



Agricultural Marketing Service

7 CFR Part 58

[Doc. No. AMS-DA-22-0064]

RIN 0581-AE20

Plant Records to Include Grade Label Butterfat Testing

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule adopts amendments to the plant records requirement for the Agricultural Marketing Service (AMS) Dairy Grading and Inspection Program. The amendments allow butterfat tests to be performed at an in-house or approved third party laboratory and add a requirement for plants to maintain and make such records available for examination by a United States Department of Agriculture (USDA) inspector. These amendments increase efficiency by conforming to current industry practice.

DATES: This final rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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SUPPLEMENTARY INFORMATION: The Secretary of Agriculture is authorized by the Agricultural Marketing Act (AMA) of 1946, as amended (7 U.S.C. 1621, *et seq.*), to provide voluntary Federal dairy inspection and grading services that enables consumers to purchase high quality dairy products and facilitates orderly marketing. Plants participating in the voluntary, fee-based AMS Dairy Grading and Inspection Program

process milk into dairy foods that enter commerce as retail products, ingredients for further processing, purchases for Federal food assistance programs, and exports to other countries. Services provided by the program enhance the marketability and add value to dairy products and foods that contain dairy. Dairy products manufactured in plants complying with the USDA inspection requirements are eligible to be graded against official quality standards and specifications established by AMS. Dairy products tested and graded by AMS have certificates issued describing the product's quality and condition.

When the Grading and Inspection Program was implemented, the quality of butter was inconsistent, and quality-control testing by USDA was necessary to ensure a consistent product for the market. Today, plants more consistently manufacture high-quality butter products and maintain the butterfat standard necessary to be granted a USDA grade label for butter.

Currently, USDA inspectors or designated plant personnel perform tests of butter samples that have been selected by a USDA inspector for quality control on randomized batches of finished product pursuant to 7 CFR 58.338. Testing frequency varies by the volume of butter processed and whether a batch is randomly selected. Typically, USDA conducts monthly or weekly testing depending on the volume of butter processed. It is also current industry practice for plants to perform routine internal tests on their butter products to ensure quality and compliance with composition standards. Specific requirements for these tests are outlined in 7 CFR 58.336.

During manufacturing it is normal to have fluctuations in butterfat composition at different stages in butter making and, consequently, test results may not be consistent throughout the process. Therefore, butter processing plants continually monitor butterfat composition throughout production and make necessary adjustments to maintain the 80

percent butterfat required for butter (7 CFR 58.305). The plant maintains these monitoring records as part of its internal quality program and testing procedures.

Under the current Dairy Grading and Inspection Program, USDA conducts a single butterfat test at the time of grading, which provides a limited perspective on overall butterfat composition of butter manufactured by the plant.

The amendments will provide plants an alternative to butterfat testing administered by a USDA inspector and allow in-plant quality control testing to satisfy butterfat testing requirements. This final rule authorizes a review of a plant's testing records performed by AMS as an alternative to testing performed by a USDA inspector at the time of grading. A records review of a plant's routine testing rather than a single-point test provides a more accurate picture of whether the plant's butter products meet quality standards. It also reduces costs to a plant by providing an alternative to duplicate butterfat testing by a USDA inspector. As explained in the Regulatory Flexibility Analysis below, AMS estimates authorizing an alternative records review option will save participating plants \$4,560 to \$31,560 annually.

Currently, the final butter product must contain a minimum of 80 percent butterfat by weight for it to comply with the regulations. That requirement will not change as a result of this final rule. However, pursuant to this rule, AMS will annually review each plant's butterfat test records to gauge the plant's compliance with the regulations. Butterfat tests are already conducted as a normal, standard business operating procedure by plants that manufacture butter. If a records review reveals a plant is out of compliance, AMS will perform more frequent reviews to determine what preventative and corrective actions are being taken. As described below, failure to rectify the problem over multiple consecutive reviews may result in ineligibility to use the USDA Grade Label shield on products produced by the plant.

Records inspected include plant records of butterfat tests performed as required under 7 CFR 58.336, and analysis of records. The change to the recordkeeping requirements applies to records kept in the regular course of business by the plant. As records will be reviewed on-site by USDA inspectors, plants will not be required to submit information to the agency.

A proposed rule was published in the *Federal Register* on August 15, 2023 (88 FR 55426). Copies of the proposed rule were made available through the internet by the USDA and the Office of the Federal Register. The rule provided a 60-day comment period which ended October 16, 2023. Seven comments were received. Four of the comments supported the proposed changes. The comments in support of the rule noted the change will continue to promote high quality products and will lower the cost to manufacturers, which will result in savings to the consumer.

