INTERNATIONAL FRESH PRODUCE ASSOCIATION

July 15th, 2026

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-N-0053; Discussion Paper: Identifying Additional Flexibilities for Satisfying the Food Traceability Rule's Lot-Level Tracking Requirement

To Whom It May Concern:

On behalf of the International Fresh Produce Association (IFPA), we appreciate FDA's continued engagement with regulated entities and interested stakeholders regarding implementation of the Food Traceability Rule and, specifically, the additional flexibilities Congress directed FDA to identify for satisfying the rule's lot-level tracking requirement. IFPA represents companies across the global fresh produce and floral supply chain, including growers, packers, shippers, fresh-cut processors, distributors, wholesalers, retailers, foodservice operators, technology providers, and allied businesses. IFPA members share FDA's goal of faster and more accurate traceback, more targeted recalls, and stronger public health protection.

IFPA strongly supports the objectives of FSMA 204. The Food Traceability Rule establishes additional recordkeeping requirements for persons who manufacture, process, pack, or hold foods on the Food Traceability List and requires records containing Key Data Elements (KDEs) associated with Critical Tracking Events (CTEs). The rule further requires records be made available to FDA within 24 hours of request, or within some reasonable time to which FDA has agreed. These objectives are directly tied to the public health purpose of faster identification and removal of potentially contaminated food.

At the same time, successful implementation depends on FDA recognizing how fresh produce actually moves through the supply chain. Produce supply chains are high-velocity, highly perishable, labor-intensive, and structurally variable. Product routinely moves through distribution centers in mixed-pallet, split-pallet, broken-case, replenished-slot, cross-docked, and store-specific order configurations. Many operations were designed to ensure that the correct product reaches the correct customer: not to confirm a unique lot identity on every outbound case at the moment of selection. A compliance interpretation that assumes universal case-level scanning will create substantial cost, operational disruption, and potential data-quality problems without necessarily improving public health outcomes compared with controlled WMS-based approaches.

Traditional retail and distribution systems were originally designed around product identification rather than lot-specific identification. Consumer packaged goods typically rely on UPC- and GTIN-based structures that remain constant across production lots and were developed primarily to support

commerce, inventory management, and point-of-sale functions. Lot-level traceability, by contrast, often depends on dynamically applied identifiers and data-capture processes that must be generated at the time of harvesting, packing, processing, or manufacturing. While the fresh produce sector has invested substantially in lot-level traceability through industry initiatives and voluntary standards, implementation remains uneven across the broader food system, label quality and readability can vary, and many warehouse systems continue to manage inventory primarily at the pallet and product level rather than at the individual lot level. These operational realities explain why final-mile lot attribution remains challenging even for firms with sophisticated inventory-management and traceability capabilities.

Executive Summary

FDA's discussion paper appropriately recognizes that traceability challenges do not arise because firms lack inventory controls or business records. Rather, the challenge is that many existing systems were optimized over decades to support inventory movement, order fulfillment, replenishment, and customer service - not to confirm and electronically communicate a unique traceability lot code for every case selected during high-volume distribution activities. Accordingly, FDA should evaluate flexibility options based on whether they preserve traceback utility and improve access to meaningful lot-level information rather than whether they replicate a theoretical case-level scanning environment that does not currently exist throughout substantial portions of the supply chain.

The central recommendation in these comments is straightforward: FDA should recognize a documented, risk-based pathway that allows distribution centers and similar operations to use warehouse management systems, inventory controls, and business-system data to provide either (1) a reasonable range of TLCs that may be associated with a shipment or (2) inferred TLCs accompanied, where appropriate, by a limited set of alternative possible TLCs. FDA should pair that flexibility with clear guardrails, documented traceability-plan expectations, and alignment with voluntary industry standards such as GS1, EPCIS/CBV, EDI 856 Advance Ship Notice capabilities, and Produce Traceability Initiative guidance. This approach would preserve traceback utility, allow FDA to receive meaningful lot-level information, and avoid forcing firms toward manual scanning practices that are expensive, error-prone, and not uniformly supported by current labeling and system infrastructure.

The necessary guardrails are not complicated: FDA should require that firms using these approaches document their methodology in the traceability plan; capture TLC and TLC-source information at receiving to the extent available; maintain WMS or equivalent business-system records linking received pallets, license plates, lots, slots, replenishments, and outbound shipments; conduct inventory reconciliation and cycle counts; verify empty slots as appropriate; train personnel; preserve exception records; and produce sortable electronic records showing inferred or possible TLCs and TLC-source information in a format that can be used during investigation.

FDA should also use this process to promote interoperable data exchange without prescribing a single technology. FSMA 204 does not require FDA to mandate one technology platform. However, FDA can recognize that voluntary industry standards (including GS1 identifiers, GS1-128 labels, GTIN and batch/lot structures, Global Location Numbers where used, EPCIS/CBV event data, EDI 856 Advance Ship Notice transactions, and PTI implementation resources) provide a practical foundation for scalable, interoperable compliance. FDA should encourage convergence around these standards and consider a safe-harbor concept under which use of recognized standards and documented controls creates a strong presumption that an entity has adopted a reasonable traceability approach. FDA should further recognize that interoperability challenges frequently arise from inconsistent implementation of otherwise recognized standards and should work with industry stakeholders to encourage greater harmonization of data-exchange practices across the food supply chain.

