CHEESE IMPORTERS ASSOCIATION OF AMERICA

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Submitted via Regulations.gov

Dockets Management Staff (HFA–305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Comments by Cheese Importers Association of America – Proposed Rule, "Requirements for Additional Traceability Records for Certain Foods" (Docket No. FDA-2014-N-0053)

Dear Sir or Madam:

The Cheese Importers Association of America ("the CIAA") respectfully offers these public comments to the Proposed Rule issued by the U.S. Food and Drug Administration ("FDA"), titled "Requirements for Additional Traceability Records for Certain Foods" and dated September 23, 2020 (85 Fed. Reg. 59,984) ("Proposed Rule").

The CIAA represents firms and individuals responsible for importing the majority of cheeses entering the United States. Our members are an integral part of the cheese supply chain and serve as an important link between foreign cheese producers and the U.S. market.

The CIAA is generally supportive of FDA's efforts to establish traceability recordkeeping requirements, and writes these comments to refine the FDA's goals of "improving the ability to quickly and efficiently trace the movement through the supply chain of foods identified as causing illness, identify and remove contaminated food from the marketplace, and develop mitigation strategies to prevent future contamination." To better achieve FDA's goals, CIAA provides the following recommendations for streamlining requirements, removing duplicative or unnecessary records and information, and reducing the regulatory burden on small businesses to ensure overall compliance.

Refine the Scope of Cheeses Included in the Food Traceability List.

FDA has proposed to subject all cheeses, except for hard cheeses, defined as those cheeses with less than 39% moisture, to the requirements of the Proposed Rule. Due to the wide variety of cheeses manufactured in and imported into the U.S., CIAA believes that FDA should more appropriately tailor the scope of cheeses subject to the Proposed rule based upon risk and science.

As noted in our comments to FDA on the "Designation of High-Risk Foods for Tracing" request for comment, FDA evaluated a variety of cheese categories, also based on moisture content, in its " Quantitative Assessment of Relative Risk to Public Health from Foodborne

Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods" ("*Lm* Risk Assessment"). *See* FDA, Quantitative Assessment of Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods (Sept. 2003), http://fda.gov/media/124721/download. In the *Lm* Risk Assessment, FDA categorized cheeses in the following manner based upon moisture content:

- Hard cheeses (*e.g.*, cheddar, Parmigiano-Reggiano (parmesan), Romano, Swiss cheese).
- Process cheeses (*e.g.*, American cheese, cheese spreads).
- Fresh soft cheeses (*e.g.*, queso fresco).
- Soft-unripened cheeses (*e.g.*, cottage, cream, ricotta cheese).
- Soft ripened cheeses (*e.g.*, brie, feta, mozzarella cheese).
- Semi-soft cheeses (*e.g.*, Monterey jack, Gouda, provolone, blue cheese).

Id.

CIAA is concerned that the all cheeses, except hard cheeses, product category is too broad to produce a meaningful risk analysis of the chesses that present a high risk as the Proposed Rule. CIAA believes that if FDA uses a more precise evaluation of cheese categories, such as those provided above, FDA will better evaluate the risks associated with certain cheese categories and ensure that the Proposed Rule when finalized is not unduly burdensome on the cheese importing community. We also believe that this would clarify the scope of the rule as some cheeses, such as process cheeses or low canned acidified cheeses, are subject to a kill step[1] when the cheeses are further processed.

As such, we urge FDA to reconsider the scope of cheeses subject to the rule and perform a more science and risk-based assessment.

Clarification of the term "Shipping" as it Applies to § 1.1350 of the Proposed Rule.

The Proposed Rule requires certain records be kept and sent when a food is shipped. Based on the language of the preamble and the definition of "shipping" in the Proposed Rule, CIAA believes that FDA intends to exempt intracompany shipments (i.e., shipments within a company between different facilities). CIAA notes that the definition of "shipping" is limited to "transport . . . from a defined location to another defined location *at a different farm, a first receiver, or a subsequent receiver.*" Proposed Rule at 60,032. This interpretation is reinforced by FDA's notes in the preamble to the Proposed Rule, where it writes that "[s]hipment or release of foods from one person in the supply chain to another is widely recognized as a critical tracking event." As intracompany shipments do not involve a different farm, first receiver or subsequent receiver, the record requirements of § 1.1350 would not apply.

CIAA believes that this interpretation helps both industry and FDA. Excluding intracompany transfers from § 1.1350 reduces the regulatory burden on industry to maintain additional

[1] We also believe that FDA should clarify the amount of pathogen reduction required for a process to be considered as a kill step (e.g. 5-log reduction) in the proposed definition at 21 C.F.R. § 1.1310. Proposed Rule at 60,031.

documentation on transfers within a company, where many of these intracompany transfers occur between buildings that have different addresses within the same general complex. This will reduce unnecessary documentation ensuring that FDA is not inundated with unnecessary data on meaningless intracompany transfers.

Eliminate Requirement to Maintain Entry Numbers for Records in §§ 1.1335 and 1.350 of the Proposed Rule.

The Proposed Rule requires documenting entry numbers for imported food in certain receiving and shipping records. Entry numbers, as noted by FDA, are numbers assigned by both the U.S. Customs and Border Protection and the import filer or broker. CIAA does not consider the entry numbers for food imports to be relevant to the question of food traceability and believes that more appropriate information may be used in its place to achieve FDA's stated goals.

