vats or tanks.
58.513 Agitators.
58.514 Container fillers.
58.515 Mixers.
58.516 Starter vats.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

58.517 General.
58.518 Milk.
58.519 Dairy products.
58.520 Nondairy ingredients.

OPERATIONS AND OPERATING PROCEDURES

58.521 Pasteurization and product flow.
58.522 Reconstituting nonfat dry milk.
58.523 Laboratory and quality control tests.
58.524 Packaging and general identification.
58.525 Storage of finished product.

REQUIREMENTS FOR COTTAGE CHEESE BEARING USDA OFFICIAL IDENTIFICATION

58.526 Official identification.
58.527 Physical requirements.
58.528 Microbiological requirements.
58.529 Chemical requirements.
58.530 Keeping quality requirements.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING, AND PACKAGING FROZEN DESSERTS

DEFINITIONS

58.605 Meaning of words.

ROOMS AND COMPARTMENTS

58.619 Mix processing room.
58.620 Freezing and packaging rooms.
58.621 Freezing tunnels.
58.622 Hardening and storage rooms.

EQUIPMENT AND UTENSILS

58.623 Homogenizer.
58.624 Freezers.
58.625 Fruit or syrup feeders.
58.626 Packaging equipment.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

58.627 Milk and dairy products.
58.628 Sweetening agents.
58.629 Flavoring agents.
58.630 Stabilizers.
58.631 Emulsifiers.
58.632 Acid.
58.633 Color.

OPERATIONS AND OPERATING PROCEDURES

58.634 Assembling and combining mix ingredients.
58.635 Pasteurization of the mix.
58.636 Homogenization.
58.637 Cooling the mix.
58.638 Freezing the mix.
58.639 Addition of flavor.
58.640 Packaging.
58.641 Hardening and storage.
58.642 Quality control tests.
58.643 Frequency of sampling.
58.644 Test methods.
58.645 General identification.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

58.646 Official identification.
58.647 Composition requirements for ice cream.
58.648 Microbiological requirements for ice cream.

58.649 Physical requirements for ice cream.
58.650 Requirements for frozen custard.
58.651 [Reserved]
58.652 Composition requirements for sherbet.
58.653 Microbiological requirements for sherbet.
58.654 Physical requirements for sherbet.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING PASTEURIZED PROCESS CHEESE AND RELATED PRODUCTS

DEFINITIONS

58.705 Meaning of words.

EQUIPMENT AND UTENSILS

58.706 General construction, repair and installation.
58.707 Conveyors.
58.708 Grinders or shredders.
58.709 Cookers.
58.710 Fillers.

QUALITY SPECIFICATIONS FOR RAW MATERIAL

58.711 Cheddar, colby, washed or soaked curd, granular or stirred curd cheese.
58.712 Swiss.
58.713 Gruyere.
58.714 Cream cheese, Neufchatel cheese.
58.715 Cream, plastic cream and anhydrous milkfat.
58.716 Nonfat dry milk.
58.717 Whey.
58.718 Flavor ingredients.
58.719 Coloring.
58.720 Acidifying agents.
58.721 Salt.
58.722 Emulsifying agents.

OPERATIONS AND OPERATING PROCEDURES

58.723 Basis for selecting cheese for processing.
58.724 Blending.
58.725 Trimming and cleaning.
58.726 Cutting and grinding.
58.727 Adding optional ingredients.
58.728 Cooking the batch.
58.729 Forming containers.
58.730 Filling containers.
58.731 Closing and sealing containers.
58.732 Cooling the packaged cheese.
58.733 Quality control tests.

