

2021 SUPPORTING STATEMENT

REGULATIONS GOVERNING THE INSPECTION AND GRADING OF MANUFACTURED OR PROCESSED DAIRY PRODUCTS – RECORD KEEPING OMB NO. 0581-0110

A. Justification.

- 1. EXPLAIN THE CIRCUMSTANCES THAT MAKE THE COLLECTION OF INFORMATION NECESSARY. IDENTIFY ANY LEGAL OR ADMINISTRATIVE REQUIREMENTS THAT NECESSITATE THE COLLECTION.**

The Agricultural Marketing Act of 1946 (7 U.S.C. 1621 et seq.) directs the Department to develop programs that will provide for and facilitate the marketing of agricultural products. One of these programs is the USDA voluntary inspection and grading program for dairy products (7 CFR Part 58) where dairy products are graded according to U.S. grade standards by a USDA grader. Dairy processors, buyers, retailers, institutional users, and consumers have requested that such a program be developed to assure the uniform quality of dairy products purchased. In order for any service program to perform satisfactorily, there must be written guides and rules, which in this case are regulations for the provider and user. For the above reasons, these regulations were developed and issued under the authority of the Act. These regulations are essential to administer the program needed by the user and to carry out the purposes of the Act.

- 2. INDICATE HOW, BY WHOM, AND FOR WHAT PURPOSE THE INFORMATION IS TO BE USED. EXCEPT FOR A NEW COLLECTION, INDICATE THE ACTUAL USE THE AGENCY HAS MADE OF THE INFORMATION RECEIVED FROM THE CURRENT COLLECTION.**

The dairy inspection program ensures that dairy products are produced under sanitary conditions and buyers are purchasing a quality product. In order for the Regulations Governing the Inspection and Grading of Manufactured or Processed Dairy Products to serve the government, industry, and the consumer, laboratory test results must be recorded.

The first section of the regulations requiring recordkeeping, Paragraph 58.139, records the quality testing of milk from new

producers. Examination of milk is done on the first shipment from producers shipping milk to a plant for the first time or after a period of no shipment. The milk must meet the requirements for “acceptable milk” as outlined in the regulations.

The second section of the regulations, Paragraph 58.148, requires maintaining records of tests and analysis performed in the laboratory or throughout the plant during storage, processing, and manufacturing on all raw milk and dairy products.

The third recordkeeping section, Paragraph 58.441, provides for recording the process for the various steps of setting, cutting, cooking, draining the whey, and milling the curd in order to promote a uniform quality of cheese.

Without requiring recordkeeping of laboratory testing results, inspectors would not be able to evaluate the quality of dairy products. The required records are routinely reviewed and evaluated during the inspection of the dairy plant facilities for USDA approval.

3. DESCRIBE WHETHER, AND TO WHAT EXTENT, THE COLLECTION OF INFORMATION INVOLVES THE USE OF AUTOMATED, ELECTRONIC, MECHANICAL, OR OTHER TECHNOLOGICAL COLLECTION TECHNIQUES OR OTHER FORMS OF INFORMATION TECHNOLOGY, E.G. PERMITTING ELECTRONIC SUBMISSION OF RESPONSES, AND THE BASIS FOR THE DECISION FOR ADOPTING THIS MEANS OF COLLECTION. ALSO DESCRIBE ANY CONSIDERATION OF USING INFORMATION TECHNOLOGY TO REDUCE BURDEN.

Currently, the respondents do not have to submit the responses to USDA. They are only required to maintain the records for review and evaluation by a USDA inspector during the time of an inspection. The format and preparation of the records is up to the respondent provided the necessary items are included. No technical or legal obstacles to reducing recordkeeping burden are foreseen.

4. DESCRIBE EFFORTS TO IDENTIFY DUPLICATION. SHOW SPECIFICALLY WHY ANY SIMILAR INFORMATION ALREADY

AVAILABLE CANNOT BE USED OR MODIFIED FOR USE FOR THE PURPOSE(S) DESCRIBED IN ITEM 2 ABOVE.

Recordkeeping of test results apply to each specific plant or operation; therefore, there is little chance of duplication. The recordkeeping of test results is not available from any other source since it is specific to a certain dairy sample.

