February 22, 2021

By Electronic Submission

Division of Dockets Management (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Requirements for Additional Traceability Records for Certain Foods; Proposed Rule, Docket No. FDA-2014-N-0053

Dear Sir or Madam:

The International Foodservice Distributors Association (IFDA) is pleased to submit these comments in response to FDA's request for comments on its Proposed Rule for Requirements for Additional Traceability Records for Certain Foods.[1] IFDA is a non-profit trade association that represents businesses in the foodservice distribution industry throughout the United States and globally. IFDA members deliver to professional kitchens across America and around the world. They supply food and related products to restaurants, colleges and universities, hospitals and care facilities, hotels and resorts, and other foodservice operations. Foodservice distribution is a $303 billion industry with more than 15,000 distribution facilities in all 50 states and the District of Columbia.

Foodservice distributors are strongly committed to food safety and security, and they devote considerable resources to compliance with federal, state, and local food safety regulations. They are also highly skilled in tracking and tracing the food they distribute. Because of the number of products in their inventory, foodservice distributors participate in multiple critical tracking events on a weekly basis, and are each directly involved with more than 200 market actions such as food recalls or withdrawals initiated by suppliers on a variety of FDA and USDA products, each year—more than any other sector of the food industry. As a result, distributors have systems in place to ensure that the large volume and wide variety of products they handle can be accurately located and removed from commerce. They have the ability to determine exactly what they have received, when they have received it and from whom, and to which customers it went and when. Foodservice distributors have a strong record of providing FDA with critical trace-back information in a timely manner—information that has proven vital to addressing past foodborne illness outbreaks. This record was highlighted by the Institute of Food Technologists' (IFT's) report on *Pilot Projects for Improving Product Tracing along the Food Supply System* (IFT Report),[2] which discussed the effectiveness of the many successful practices foodservice distributors currently have in place.

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[1] 85 Fed. Reg. 59984 (Sept. 23, 2020).

[2] IFT, *Pilot Projects for Improving Product Tracing Along the Food Supply System — Final Report*, http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM341810.pdf [hereafter "IFT Report"]. IFDA notes that FDA provided funding for this report with the intent that IFT's findings be used to inform this rulemaking.

This record is particularly impressive given the unique challenges foodservice distributors face by virtue of their position in the food supply chain—challenges that FDA must account for when assessing the impact of the proposed rule. The foodservice distribution sector is very different from other sectors in the food industry, both in terms of the volume and fluidity of the products distributed. Each day, distributors transport tens of thousands of products from thousands of manufacturers to nearly one million different foodservice customers. On any given day, a single foodservice distributor will receive and ship thousands of food products that would be subject to the proposed rule. This product mix evolves constantly and rapidly as the needs and desires of our restaurant and foodservice customers change. Further, foodservice distributors' suppliers are often chosen by distributors' customers, not distributors themselves, leaving distributors with relatively little leverage to ensure that their suppliers comply with and pass forward the records required by the proposed rule.

While we provide specific comments below on various elements of the proposal, it is IFDA's overall view that the entirely new recordkeeping regime envisioned by the proposal is not practical when applied to the complex and dynamic foodservice industry supply chain. As a result, we strongly urge the agency to consider publishing a new notice of proposed rulemaking that takes into account the numerous stakeholder comments we understand FDA is likely to receive. While IFDA recognizes that FDA is under a court-ordered deadline to promulgate a final traceability rule, the proposed rule is so divergent from current industry practices that we expect the agency's approach will likely change significantly upon considering the comments FDA will receive. If FDA proceeds to a final rule that is vastly different from that proposed, the regulated industry would not have had an adequate opportunity to provide notice and comment, as required by the Administrative Procedure Act. There is also little assurance that such a final rule would remedy the deficiencies of this proposal. Therefore we believe it would be in the interest of both the agency and the regulated community that FDA should release a revised proposal for comment before finalizing its traceability rules, as it did in 2014 for four other Food Safety Modernization Act regulations while also under court-ordered deadlines.

I. General Comments

A. Compliance with the proposed rule will be immensely complex and unreasonably costly for foodservice distributors.

FDA's proposed rule is immensely complex, and, at least with regard to the foodservice distribution industry, the costs of complying with the rule would far outweigh the rule's public health benefits. While other FSMA rules have essentially codified existing food safety best practices, the proposed rule would create an entirely new—and at times duplicative—recordkeeping system for the food industry. FDA could fulfill its statutory mandate and achieve similar public health benefits through simpler and less costly alternatives that leverage already successful traceability recordkeeping systems, like those currently maintained by foodservice distributors. Thus, as a general matter, the proposed rule fails to comply with FDA's statutory mandate to ensure that the public health benefits of the rule's requirements "outweigh the cost

of compliance of such requirements," and that the rule "not require the creation and maintenance of duplicate records."[3]

The high costs of the proposed rule are particularly stark for foodservice distributors, who often have hundreds of thousands of products in their systems at any given moment. Each day, foodservice distributors engage in hundreds of thousands of transactions that would be subject to the rule's recordkeeping requirements. As written, the proposed rule would thus require foodservice distributors to establish and maintain thousands of new records every day, many of which are not maintained under current industry practices. The FDA's own economic analysis indicates that an oversized share of the costs of the rule falls on this sector of the supply chain.

These challenges are made more complex by the fluidity of the foodservice distribution sector. The needs and desires of our restaurant and foodservice customers change frequently. To keep up with demand, foodservice distributors often must use multiple suppliers for the same product, which requires the use of different procurement methods that can impact the records foodservice distributors must keep for each product and how they need to be transmitted. As a result, the inventory maintained by foodservice distributors is constantly evolving, even on a daily basis. Accounting for the regulated status of each product under the proposed rule would thus require a case-by-case analysis of both the products being received and the characteristics of individual suppliers, including an assessment of whether specific products or suppliers are wholly or partially exempt from the rule. These assessments would also be likely to vary depending upon the sourcing of the product which can change on a regular basis due to activities by distributors or suppliers. As an example, the same supplier could process products in a field or at a facility depending upon where the product originates, creating different requirements for the same product. Such examples occur with considerable regularity and the distributor would have little insight into the processes that have occurred upstream that could result in significantly differing requirements.