Summary of IFPA Recommendations

FDA Topic	IFPA Position	Recommended FDA Action
Reasonable Range of TLCs	Support, if defined as the smallest reasonable set of possible TLCs based on documented system and inventory records.	Do not impose a fixed numerical cap; require traceability-plan methodology and inventory controls.
Inferred TLCs with Flexibility	Strongly support; this is the most practical and traceback-useful pathway for DC-to-retail/restaurant shipments.	Recognize WMS-calculated inferred TLCs plus limited possible alternatives as an acceptable flexibility.
Eaches	Support flexibility for broken-case product where exact TLC linkage can be difficult after case integrity is broken.	Permit reasonable-range or inferred-TLC methods and clarify labeling/container expectations.
Returns and Reclamations	Treat as exception flows, often overlapping with eaches or unsaleable product handling.	Allow reliance on original shipment, inventory transaction, and reclamation-system records.
Food Waste Recovery	Donation exclusion addresses much of the issue, but examples are needed.	Provide examples involving food banks, secondary redistribution, and mixed donated/commercial inventory.

Intracompany Shipments	Avoid duplicative recordkeeping where integrated systems preserve lot continuity.	Permit enterprise-level reconstruction without redundant records at every internal transfer.
Retail Kitchens Supplying Other Retail Locations	Support modified records for limited retail-kitchen transfers.	Create a limited flexibility for local, affiliated, small-volume transfers where public-health value of full transformation records is limited.
Data Standardization	Essential for scalable implementation.	Encourage GS1/PTI-aligned standards, EPCIS/CBV event data, EDI 856 ASN, and standardized sortable spreadsheet templates.

Background and Principles for FDA Flexibilities

The Food Traceability Rule identifies CTEs such as harvesting, cooling before initial packing, initial packing, first land-based receiving of seafood from fishing vessels, shipping, receiving, and transformation. For entities subject to the rule, records must contain the required KDEs associated with the relevant CTEs. The rule's definitions of TLC, TLC source, TLC source reference, shipping, receiving, and transformation are central to this discussion because the flexibility FDA is considering concerns how TLC information can be maintained and transmitted in complex distribution environments.

The rule requires traceability plans. Under 21 CFR 1.1315, covered entities must establish and maintain a traceability plan describing procedures used to maintain required records, procedures used to identify FTL foods, and how TLCs are assigned when applicable. This existing traceability-plan framework is the appropriate place for firms to document reasonable-range and inferred-TLC methodologies. FDA need not create an entirely new compliance architecture; rather, FDA can clarify that documented business-system methods are acceptable where they preserve useful traceback information.

The rule's shipping and receiving provisions already rely on linking records to reference documents and providing required information to subsequent recipients. Nothing in the regulatory text requires case-level scanning as the exclusive method of identifying TLCs. IFPA's recommendation is therefore not a request to weaken traceability. It is a request that FDA recognize valid methods of producing and linking TLC information based on current business systems, provided that those methods are transparent, documented, and auditable.

FDA should evaluate any flexibility against four principles. First, the flexibility must preserve public health value by enabling FDA to identify a focused path of likely product movements. Second, it must be operationally feasible in high-velocity, perishable supply chains. Third, it must promote interoperability

so information can move between trading partners without custom one-off systems. Fourth, it must create a continuous-improvement pathway so firms have incentives to improve data precision over time rather than divert investment into temporary manual workarounds.

IFPA believes that the reasonable-range and inferred-TLC concepts satisfy these principles. Both approaches can provide FDA with useful lot-level information. Both can be documented in traceability plans. Both can be supported by WMS controls, receiving records, replenishment history, cycle counts, and inventory reconciliation. Both are consistent with the direction of GS1 and PTI implementation resources, which emphasize standardized identifiers, standardized data capture, and interoperable data exchange.

IFPA further believes these flexibilities are most appropriate for final-mile distribution activities involving shipments from distribution centers to retail food establishments, restaurants, and similar endpoints in the supply chain. Applying reasonable-range or inferred-TLC methodologies earlier in the distribution chain could compound uncertainty across multiple successive transactions. By contrast, when applied at the final stage of distribution, these approaches preserve traceback value while limiting potential cumulative error and allowing FDA investigators to focus on a defined and documented set of TLCs associated with a shipment.

I. Reasonable Range of Traceability Lot Codes for Distributors Shipping to Retailers

FDA Question 1. How does industry define a "reasonable" range of TLCs? Would it be feasible to have a specified limit, and if not, how else can a "reasonable" range be defined?

IFPA recommends that FDA define a reasonable range as the smallest set of TLCs that a firm can determine may reasonably be associated with a shipment based on documented inventory-management practices, receiving records, WMS data, replenishment records, slot history, and shipment records. The definition should be outcome-oriented rather than numerical. Produce operations differ by commodity, season, shelf life, facility design, customer mix, slotting method, and system maturity. A fixed cap of two or three TLCs may be workable in some settings but impossible or misleading in others. A cap may also create perverse incentives to under-report plausible lots or redesign records to satisfy an arbitrary threshold rather than improve traceback accuracy.