5. IF THE COLLECTION OF INFORMATION IMPACTS SMALL BUSINESSES OR OTHER SMALL ENTITIES (ITEM 5 OF THE OMB FORM 83-1), DESCRIBE THE METHODS USED TO MINIMIZE BURDEN.

The Small Business Administration defines, in 13 CFR part 121, small agricultural producers as those having annual receipts of no more than \$750,000 and small agricultural service firms (first handlers and importers) as those having annual receipts of no more than \$6.5 million. Under these definitions, we estimate 10% of producers, first handlers, and importers would be classified as small entities. The information collection and reporting burden is relatively small, and requiring the same reporting requirements for all first handlers and producers does not significantly disadvantage any first handler or producer that is smaller than the industry average.

6. DESCRIBE THE CONSEQUENCE TO FEDERAL PROGRAM OR POLICY ACTIVITIES IF THE COLLECTION IS NOT CONDUCTED OR IS CONDUCTED LESS FREQUENTLY, AS WELL AS ANY TECHNICAL OR LEGAL OBSTACLES TO REDUCING BURDEN.

If this collection is not approved, the quality of raw milk used in graded dairy products could not be evaluated. The quality of raw milk can have public health significance.

7. EXPLAIN ANY SPECIAL CIRCUMSTANCES THAT WOULD CAUSE AN INFORMATION COLLECTION TO BE CONDUCTED IN A MANNER:

- **REQUIRING RESPONDENTS TO REPORT INFORMATION TO THE AGENCY MORE OFTEN THAN QUARTERLY;**
- **REQUIRING RESPONDENTS TO PREPARE A WRITTEN RESPONSE TO A COLLECTION OF INFORMATION IN FEWER THAN 30 DAYS AFTER RECEIPT OF IT;**

- **REQUIRING RESPONDENTS TO SUBMIT MORE THAN AN ORIGINAL AND TWO COPIES OF ANY DOCUMENT;**

Respondents are not required to submit information to the agency. The records are to be maintained and made available for evaluation by a USDA inspector during the time of an inspection.

- **REQUIRING RESPONDENTS TO RETAIN RECORDS, OTHER THAN HEALTH, MEDICAL, GOVERNMENT CONTRACT, GRANT-IN-AID, OR TAX RECORDS FOR MORE THAN 3 YEARS;**

Respondents are required to retain records pertaining to the shipment of product exported for 1 year or until the records are reviewed by USDA AMS representatives.

- **IN CONNECTION WITH A STATISTICAL SURVEY, THAT IS NOT DESIGNED TO PRODUCE VALID AND RELIABLE RESULTS THAT CAN BE GENERALIZED TO THE UNIVERSE OF STUDY;**

- **REQUIRING THE USE OF A STATISTICAL DATA CLASSIFICATION THAT HAS NOT BEEN REVIEWED AND APPROVED BY OMB;**

- **THAT INCLUDES A PLEDGE OF CONFIDENTIALITY THAT IS NOT SUPPORTED BY AUTHORITY ESTABLISHED IN STATUE OR REGULATION, THAT IS NOT SUPPORTED BY DISCLOSURE AND DATA SECURITY POLICIES THAT ARE CONSISTENT WITH THE PLEDGE, OR WHICH UNNECESSARILY IMPEDES SHARING OF DATA WITH OTHER AGENCIES FOR COMPATIBLE CONFIDENTIAL USE; OR**

- **REQUIRING RESPONDENTS TO SUBMIT PROPRIETARY TRADE SECRET, OR OTHER CONFIDENTIAL INFORMATION UNLESS THE AGENCY CAN DEMONSTRATE THAT IT HAS INSTITUTED PROCEDURES**

**TO PROTECT THE INFORMATION'S CONFIDENTIALITY
TO THE EXTENT PERMITTED BY LAW.**

There are no other special circumstances. The collection of information is conducted in a manner consistent with the guidelines in 5 CFR 1320.6, which gives administrative personnel instructions on controlling paperwork burdens on the public.

