DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. FDA–2024–N–1939]

Requirements for Additional Traceability Records for Certain Foods; Proposed 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: Proposed exemption.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to grant an exemption for certain cottage cheese products from the requirements of the Requirements for Additional Traceability Records for Certain Foods rule (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: Submit either electronic or written comments on the notice by September 16, 2024 to ensure that the Agency considers your comment on the proposed exemption.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2024–N–1939 for ''Requirements for Additional Traceability Records for Certain Foods; Proposed Exemption for Cottage Cheese Regulated by the National Conference on Interstate Milk Shipments Grade ''A'' Pasteurized Milk Ordinance.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Katherine Vierk, Office of Analytics and Outreach, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2122, *Katherine.Vierk@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 2022, FDA published in the **Federal Register** (87 FR 70910) a final rule entitled ''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) (Grade ''A'' cottage cheese) from the requirements of the Food Traceability Rule (87 FR 70910 at 70932).

As contemplated in the preamble to the final rule, we are 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 requirements of the Food Traceability Rule. Section 1.1360(a) states, in part, that FDA will exempt a food or type of entity from the requirements of subpart S 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. Under § 1.1385 (21 CFR 1.1385), if FDA, on our own initiative, determines that granting an exemption from subpart S for a food or type of entity is appropriate, we will publish a notice in

the **Federal Register** setting forth the proposed exemption and the reasons for the proposal. The notice will establish a public docket so interested persons may submit written comments on the proposal.

Currently, cottage cheese is 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 U.S. Public Health Service (USPHS), FDA, the States, and the dairy industry, with the objective of promoting the availability of a high quality milk supply (Refs. 1 and 2). FDA and NCIMS have together developed a cooperative, Federal-State program (the 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 PMO, which 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).

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. Cottage cheese—including lowfat, nonfat, and dry curd—is identified using product code 7 in the IMS sanitation compliance and enforcement ratings (Ref. 4). The proposed exemption would only apply to manufacturers of cottage cheese that are both regulated under PMO requirements and IMS listed for cottage cheese.

As discussed above, cottage cheese is on the FTL because it is included in the commodity ''Cheese (made from pasteurized milk), fresh soft or soft unripened.'' FDA developed a Risk-Ranking Model for Food Tracing (RRM–FT) to inform the FTL. The RRM–FT is a semiquantitative risk-ranking model that evaluates known or reasonably foreseeable hazards in a wide range of commodities for FDA-regulated human foods, and scores commodity-hazard pairs according to data and seven criteria consistent with the requirements in the FDA Food Safety Modernization Act (FSMA), section 204(d)(2)(A) (Ref. 5). Results from the RRM–FT provide a risk ranking of commodities and commodity-hazard pairs. Based on data and results from the RRM–FT, the Agency considered commodities and associated commodity-hazard pairs with criteria scores in the moderate to strong range and identified commodities for inclusion on the FTL (Ref. 6). The risk score for the commodity ''Cheese (made from pasteurized milk), fresh soft or soft unripened'' is 430, which is driven by the risk score for the commodity-hazard pair associated with *Listeria monocytogenes* (Ref. 7). Because of this risk score, the commodity ''Cheese (made from pasteurized milk), fresh soft or soft unripened'' is included on the FTL (Ref. 6).

As explained in the preamble to the final rule, products such as soft cheeses made from pasteurized milk and nut butters made from roasted nuts can be on the FTL regardless of the fact that some or all of their ingredients were previously subjected to a kill step (87 FR 70910 at 70931–32, responses 60 and 64). This is because the RRM–FT considers potential hazards that may be introduced from exposure to the processing environment after a lethality treatment (id.). In the case of the commodity ''Cheese (made from pasteurized milk), fresh soft or soft unripened,'' which includes cottage cheese, the RRM–FT took into account the risk from contamination with environmental pathogens, such as *L. monocytogenes,* which could occur during the manufacturing process, after the pasteurization steps. Thus, while pasteurization of the incoming ingredients provides a significant level of risk-reduction, this commodity nonetheless appears on the FTL because of the risk from post-pasteurization in-process contamination, most notably with *L. monocytogenes.*

We are proposing 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 because of the enhanced regulatory oversight of the manufacturing of such products. As discussed in the following paragraphs, manufacturers of IMS listed Grade ''A'' cottage cheese must comply with requirements intended to control pathogens during pasteurization and to prevent contamination during post-pasteurization processing. Additionally, there are requirements pertaining to information that must be documented in records, and provisions that dictate inspectional and sampling frequencies (Ref. 3).

Pasteurization. Both the milk and creaming mixture used in making cottage cheese must be pasteurized. The PMO requires that all pasteurization equipment be tested and inspected by the relevant Regulatory Agency every 3 months.