A practical definition would be: "the narrowest set of TLCs that could reasonably have supplied the quantity of product shipped, as determined through a documented and consistently applied method using available business-system records and inventory controls." This definition gives FDA a standard to evaluate reasonableness without dictating facility-specific numerical outcomes. It also allows FDA investigators to review the methodology and determine whether the range was appropriately narrow given the facts.

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FDA Question 2. What guardrails would need to be in place to ensure that this flexibility would not erode public health benefits?

The guardrails should be tied to transparency, repeatability, and traceback utility. IFPA recommends that FDA require a written methodology in the traceability plan; capture of TLC and TLC-source information at receiving when available; linkage of inbound inventory to pallets, license plates, locations, slots, or other inventory units; documented replenishment and picking logic; routine inventory reconciliation; cycle counts; empty-slot confirmation where operationally relevant; exception handling; employee training; and retention of the system records used to determine the range.

The purpose of these guardrails is not to require a specific technology. The purpose is to ensure that a reasonable range is not speculative. A reasonable range should be generated from records that reflect how the facility actually received, stored, replenished, selected, and shipped product. FDA should also require that firms be able to explain the range during a traceback investigation and produce the relevant records in a sortable electronic format. These controls preserve public health benefit by giving investigators a transparent, reviewable basis for narrowing the universe of potential lots.

FDA Question 3. At most, how many different TLCs are likely to be on one pallet?

IFPA recommends that FDA not establish a universal maximum. The number of TLCs on a pallet depends on product type, supplier practices, packing date, lot definition, case configuration, customer requirements, consolidation practices, and whether the pallet is received as a full single-lot pallet, a mixed-lot pallet, or a pallet that reflects upstream consolidation. In many high-velocity produce channels the number may be low, but in other channels multiple TLCs may appear on a pallet for legitimate reasons.

The better regulatory question is whether the firm can identify the TLCs present or potentially present and whether its records allow FDA to narrow the traceback universe in a meaningful way. A numerical answer detached from operational context will not improve public health. FDA should ask firms to describe, in their traceability plan, how pallet-level TLC information is captured and how mixed-lot pallets are handled.

FDA Question 4. At most, how many different TLCs are likely to be in a pick slot at any given time?

As with pallets, the number of TLCs in a pick slot varies by commodity, slot design, replenishment practices, lot turnover, shelf life, and facility procedures. Some facilities attempt to maintain one active pallet or lot in a slot, while others may have multiple pallets or remnants of prior pallets in a location due to replenishment timing and space constraints.

FDA should not treat the existence of more than one TLC in a pick slot as a failure. It is a predictable feature of high-velocity distribution. What matters is whether the firm's system can identify the TLCs reasonably associated with the slot during the relevant time period and whether inventory controls prevent the resulting range from becoming overly broad. Empty-slot verification, cycle counts, replenishment controls, and exception records are more meaningful safeguards than a fixed TLC count.

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FDA Question 5. How likely is it that an incoming pallet will contain multiple TLCs from the same TLC source or different TLC sources?

Both scenarios can occur. The likelihood depends on supplier practices, commodity, lot definition, harvest and packing patterns, repacking, consolidation, and procurement model. A pallet may contain multiple TLCs from one packer or shipper, or it may contain product from multiple TLC sources if upstream consolidation has occurred. IFPA recommends that FDA explicitly allow range-based or inferred-TLC records to include TLCs from more than one TLC source when supported by the underlying records.

Limiting flexibility to a single TLC source would not reflect actual distribution practices and could reduce rather than increase accuracy. In a traceback investigation, FDA is better served by receiving a transparent list of plausible TLCs and sources than by a forced simplification that excludes plausible lots because they come from more than one source.

FDA Question 6. For an outgoing shipment, should the reasonable range be from the same TLC source, or could it include multiple TLC sources?

The range should be allowed to include multiple TLC sources when the facility's receiving and inventory records indicate that product from multiple TLC sources could reasonably have contributed to the shipment. FDA should not restrict the range to a single source. Such a restriction would be inconsistent with mixed-lot and mixed-source distribution realities and may undermine traceback integrity.

The appropriate guardrail is not a same-source requirement. The appropriate guardrail is that the firm must identify the TLC source or TLC-source reference associated with each TLC in the range to the extent that information is available and required. FDA investigators can then evaluate potential source pathways without losing visibility into the diversity of possible sources.

FDA Question 7. What best practices should distribution centers incorporate?

Best practices should include: inbound capture of TLC and TLC-source information; use of WMS or equivalent systems to link inbound lot information to inventory units; directed replenishment; directed picking; inventory reconciliation; cycle counts; empty-slot confirmation; clear exception procedures; documented handling of mixed pallets and partial pallets; training for receivers, replenishment staff, selectors, and supervisors; and periodic review of the methodology used to generate ranges.

Additional best practices should include encouraging suppliers to provide pallet-level traceability information where available; reducing unnecessary creation of mixed-lot pallets; maintaining unique pallet, license-plate, or inventory identifiers that preserve traceability associations throughout warehouse operations; maintaining uniquely identified pick locations and inventory slots; and designing replenishment and selection practices that minimize unnecessary lot commingling where operationally feasible. Adoption of these controls can significantly improve the precision of reasonable-range and inferred-TLC methods without requiring universal case-level scanning.

FDA should encourage firms to document these controls in traceability plans and maintain evidence that they are implemented consistently. Firms should also review whether the range generated by their method is useful during mock traceback or recall exercises. These exercises can help ensure that the method is not merely administratively compliant but practically useful for investigations.