8. **IF APPLICABLE, PROVIDE A COPY AND IDENTIFY THE DATE AND PAGE NUMBER OF PUBLICATION IN THE FEDERAL REGISTER OF THE AGENCY'S NOTICE, REQUIRED BY 5 CFR 1320.8(d), SOLICITING COMMENTS ON THE INFORMATION COLLECTION PRIOR TO SUBMISSION TO OMB. SUMMARIZE PUBLIC COMMENTS RECEIVED IN RESPONSE TO THAT NOTICE AND DESCRIBE ACTIONS TAKEN BY THE AGENCY IN RESPONSE TO THESE COMMENTS. SPECIFICALLY ADDRESS COMMENTS RECEIVED ON COST AND HOUR BURDEN.**

The agency published a notice in the Federal Register on April 13, 2021, Vol. 86 No. 69 (86 FR 19211) announcing its request for comments. No comments were received.

DESCRIBE EFFORTS TO CONSULT WITH PERSONS OUTSIDE THE AGENCY TO OBTAIN THEIR VIEWS ON THE AVAILABILITY OF DATA, FREQUENCY OF COLLECTION, THE CLARITY OF INSTRUCTIONS AND RECORDKEEPING, DISCLOSURE, OR REPORTING FORMAT (IF ANY), AND ON THE DATA ELEMENTS TO BE RECORDED, DISCLOSED, OR REPORTED.

CONSULTATION WITH REPRESENTATIVES OF THOSE FROM WHOM INFORMATION IS TO BE OBTAINED OR THOSE WHO MUST COMPILE RECORDS SHOULD OCCUR AT LEAST ONCE EVERY 3 YEARS -- EVEN IF THE COLLECTION OF INFORMATION ACTIVITY IS THE SAME AS IN PRIOR PERIODS. THERE MAY BE CIRCUMSTANCES THAT MAY PRECLUDE CONSULTATION IN A SPECIFIC SITUATION. THESE CIRCUMSTANCES SHOULD BE EXPLAINED.

The information requested by the Department is data routinely collected by the respondents for their internal quality control needs. The Department only reviews records already existing. The Department routinely consults with the Trade Associations representing the segments of the dairy industry in which we provide service on topics of mutual concern. The four organizations identified (ADPI, USDEC, IDFA, and NMPF) are the nationally recognized membership organizations for U.S. dairy producers, processors and exporters. Specific consultations on the reporting requirements may or may not have been discussed with each of the following:

Mr. David Thomas

Chief Executive Officer
American Dairy Products Institute
116 N. York St. Suite 200
Elmhurst, IL 60126

Mr. Matt McKnight
Chief Operating Officer
U.S. Dairy Export Council
2107 Wilson Blvd. Suite 600
Arlington, VA 22201-3061

Ms. Cary Frye
Senior Vice President of Regulatory Affairs
International Dairy Foods Association
1250 H Street, NW, Suite 900
Washington, D.C. 20005

9. EXPLAIN ANY DECISION TO PROVIDE ANY PAYMENT OR GIFT TO RESPONDENTS, OTHER THAN REMUNERATION OF CONTRACTORS OR GRANTEES.

No payments or gifts are provided to respondents.

10. DESCRIBE ANY ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS AND THE BASIS FOR THE ASSURANCE IN STATUTE, REGULATION, OR AGENCY POLICY.

Dairy Grading Branch policy instructs employees that all record information concerning an inspected dairy plant shall be maintained as confidential and subject only to disclosures required by Department policy for the response to Freedom of Information Act (FOIA) requests.

11. PROVIDE ADDITIONAL JUSTIFICATION FOR ANY QUESTIONS OF A SENSITIVE NATURE, SUCH AS SEXUAL BEHAVIOR AND ATTITUDES, RELIGIOUS BELIEFS, AND OTHER MATTERS THAT ARE COMMONLY CONSIDERED PRIVATE. THIS JUSTIFICATION SHOULD INCLUDE THE REASONS WHY THE AGENCY CONSIDERS THE QUESTIONS NECESSARY, THE SPECIFIC USES TO BE MADE OF THE INFORMATION, THE EXPLANATION TO BE GIVEN TO PERSONS FROM WHOM THE INFORMATION IS REQUESTED, AND ANY STEPS

TO BE TAKEN TO OBTAIN THEIR CONSENT.

There are no requested responses of a sensitive nature.

