



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-1939]

Requirements for Additional Traceability Records for Certain Foods; Exemption for Cottage Cheese Regulated by the National Conference on Interstate Milk Shipments Grade “A” Pasteurized Milk Ordinance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of exemption

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing that we are granting an exemption for certain cottage cheese products from the requirements of the rule titled “Requirements for Additional Traceability Records for Certain Foods” (the Food Traceability Rule). The Agency is taking this action in accordance with the FDA Food Safety Modernization Act and FDA’s implementing regulations.

DATES: This exemption is effective on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this document into the “Search” box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Katie Vierk, Office of Surveillance Strategy and Risk Prioritization, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-2122, Katherine.Vierk@fda.hhs.gov; or Alissa Van Wie, Office of Policy and International Engagement, Human Foods Program, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-654-7524, Alissa.VanWie@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 2022, FDA published in the *Federal Register* (87 FR 70910) a final rule titled “Requirements for Additional Traceability Records for Certain Foods” (the Food Traceability Rule), which established additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods the Agency has designated for inclusion on the Food Traceability List (FTL). In the preamble to the final rule, we announced our intention to consider initiating a process under the new regulation (codified in subpart S of part 1 of title 21 of the Code of Federal Regulations (CFR)) to determine whether to exempt cottage cheese regulated under the Grade “A” Pasteurized Milk Ordinance (PMO) from the requirements of the Food Traceability Rule (87 FR 70910 at 70932).

On June 17, 2024, FDA published a notice in the *Federal Register* (89 FR 51281) (“2024 Notice”) announcing that the Agency was initiating a process in accordance with § 1.1360 (21 CFR 1.1360) *et seq.* to determine whether it would be appropriate to exempt Grade “A” cottage cheese that appears on the Interstate Milk Shippers (IMS) List (“IMS listed Grade “A” cottage cheese”) from the Food Traceability Rule. FDA received several comments in response to the notice of the proposed exemption, as discussed below. In this notice we are announcing our determination that granting this exemption is appropriate, and we are therefore granting the exemption.

This action exempts entities that handle IMS listed Grade “A” cottage cheese from the regulatory requirements of the Food Traceability Rule that would otherwise apply to their handling of that product.

II. IMS Listed Grade “A” Cottage Cheese

As noted in the 2024 Notice, cottage cheese is currently covered by the Food Traceability Rule because it is included on the FTL in the commodity “Cheese (made from pasteurized milk), fresh soft or soft unripened.” However, FDA recognizes that much of the

cottage cheese produced in the United States is regulated through the National Conference on Interstate Milk Shipments (NCIMS). NCIMS is a cooperative program among the United States Public Health Service (USPHS), FDA, the States, and the dairy industry, with the objective of promoting the availability of a high-quality milk supply (Ref. 1 and Ref. 2). FDA and NCIMS have together developed a cooperative, Federal-State program (the Interstate Milk Shippers Program, or IMS Program) to ensure the sanitary quality of milk and milk products shipped interstate. All 50 States and the District of Columbia participate in the IMS Program.

The IMS Program is implemented and enforced by the States, with FDA providing oversight, including scientific, technical, and inspection expertise as set forth in an active 1977 Memorandum of Understanding (MOU) between FDA and NCIMS (Ref. 2). As described in the MOU, the IMS Program relies on the Pasteurized Milk Ordinance (PMO). The PMO incorporates relevant Federal requirements and related technical documents for the sanitary standards, requirements, and procedures it follows to ensure the safety and wholesomeness of Grade “A” milk and milk products, including cottage cheese. FDA considers these standards, requirements, and procedures to be adequate for the protection of the health and safety of the consumer (Ref. 2). The NCIMS recommends changes and modifications to the PMO and other related technical documents at its biennial conferences (Ref. 3). This ensures that the PMO represents the most current science-based knowledge and experience concerning the safe production and processing of Grade “A” milk products and incorporates the latest Federal requirements for food safety (Ref. 3).

The discussion of the PMO in the 2024 Notice was based on the 2019 Revision of the PMO. On August 9, 2024, FDA announced the availability of the 2023 Revision of the PMO (Ref. 4 and Ref. 5). This revision does not include any significant changes to the processing requirements for cottage cheese. We noted in the 2024 Notice that we did not expect future revisions of the PMO to deviate from the 2019 Revision in material ways that would affect our conclusion that IMS listed Grade “A” cottage cheese should be exempt from the requirements of

subpart S, nor did we think past revisions were materially different in ways that would affect this conclusion. This continues to be our expectation, and after reviewing the 2023 Revision we have concluded that it does not deviate from the 2019 Revision in ways that are material to our conclusion that IMS listed Grade “A” cottage cheese should be exempt from the requirements of subpart S.