Of the four supportive comments, the American Butter Institute (ABI) requested clarification on four items related to this rulemaking. First, ABI asked which tests will be reviewed. The tests reviewed must be sufficient to evaluate the plant's process to control quality and adjust butterfat composition during manufacturing and ensure final butterfat composition meets the 80 percent requirement. Tests may include but are not limited to Kohman method or inline and benchtop infrared analysis.

Second, ABI sought clarification on which records will be reviewed. Records reviewed will vary by plant depending on which records are kept by the individual plant in the normal course of business. Records reviewed may include the plant's sample selection process, butterfat testing methods, quality control of butterfat composition during manufacturing, final butterfat results, management of out of specification product, and training documentation. Review of records will be on an annual basis.

Third, ABI sought clarification on accepted butterfat testing methodologies. Acceptable testing methodologies include those that are intended for the analysis of

butterfat composition in butter. Testing equipment may be calibrated using the Kohman or modified Kohman as a reference testing method. Additional validated methodologies available in the future may be considered provided the purpose of the test is for the analysis of butterfat composition.

Fourth, ABI requested clarification on compliance and enforcement. If during a normal review of records, a plant is found to have test records demonstrating the plant's butter products did not meet composition requirements, USDA will review additional documentation. Such additional documentation will include the plant's policy to maintain butterfat composition, corrective actions taken after product was found to not meet the 80 percent requirement, and training and/or preventative measures taken to reduce the occurrence of butter products not meeting composition requirements.

If a plant fails to take corrective action as instructed by USDA over the course of three consecutive reviews, or releases product not meeting the composition requirement on three occasions, USDA may notify the plant to discontinue use of the butter shield.

Two commenters opposing the proposed rule expressed concern that allowing plants to forego a USDA inspection in favor of a records review of an in-house or third-party testing regime could jeopardize quality for consumers. An additional commenter expressed the change would impact the value of the 'Made in Wisconsin' butter symbol because of what the commentor viewed as less regulatory oversight. The rule does not lessen USDA's oversight of plants to ensure adherence to the regulations and the quality standards set by USDA. USDA will conduct a review of each butter manufacturing plant's quality production records to verify the butterfat testing program meets regulatory requirements. Additionally, third-party industry laboratory test experts routinely audit and validate non-USDA-laboratory test procedures. The review of records provided by this rule offers USDA a more thorough view of the composition of a plant's butter

products over time, rather than a single point in time test, to ensure product is meeting the required butterfat composition standard.

AMS is making no changes to the proposed rule based on these comments.

Finally, this final rule corrects a misspelling in the regulations. A revision to § 58.336(a) replaces the word “insure” with “ensure.” ABI commented that the correction should also be made to the new § 58.336(b). AMS agrees and is making the corresponding change.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. chapter 35), AMS requested approval of new information collection and recordkeeping requirements for the AMS Dairy Grading and Inspection Program and comments were invited on this new information collection. AMS received no public comments on the Office of Management and Budget (OMB)-approved information collection portion of the final rule.

Title: Regulations Governing the Review of Butterfat Testing Records for the Dairy Grading and Inspection Butter Program.

OMB Number: 0581-0340

Expiration Date of Approval: This is a NEW collection.

Type of Request: Approval of New Information Collection.

Abstract: The Dairy Grading and Inspection Program is a voluntary, fee-based program authorized under the Agricultural Marketing Act (AMA) of 1946 (7 U.S.C. 1621-1627). The regulations governing inspection and grading services of manufactured or processed dairy products are contained in 7 CFR part 58. Under the program, a plant can submit to grading and inspection of its butter products by a USDA grader following the U.S. Grade Standards to ensure each product meet the U.S. grade requirements. This program provides uniform quality of dairy products in the marketplace. The information

collection requirements in this request are essential to carry out the intent of the AMA—to ensure that dairy products are produced under sanitary conditions and buyers are purchasing a quality product.

Estimate of Burden: Public recordkeeping burden for this collection of information is estimated to average 2.5 hours per year.

Recordkeepers: Butter manufacturers.

Estimated Number of Recordkeepers: 17.

Estimated Number of Hours per Recordkeeper: 2.5 hours.

Estimated Total Annual Burden on Recordkeepers: 42.5 hours.

Comments: No comments were received on the information collection in the proposed rule.