Foodservice distributors' ability to comply with the proposed rule will therefore be highly dependent on whether upstream suppliers provide the records necessary to facilitate compliance, since distributors themselves simply will not be able to seek out and obtain the proposed key data elements (KDEs) for each product that may be subject to the proposed rule. Moreover, distributors' customers often choose the suppliers from which members must source their products, leaving foodservice distributors with limited leverage to require that suppliers provide certain records. And, because FDA has not created data standards for any of the proposed rule's KDEs, it will be particularly difficult to ensure interoperability between the systems developed by foodservice distributors and the millions of suppliers and customers with whom they engage and serve. These added burdens will offer only marginal public health benefits, since foodservice distributors have a demonstrated record of being able to quickly and effectively conduct recalls and tracing activities. More detailed information regarding how distributors track product through their systems is included in the Appendix at the end of these comments.

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[3] *See* FSMA, Pub. L. No. 111-353, tit. II, § 204(d)(1), 124 Stat. 3885, 3931 (2011) (codified at 21 U.S.C. § 2223(d)(1)).

FDA therefore could fulfill its statutory obligations and achieve the same public health objectives by implementing far simpler alternatives. For example, FDA could require that two standardized pieces of information identifying the originator or creator of a product in a method that does not require the disclosure of confidential business information be passed through the supply chain, rather than requiring an elaborate set of additional KDEs.[4] This, coupled with adequate enforcement of FDA's Subpart J requirements, would allow for effective tracking and tracing of foods on the Food Traceability List (FTL) by permitting the agency to quickly identify the creator of the product. Alternatively, FDA could allow the use of a linking identifier already established by the receivers and shippers of FTL foods—such as a purchase order number, bill of lading or other reference record—that links products being shipped to products that are received. This approach, which the IFT Report identified as an effective alternative to a lot code-based system,[5] would be far less cumbersome and costly to implement, but would still enhance the recordkeeping requirements for FTL foods compared to the current requirements under Subpart J.

Even if FDA is unwilling to adopt a full alternative to its proposed approach, at a minimum it must incorporate the recommendations below. These changes would provide greater clarity regarding how foodservice distributors can comply with the requirements of the regulation while still advancing FDA's public health goals.

B. The scope of foods subject to the proposed rule is overly broad.

IFDA appreciates FDA's efforts to revise its proposed FTL in January 2021 in response to stakeholder concerns.[6] However, many aspects of the revised FTL remain poorly defined and overly broad. These problems are compounded by FDA's decision to subject all foods that contain FTL ingredients to the rule, including many low-risk foods that have not been historically associated with foodborne illness outbreaks. This approach would exponentially increase the burden of the rule, particularly for foodservice distributors. IFDA requests that FDA take the following steps to mitigate these concerns.

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[4] IFDA notes that this approach would be similar to—and could be modeled off of—the U.S. Department of Agriculture Food Safety and Inspection Service's (USDA-FSIS's) requirement that the packages of foods subject to USDA-FSIS jurisdiction be labeled with the manufacturer's establishment number, which is then passed forward through the supply chain.

[5] *See* IFT Report, *supra* note 2, at 205–06 ("In the absence of [lot/batch/serial numbers], other documents can be used to [link product shipments] within a supply chain. One data element that is of particular relevance . . . is an 'Activity ID' which is an identifier associated with an 'Activity Type' such as a PO or invoice number that can be used to link products between supply chain partners . . . The pilot showed that Activity IDs were a key piece of information used to follow the path a product takes through the supply chain.")

[6] *See* FDA, *Memorandum to the Record regarding Food Traceability List for "Requirements for Additional Traceability Records for Certain Foods" Proposed Rule – Clarified Language* (Jan. 12, 2021), https://www.fda.gov/media/145050/download.

1. Non-FTL foods that contain FTL foods as ingredients should not be subject to the rule.

FDA's proposal to subject all foods that contain FTL foods as ingredients to the rule violates FSMA and is unsupported by both FDA's own rationale and practical policy considerations. From a statutory standpoint, section 204(d)(2)(A) of FSMA puts the burden on FDA to develop a list of "high-risk" foods. This provision lists six factors FDA must consider when designating foods as "high-risk," four of which require FDA to assess the risks associated with "particular" foods.[7] Congress's repeated use of the modifier "particular" indicates that it intended for FDA to designate a list of *specific* food items with identifiable risks, and to subject only those *particular* foods to the rule's requirements. This interpretation is supported by fundamental principles of statutory interpretation, which hold that statutes "must be interpreted, if possible, to give each word some operative effect."[8] By subjecting all foods that contain FTL ingredients to the rule, FDA has violated its statutory mandate to designate a list of "particular" high-risk foods.

FDA's rationale for subjecting all foods that contain FTL ingredients to the proposed rule fails to justify this sweeping position. In the preamble, FDA asserts that "the potential risks associated with [FTL] foods are not diminished when the foods are used as ingredients in other food products (absent application of a kill step)."[9] This is a conclusory statement that fails to account for the fact that the vast majority of non-FTL foods containing FTL ingredients have not been associated with past outbreaks or may be subject to kill steps prior to consumption. For example, under FDA's current approach, frozen cheese pizzas would be subject to the rule, despite the fact that these products—like most varieties of frozen pizza—have never been associated with foodborne illness outbreaks.

FDA's preamble also asserts that "it would be unwieldy and impractical for the [FTL] to specify every food of this sort, *i.e.*, food products whose risk derives from their having a listed food as an ingredient."[10] This rationale is flawed on two fronts. First, it ignores the fact that Congress explicitly put the burden on FDA—not industry—to identify a list of "particular" high risk foods. Congress did not provide for an exception based on the difficulty or complexity of this task. Second, just as it would be "unwieldy and impractical" for FDA to identify every food whose risk derives from containing an FTL ingredient, it would be unwieldy, impractical, and immensely costly for industry to do so, particularly for foodservice distributors. For example, from the outset, foodservice distributors would face an immense task to just determine which products they handle contain FTL foods. Unless suppliers have already determined that their

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[7] *See* FSMA § 204(d)(2)(A) ("Each designation shall be based on . . . (i) the known safety risks of a *particular* food . . . (ii) the likelihood that a *particular* food has a high potential risk for microbiological or chemical contamination . . . (v) the likelihood that consuming a *particular* food will result in a foodborne illness due to contamination of the food; and (vi) the likely or known severity . . . of a foodborne illness attributed to a *particular* food.") (emphasis added).