Post-pasteurization processing requirements. The cottage cheese processing steps that occur after milk pasteurization prior to packaging can be performed in vessels that are open to the environment, which presents a risk for contamination of in-process food with environmental pathogens, such as *L. monocytogenes,* if sanitary conditions are not maintained. 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 (Refs. 3 and 6). These requirements include:

- Ensuring that all critical factors are monitored and documented by the processing facility, the records of which are verified by the Regulatory Agency;
- Ensuring that capping, closing, and sealing of containers is done in a sanitary manner by approved mechanical equipment (hand capping of IMS listed Grade ''A'' cottage cheese is not permitted);
- Ensuring that Grade ''A'' cottage cheese is at a pH of 5.2 or below and is either:
  - Hot-filled at a temperature at or above 145 °F for containers of 4 ounces or larger, and at a temperature of 155 °F or above for containers of 2.9 ounces (these temperatures prevent the survival of *L. monocytogenes,* a pathogen that

might have been introduced into the product from the environment); or

o cold-filled at a temperature of 55 °F or less, with addition of the microbial inhibitor potassium sorbate at a minimum concentration of 0.06 percent, or another approved inhibitor that provides sustained inhibition of *L. monocytogenes;* and

• Communicating to the Regulatory Agency if there are any formulation or processing changes that affect critical food safety factors (Ref. 3).

Enhanced regulatory oversight. IMS listed Grade ''A'' cottage cheese manufacturers are subject to stringent regulatory oversight. All milk and milk products manufacturers regulated by the PMO, including IMS listed cottage cheese manufacturers, are subject to a three-tier inspection oversight program that includes inspections by the Regulatory Agency every 3 months, a rating performed by FDA-certified State Rating Officers every 2 years for IMS listing purposes, and check ratings performed by FDA Milk Specialists every 3 years (Refs. 1, 3, and 8). Additionally, during any consecutive 6 months, at least four samples of packaged cottage cheese made from pasteurized milk from each plant that manufactures IMS listed cottage cheese is collected by the Regulatory Agency for analysis (Ref. 3).

Considering the aforementioned features of regulation of IMS-listed Grade ''A'' cottage cheese, we tentatively conclude that application of the subpart S requirements to IMS listed Grade ''A'' cottage cheese is not necessary to protect the public health. As described above, the primary hazard associated with ''Cheese (made from pasteurized milk), fresh soft or soft unripened,'' which includes cottage cheese, is the risk of post-pasteurization, in-process contamination, specifically with *L. monocytogenes.* This hazard is well controlled when cottage cheese is manufactured in accordance with the PMO. The post-pasteurization processing requirements in the PMO (*e.g.,* requirements for processing steps, including container filling, to be performed under sanitary conditions; requirements relating to pH; requirements for hot-filling and cold-filling; and the requirement that all critical factors are monitored and documented by the manufacturing facility, the records of which are verified by the Regulatory Agency) provide effective control measures for this hazard. Furthermore, cottage cheese with a maximum pH of 5.2 and containing a minimum of 0.06 percent potassium sorbate, when stored at appropriate refrigeration temperature, will prevent *L. monocytogenes* growth. More generally, the PMO imposes stringent food safety requirements at every stage of the manufacturing process, covering both pasteurization and post-pasteurization processing, and also requires labeling to include the plant name or IMS number for product traceability. Frequent inspections that include reviewing production records documenting control of critical factors by both the States and FDA Milk Specialists provide a high level of oversight of these cottage cheese manufacturers. FDA's own involvement in the PMO and the Grade ''A'' program—along with the involvement of other public health governmental entities, such as USPHS and our State, Territorial, and municipal partners—provides a high degree of confidence regarding the safety of Grade ''A'' dairy products. Therefore, we propose to exempt from the Food Traceability Rule IMS listed Grade ''A'' cottage cheese that is produced and distributed in accordance with the PMO.

The discussion of the PMO in this document is based on the 2019 Revision.[1] However, this proposed exemption would apply to any IMS listed Grade ''A'' cottage cheese, including Grade ''A'' cottage cheese regulated under past revisions of the PMO (in jurisdictions that might not have adopted the 2019 Revision) and any IMS listed Grade ''A'' cottage cheese manufacturers regulated under future revisions of the PMO, once such revisions are released and adopted. We do 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 do we think that past revisions were materially different in ways that would affect this conclusion. If this exemption is finalized but 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 21 CFR 1.1395 and 1.1400.

In accordance with § 1.1385, we request comments on this proposed exemption. Interested persons may submit written comments on the proposed exemption in the docket established by this notice in accordance with the instructions in the **ADDRESSES** section of this notice. In accordance with § 1.1385(b), after considering any comments timely submitted, we will publish a notice in the **Federal Register** stating whether we are granting the proposed exemption for IMS listed Grade ''A'' cottage cheese and the reasons for our decision.

[1] The PMO is typically updated every 2 years. However, due to the COVID–19 pandemic, the NCIMS Conference was postponed to April 2023, so there was no 2021 Revision.