The information collection adds an annual review of a plant's butterfat testing records as an alternative to testing by USDA inspectors. The review encompasses plant records of butterfat tests performed as required under 7 CFR 58.336, and analysis of records. Plants seeking USDA inspection for butter grading conduct their own routine, audited, butterfat tests to ensure quality and compliance with composition standards. The information sought in this collection is contained in records kept in the regular course of business by the inspected plant. Records will be reviewed on-site by a USDA inspector. The plant will not be required to submit information to the agency.

E-Government Act

USDA is committed to complying with the E-Government Act (44 U.S.C. 3601, *et seq.*) by promoting the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Orders 12866 and 13563

USDA is issuing this rule in conformance with Executive Orders 12866 and 13563, which direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866; and therefore, has not been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have a retroactive effect. This rule will not preempt any State or local laws, regulations, or policies unless they present an irreconcilable conflict with this rule.

Regulatory Flexibility Analysis

Pursuant to the requirements set forth in the Regulatory Flexibility Act (5 U.S.C. 601-612), AMS has considered the economic impact of the action on small entities. Accordingly, AMS has prepared this Regulatory Flexibility Analysis (RFA).

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions so that small businesses will not be unduly or disproportionately burdened. The Small Business Administration's definition (13 CFR 121.201) of small agricultural service firms, which includes dairy processors, varies based on the type of dairy product manufactured. Small butter manufacturers processors are defined as having 750 or fewer employees. Seventeen (17) plants producing grade label butter in the U.S. participate in the Grade Label Program. According to AMS calculations, about twelve (12), or approximately two-thirds, are operated by dairy farmer cooperatives, while the

remaining five (5) are independently owned. AMS estimates that six (6) of the seventeen (17) participating butter processors would be considered small businesses.

AMS has determined that establishment of this proposal will not have a significant economic impact on small entities. The Dairy Program Grading and Inspection Program is a voluntary program. Small businesses have the option to participate. The change will not unduly or disproportionately burden small butter processing entities. It will reduce costs to small businesses by providing an alternative to a redundant butterfat test currently performed by USDA. AMS expects most or all plants to choose a review of records. AMS estimates the cost to plants for meeting USDA butterfat testing requirements ranges from \$5,000 to \$32,000 annually. The significant cost difference depends on whether the plant has an approved onsite laboratory or must ship samples to an outside AMS laboratory, and the frequency of butterfat samples submitted for testing.

The change will add a review of records of butterfat tests that manufacturers currently conduct in the normal course of business to ensure quality and compliance with composition standards as an alternative to a USDA-inspector test. The plants will be charged for the inspectors' time to conduct the records review, estimated to take four hours annually. At an hourly rate of \$110, a records review will cost the plant approximately \$440. This results in annual net saving to plants ranging from \$4,560 to \$31,560.

Program provisions will be applied uniformly to both large and small businesses and is not expected to burden small entities unduly or disproportionately.

Executive Order 13175

This rule has been reviewed under E.O. 13175—Consultation and Coordination with Indian Tribal Governments, which requires agencies to consider whether their rulemaking actions would have Tribal implications. AMS has determined that this rule is

unlikely to have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

List of Subjects in 7 CFR Part 58

Dairy product, Food grades and standards, Food labeling, Reporting and recordkeeping requirements.

For reasons set forth in the preamble, the Agricultural Marketing Service amends 7 CFR part 58 as follows:

PART 58 – GRADING AND INSPECTION, GENERAL SPECIFICATIONS FOR APPROVED PLANTS AND STANDARDS FOR GRADES OF DAIRY PRODUCTS

1. The authority for part 58 continues to read as follows:

Authority: 7 U.S.C. 1621-1627.

2. Amend § 58.148 by adding paragraph (h) to read as follows:

§ 58.148 Plant records.

* * * * *

(h) Butterfat test records. Retain for 12 months.

3. Amend § 58.336 by revising paragraphs (a) and (b) to read as follows:

§ 58.336 Frequency of sampling for quality control of cream, butter and related products.

(a) *Microbiological.* Samples shall be taken from churnings or batches and should be taken as often as is necessary to ensure microbiological control.

(b) *Sampling and testing.* -- (1) *Composition.* Sampling and testing for product composition shall be made on churns or batches as often as is necessary to ensure adequate composition control. For in-plant control, the Kohman or modified Kohman test may be used.

(2) *Sampling.* Butterfat sampling may be performed as part of an in-plant quality program.

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Erin Morris,

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Agricultural Marketing Service.

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