[8] Walters v. Metropolitan Ed. Enterprises, Inc., 519 U.S. 202, 209 (1997).

[9] 85 Fed. Reg. 59984, 59995.

[10] *Id.* at 59995.

products contain FTL foods and pass the corresponding KDEs to foodservice distributors, distributors themselves will need to analyze the ingredient list of every product to determine whether they contain FTL ingredients.

Finally, from a practical standpoint, FDA should note the immense costs associated with subjecting all foods that contain FTL ingredients to the rule. Because foodservice distributors receive thousands of multi-ingredient foods each day, subjecting foods with FTL ingredients to the rule would exponentially increase the number of records foodservice distributors would need to maintain. Further, foodservice distributors will be forced to assess the precise ingredients in each product they receive on a shipment-by-shipment basis. This would require distributors to maintain and analyze data that they do not currently receive and are not required to receive, such as ingredient statements. This challenge is made more complex by the fact that suppliers' ingredient statements for certain products often change, and by the fact that suppliers are not required to notify foodservice distributors of these changes.[11] Because a vast majority of non-FTL foods containing FTL ingredients pose little or no foodborne illness outbreak risk, these costs would be unwarranted.

To avoid these untenable consequences, FDA's final rulemaking should state that only the foods listed on the FTL are subject to the rule's requirements. If there are multi-ingredient foods that merit inclusion on the list based on FDA's risk-ranking model, FDA should specifically identify those items on the FTL, as it has already done for various multi-ingredient foods like nut butters and deli salads.

2. The revised FTL still contains multiple overly broad and poorly defined items.

While FDA's January 2021 update to the FTL was helpful, multiple items on the FTL require further revision. Various items on the FTL refer to broad categories of foods, each of which could encompass specific foods that, by themselves, would not qualify as FTL foods under FDA's risk-ranking model. This exceeds FDA's statutory mandate, which requires that FDA assess the risks of "particular" high-risk foods, and unreasonably expands the scope of the rule to include foods that do not pose significant public health risks. Specific examples of overly broad items on the FTL include:

- "Melons (fresh)" — This category includes low-risk foods like whole watermelons. FDA should instead list specific high-risk melons, such as fresh cantaloupe.

[11] For example, a supplier of multi-ingredient quiches may alternate between using pickled jalapenos and fresh jalapenos. The former would not be subject to the proposed rule (under the modified requirement for foods subject to a kill step), while the latter would. To determine whether each shipment of quiche from the supplier is subject to the rule, foodservice distributors would need to obtain and analyze an ingredient list specific to each shipment. Doing so would not be possible under current industry practice, and would thus require fundamental and costly changes for foodservice distributors and their suppliers.

- "Tropical Tree Fruits (fresh)" — This category could include low-risk foods like bananas. FDA should instead list specific high-risk tropical tree fruits like fresh papayas and fresh mangoes.

- "Herbs (fresh)" — There are many fresh herbs that have not been historically implicated in foodborne illness outbreaks. FDA should instead list specific high-risk herbs, such as fresh cilantro.

- "Cheeses, other than hard cheeses" — This category could include many low-risk soft and semi-soft cheeses that have not been historically implicated in foodborne illness outbreaks, including Asiago and Manchego.

- "Finfish, including smoked fish" and "Crustaceans" — The finfish category could include low-risk foods like salted cod, pickled herring, and other acidified finfish products. Both of these categories could also include frozen seafood products, which have a much lower risk than refrigerated seafood because of the null potential for pathogen growth after freezing. FDA should instead list specific high-risk types of finfish and crustaceans, and should consider the impact of freezing on the risk profile of these products.

The revised FTL also includes multiple items that remain poorly defined. Absent further clarification, this could result in confusion and misapplication of the rule. IFDA requests that FDA revise the FTL to address the following questions:

- "Cheeses, other than hard cheeses" — Does this category encompass non-hard cheeses packed in wax (*e.g.*, fontina in wax)?

- "Tropical Tree Fruits (fresh)" — In addition to the examples provided in the revised FTL, how will FDA determine whether a fruit is a tropical tree fruit? For example, does this category include bananas?

- "Melons (fresh)" — In addition to the examples provided in the revised FTL, how will FDA determine whether a fruit is a melon?

IFDA requests that, in its final rulemaking, FDA address and revise its description of the above-cited items to ensure that the FTL clearly identifies specific, high-risk foods.

3. FDA should implement a structured and transparent process for adding or removing items from the FTL.

Section 1.1465 of the proposed rule ambiguously states that FDA will propose updates to the FTL when it "tentatively concludes" that updates are appropriate, and the preamble notes that FDA will conduct "periodic" reviews to determine whether updates are appropriate. However, neither the text nor the preamble of the proposed rule specify the frequency with which FDA will conduct these "periodic" reviews. Moreover, the proposed rule fails to include a mechanism by which stakeholders can formally request updates to the FTL. This leaves stakeholders with little certainty as to when FDA will propose updates to the FTL, and fails to account for the valuable role stakeholders can—and should—play in identifying the need for future revisions to the FTL. IFDA thus requests that FDA clarify how often it plans to conduct

periodic reviews of the FTL, that FDA establish a mechanism by which foods can be removed from the FTL if risk models show that is warranted and that FDA allow stakeholders to request revisions to the FTL.

IFDA also notes that section 1.1465 of the proposed rule states that future additions to the FTL will take effect one year after such additions are published in the Federal Register. Given the significant process adjustments that will be required to prepare for new additions to the FTL, IFDA requests that FDA establish a two-year compliance period for new additions to the FTL. This would mirror the two-year compliance period FDA established for the rule itself.