Interstate milk and milk product shippers who have been certified by Milk Sanitation Rating Officers as having attained certain identified sanitation compliance, and enforcement ratings are listed on the IMS List. Such certification is based on compliance with the requirements of the PMO. The 2024 Notice proposed to exempt IMS listed Grade “A” cottage cheese from the requirements of the Food Traceability Rule because of the specific processing requirements specified in the PMO that address the risk factors that resulted in the commodity “Cheese (made from pasteurized milk), fresh soft or soft unripened” being on the FTL (and that therefore resulted in cottage cheese being on the FTL), and because of the enhanced regulatory oversight of the manufacturing of IMS listed Grade “A” cottage cheese. As discussed below, this document affirms that conclusion.

III. Comments on Notice of Proposed Exemption

FDA received several comments in response to the 2024 Notice. We summarize and respond to relevant portions of comments in this notice. To make it easier to identify comments and FDA’s responses to the comments, the word “Comment” will appear in parentheses before the description of the comment, and the word “Response” will appear in parentheses before FDA’s response. We have also numbered each comment to help distinguish between different comments. The number assigned to each comment is for organizational purposes only and does not signify the comment’s value, importance, or the order in which it was submitted.

(Comment 1) Several comments assert that an exemption for IMS listed Grade “A” cottage cheese would reduce the regulatory burden without compromising food safety. These comments also maintain that the primary risks associated with cottage cheese, specifically contamination with *Listeria monocytogenes*, are adequately mitigated through the PMO’s requirements for pasteurization, environmental controls, and regular inspections. Comments also assert that enhanced regulatory oversight through the IMS Program provides ample safeguards that render additional traceability records unnecessary for IMS listed Grade “A” cottage cheese.

(Response 1) FDA agrees. As discussed in the 2024 Notice, with regard to IMS listed Grade “A” cottage cheese, we believe an exemption is appropriate because of the processing requirements specified in the PMO that address the risk factors that ultimately resulted in cottage cheese being included on the FTL as part of the commodity “Cheese (made from pasteurized milk), fresh soft or soft unripened,” and because of the enhanced regulatory oversight of the manufacturing of IMS listed Grade “A” cottage cheese through the IMS Program.

(Comment 2): One comment maintains it will be important to ensure that future revisions of the PMO continue to uphold these stringent standards and that if any changes in the PMO weaken safety controls, the exemption should be reconsidered to ensure ongoing protection of public health.

(Response 2) FDA agrees with this comment. As noted in the 2024 Notice, this exemption applies to any IMS listed Grade “A” cottage cheese, including Grade “A” cottage cheese regulated under the 2019 Revision of the PMO or earlier revisions of the PMO (in jurisdictions that might not have adopted the 2019 Revision) and any IMS listed Grade “A” cottage cheese regulated under future revisions of the PMO, once such revisions are released and adopted. As discussed above, we have reviewed the 2023 Revision of the PMO and concluded that it does not deviate from the 2019 Revision in ways that are material to our conclusion that IMS listed Grade “A” cottage cheese should be exempt from the requirements of subpart S.

Given that the PMO’s requirements are based on well-established scientific principles and processes, and given FDA’s own involvement in the PMO and the Grade “A” program (along with the involvement of other public health governmental entities), we do not expect future revisions of the PMO to deviate from the 2019 and 2023 Revisions in material ways that would affect this conclusion. If we subsequently determine that it is necessary to revise or revoke the exemption in order to protect the public health—either because of changes to the PMO or for any other reason—we will follow the procedures set forth in §§ 1.1395 and 1.1400 (21 CFR 1.1395 and 1.1400).

(Comment 3) Some comments maintain that given the rise in popularity of cottage cheese as a protein source, the exemption could lower manufacturing costs and increase production and sales. They assert that these cost reductions should be passed on to consumers, and the exemption should not come at the risk of public health.

(Response 3) FDA agrees that any exemption from the requirements of the Food Traceability Rule should be based on the risk to public health. As noted above, FDA is finalizing this exemption in accordance with § 1.1360 *et seq.* Section 1.1360(a) states, in part, that FDA will exempt a food or type of entity from the Food Traceability Rule when we determine that application of the requirements that would otherwise apply to the food or type of entity is not necessary to protect the public health. We are exempting IMS listed Grade “A” cottage cheese from the requirements of the Food Traceability Rule because the processing requirements specified in the PMO address the risk factors that resulted in cottage cheese being included on the FTL, and because of the enhanced regulatory oversight of the manufacturing of IMS listed Grade “A” cottage cheese through the IMS Program. The popularity of cottage cheese as a protein source and the potential impact of the exemption on manufacturers’ production costs are not relevant to the standard set forth in § 1.1360(a) and therefore were not considered in our evaluation to determine whether an exemption is appropriate.