FDA Question 8. Should the range apply to a given quantity or the entire shipment line?

IFPA recommends that FDA allow the range to apply at the shipment-line level, with flexibility to provide more granular quantity associations where systems can do so. Requiring firms to develop artificial sub-line ranges for arbitrary case quantities would add complexity and cost and may not improve traceback usefulness. Shipment records, bills of lading, ASNs, and invoices commonly operate at line-item levels.

Where WMS data can associate specific quantities with specific inferred or possible TLCs, FDA should encourage (but not universally require) that additional granularity. The regulatory baseline should be practical: the firm should provide the narrowest useful association its system can reasonably generate, and the traceability plan should explain the level of granularity used.

FDA Question 9. How would a range of TLCs be communicated to a retailer, and can ASNs currently transmit a range?

IFPA recommends that FDA work with GS1, PTI, EDI standards groups, retailers, distributors, foodservice operators, and technology providers to develop consistent implementation guidance for transmitting multiple TLCs, TLC-source information, inferred TLCs, and possible alternative TLCs. The GS1 US FSMA 204 resources identify EDI 856 Advance Ship Notice implementation recommendations for FSMA 204 Shipping CTEs and EPCIS recommendations for capturing event information that can supplement CTE/KDE needs. PTI resources also include EDI 856 ASN guidance and sortable spreadsheet templates.

FDA should not require every trading partner to adopt a single transmission technology. However, FDA should strongly encourage standardized data structures so that the same KDEs are not transmitted differently for every customer. The absence of standardization is a major implementation barrier and increases the risk of errors, delays, and costly custom integrations.

Although EDI 856 Advance Ship Notices, EPCIS event-based systems, and other electronic communication tools may be capable of transmitting multiple TLC associations, implementation capabilities vary significantly among trading partners. FDA should therefore permit functionally equivalent communication methods, provided the information remains associated with the relevant shipment, product description, and source information and can be produced in a standardized, sortable format during an investigation. Maintaining technology neutrality will encourage broader participation while supporting long-term interoperability goals.

FDA Question 10. Would these investments help or hinder full compliance?

Investments in WMS functionality, inventory controls, EDI/ASN capability, GS1 identifier adoption, EPCIS-capable event data, product-master-data governance, and standardized KDE formatting all support

long-term compliance. In contrast, investments in temporary manual scanning or paper-intensive workarounds may divert resources from scalable digital systems.

Examples of investments that would support both reasonable-range flexibility and long-term FSMA 204 implementation include improved capture of multiple TLCs associated with palletized inventory; enhanced receiving processes for TLC and TLC-source information; stronger inventory-management controls; expanded use of pallet, license-plate, and location-level traceability identifiers; inventory-verification programs; and periodic validation activities designed to confirm traceability assumptions against actual operational conditions. These investments improve the accuracy of inferred and range-based methods while simultaneously supporting more mature traceability capabilities over time.

FDA should frame reasonable-range flexibility as part of a continuous-improvement pathway. The goal should be to encourage firms to narrow ranges over time as systems improve. A facility that begins with a reasonable range may later move to inferred TLCs, probability-weighted TLCs, more granular inventory transactions, RFID, machine vision, or other technologies. FDA should not require firms to make premature investments in technologies or procedures that may not fit their product flow or deliver meaningful improvements in traceback.

II. Inferred Traceability Lot Codes, With Flexibility, for Distributors Shipping to Retailers

FDA Question 1. Is the example viable, and are there other ways to provide flexibility with similar or better accuracy?

Yes. IFPA strongly supports FDA's inferred-TLC concept because it aligns with the industry's WMS-calculation proposal and provides more useful information than a simple range. Under the example, the distribution center identifies the TLCs it believes were shipped and separately identifies other TLCs that might also have been included. This preserves investigative prioritization. FDA can begin with the inferred TLCs and then expand to the possible alternatives if the investigation warrants.

This approach mirrors how modern distribution systems operate: WMS records can link inbound TLC data to license plates, locations, slots, replenishment events, and outbound orders. The method may not always prove exact at the case level, but it can provide a structured, evidence-based reconstruction of likely product movement. IFPA recommends FDA accept inferred TLCs when the method is documented, consistently applied, supported by inventory controls, and auditable.

FDA Question 2. Should there be a limit on additional TLCs, and what factors should be considered?

Any limit should be risk-based and contextual, not a universal number. Relevant factors include product shelf life; lot turnover; number of active lots in the slot or replenishment path; inventory velocity; whether the product is a high-volume or low-volume item; whether the facility maintains empty-slot verification; whether cycle counts are performed; whether replenishment events are recorded; whether

inbound pallets are linked to TLCs; and whether the firm can demonstrate that the method produces a narrow, useful set of alternatives.

FDA could state that additional possible TLCs should be limited to those that could reasonably have contributed to the shipment under the documented method. This standard gives FDA a basis to challenge overly broad reporting while avoiding arbitrary caps that may not fit real operations.

FDA Question 3. How could this serve as a steppingstone to compliance?