C. The proposed rule would impose a case-level tracking requirement throughout the supply chain.

As written, FDA's proposed rule would impose a de facto case-level tracking requirement on foodservice distributors and indeed throughout the supply chain. This violates section 204(d)(1)(L)(iii) of FSMA, which states that the enhanced recordkeeping requirements established by this rule shall "not require . . . product tracking to the case level." This becomes apparent upon consideration of the structure of the foodservice distribution industry: Foodservice distributors receive products from their suppliers in pallet level quantities. Each pallet typically contains multiple cases of product, each of which could be associated with different "traceability lot codes." When receiving products, distributors will only be able to comply with the proposed rule by determining which lot codes are associated with each case on the pallets they receive, *i.e.*, by engaging in case-level tracking. Further, when assembling orders for customers, foodservice distributors are highly likely to pull multiple cases from a single pallet. Each of these cases could contain products linked to a different traceability lot code. Foodservice distributors would not be able to identify the exact traceability lot codes associated with a specific shipment without engaging in case-level tracking.

The following example illustrates this problem: A foodservice distributor is assembling an order using tomatoes from Pallet 1. Pallet 1 contains cases of tomatoes linked to traceability lot codes A, B, and C, with multiple cases on the pallet linked to these different traceability lot codes. Some customer shipments created from Pallet 1 may contain cases from all three lot codes, some may contain products from just two codes, and some may contain products from just one code. FDA's proposed rule would require distributors to maintain and send shipping KDEs linked to the specific traceability lot codes of the products in each shipment. But, absent case-level tracking, there would be no practical way for foodservice distributors to know which precise lot codes (or combination of lot codes) are in any given shipment to their customers. Rather, they would only be able to know that the shipment *may* contain products from lots A, B, and/or C. Thus, the only way to comply with the proposed rule would be to engage in case-level tracking.

In addition to violating section 204(d)(1)(L)(iii), this case-level tracking requirement is unnecessary. The reference record system used by distributors is equally effective with regard to trace-back activities, as demonstrated by the IFT Report, which found—consistent with our industry's experience—that identifiers such as POs, BOL's or other reference records can be a

useful tool for conducting product tracing investigations.[12] In addition such tracking may not be as effective from a public health standpoint as the current method. This system allows distributors to recognize which lots are included in shipments they receive and to track where product from that shipment goes. This may result in removing more product than is strictly necessary during a recall, but it also creates greater assurance that all of the adulterated or misbranded product has been removed. From a public health view, a narrow focus on a particular lot could result in an insufficient and prolonged withdrawal creating additional health risk.

To avoid imposing an illegal and unnecessary case-level tracking requirement on foodservice distributors, FDA should instead adopt one of the alternative traceability program structures presented above in section I.A. If FDA is unwilling to adopt one of those alternatives, it should modify the proposed rule to specifically allow foodservice distributors to keep and send shipping KDEs linked to the set of *potential* traceability lot codes contained in a shipment, rather than the *exact* traceability lot codes in each shipment. For example, in the situation above, this would allow the distributor to link its shipping KDEs for shipments made using Pallet 1 to traceability lot codes A, B, *and* C, even though each shipment assembled from Pallet 1 might not contain products from all three lots.

II. Specific Comments

A. Disclosure of Confidential Business Information

IFDA requests that FDA eliminate the requirement that receivers and shippers maintain and send KDEs identifying the "location identifier, location description, and point of contact" for the "traceability lot code generator." Section 1.1210 of the proposed rule defines the term "traceability lot code generator" to include "the person who assigns a traceability lot code to a product," *i.e.*, the person who originates, transforms, or creates the product. In practice, the identity of upstream originators and manufacturers is often considered confidential business information, particularly in the case of private label production of food products. Requiring the disclosure of this information equates to requiring widespread disclosure of confidential information, which would harm entities throughout the supply chain.

Mandating the disclosure of this information offers little public health benefit, since other KDEs and existing record requirements under Subpart J will allow for effective tracking and tracing. Mandating that covered entities pass confidential information through the supply chain also conflicts with the aims of section 204(d)(3) of FSMA, which requires FDA to "take appropriate measures to ensure that there are effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information" that FDA obtains pursuant to the rule. By eliminating the requirement that shippers and receivers maintain and send records identifying the "traceability lot code generator," FDA can avoid these issues without detracting from the effectiveness of the proposed rule.

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[12] *See, e.g.*, IFT Report, *supra* note 2, at 113–14 ("Activity IDs [including purchase orders], particularly when used in conjunction with a system to analyze data, can provide meaningful information to aid in product tracing investigations when firms also maintain good internal tracing.").

B. Requirements for Entities that Receive Products from Exempt Originators or Manufacturers

Distributors who receive products from exempt originators or manufacturers will be unable to reasonably obtain the required "receiver" and "first receiver" KDEs. There are multiple scenarios under which foodservice distributors may receive products from exempt entities. For example, increasing demand for locally-sourced produce and other products has led to increases in product sourced from "small originators" that would be exempt under section 1.1305(a) of the proposed rule. In such cases, distributors would be required to establish and maintain receiver and first receiver KDEs, despite the fact that it would be highly difficult for foodservice distributors to obtain some of the information required by those KDEs. For example, it would be virtually impossible to obtain the "location identifier and description of the immediate previous source" and "information about harvesting, cooling, and packing dates, times, and locations" unless that information was provided by the originator.

To avoid these impracticalities, FDA should revise the rule so that products that are produced by exempt originators or manufacturers are exempt throughout the supply chain. This revision would make it easier—and far more practical—for downstream actors to ensure proper compliance with the rule. Further, this change would pose minimal public health risks, since one-up/one-back records would still be maintained for these products under Subpart J. This is particularly the case with regard to section 1.1305(a)'s exemption for "small originators" since, as FDA noted in its rationale for that exemption, such entities still produce a "relatively low volume of food" and including these entities within the scope of the rule would produce "little measurable public health benefit."[13]

This issue also demonstrates the significant degree to which foodservice distributors, along with many other downstream entities in the supply chain, will be forced to rely on their upstream suppliers when assessing whether products are subject to the rule. Since suppliers are not required to notify receivers when they are exempt, receivers will be left to assume that suppliers who fail to provide the records required by the rule are subject to an exemption. Whether their supplier is exempt or not, foodservice distributors would not be in a position to obtain the required information unless it is provided by the supplier. As such, FDA should clarify that it will not hold downstream actors liable for non-compliance resulting from good faith reliance upon upstream actors, whether exempt or not, who fail to pass forward records required by the rule.