(Comment 4) One comment notes that the inclusion of cottage cheese on the FTL was based on a comprehensive risk-ranking model, which identified “Cheese (made from pasteurized milk), fresh soft or soft ripened” as having a significant risk of contamination by *Listeria monocytogenes*, primarily based on the potential for post-pasteurization contamination. The comment expresses concern that the proposed exemption overlooks that environmental risks associated with such contamination are still substantial, and maintains that ensuring traceability is essential for promptly identifying and mitigating public health risks. The comment also contends that the effectiveness of the IMS Program heavily depends on consistent implementation and enforcement across all states.

(Response 4) FDA disagrees with this comment insofar as it argues that exempting IMS listed Grade “A” cottage cheese would have an adverse effect on the public health. As described in detail in the 2024 Notice, manufacturers of IMS listed Grade “A” cottage cheese must comply with PMO requirements intended to control pathogens during pasteurization and to prevent contamination during post-pasteurization processing (Ref. 5). Additionally, there are requirements in the PMO pertaining to information that must be documented in records, and provisions that dictate inspectional and sampling frequencies (Ref. 5). We have concluded that these measures provide protections adequate to address the risk factors that resulted in the commodity “Cheese (made from pasteurized milk), fresh soft or soft unripened” being on the FTL.

More specifically, FDA recognizes that the cottage cheese processing steps that occur after milk pasteurization but prior to packaging can present a risk for contamination of in-process food with environmental pathogens, such as *L. monocytogenes*, if sanitary conditions are not maintained. However, we believe the post-pasteurization processing requirements included in the PMO adequately address these risk factors. The PMO contains specific requirements for the

control of critical factors including, but not limited to, pH, filling temperature, and the use of microbial inhibitors and preservatives to address post-pasteurization contamination (Ref. 3).

Finally, we note that this exemption from the Food Traceability Rule's enhanced recordkeeping requirements does not alter the applicability of other laws and regulations related to the manufacturing, processing, packing, or holding of food. Furthermore, in accordance with § 1.1360(b), if a person to whom this exemption applies (including a person who manufactures, processes, packs, or holds IMS listed Grade "A" cottage cheese) is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (per the requirements of 21 CFR part 1, subpart H) with respect to the manufacturing, processing, packing, or holding of the applicable food, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345 (21 CFR 1.337 and 1.345). Such records must be maintained for 2 years.

(Comment 5) One comment questions the need to exempt cottage cheese from the Food Traceability Rule while other dairy products are not exempted. The comment maintains that despite the controls put in place by the PMO, cottage cheese still falls into the category of higher-risk dairy products. This comment also asserts that despite the enhanced regulatory oversight provided by the IMS Program and the PMO, cottage cheese manufactured in the U.S. is already below international quality standards, and it is unclear how lowering the safety standards could be beneficial for end consumers.

(Response 5) There are many dairy products that are not included on the FTL and therefore are not subject to the Food Traceability Rule. Of the dairy products that are on the FTL, cottage cheese is the only one that is addressed by the PMO. As noted above, FDA has concluded that the requirements and other provisions associated with IMS listed Grade "A"

cottage cheese are adequate to address the risk factors that resulted in the commodity “Cheese (made from pasteurized milk), fresh soft or soft unripened” being on the FTL.

The comment does not indicate which international quality standards they are referring to; regardless, food quality measures do not necessarily ensure food safety. In addition, we note that exempting IMS listed Grade “A” cottage cheese from the Food Traceability Rule does not lower safety standards; rather, it reflects the determination that existing regulatory requirements applicable to these products make it unnecessary to apply the recordkeeping requirements of the Food Traceability Rule.

(Comment 6) One comment maintains that in modern society, consumers value transparency and accountability in the food supply chain. The comment asserts that the proposal to exempt certain products from a rule previously in place could erode consumer confidence, particularly if there are subsequent food safety incidents involving cottage cheese or similar products. The comment argues that ensuring full traceability aligns with FDA’s mission to protect public health and reinforces the Agency’s credibility.

(Response 6) In the preamble to the Food Traceability Rule, FDA announced that we were considering initiating a process to determine whether to exempt cottage cheese regulated under the PMO from the rule’s requirements (87 FR 70910 at 70932). We have taken steps to finalize this exemption prior to the rule’s compliance date. We therefore do not agree with the comment’s implication that this exemption will be inconsistent with consumers’ expectations.