The inferred-TLC framework can operate as a bridge to increasingly precise traceability. First, it allows firms to use existing systems rather than wait for universal case-level automation. Second, it incentivizes firms to improve WMS logic, receiving accuracy, slot discipline, replenishment controls, and outbound data transmission because better controls narrow the set of possible alternatives. Third, it creates a practical migration path toward RFID, machine vision, enhanced barcode capture, EPCIS event data, and other emerging tools where appropriate.

This is preferable to a binary compliance model under which firms must either scan every case or be considered noncompliant. A binary model may discourage investment by setting an unattainable standard for many operations. A continuous-improvement model encourages measurable progress and better data quality over time.

Continued advancement of traceability technologies is likely to further improve lot-level precision. Emerging tools include enhanced barcode technologies, two-dimensional data carriers, improved electronic data exchange, EPCIS-based event capture, RFID applications, machine-vision systems, and other evolving methods that may support more automated identification and communication of traceability information. FDA should ensure that any flexibility framework remains compatible with future innovation and does not inadvertently discourage adoption of emerging technologies that may improve traceback effectiveness over time.

FDA Question 4. How would this information be communicated to a retailer?

FDA should encourage industry to establish common data fields for (1) TLCs believed to be included, (2) other TLCs that may have been included, (3) TLC source or source reference, (4) quantity where known, (5) whether the TLC is inferred or observed and (5) confidence or method indicator where systems can support it. The communication could occur through EDI 856 ASN, EPCIS event data, customer portals, or sortable spreadsheets, depending on trading-partner capability.

FDA should not require confidence percentages in all cases, but it should allow them. Where a WMS can produce probability-weighted TLCs, that information may significantly assist traceback. For example, investigators may prioritize a lot that system records suggest supplied most of the shipped quantity while preserving visibility into lower-probability alternatives.

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III. Eaches

FDA Question 1. Is there an industry or generally understood definition of eaches?

IFPA recommends FDA define "eaches" as individual saleable or usable units removed from a larger case or master container, where the case-level label or case-level TLC information may no longer travel with each individual unit. This definition should be flexible enough to cover foodservice, convenience, retail, and institutional distribution models.

The central issue is not whether product remains traceable in concept. The issue is that once a case is opened, individual units may not carry the same data elements that appeared on the case label. FDA should recognize that eaches are an exception flow that requires practical records rather than an assumption that case-level data can always remain physically attached.

FDA Question 2. Are there circumstances where a case may be broken up throughout the supply chain?

Yes. Cases may be broken in foodservice distribution, convenience distribution, retail replenishment, commissary operations, and specialized customer fulfillment. Although this may often occur immediately before shipment to retail or restaurant customers, it is not limited to that point. FDA should avoid framing eaches as a rare or uniform practice.

The appropriate flexibility should apply whenever case integrity is broken and the firm can preserve product description, supplier or source information, order records, inventory history, and a reasonable or inferred TLC association.

FDA Question 3. How common are eaches in different sectors?

The frequency varies substantially. Eaches are more common in channels serving small-format stores, restaurants, convenience stores, and customers that order in quantities smaller than a full case. They may be less common in full-case grocery distribution but still occur in exception flows or specialized operations. FDA should gather additional data from sector-specific stakeholders before establishing any assumptions about volume.

For regulatory purposes, the more important issue is not the average percentage. It is whether FDA provides a feasible method for retaining traceback value when eaches occur.

FDA Question 4. What additional labeling information could appear on the outside container?

Where eaches are placed into a tote, carton, bin, or other outbound container, the container could include product description, supplier identity, internal item identifier, and TLC or inferred/range TLC information when available. FDA should allow electronic records to serve this function where physical labeling is impractical.

The obstacle is that eaches may be picked quickly into mixed containers with multiple products, and adding label creation at the each level can slow operations and introduce errors. FDA should therefore

accept electronic association through WMS or order-management systems where the outer container does not carry all KDEs physically.

FDA Question 5. What percentage of outgoing inventory is shipped as eaches?

IFPA does not recommend that FDA establish a universal percentage assumption. Eaches vary by business model. A specialty foodservice distributor may ship a higher proportion of eaches than a conventional retail DC. A convenience distributor may rely on each picking as a routine business model.

FDA should request data from sectors where eaches are common and use those data to design flexibility. The regulatory standard should be scalable across different business models rather than tied to a presumed percentage.

FDA Question 6. Are eaches created only when small quantities are needed?

Small-quantity fulfillment is a major driver, but not the only one. Eaches may also be created for assortment, customer-specific pack-out, short supply, quality checks, damage replacement, convenience-store replenishment, institutional orders, or operational recovery. FDA should describe eaches broadly enough to capture these scenarios.

The common denominator is that the original case-level traceability data may no longer be physically attached to each unit. That is the problem FDA's flexibility should solve.

FDA Question 7. What are the traceability challenges for eaches?

The principal challenge is preserving TLC and TLC-source association after the case is opened. Other KDEs—such as product description, supplier, purchase order, shipment reference, and quantity—often remain available through business records. The lot identity is the element most likely to become more difficult when case labeling no longer accompanies each unit.

A related challenge is that many consumer-saleable units are identified through product-level identifiers rather than machine-readable lot identifiers. In some cases, lot information is not present on the individual unit; in others, the information may appear only as a human-readable date or production code. Consequently, once a case is opened and individual units are distributed, preserving lot-level linkage often depends on business-system records, inventory transactions, and documented operational controls rather than continued physical association of traceability information with every unit. This reality reinforces the need for practical approaches that preserve traceback utility without requiring technologies or labeling practices that are not yet widely implemented.
FDA should allow firms to use original case records, inventory history, WMS data, and reasonable-range or inferred-TLC logic to preserve traceability for eaches. This approach maintains investigative value without imposing impractical item-level labeling requirements.