C. Modified Requirement for Foods Subjected to a Kill Step

IFDA applauds FDA for establishing modified requirements for foods subject to a kill step. As FDA acknowledged in the preamble to the proposed rule, these foods pose little public health risk, and thus it would be unduly burdensome to subject them to the rule. However, in practice, it will be important for FDA to exercise flexibility for downstream entities who will have to rely on upstream entities to assess whether the products they receive have been subjected to a kill step.

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[13] *See* 85 Fed. Reg. 59984, 59995.

For example, foodservice distributors receive many foods that may or may not have been previously subjected to a kill step, depending on the supplier. On a given day, a single foodservice distributor may receive jarred salsa from multiple suppliers, some of whom have applied a kill step and some of whom have not. In fact, even the same supplier may provide salsa that has been subjected to a kill step in one shipment, and salsa that has not been subjected to a kill step in another. In such cases, distributors will not have the capacity to assess whether each of the thousands of products they receive on a daily basis have been subjected to a kill step. Instead, they will need to rely on their suppliers to provide that information. FDA should thus exercise enforcement discretion for foodservice distributors and other downstream actors who rely in good faith on upstream actors to determine whether the products they receive have been subjected to a kill step. As noted above, FDA should not hold downstream actors liable for non-compliances resulting from good faith reliance upon upstream actors.

IFDA also requests that FDA extend this modified requirement to exempt foods that are *destined for* a validated kill step or cooking process that will significantly minimize the presence of pathogens in the food prior to consumption.[14] Such foods would include, for example, frozen entrées and frozen dough destined for restaurants and foodservice, both of which will always be cooked prior to consumption. From a public health perspective, it makes little sense to subject these foods to the rule's requirements, since, by virtue of the fact that they will always undergo a kill step or cooking process before consumption, there is minimal risk that they will be involved in a foodborne illness outbreak. Subjecting these foods to the rule prior to the application of a kill step or cooking process would thus impose unnecessary costs.

D. Partial Exemption for Farm to School and Farm to Institution Programs

FDA's proposed partial exemption for farm to school and farm to institution programs would apply only to the "entit[ies] conducting [such programs] with respect to a food on the [FTL] that is produced on a farm . . . and sold *directly* to the school or institution."[15] As drafted, it appears that this partial exemption would *not* apply to foods purchased by farm to school/institution programs through distributors. However, as FDA recognizes in the preamble to the proposed rule,[16] distributors—including foodservice distributors—play a vital role in implementing farm to school/institution programs. To realize its stated goal of not "placing

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[14] Foodservice distributors send many products to customers whose foodservice operations are regulated by state and local food safety authorities, the majority of which enforce some version of FDA's model Food Code. Thus, many products that are not destined for a validated kill step are destined for cooking processes that, in compliance with state and local regulations, significantly minimize the presence of pathogens in the food prior to consumption. Such foods thus pose the same limited foodborne illness risks as foods that have been subjected to a validated kill step.

[15] 85 Fed. Reg. 59984, 60030 (emphasis added).

[16] *Id.* at 59998 (recognizing that farm to school/institution programs can include programs in which farms sell food to "competitively procured food distributors").

undue burdens on these programs,"[17] FDA should clarify that this exemption also applies to foods that farm to school/institution programs purchase through distributors.

E. First Receiver KDE Requirements

FDA's rationale for imposing additional requirements on "first receivers" is based on the agency's assertion that these entities are "best positioned to maintain comprehensive information about the origination and subsequent handling of a food."[18] FDA supports this claim by noting that some "firms that conduct on-farm production and handling activities may not own the food and may not be well-positioned to maintain necessary records" while also noting that "on-farm activities can involve movement of a food between different entities . . . without sale of the food, and the relevant business relationships can be complex."[19] This rationale fails to justify the sweeping and impractical obligations the proposed rule would impose on "first receivers."

First, as FDA recognizes, on-farm activities can be highly complex and hard to track. Applying FDA's own logic, there is no reason to expect that receiving entities—who do not have any direct visibility into on-farm activities—would be better positioned than farms themselves or the entities engaging in on-farm activities to gather this information. The only reasonable manner in which a first receiver could maintain these KDEs would be if the originator sent this information to the first receiver. This appears to be why FDA created extra "shipping" KDEs for farms, which essentially require farms to keep and send the information required under the first receiver KDEs. Since FDA is already requiring farms to maintain this information, there is no reason to require first receivers to maintain this information as well. Further, when an originator is exempt, there would be no way for first receivers to access the information necessary to maintain many first receiver KDEs, including the "location identifier and location description of the place where a food was cooled or packed." In practice, this requirement would have the unintended consequence of forcing first receivers to avoid working with exempt originators, which would disproportionately harm small originators who are exempt from the rule under proposed section 1.1305(a). While this is certainly true of exempt suppliers, it is likely that distributors would not be able to obtain the necessary information in the case of non-exempt suppliers as well.

FDA should also recognize that it will be particularly difficult for foodservice distributors to determine when they even qualify as a "first receiver." There are many instances in which foodservice distributors can source the same item from both farms and non-farms depending upon the actions of the suppliers. For example, the supply chain for produce is incredibly variable, and includes companies such as co-ops, packing houses, consolidators and brokers. This will make it difficult to determine when the supplier from whom the product was purchased is in fact a "farm" under the rule. This is especially true as supplier practices can vary

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[17] *Id.* This goal is also mandated by FSMA. *See* FSMA § 204(d)(6)(A) (requiring FDA to ensure that the requirements of this rule "do not place undue burdens on farm to school or farm to institution programs").

[18] 85 Fed. Reg. 59984, 60008.

[19] *Id.*

significantly depending upon location, even for the same product. This variability will make it extremely challenging for foodservice distributors to comply with the first receiver requirement and will require significant reliance upon the information provided to distributors by upstream entities. This is complicated further by the fact that distributors often purchase and need to receive such information from entities such as brokers who are not covered by the rule. Once again, this demonstrates the need for FDA to provide an exemption for downstream entities who rely in good faith upon upstream entities.