II. 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 June 3, 2024.
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 June 3, 2024.
3. FDA, ''Grade ''A'' Pasteurized Milk Ordinance (2019 Revision),'' 2019. Available at: *https://www.fda.gov/media/140394/download?attachment.* Accessed June 3, 2024.
4. FDA, ''2024 Interstate Milk Shippers List,'' 2024. Available at: *https://www.fda.gov/media/177531/download?attachment.* Accessed June 3, 2024.
5. FDA Memorandum, ''Methodological Approach to Developing a Risk-Ranking Model for Food Tracing FSMA Section 204 (21 U.S.C. 2223),'' September 2022. Available at: *https://www.fda.gov/media/142247/download?attachment.* Accessed June 3, 2024.
6. FDA Memorandum, ''Designation of the Food Traceability List Using the Risk-Ranking Model for Food Tracing,'' October 2022. Available at: *https://www.fda.gov/media/142282/download?attachment.* Accessed June 3, 2024.
7. FDA, ''Risk-Ranking Model for Food Tracing: Web-based Tool for Criteria and Results,'' 2022. Available at: *https://cfsanappsexternal.fda.gov/scripts/FDARiskRankingModelforFoodTracingfinalrule/.* Accessed June 3, 2024.
8. FDA, ''Compliance Program Guidance Manual 7318.003: National Conference on Interstate Milk Shipments (NCIMS) Milk Safety Program,'' 2012. Available at: *https://www.fda.gov/media/142503/download?attachment.* Accessed June 3, 2024.

Dated: June 11, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13236 Filed 6–14–24; 8:45 am]

BILLING CODE 4164–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[PS Docket Nos. 24–146, 22–90; RIN 3060–AL83; FCC 24–62; FR ID 225236]

Reporting on Border Gateway Protocol Risk Mitigation Progress; Secure Internet Routing

AGENCY: Federal Communications Commission

ACTION: Proposed rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) seeks to increase the security of the information routed across the internet by proposing certain reporting obligations on providers of broadband internet access service (BIAS providers) and their use of the Border Gateway Protocol (BGP). Internet traffic can be disrupted, intercepted, and blackholed—when a service provider drops traffic addressed to a targeted IP address or range of addresses by redirecting it to a null route—due to either accidental or deliberate adversarial manipulation of security vulnerabilities inherent to BGP. Together, the intended effect of the plans, filings, and measures the Commission proposes would be to mitigate such threats. BIAS providers would be required to develop BGP Routing Security Risk Management Plans that describe their plans for and progress in implementing security measures that utilize the Resource Public Key Infrastructure (RPKI). Nine of the largest service providers would be required to file specific additional data on a quarterly basis. The FCC also seeks comment on issues related to implementing RPKI-based security measures.

DATES: Comments are due on or before July 17, 2024 and reply comments are due on or before August 1, 2024. Written comments on the Paperwork Reduction Act proposed information collection requirements must be submitted by the public and other interested parties on or before August 16, 2024.

ADDRESSES: You may submit comments, identified by PS Docket Nos. 24–146 and 22–90, by any of the following methods:

- *Federal Communications Commission's website: https://www.apps.fcc.gov/ecfs/.* Follow the instructions for submitting comments.
- *Mail:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number. Filings can be sent by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission. Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701. U.S. Postal Service first-class, Express, and Priority mail must be addressed to 45 L Street NE, Washington, DC 20554.

Effective March 19, 2020, and until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID–19. *See FCC Announces Closure of FCC Headquarters Open Window and Change in Hand-Delivery Policy,* Public Notice, DA 20–304 (March 19, 2020). *https://www.fcc.gov/document/fcc-closes-headquarters-open-window-and-changes-hand-delivery-policy.*

People with Disabilities. To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

FOR FURTHER INFORMATION CONTACT: George Donato, Associate Division Chief, Cybersecurity and Communications Reliability Division, Public Safety and Homeland Security Bureau, (202) 418–0729, or by email to *george.donato@fcc.gov;* or James Zigouris, Attorney-Advisor, Cybersecurity and Communications Reliability Division, Public Safety and Homeland Security Bureau, (202) 418–0697, or by email to *james.zigouris@fcc.gov;* or Bradley Rosen, Attorney-Advisor, Cybersecurity and Communications Reliability Division, Public Safety and Homeland Security Bureau, (202) 418–0226, or by email to *bradley.rosen@fcc.gov.* For additional information concerning the Paperwork Reduction Act information collection requirements contained in this document, send an email to *PRA@fcc.gov* or contact Nicole Ongele, Office of Managing Director, Performance Evaluation and Records Management, 202–418–2991, or by email to *PRA@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking (NPRM),* PS Docket Nos. 24–146 and 22–90; FCC 24–62, adopted June 6, 2024, and released June 7, 2024. The full text of this document is available by downloading the text from the Commission's website at: *https://www.fcc.gov/document/fcc-proposes-internet-routing-security-reporting-requirements-0.* When the FCC Headquarters reopens to the public, the full text of this document will also be available for public inspection and copying during regular business hours in the FCC Reference Center, 45 L Street NE, Washington, DC 20554. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (TTY).

Ex Parte Rules—Permit-But-Disclose: This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules, with a limited exception described in the following paragraph. 47 CFR 1.1200, 1.1206. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to