FDA Question 8. Would reasonable-range or inferred-TLC flexibilities help?

Yes. Inferred-TLC and reasonable-range methods are especially useful for eaches because they acknowledge that exact physical linkage may be difficult after case break. A firm can identify the TLCs

associated with the source case or cases from which eaches were selected and can communicate that information in records.

FDA should explicitly state that use of these flexibilities for eaches is acceptable where the firm documents how eaches are created, how source cases are identified, and how records are maintained.

IV. Returns and Reclamations

FDA Question 1. Are returns and reclamations of individual items considered under the industry definition of eaches?

They may overlap, but FDA should not treat them as identical. Eaches describe a unit configuration after a case is opened. Returns and reclamations describe product moving outside the normal forward distribution flow. A returned item may be an each, a case, or a broader quantity. A reclamation may involve damaged, unsaleable, expired, recalled, or otherwise non-saleable product.

FDA should provide separate definitions while allowing the same practical recordkeeping principles to apply where the traceability challenge is the same: preserving association to original product and lot records after product has left normal inventory flow.

FDA Question 2. Are there standard definitions?

Definitions vary by sector and company. IFPA recommends FDA define returns as product sent back or credited after delivery or attempted delivery, and reclamations as product removed from sale or normal distribution for credit, disposal, quality, damage, recall, or supplier recovery purposes. FDA should emphasize that definitions are for traceability purposes and should not override commercial terms used in contracts.

Clear definitions will help firms identify when modified records are appropriate and prevent unnecessary debate during inspections.

FDA Question 3. What are the biggest KDE challenges?

The most difficult KDEs are TLC and TLC-source information when product has been removed from original packaging or when returns are consolidated. Product description, supplier, customer, date, and quantity may often be available through commercial systems. Precise lot identity may be more difficult if product is returned without its original case or label.

FDA should recognize that returns and reclamations are exception processes and permit firms to rely on original shipment records, customer records, credit records, and inventory transaction histories to identify the most likely associated TLC or range of TLCs.

FDA Question 4. What flexibilities would help?

FDA should permit modified records for returns and reclamations that identify the product, returning location or customer, date of return or reclamation, quantity, reason code where available, reference document, and TLC or reasonable/inferred TLC association where exact TLC is not available. FDA should

not require firms to reconstruct lot information that cannot reasonably be recovered from normal records after the product has left controlled inventory.

This approach preserves traceback value while recognizing that returns and reclamations often involve product that is damaged, out of package, consolidated, or otherwise outside normal salable inventory.

V. Food Waste Recovery

FDA Topic. What challenges exist around food waste recovery not covered by the existing exemption for donated food?

IFPA appreciates FDA's clarification that the definition of shipping does not include donation of surplus food. FDA should provide examples showing how this principle applies to food banks, secondary redistribution organizations, community recovery programs, retail donation programs, and mixed inventory where some product is donated and some remains in commercial channels.

The principal concern is not that donated food should be subjected to extensive new recordkeeping. Rather, stakeholders need clarity so food recovery is not discouraged by uncertainty. FDA should ensure that traceability expectations do not create barriers to donation or increase food waste. If product moves from commercial inventory to donation, firms should be allowed to maintain existing commercial records without creating new FSMA 204 shipping records solely because the product was donated.

VI. Intracompany Shipments

FDA Question 1. Does the rule require duplicate records for intracompany shipments?

IFPA appreciates FDA's reference to 21 CFR 1.1455(f) and (g), which recognize that firms need not duplicate existing records if those records contain required information and need not keep all required information in a single set of records. Nonetheless, companies remain concerned that intracompany movements may be interpreted as requiring duplicative data transactions even where enterprise systems already preserve inventory and lot continuity.

FDA should clarify that an enterprise may use existing ERP, WMS, transportation, and inventory records to satisfy intracompany shipment requirements, provided those records can reconstruct product movement and provide required information during an FDA request.

FDA Question 2. Are TLCs tracked within systems?

Many larger companies track lots within ERP or WMS systems, although the degree of precision varies by operation. Some systems track lots at receiving and inventory locations; others track at pallet, license plate, slot, item, or order level. FDA should not assume uniform system architecture.

The important question should be whether the system preserves enough information to identify which TLCs came into the enterprise, how product moved among facilities at a meaningful level, and which TLCs or inferred TLCs ultimately left the enterprise to another company or customer.

FDA Question 3. What challenges are unique to intracompany shipments?

Intracompany shipments often involve internal replenishment, hub-and-spoke distribution, temporary holding, consolidation, or transfer between related facilities. Because the sender and receiver are part of the same enterprise, the public-health need for duplicative transmission may be lower than in intercompany transfers, especially where a shared system already stores the information.

The challenge is avoiding redundant records that add administrative burden without improving traceback. FDA should focus on reconstructability. If the company can show where product was received, where it moved internally, and where it was ultimately shipped externally, the public-health purpose is served.