To avoid these impracticalities altogether, FDA should eliminate the KDE requirements for first receivers. Instead, FDA should require that the originators who ship products maintain these KDEs, since those entities are best positioned to access this information. And, when an originator is exempt, first receivers should also be exempt from having to maintain first receiver KDEs.

F. "Transformation" Definition

Foodservice distributors frequently engage in the practice of taking a master case of product and breaking it into smaller units, which is often referred to as "breaking a case." This practice includes, for example, taking a master case that contains individual cases of tomatoes, and selecting and shipping individual cases from the master case. It is unclear whether FDA would consider this to be "transformation" under the proposed rule, which defines transformation to include activities like "cutting, cooking, commingling, repacking or repackaging." IFDA notes that there is no basis for requiring transformation KDEs for this activity, since the product itself is unchanged and can be easily linked to the lot code for the master case.[20] In fact, there is a public health harm in that this would require the establishment of a new traceability lot code for a product that has not been "transformed" in any meaningful way. IFDA requests that, in its final rulemaking, FDA clarify that the above-described activity does *not* qualify as "transformation" for purposes of this rule.

G. Traceability Program Records—List of FTL Foods

Proposed section 1.1315(a)(2) would require covered entities to establish and maintain a list of the FTL foods that they ship, including the "traceability identifier" and "traceability product description" for each food.[21] Because a product's "traceability product description" must include detailed information such as the brand name of the product, IFDA understands that, in practice, this would require foodservice distributors to maintain a list of each individual supplier for each covered product they ship.

Due to the very high volume of products and suppliers they work with, foodservice distributors would be required to maintain a list with thousands of products that would change with great frequency. Distributors estimate that, based on current practices, the precise contents of this list could change, on average, every three minutes. Maintaining such an expansive,

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[20] When this activity occurs, all required labeling information is transferred to the new product package.

[21] 85 Fed. Reg. 59984, 60005.

rapidly changing list would be costly and unwieldy for foodservice distributors, and would not provide any value when conducting tracking and tracing activities. Further, FDA's rationale for this requirement—which cites to past peanut butter outbreaks, and asserts that compliance with this requirement would support trace-forward efforts in such scenarios[22]—is not relevant to foodservice distributors, since they do not use the products they receive to create new foods.

Because such a list would not provide FDA with any assistance in their trace-forward effort, IFDA sees little reason this requirement should remain. If such a list is considered necessary for other purposes, FDA should directly exempt foodservice distributors from this requirement. Alternatively FDA could also modify this requirement to only mandate a general list of FTL foods an entity ships (e.g., listing "tomatoes" rather than each tomato supplier).

Separately, IFDA appreciates FDA's recognition in the preamble that covered entities can enter into agreements with other entities to "create and keep the records required under [the proposed rule] on their behalf."[23] IFDA supports this position, but notes that the text of the proposed rule does not discuss this point. To avoid confusion, IFDA requests that FDA amend section 1.1315 of the proposed rule to explicitly codify the ability of covered entities to enter into third-party recordkeeping agreements and provide additional details regarding how it would foresee such agreements functioning.

H. Sortable Spreadsheet Requirement

Distributors generally anticipate that they will be able to comply with the proposed rule's requirement that covered entities provide FDA with an electronic, sortable spreadsheet with records required by the rule under certain exigent conditions. However, there are at least two instances under which it will not be feasible for foodservice distributors to comply with this requirement.

First, it will be difficult—if not impossible—to produce such a spreadsheet within 24 hours that includes records from the many suppliers who do not provide distributors with electronic records. FDA should introduce flexibility for non-electronic records, such as giving entities at least 72 hours to compile a spreadsheet that contains information from such records. These records can be extensive and the agency should also provide flexibility if warranted by the amount of information requested. Absent additional flexibility, this would function as a de facto electronic recordkeeping requirement, in violation of FSMA section 204(d)(1)(C), which prohibits FDA from "prescribing specific technologies for the maintenance of records" required by the rule. Practically speaking, this would also discourage entities from working with suppliers who maintain only non-electronic records, which, in turn, would disproportionately harm small businesses, who are most likely to fall into this category.

Second, it will be impractical to comply with the 24-hour requirement for requests that span a large quantity of products and/or long periods of time, even if distributors have electronic records of for all of the products covered by such requests. As such, FDA should

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[22] *Id.* at 60005.

[23] *Id.* at 60004.

revise the 24-hour requirement to be commensurate with the size and scope of FDA's records request, such as by allowing 72 hours to comply with requests that exceed a certain size.

I. Application of Rule to Restaurants

The proposed rule expressly applies to "retail food establishments" and in the preamble, FDA states that this includes both retail grocery stores and restaurants. It is IFDA's view that restaurants should be exempt from the requirements of the rule. The rule would create an extremely complex and lengthy new requirement for foodservice operations well beyond their current capabilities. The restaurant industry is extremely diverse ranging from small, independent local restaurants to multi-national brands, food trucks, catering companies, and contract foodservice companies. More than 70 percent of foodservice establishments are single unit establishments and 90 percent qualify as small businesses. Many of these operations continue to use paper records and do not have the adequate resources necessary to make the technological and staffing changes that would be required to comply with the proposed rule. Even among the largest restaurant chain companies, many use a franchise business model meaning these outlets are also small businesses. Under the franchisee model brand owners would be unlikely to have the ability to standardize data collection, storage methods and employee training. .

J. Small Retail Food Establishment Co-Proposal

IFDA supports Option #1 of FDA's co-proposal for small retail food establishments, which would fully exempt small retail food establishments from the rule. However, we believe that the threshold of 10 full-time employees (FTE's) to qualify as a "small" retail food establishment is far too low. Restaurants, even smaller operations, often have more than 10 FTE's in positions such as servers, bussers, hosts, bartenders, chefs, cook staff, managers, dishwashers, etc. As a result, this exemption would apply to only an extraordinarily limited number of operations and have little practical impact. If FDA does subject restaurants to the requirements of its final regulation, a broader small business exemption would be necessary. The agency should also consider if there would be a more appropriate method for determining eligibility such as sales revenue or volume of food sold.