12. PROVIDE ESTIMATES OF THE HOUR BURDEN OF THE COLLECTION OF INFORMATION.

THE STATEMENT SHOULD:

- **INDICATE THE NUMBER OF RESPONDENTS, FREQUENCY OF RESPONSE, ANNUAL HOUR BURDEN, AND AN EXPLANATION OF HOW THE BURDEN WAS ESTIMATED. UNLESS DIRECTED TO DO SO, AGENCIES SHOULD NOT CONDUCT SPECIAL SURVEYS TO OBTAIN INFORMATION ON WHICH TO BASE HOUR BURDEN ESTIMATES. CONSULTATION WITH A SAMPLE (FEWER THAN 10) OF POTENTIAL RESPONDENTS IS DESIRABLE. IF THE HOUR BURDEN ON RESPONDENTS IS EXPECTED TO VARY WIDELY BECAUSE OF DIFFERENCE IN ACTIVITY, SIZE, OR COMPLEXITY, SHOW THE RANGE OF ESTIMATED HOUR BURDEN, AND EXPLAIN THE REASONS FOR THE VARIANCE. GENERALLY, ESTIMATES SHOULD NOT INCLUDE BURDEN HOURS FOR CUSTOMARY AND USUAL BUSINESS PRACTICES.**

- **IF THIS REQUEST FOR APPROVAL COVERS MORE THAN ONE FORM, PROVIDE SEPARATE HOUR BURDEN ESTIMATES FOR EACH FORM AND AGGREGATE THE HOUR BURDENS IN ITEM 13 OF OMB FORM 83-I.**

Estimates of the recordkeeping burden have been summarized on the AMS-71 form.

- **PROVIDE ESTIMATES OF ANNUALIZED COST TO RESPONDENTS FOR THE HOUR BURDENS FOR COLLECTIONS OF INFORMATION, IDENTIFYING AND USING APPROPRIATE WAGE RATE CATEGORIES.**

The estimated total recordkeeping burden for all users of the service is estimated at 962 burden hours or 362 recordkeepers.

According to the Bureau of Labor Statistics (www.bls.gov) the typical hourly rate of a Quality Manager; is \$36.93 per hour. The hourly rate is based on the May 2020, BLS data for Farmers, Ranchers, and Other Agricultural Manager Occupational Profile. The annualized cost to all respondents is \$35,527 (\$36.93 x 962). As an offsetting benefit, the records required by USDA are also records that are routinely used by the inspected facility for their own supervisory and quality control purposes.

13. PROVIDE AN ESTIMATE OF THE TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORDKEEPERS RESULTING FROM THE COLLECTION OF INFORMATION. (DO NOT INCLUDE THE COST OF ANY HOUR BURDEN SHOWN IN ITEMS 12 AND 14).

- **THE COST ESTIMATE SHOULD BE SPLIT INTO TWO COMPONENTS: (a) A TOTAL CAPITAL AND START-UP COST COMPONENT (ANNUALIZED OVER ITS EXPECTED USEFUL LIFE); AND (b) A TOTAL OPERATION AND MAINTENANCE AND PURCHASE OF SERVICES COMPONENT. THE ESTIMATES SHOULD TAKE INTO ACCOUNT COSTS ASSOCIATED WITH GENERATING, MAINTAINING, AND DISCLOSING OR PROVIDING THE INFORMATION. INCLUDE DESCRIPTIONS OF METHODS USED TO ESTIMATE MAJOR COST FACTORS INCLUDING SYSTEM AND TECHNOLOGY ACQUISITION, EXPECTED USEFUL LIFE OF CAPITAL EQUIPMENT, THE DISCOUNT RATE(S), AND THE TIME PERIOD OVER WHICH COSTS WILL BE INCURRED. CAPITAL AND START-UP COSTS INCLUDE, AMONG OTHER ITEMS, PREPARATIONS FOR COLLECTING INFORMATION SUCH AS PURCHASING COMPUTERS AND SOFTWARE; MONITORING, SAMPLING, DRILLING AND TESTING EQUIPMENT; AND RECORD STORAGE FACILITIES.**

- **IF COST ESTIMATES ARE EXPECTED TO VARY WIDELY, AGENCIES SHOULD PRESENT RANGES OF COST BURDENS AND EXPLAIN THE REASONS FOR THE VARIANCE. THE COST OF PURCHASING OR CONTRACTING OUT INFORMATION COLLECTION SERVICES SHOULD BE A PART OF THIS COST BURDEN ESTIMATE. IN DEVELOPING COST BURDEN ESTIMATES, AGENCIES MAY CONSULT WITH A SAMPLE OF**

RESPONDENTS (FEWER THAN 10), UTILIZE THE 60-DAY PRE-OMB SUBMISSION PUBLIC COMMENT PROCESS AND USE EXISTING ECONOMIC OR REGULATORY IMPACT ANALYSIS ASSOCIATED WITH THE RULEMAKING CONTAINING THE INFORMATION COLLECTION, AS APPROPRIATE.