Additional complexity may arise because inventory-management systems, transportation-management systems, warehouse-management systems, procurement platforms, and enterprise-resource-planning systems are not always fully integrated. In many enterprises, the information necessary to reconstruct product movement exists but may reside in multiple systems that were developed for different operational purposes. FDA should recognize that the principal challenge in many intracompany scenarios is not lack of traceability information but rather the need to link related records across multiple systems efficiently during a traceability investigation.

FDA Question 4. What flexibility would help?

FDA should permit a simplified intracompany framework. Under this approach, the company would maintain records of incoming TLCs from external suppliers, internal inventory movements at a level sufficient to reconstruct product flow, and final outgoing shipments to external recipients. The company should not be required to generate duplicative records at every internal transfer if existing systems already maintain the necessary information.

FDA should also clarify that TLC and TLC-source information should remain available at the retail food establishment or restaurant receiving the product, regardless of whether that location is within the same enterprise, but that the mechanism for making that information available may be through centralized systems rather than duplicative local records.

VII. Shipments for Retailers Transforming Food and Sending to Other Retailers

FDA Question 1. Are there flexibilities that could alleviate concerns?

FDA should consider a limited modified recordkeeping framework for retail kitchens, commissary-style operations, and retail food establishments that primarily manufacture food for sale at the originating location but transfer limited quantities to nearby affiliated retail locations. Examples may include sushi, fresh-cut fruit, salads, or similar retail-prepared items.

The flexibility could be limited to scenarios where the majority of production is sold on-site, transfers are to affiliated or nearby locations, the product has a short shelf life, records identify the originating kitchen, production date, product description, quantity, destination, and ingredient lot information where available, and standard retail food safety controls remain in place. FDA should evaluate whether full

transformation KDEs in these cases provide meaningful incremental traceback value relative to the burden.

FDA Question 2. Are there other implementation concerns?

Retail kitchens and restaurants often operate with labor constraints, rapid production cycles, limited back-office staff, and systems not designed for manufacturing-style traceability. Applying full transformation records to small transfers may require operational processes that are disproportionate to the volume and risk profile.

FDA should provide examples that distinguish large commissary manufacturing operations from limited retail-kitchen transfers. The former may be more capable of full transformation records; the latter may need modified records focused on practical traceback.

FDA Question 3. What best practices could help?

Best practices include standardized production logs, date and time of preparation, destination records, ingredient reference documents, product description, quantity produced, quantity transferred, and retention of supplier and receiving records for ingredients on the FTL. FDA should encourage digital templates that can be used by retail kitchens without requiring complex manufacturing execution systems.

FDA should also allow firms to group limited retail-kitchen production into practical production lots based on date, shift, recipe, and ingredient set where the firm can explain the approach in its traceability plan.

VIII. Data Standardization

FDA Question 1. Is there a specific data standard that industry should coalesce around?

IFPA recommends that FDA encourage convergence around GS1 and PTI-aligned standards while avoiding a requirement that every entity use a single technology. GS1 Standards provide a common language for identifying, capturing, and sharing supply-chain data. GS1 US has issued FSMA 204 resources including a retail grocery and foodservice guideline, EPCIS recommendations for FSMA 204 CTEs, and EDI implementation recommendations for the X12 EDI 856 Advance Ship Notice. GS1 describes EPCIS as a data-sharing standard for supply-chain visibility that helps provide the what, when, where, why, and how of products and assets. PTI resources provide produce-specific implementation guidance, TLC source and reference guidance, EDI 856 ASN guidance, and sortable spreadsheet templates.

FDA should encourage the following baseline concepts: use of standardized product identifiers such as GTIN where available; standardized location identifiers such as GLN where used; standardized lot/batch representation; clear TLC-source or TLC-source-reference data; consistent shipping and receiving KDE fields; EDI 856 ASN capability for Shipping CTE information where trading partners use EDI; EPCIS/CBV event data for firms capable of event-based traceability; and FDA-aligned sortable spreadsheet templates for firms that are not yet able to exchange data electronically.

FDA should also recognize that implementation barriers frequently arise not from the absence of standards but from the proliferation of customer-specific adaptations of otherwise standardized data-exchange methods. Even where EDI and related standards are used, trading partners often maintain unique specifications that increase implementation costs and create interoperability challenges. FDA therefore has an opportunity to encourage more consistent industry implementation by promoting common data structures and standardized approaches for communicating FSMA 204 information across supply chains.

FDA should also consider recognizing voluntary standards as a safe harbor or compliance pathway. A safe harbor would not mandate technology. Rather, it would state that a firm using recognized standards and maintaining required KDEs in a documented, retrievable, and interoperable manner will generally be considered to have adopted a reasonable data-exchange approach. This would reduce fragmentation, support smaller firms, and give technology providers a clearer implementation target.