K. FDA's Proposed Compliance Timeline

FDA has proposed that all covered entities be required to comply with the proposed rule two years after the effective date of the rule.[24] FDA specifically notes that implementing staggered compliance dates that permit small and very small entities to comply later than other entities would be impractical, since this could lead to downstream entities being subject to the rule prior to the upstream entities upon whom downstream entities must rely to receive many of the records required by the rule.[25] Because, as noted repeatedly above, downstream entities will need to rely on upstream entities to establish and pass along many of the records required by the

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[24] *Id.* at 60019–20.

[25] *Id.* at 60020.

proposed rule, IFDA agrees with FDA's rationale for not implementing staggered compliance dates for small and very small entities.

Applying this same rationale, FDA should recognize that if all entities are required to comply on the same date, there will be a period of time during which downstream entities will be unable to comply with the rule, since they will need to wait for upstream entities to pass required records through the supply chain. Downstream entities will also need to understand the process changes and other steps upstream actors take to comply with the rule before they can enact their own compliance plans. IFDA thus requests that FDA implement staggered compliance dates starting with entities at the beginning of the supply chain and exempting product already in the system. This will ensure that downstream entities can access the information they need from upstream entities in order to effectively and efficiently comply with the rule. If FDA is unwilling to implement staggered compliance dates, it should at least clarify in its final rulemaking that it will exercise enforcement discretion for downstream entities who are unable to immediately comply with the rule due to their good faith reliance on upstream entities.

L. FDA's Economic Impact Analysis

Finally, IFDA notes that FDA's economic analysis vastly underestimates the costs of complying with the proposed rule. For example, FDA estimates that it will take an average of 3.3 hours for each "respondent" who is subject to the rule to "read and understand the new recordkeeping requirements."[26] This is an immense understatement. FDA's proposed rule and preamble span 55 three-column pages in the Federal Register (more than 200 pages in pre-publication form), and includes multiple cross-references to FSMA and existing FDA regulations. FDA held three full-day public meetings to explain the rule, and has published multiple supplemental materials to help stakeholders understand the rule, including a recent revision to the FTL, a Frequently Asked Questions document that was necessitated by widespread stakeholder confusion and a 45 page document outlining supply chain scenarios that was released just more than a week prior to the closing of the comment period. FDA also acknowledges that it is unable to determine the breadth of products on the FTL. IFDA thus urges FDA to recognize that "reading and understanding" the final rule will take far more than 3.3 hours per *person*, and more than one person per covered entity will need to read and understand the rule.

FDA also projects that only a relatively modest number of firms will incur costs associated with training employees on the proper documentation of KDEs, and that such firms will only need to conduct "an average of 2 hours of training with respect to an average of 3 records."[27] Again, this is a vast understatement. The proposed rule establishes an entirely new set of key terms and definitions, many of which deviate significantly from current, widespread understandings of similar terms and concepts. Covered entities, including foodservice distributors, will need to implement entirely new business processes and systems in order to fully comply with the rule. These new processes and systems will involve virtually all

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[26] *Id.* at 60025.

[27] *Id.* at 60026.

departments and management within a company, creating the need to train significant numbers of employees in the requirements of the rule. As drafted, the proposed rule will thus require extensive, ongoing company-wide trainings that far exceed FDA's projections.

The proposed rule would also impose significant upfront and ongoing costs for foodservice distributors, who will need to develop and implement entirely new business systems in order to comply with the rule. For example, many distributors will need to adopt new programs for identifying and tracking traceability lot codes upon the receipt and shipping of products. As discussed in section I.C, this would require breaking down each pallet to identify the lot codes associated with specific cases in violation of the statute. As written, however, this would be a fundamental alteration of foodservice distributors' current business practices, and would require substantial investment in new technologies, new recordkeeping systems, new personnel, and extensive employee training. Further, as discussed in section I.B.1, distributors would need to implement entirely new technologies and recordkeeping systems at enormous cost to determine whether the products they receive in each individual shipment contain FTL foods as ingredients. The upfront investment costs, ongoing process delays, and significant personnel needs associated with these requirements alone will far exceed the costs projections in FDA's current analysis.

Based on extensive conversations with our members, IFDA conservatively projects that one-time program implementation costs—which would include vendor solicitation, warehouse management system upgrades or replacements, and new warehouse scanning devices—would total at least 10 million dollars for a mid-to-large-sized foodservice distributor. In addition to these upfront costs, foodservice distributors would incur ongoing costs to gather, track, and send KDEs. These ongoing costs would amount to at least a 1 dollar for every case that is subject to the rule. Beyond these costs, the added time required to move product through the system would incur additional labor and other costs. Because foodservice distributors ship 8.7 billion cases of product each year, all of these changes would result in hundreds of millions of annual, ongoing costs for distributors, even under the most conservative estimates. Again, these costs far exceed FDA's projections.

Finally, IFDA notes that FDA's economic analysis acknowledges the outsized costs to the distribution sector while demonstrating extremely limited benefit for these companies. Yet even this limited benefit of the proposed rule is overstated. FDA based its projection of the monetized benefits from annual illnesses averted by the rule on an assumption that the rule will result in an 84 percent reduction in trace-back time.[28] This is not an accurate assumption. As noted extensively above, foodservice distributors have a strong track record of rapidly providing FDA with accurate trace-back information. The effectiveness of distributors' current trace-back capabilities has been consistently demonstrated through their interactions with FDA, and were also highlighted in the IFT Report. IFDA thus disagrees with FDA's core assumption that the proposed rule's requirements would lead to an 84 percent reduction in trace back time, and urges FDA to revise its projected benefit calculation accordingly.

In light of these realities, IFDA urges FDA to revise its economic analysis to adequately account for the rule's true compliance costs. Upon doing so, FDA should revisit its assessment

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[28] *Id.* at 60021.

of whether the limited public health benefits achieved by the proposed rule outweigh the outsized costs it will impose especially on foodservice distributors as well as other entities throughout the supply chain.

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IFDA appreciates the opportunity to provide our thoughts on FDA's proposed rule, and would be pleased to provide FDA with any additional information regarding the foodservice distribution sector that might be helpful to the agency as it develops its final rulemaking.