REQUIREMENTS FOR PROCESSED CHEESE PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

58.734 Official identification.
58.735 Quality specifications for raw materials.

QUALITY SPECIFICATIONS FOR FINISHED PRODUCTS

58.736 Pasteurized process cheese.
58.737 Pasteurized process cheese food.
58.738 Pasteurized process cheese spread and related products.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING, AND PACKAGING WHEY, WHEY PRODUCTS AND LACTOSE

DEFINITIONS

58.805 Meaning of words.

ROOMS AND COMPARTMENTS

58.806 General.

EQUIPMENT AND UTENSILS

58.807 General construction, repair and installation.

QUALITY SPECIFICATIONS FOR RAW MATERIALS

58.808 Whey.

OPERATIONS AND OPERATING PROCEDURES

58.809 Pasteurization.
58.810 Temperature requirements.
58.811 General.
58.812 Methods of sample analysis.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

58.813 Dry whey.

SUPPLEMENTAL SPECIFICATIONS FOR PLANTS MANUFACTURING, PROCESSING AND PACKAGING EVAPORATED AND CONDENSED MILK OR ULTRA-PASTEURIZED PRODUCTS

DEFINITIONS

58.905 Meaning of words.

EQUIPMENT AND UTENSILS

58.912 General construction, repair and installation.
58.913 Evaporators and vacuum pans.
58.914 Fillers.
58.915 Batch or continuous in-container thermal processing equipment.
58.916 Homogenizer.

OPERATIONS AND OPERATING PROCEDURES

58.917 General.
58.918 Standardization.
58.919 Pre-heat, pasteurization.
58.920 Homogenization.
58.921 Concentration.
58.922 Thermal processing.
58.923 Filling containers.
58.924 Aseptic filling.
58.925 Sweetened condensed.
58.926 Heat stability.
58.927 Storage.
58.928 Quality control tests.
58.929 Frequency of sampling for quality control.
58.930 Official test methods.
58.931 General identification.

QUALITY SPECIFICATIONS FOR RAW MATERIALS

58.932 Milk.
58.933 Stabilizers.
58.934 Sugars.
58.935 Chocolate and cocoa.

REQUIREMENTS FOR FINISHED PRODUCTS BEARING USDA OFFICIAL IDENTIFICATION

58.936 Milk.
58.937 Physical requirements for evaporated milk.
58.938 Physical requirements and microbiological limits for sweetened condensed milk.

Subparts C–V [Reserved]

Subpart W—United States Department of Agriculture Standard for Ice Cream

58.2825 United States Standard for ice cream.
58.2826 General identification.
58.2827 Official identification.

AUTHORITY: 7 U.S.C. 1621—1627.

SOURCE: 23 FR 9410, Dec. 5, 1958, unless otherwise noted. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981.

NOTE: Compliance with these standards does not excuse failure to comply with the provisions of the Federal Food, Drug, and Cosmetic Act.

Subpart A—Regulations Governing the Inspection and Grading Services of Manufactured or Processed Dairy Products

SOURCE: 37 FR 22363, Oct. 19, 1972, unless otherwise noted. Redesignated at 42 FR 32514, June 27, 1977, and further redesignated at 46 FR 63203, Dec. 31, 1981.

DEFINITIONS

§ 58.1 Meaning of words.

For the purpose of the regulations in this subpart, words in the singular form shall be deemed to import the plural and vice versa, as the case may demand. Unless the context otherwise requires, the following terms shall have the following meaning:

Act means the applicable provisions of the Agricultural Marketing Act of 1946 (60 Stat. 1087, as amended; 7 U.S.C. 1621–1627) or any other act of Congress conferring like authority.

Administrator means the Administrator of the Agricultural Marketing Service or any other officer or employee of the Agricultural Marketing Service to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated, to act in his stead.

Agricultural Marketing Service or *AMS* means the Agricultural Marketing Service of the Department.

Applicant means any interested party who has applied for inspection or grading service.

Approved laboratory means a laboratory in which the facilities and equipment used for official testing have been adequate to perform the necessary official tests in accordance with this part.

Approved plant means one or more adjacent buildings, or parts thereof, comprising a single plant at one location in which the facilities and methods of operation therein have been surveyed and approved by the Administrator as suitable and adequate for inspection or grading service in accordance with this part.

Area Supervisor means any employee of the Branch in charge of dairy inspection or grading service in a designated geographical area.