FDA, in discussing the requirements of section 1.1335, states generally that the information included in that section "is widely regarded in the food industry as essential for effective tracing of food." Proposed Rule at 60,009. CIAA, however, disputes that assertion with respect to entry numbers. CIAA is not aware of anyone in the food industry that relies on entry numbers to perform traceability. FDA also suggests that the entry number would "help FDA identify the shipper of an imported food." Proposed Rule at 60,009. Entry numbers, while providing the identity of the importer, otherwise have little to no relationship to lot codes, manufacturers, or food types. In some cases, a single-entry number may contain different types of food (both included in the Food Traceability List and not) produced by different manufacturers. The difficulty in maintaining this information by industry does not provide sufficient benefits to food traceability.

For these reasons, CIAA recommends that FDA omit any requirement to track import entry numbers on food traceability records.

Remove the Requirement in §§ 1.1335 and 1.1350 that Receivers and Shippers Maintain Records of Location Identifier, Location Description, and a Point of Contact for the Lot Code Generator or Clarify the Requirement as It Applies to Imported Foods.

The Proposed Rule requires that receivers and shippers of a food on the Food Traceability List maintain records of the location identifier, location description, and point of contact for the traceability lot code generator. In many instances for imported cheeses, the traceability lot code generator for cheese will be the manufacturer of the product. CIAA believes this adds unnecessary complexity and information shared along the supply chain for imported cheeses. Specifically, these requirements would result in some entities sharing their confidential commercial information with a receiver of a product. For example, for a cheese that does not undergo transformation or any other step that requires the generation of a new traceability lot code, the manufacturer's information would need to be provided to subsequent receivers of the cheese. This could result in the retailer purchasing the product directly from the manufacturer and import the product, which is why many importers treat this information as confidential commercial information. Alternatively, CIAA believes that FDA could clarify that for all imported foods, the traceability lot code generator is the importer of the food that physically possess the product regardless of whether the food undergoes a transformation or other activity that would require the generation of a new traceability lot code. We believe this would

ensure that importer commercial supply chain contact information remains confidential and are not shared with retailers.

For these reasons, CIAA recommends that FDA omit the requirement to provide certain traceability lot code generator information with receivers or clarify that the U.S. importer that physically possess the product is the lot code generator for imported products.

Change the Requirement to Provide an Electronic Sortable Spreadsheet in § 1.1455(b)(3) of the Proposed Rule Voluntary.

The Proposed Rule states that "[y]ou do not need to duplicate existing records you have (e.g., records that you keep in the ordinary course of business or that you maintain to comply with other Federal, State, Tribal, territorial, or local regulations) if they contain the information required by this subpart." Proposed Rule at 60,037. Further, records may be kept "as original paper or electronic records or true copies (such as photocopies, pictures, scanned copies, or other accurate reproductions of the original records)." *Id.*

These requirements, however, are clearly complicated by FDA's demand that:

> When necessary to help FDA prevent or mitigate a foodborne illness outbreak, or to assist in the implementation of a recall, or to otherwise address a threat to the public health, including but not limited to situations where FDA has a reasonable belief that an article of food (and any other article of food that FDA reasonably believes is likely to be affected in a similar manner) presents a threat of serious adverse health consequences or death to humans or animals as a result of the food being adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act or misbranded under section 403(w) of the Federal Food, Drug, and Cosmetic Act, you must make available, within 24 hours of request by an authorized FDA representative, an electronic sortable spreadsheet containing the information in the records you are required to maintain under this subpart, for the foods and date ranges specified in the request. FDA will withdraw a request for such a spreadsheet when necessary to accommodate a religious belief of a person asked to provide such a spreadsheet.

Proposed Rule at 60,037.

The requirement to be able to identify, collect and convert traceability information into an electronic sortable spreadsheet within 24 hours is in direct contravention with the more permissive requirements to maintain traceability information in non-electronic forms. While we understand such information would be more useful to the Agency in an electronic form, the requirement may not be possible for smaller importers. For this reason, CIAA recommends that the requirement either be made voluntary, or change the timeframe to a more appropriate period, such as three to seven days. For example, FDA could request documents in any format within the 24-hour period, with the requirement to convert into an electronic sortable spreadsheet within seven days.

Additionally, CIAA questions how FDA will handle this confidential business information when it is provided to FDA. As mentioned above, CIAA members are concerned about providing FDA as well as receivers with information for manufacturers used to produce a product, which could result in the disclosure of confidential commercial information. This is a particularly a concern when the information is provided to FDA through a legitimate request by the Agency. While FDA has a

duty to protect from the disclosure of a company's trade secret or confidential commercial information under Section 401(a) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 350c(c), we question whether FDA will appropriately prevent disclosure of this information from public disclosure through a Freedom of Information Act request and other disclosure. We request that FDA explain in the final rule how the Agency intends to protect this information from disclosure

Extend the Proposed Compliance Time Period.

The Proposed Rule includes a two-year compliance period for entities subject to the Proposed Rule to implement compliance traceability programs and records. CIAA urges FDA to provide a compliance period of at least four years. Due to the complexity and burden of the Proposed Rule, we do not believe that two years is enough time for entities to come into compliance. We think it is essential that FDA issue all relevant guidance well in advance of the compliance date to ensure importers have an opportunity to both implement their own products as well as educate their foreign suppliers regarding the rule.

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CIAA appreciates the opportunity to provide this information to FDA. Please do not hesitate to contact CIAA should you have questions or require further information regarding our comments.

Sincerely,

Daniel Schnyder

Daniel Schnyder
President, Cheese Importers Association of America