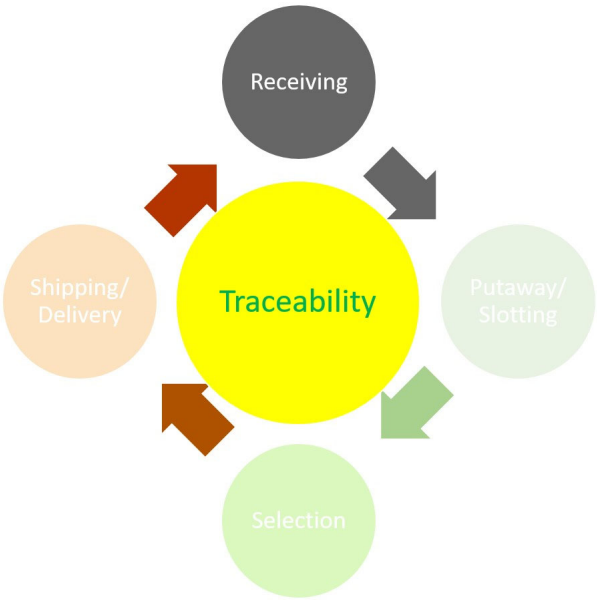
Sincerely,

Mark Allen
President and CEO

Foodservice Distribution Traceability Process

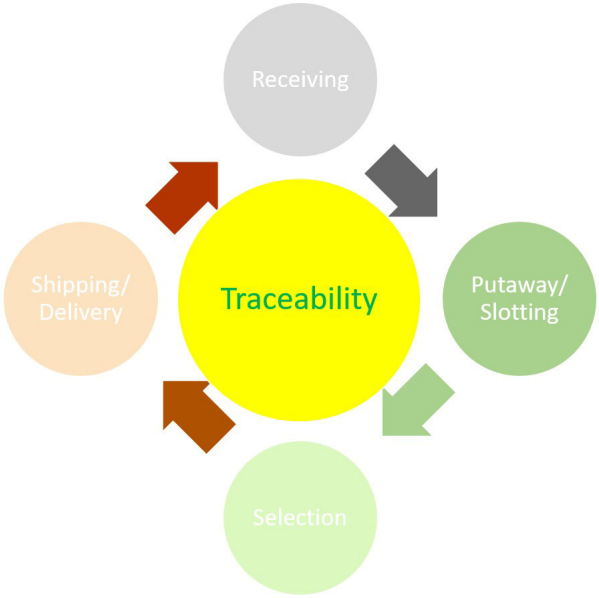
Traceability – Receiving Step

- All products are accompanied with Receiving Documents (Reference Records) outlining information about the products , e.g.: Bill of Lading, Invoice, Purchase Order, etc.
- Information transmitted on the Receiving Documents varies by product and by supplier
- All loads are received and verified to ensure food safety, quality and other standards are met
- Pallets may contain mixed lot codes/production dates
- Utilize both “First In First Out” and “First Expired First Out: to manage product rotation, depending on the product
- All pallets receive a Pallet License Plate, which is linked back to the Purchase Order and/or Receiving Documents



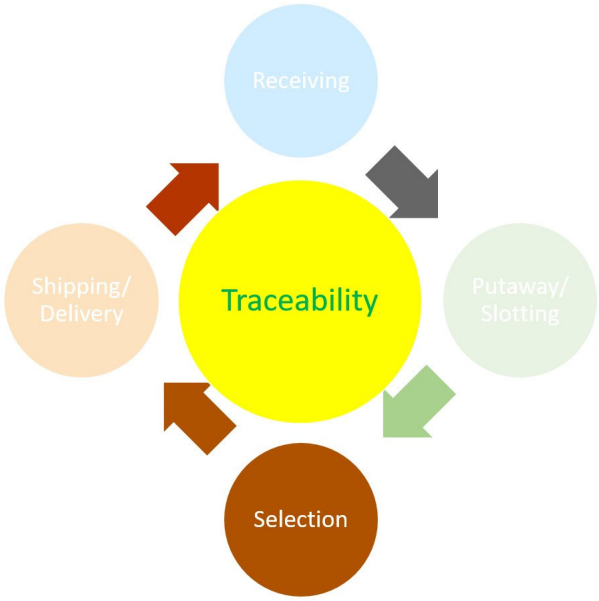
Traceability – Putaway/Slotting Step

- Distributors utilize Warehouse Management Systems to appropriately slot products
- Pallets are stored according to the Pick Path and food safety parameters
- Pallet License Plates are allocated to a slot for inventory tracking and traceability
- After receipt, product is typically placed in a "Reserve Slot", slots for products to be shipped at a later time - not currently being selected
- When product in a Reserve Slot is needed to fill orders, the inventory management system orders a pallet to be moved into the "Pick Slot" where individual cases are selected for customer orders



Traceability – Selection Step

- Orders are allocated automatically by the warehouse management system
- Selectors follow a predetermined pick path, dictated by their scan gun or other equipment for efficiency and food safety (prevention of cross contamination) based on customer orders
- At selection, selectors scan the pick slot location label
- If additional information (i.e. catch weight) is required for the product, the equipment will prompt the selector to enter the information which will print on the invoice
- A Selection Label is applied to each case of product selected for a customer order; Selection Labels do not contain any information from the food manufacturer



Traceability – Shipping/Delivery Step

- All trucks are temperature controlled, most have 2-3 zones
- Trucks are loaded and unloaded by stop
- Each case's Selection Label is checked at the time of delivery to assure the right product is being delivered to the right customer; no traceability data elements are transferred during this process
- Customers receive an invoice outlining which products were purchased/delivered
- With the Customer Invoice Number, distributors can determine which products were delivered to that customer

Traceability – Summary

- Distributors are able to trace product from the supplier Purchase Order and/or other Reference Records, through the Pallet License Plate, to the Customer Invoice or Selection Label to Pick Slot to Supplier Reference Records (e.g. Purchase Order, BOL, Invoice, etc.)
- This example does not cover non-normal situations such as:
  - Drop Shipment
  - Re-distribution
  - Cross Docking
  - Repacking/Breaking Master Cases