More generally, while we acknowledge the goals expressed in the comment, FDA’s authority to promulgate the Food Traceability Rule stems from section 204(d) of the FDA Food Safety Modernization Act (FSMA), under which the rule’s requirements must be limited to foods §the Agency designates for inclusion on the Food Traceability List. The rule’s procedures in 21 CFR 1.1360 *et seq.* for granting modified requirements and exemptions stem from section

204(d)(6)(E) of FSMA. In keeping with both of those provisions, FDA may exempt a food or type of entity from the rule's requirements when we determine that application of the requirements that would otherwise apply to the food or type of entity is not necessary to protect the public health. As stated above, we believe an exemption for IMS listed Grade "A" cottage cheese is appropriate because of the processing requirements specified in the PMO that address the risk factors that resulted in cottage cheese being included on the FTL, and because of the enhanced regulatory oversight of the manufacturing of IMS listed Grade "A" cottage cheese through the IMS Program. If we subsequently determine that it is necessary to revise or revoke the exemption for these products in order to protect the public health, we will follow the procedures set forth in §§ 1.1395 and 1.1400.

(Comment 7) One comment asserts that while cottage cheese is currently strictly monitored under the NCIMS based on the PMO standards, there have not been any significant changes to the current PMO regulations that would prompt the potential exclusion of cottage cheese from the Food Traceability Rule.

(Response 7) This exemption is not based on changes to the PMO requirements. As discussed in Response 6, FDA's announcement that we were considering initiating the process for this exemption was simultaneous with our publication of the Food Traceability Rule. Moreover, as discussed in Response 2, this exemption applies to IMS listed Grade "A" cottage cheese regulated under earlier revisions of the PMO (in jurisdictions that might not have adopted the 2019 Revision or the 2023 Revision), because we do not think that past revisions were materially different in ways that would affect our conclusion that this exemption is appropriate.

IV. Conclusion

As discussed above and as set forth in the 2024 Notice, we proposed exempting IMS listed Grade "A" cottage cheese from the requirements of the Food Traceability Rule because we tentatively concluded that application of the Food Traceability Rule to IMS listed

Grade “A” cottage cheese is not necessary to protect the public health in light of how such cottage cheese is regulated. Based on the comments received on the 2024 Notice, and as discussed above, we conclude an exemption for IMS listed Grade “A” cottage cheese is appropriate because of the processing requirements specified in the PMO that address the risk factors that resulted in cottage cheese being included on the FTL, and because of the enhanced regulatory oversight of the manufacturing of IMS listed Grade “A” cottage cheese through the IMS Program.

Having considered all timely submitted comments, and in accordance with 21 CFR 1.1385(b), we are publishing this document to state that we are granting an exemption from the Food Traceability Rule for IMS listed Grade “A” cottage cheese, for the reasons stated above.

We note that, in accordance with § 1.1360(b), if a person to whom this exemption applies (including a person who manufactures, processes, packs, or holds IMS listed Grade “A” cottage cheese) is required to register with FDA under section 415 of the FD&C Act (per the requirements of 21 CFR Part 1, Subpart H) with respect to the manufacturing, processing, packing, or holding of the applicable food, such person must maintain records identifying the immediate previous source of such food and the immediate subsequent recipient of such food in accordance with §§ 1.337 and 1.345. Such records must be maintained for 2 years.

In accordance with 21 CFR 1.1390, this exemption is effective as of the date this document publishes in the *Federal Register*.

V. References

The following references are on display at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <http://www.regulations.gov>. Although

FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. FDA and NCIMS, “Procedures Governing the Cooperative State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipment (2019 Revision)”, 2019. Available at <https://www.fda.gov/media/138115/download?attachment>. Accessed April 17, 2025.

2. FDA and NCIMS, “Memorandum of Understanding Between the National Conference on Interstate Milk Shipments and the Food and Drug Administration”, 1977. Available at: <https://www.fda.gov/about-fda/mou-225-78-1000>. Accessed March 26, 2025.

3. FDA, “Grade “A” Pasteurized Milk Ordinance (2019 Revision),” 2019. Available at: <https://www.fda.gov/media/140394/download?attachment>. Accessed April 17, 2025.

4. FDA Memorandum, “2023 Revision of the Grade “A” Pasteurized Milk Ordinance (PMO),” M-I-24-02, August 9, 2024. Available at: <https://gams.fda.gov/active/M-I-24-02-PMO-2023-Revision.pdf>. Accessed May 1, 2025.

5. FDA, “Grade “A” Pasteurized Milk Ordinance (2023 Revision),” 2023. Available at: <https://www.fda.gov/media/180975/download?attachment>. Accessed April 17, 2025.

Grace R. Graham,

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