Branch means the Dairy Inspection Branch of the Poultry and Dairy Quality Division.

Chief means the Chief of the Branch, or any officer or employee of the Branch to whom authority has been heretofore delegated, or to whom authority may hereafter be delegated, to act in his stead.

Class means any subdivision of a product based on essential physical characteristics that differentiate between major groups of the same kind or method of processing.

Condition of container means the degree of acceptability of the container with respect to freedom from defects which affect its serviceability, including appearance as well as usability, of the container for its intended purpose.

Condition of product or *condition* is an expression of the extent to which a product is free from defects which affect its usability, including but not limited to, the state of preservation, cleanliness, soundness, wholesomeness, or fitness for human food.

Continuous resident service or *resident service* is 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, year-round, resident basis.

Department or *USDA* means the U.S. Department of Agriculture.

Director means the Director of the Poultry and Dairy Quality Division, or any other officer or employee of the Division to whom authority has heretofore been delegated or to whom authority may hereafter be delegated, to act in his stead.

Division means the Poultry and Dairy Quality Division of the Agricultural Marketing Service.

Inspection or grading service or *service* means in accordance with this part, the act of (a) drawing samples of any product; (b) determining the class, grade, quality, composition, size, quantity, or condition of any product by examining each unit or representative samples; (c) determining condition of product containers; (d) identifying any product or packaging material by means of official identification; (e) regrading or appeal grading of a previously graded product; (f) inspecting dairy plant facilities, equipment, and operations; such as, processing, manufacturing, packaging, repackaging, and quality control; (g) supervision of packaging inspected or graded product; (h) reinspection or appeal inspection; and (i) issuing an inspection or grading certificate or sampling, inspection, or other report related to any of the foregoing.

Inspector or grader means any Federal or State employee to whom a license has been issued by the Administrator to perform one or more types of inspection or grading services.

Inspection or grading office means the office of any inspector or grader.

Interested party means any person financially interested in a transaction involving any inspection or grading service.

Licensed plant employee means an employee of an approved plant to whom a license is issued by the Administrator to supervise packaging of officially inspected or graded product, perform laboratory tests, or perform other duties as assigned by the Administrator. A licensed plant employee is not authorized to issue any inspection or grading certificate.

Product means butter, cheese (whether natural or processed), milk, cream, milk products (whether dried, frozen, evaporated, stabilized, or condensed), ice cream, dry whey, dry buttermilk, and any other food product, which is prepared or manufactured in whole or in part from any of the aforesaid products, as the Administrator may hereafter designate.

Person means any individual, partnership, association, business, trust, corporation, or any organized group of persons, whether incorporated or not.

Plant survey means an appraisal of the plant to determine extent to which facilities, equipment, method of operation, and raw material being received are in accordance with the provisions of this part. The survey shall be used to determine suitability of the plant for inspection or grading service.

Quality means the inherent properties of any product which determine its relative degree of excellence.

Regulations means the provisions of this subpart.

Sampling report means a statement issued by an inspector or grader identifying samples taken by him for inspection or grading service.

Supervisor of packaging means an employee of the Department or other person licensed by the Administrator to supervise the packaging and official identification of product or any repackaging of bulk product.

(60 Stat. 1087, 7 U.S.C. 1621 *et seq.*; 84 Stat. 1620, 21 U.S.C. 1031 *et seq.*)

[37 FR 22363, Oct. 19, 1972, as amended at 38 FR 4381, Feb. 14, 1973. Redesignated at 42 FR 32514, June 27, 1977, as amended at 43 FR 60138, Dec. 26, 1978. Redesignated at 46 FR 63203, Dec. 31, 1981, as amended at 54 FR 15167, Apr. 17, 1989]

§ 58.2 Designation of official certificates, memoranda, marks, identifications, and devices for purpose of the Agricultural Marketing Act.

Subsection 203(h) of the Agricultural Marketing Act of 1946, as amended by Pub. L. 272, 84th Congress, provides criminal penalties for various specified