- **GENERALLY, ESTIMATES SHOULD NOT INCLUDE PURCHASES OF EQUIPMENT OR SERVICES, OR PORTIONS THEREOF, MADE: (1) PRIOR TO OCTOBER 1, 1995, (2) TO ACHIEVE REGULATORY COMPLIANCE WITH REQUIREMENTS NOT ASSOCIATED WITH THE INFORMATION COLLECTION, (3) FOR REASONS OTHER THAN TO PROVIDE INFORMATION OR KEEPING RECORDS FOR THE GOVERNMENT, OR (4) AS PART OF CUSTOMARY AND USUAL BUSINESS OR PRIVATE PRACTICES.**

There are no capital start-up or operation and maintenance costs.

- 14. PROVIDE ESTIMATES OF ANNUALIZED COST TO THE FEDERAL GOVERNMENT. ALSO, PROVIDE A DESCRIPTION OF THE METHOD USED TO ESTIMATE COST, WHICH SHOULD INCLUDE QUANTIFICATION OF HOURS, OPERATION EXPENSES (SUCH AS EQUIPMENT, OVERHEAD, PRINTING, AND SUPPORT STAFF), AND ANY OTHER EXPENSE THAT WOULD NOT HAVE BEEN INCURRED WITHOUT THIS COLLECTION OF INFORMATION. AGENCIES ALSO MAY AGGREGATE COST ESTIMATES FROM ITEMS 12, 13, AND 14 IN A SINGLE TABLE.**

There is no direct cost to the Federal government because this is a voluntary, user-fee funded program and all costs are recovered.

- 15. EXPLAIN THE REASON FOR ANY PROGRAM CHANGES OR ADJUSTMENTS REPORTED IN ITEMS 13 OR 14 OF THE OMB FORM 83-1.**

Dairy Program has reduced the number of respondents by 7 and the burden by 45 hours since the last submission of this collection. The burden hours which are based on the number of inspections have

declined due to the number of plants participating in voluntarily inspections.

- 16. FOR COLLECTIONS OF INFORMATION WHOSE RESULTS WILL BE PUBLISHED, OUTLINE PLANS FOR TABULATION, AND PUBLICATION. ADDRESS ANY COMPLEX ANALYTICAL TECHNIQUES THAT WILL BE USED. PROVIDE THE TIME SCHEDULE FOR THE ENTIRE PROJECT, INCLUDING BEGINNING AND ENDING DATES OF THE COLLECTION OF INFORMATION, COMPLETION OF REPORT, PUBLICATION DATES, AND OTHER ACTIONS.**

Information under this request is not published.

- 17. IF SEEKING APPROVAL TO NOT DISPLAY THE EXPIRATION DATE FOR OMB APPROVAL OF THE INFORMATION COLLECTION, EXPLAIN THE REASONS THAT DISPLAY WOULD BE INAPPROPRIATE.**

The records that are reviewed by USDA are also records that are routinely used by the inspected facility for their own supervisory and quality control purposes. USDA does not require the submission of this information on any forms.

- 18. EXPLAIN EACH EXCEPTION TO THE CERTIFICATION STATEMENT IDENTIFIED IN ITEM 19, "CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS," OF OMB FORM 83-1.**

The agency is able to certify compliance with all provisions under Item 19 of OMB Form 83-I.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

THE AGENCY SHOULD BE PREPARED TO JUSTIFY ITS DECISION NOT TO USE STATISTICAL METHODS IN ANY CASE WHERE SUCH METHODS MIGHT REDUCE BURDEN OR IMPROVE ACCURACY OF RESULTS. WHEN ITEM 17 ON THE FORM OMB 83-1 IS CHECKED "YES", THE FOLLOWING DOCUMENTATION SHOULD BE INCLUDED IN THE SUPPORTING STATEMENT TO THE EXTENT THAT IT APPLIES TO THE METHODS

PROPOSED.

The proposed information collection procedures do not employ statistical methods of collection. The records must be maintained for each individual producer, as the data has no relation to other producers.