Summary of Proposed Guardrails for FDA Recognition of Reasonable-Range and Inferred-TLC Methods

Traceability Plan Documentation: The firm should describe the method used to determine inferred TLCs or reasonable ranges; the types of records used; the level of granularity; the circumstances in which the method applies; and how exceptions are handled.
Receiving Controls: The firm should capture TLC and TLC-source information at receiving through available means such as ASN, GS1-128 label scan, supplier document, data entry, or other business record.
Inventory Linkage: The firm should link received inventory to pallets, license plates, lots, locations, slots, or other inventory units sufficient to support later reconstruction.
Replenishment and Picking Logic: The firm should maintain records or system logic showing how product is replenished and picked, including FEFO/FIFO or other selection rules where applicable.
Inventory Accuracy Program: The firm should conduct cycle counts, reconcile inventory exceptions, and verify empty slots where needed to prevent ranges from becoming overly broad.
Exception Handling: The firm should document how it handles missing supplier data, unreadable labels, mixed pallets, damaged cases, returns, eaches, and manual overrides.
Record Production: The firm should be able to produce records showing inferred TLCs, possible alternative TLCs, TLC source/source reference, product description, quantity, shipment date, destination, and reference document numbers in a sortable electronic format.
Continuous Improvement: The firm should periodically assess whether its method can be narrowed or improved as systems, data standards, and trading-partner capabilities advance.

INTERNATIONAL FRESH PRODUCE ASSOCIATION

Illustrative WMS-Based Inferred-TLC Model

The following example is provided for discussion purposes. A distribution center receives two pallets of bagged salad. Pallet A contains TLC 001A and TLC 001B; Pallet B contains TLC 001B and TLC 001C. The WMS assigns internal license plates to each pallet and records their placement into reserve or pick slots. As customer orders are filled, the WMS records the pick location, replenishment history, and quantity selected. If the WMS logic indicates that ten cases were most likely picked from inventory associated with TLC 001B, but the slot history shows that residual product from TLC 001A or TLC 001C could also have been present, the outbound record would identify TLC 001B as inferred and TLC 001A/001C as possible alternatives.

This model provides FDA with more actionable investigative information than a broad uncontrolled range. It identifies the most likely lot while preserving a transparent view of plausible alternatives. It also allows investigators to understand how the facility generated the record. If FDA later determines that the inferred TLC is not implicated, it can expand to the possible alternatives without starting from a blank slate.

Where a firm can generate confidence indicators or probabilities, FDA should allow those indicators to be transmitted. For example, the firm may report that one TLC supplied the majority of the inventory available for selection while another TLC was present only as a residual possibility. FDA should treat confidence indicators as supplemental investigative information, not as a new required KDE unless and until industry has standardized the approach.

Shipment Line	Product	Quantity	Inferred TLC	Possible Alternative TLCs	Method Indicator
BOL 213123-01	Bagged Salad	10 cases	001B	001A; 001C	WMS slot/replenishment logic

Regulatory and Standards Alignment

FSMA 204 requires covered entities to maintain KDEs associated with CTEs and to make required information available to FDA within the regulatory timeframe. The flexibility requested here does not alter the underlying requirement to maintain and provide records. It clarifies how firms may determine and communicate TLC information when exact outbound case-level confirmation is not operationally feasible.

The traceability plan requirement provides the regulatory mechanism for documenting these methods. FDA should use guidance or an FAQ to explain that a firm's traceability plan may include WMS-supported reasonable-range or inferred-TLC procedures for defined shipment scenarios, provided the procedures are supported by documented controls and consistently applied.

GS1 and PTI resources provide the standards environment in which these flexibilities can operate. GS1 US resources for FSMA 204 include guidance on using GS1 Standards for traceability, EPCIS recommendations for FSMA 204 CTEs, and EDI 856 ASN implementation recommendations. PTI resources include implementation guidance, TLC-source materials, EDI ASN guidance, and sortable spreadsheet templates. FDA should leverage these resources to promote common data fields and reduce one-off customer-specific requirements.

EPCIS/CBV should be recognized as an important optional pathway for event-based traceability. EPCIS is designed to capture and share interoperable event information, including the what, when, where, why, and how of product movement. Not every firm will implement EPCIS immediately, but FDA should encourage its use where appropriate and ensure that FDA-recognized flexibility is compatible with EPCIS event concepts.

Conclusion

IFPA appreciates FDA's willingness to engage stakeholders on practical flexibilities for lot-level tracking. The fresh produce industry supports the public-health objectives of FSMA 204 and recognizes the importance of faster, more accurate traceback. The question before FDA is not whether traceability should improve. It is how to improve traceability in a manner that is accurate, interoperable, scalable, and feasible in real supply chains.

FDA should recognize that universal outbound case-level scanning is not the only, or necessarily the best, path to traceback improvement. In many high-velocity distribution environments, WMS-supported methods can provide a transparent, auditable, and useful reconstruction of likely and possible TLCs while avoiding labor-intensive practices that may not meaningfully improve accuracy. A well-designed inferred-TLC framework, supported by reasonable-range flexibility and clear guardrails, would advance public health by giving FDA actionable information and would advance implementation by aligning regulatory expectations with operational reality.

IFPA therefore requests that FDA issue a formal flexibility recognizing WMS-supported inferred TLCs and reasonable TLC ranges for distribution-center-to-retail and distribution-center-to-restaurant shipments, including eaches and related exception flows where appropriate. FDA should couple this flexibility with traceability-plan expectations, inventory-control guardrails, and encouragement of GS1/PTI-aligned data standards. IFPA and its members stand ready to work with FDA, GS1, PTI, retailers, distributors, foodservice operators, technology providers, and other stakeholders to develop implementation examples, pilot approaches, and standardized templates that preserve traceback effectiveness while enabling practical compliance.

Respectfully,

INTERNATIONAL FRESH PRODUCE ASSOCIATION

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