

## **FDA Issues Final Rule on Recordkeeping, Product Tracing Requirements for High-Risk Foods**

FDA on Nov. 15 released its [final rule](#) setting new record-keeping requirements for foods it deems high-risk. Set for publication in the Nov. 21 *Federal Register*, the “traceability” rule requires entities at key points in the supply chain to keep records of certain high-risk foods as they move through the supply chain, and also to provide more general records of their traceability record-keeping program.

Compliance with the requirements set by the new regulations is required by three years after the Jan. 20 effective date of the final rule, i.e., Jan. 20, 2026. That’s an additional year from what was originally proposed by FDA (see [ITT 09/22/2020](#)), and will give entities subject to the final rule additional time to understand the requirements of the rule, purchase or update tracing technology, train staff, coordinate with supply chain partners, and establish or update record-keeping systems, the agency said.

Required by the Food Safety Modernization Act over a decade ago, the final rule requires entities that “manufacture, process, pack, or hold FTL foods maintain and provide to their supply chain partners specific information (key data elements, or KDEs) for certain critical tracking events (CTEs) in the handling of the food, consistent with the developing industry consensus approach to food tracing,” FDA said.

“The information that firms must keep and send forward under the rule varies depending on the type of supply chain activities they perform with respect to” foods listed on the FDA’s new Food Traceability List, “from harvesting or production of the food through processing, distribution, and receipt at retail or other point of service,” FDA said. “Central to the proposed requirements is the assignment, recording, and sharing of traceability lot codes for” listed foods, “as well as linking these lot codes to other information identifying the foods as they move through the supply chain.”

Entities covered by the final rule also will have to “establish and maintain a traceability plan that, among other things, describes their procedures for maintenance of records under the new requirements, identification of [listed] foods handled, and assignment of traceability lot codes to” listed foods, FDA said.

FDA’s [list of high-risk foods](#) subject to the rule’s requirements—unchanged from the list released alongside FDA’s proposed rule, but with additional detail added since—covers cheeses (other than hard cheeses), shell eggs, nut butters, cucumbers (fresh), herbs (fresh), leafy greens (fresh and fresh-cut), melons (fresh), peppers (fresh), sprouts (fresh), tomatoes (fresh), tropical tree fruits (fresh), fruits (fresh-cut), vegetables (fresh-cut), finfish (fresh, frozen and smoked), crustaceans (fresh and frozen), molluscan shellfish and bivalves (fresh and frozen) and ready-to-eat deli salads (refrigerated).

As with FDA’s proposed rule, the agency’s final rule includes mechanisms for adding and removing foods from the Food Traceability List.

FDA made several changes in the final rule in response to comments received on its proposal “that will make the final rule easier for supply chain entities to understand and comply with, while still ensuring that the rule substantially improves FDA’s ability to respond quickly and effectively to foodborne illness outbreaks involving foods on the” Food Traceability List, FDA said.

The agency “streamlined” requirements for what must be included in a traceability plan, and deleted a proposed requirement to keep a list of listed foods shipped. Those who grow or raise a listed food must now keep a farm map containing geographic coordinates instead of proposed records documenting the growing area coordinates for individual traceability lots of the food. The final rule also changes some “critical triggering events” for which entities are required to maintain records. Some responsibilities for records on origination, harvesting, cooling and packing of

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food are transferred from the “first receiver” to the initial packer, FDA said.

Key data elements required for shipping and receiving listed foods “have been streamlined” and shipping record requirements no longer apply to shipments that occur before a raw agricultural commodity is initially packed, FDA said. FDA added a new critical triggering event specific to harvesting and cooling of raw agricultural commodities before they are initially packed, and events for “transformation” and “creation” of a listed food have been combined under a single transformation event.

The final rule also includes privacy-related changes, including now requiring only the title and phone number of an entity’s listed point of contact, rather than the name. Addressing concerns related to revealing information about an entity’s supplier, FDA now will allow alternative methods to pass forward information on a listed food, such as through websites that only allow access to a government email address.

FDA also made several changes to exemptions from the rule’s requirements, including a revised exemption for small producers, an expanded exemption for food sold by farms directly to consumers, an expanded exemption for foods subject to a kill step, and the addition of new partial or full exemptions from the regulations, including for raw bivalve molluscan shellfish, foods subject to regulation by USDA and food for research or evaluation.

### House to Take Up Bill to Avoid Rail Shutdown Amid Union Objections

The House this week will look to impose a labor deal on the rail industry in a bid to avoid a looming strike that could cause widespread disruptions to supply chains. The effort, [announced](#) by Speaker Nancy Pelosi, D-Calif, came hours after President Joe Biden [urged](#) lawmakers to adopt the tentative agreement between labor unions and rail companies from September (see [ITT 09/15/2022](#)) “without any modifications or delay” to “avert a potentially crippling national rail shutdown.”

Pelosi said the agreement includes a 24% raise, time off for some medical care and other benefits. The National Railway Labor Conference, which represents major rail

companies, said the agreement was the “product of good faith negotiations” and said Congress should approve it. “We support President Biden’s call for Congress to promptly implement the agreements for the remaining unions in order to avoid a work stoppage,” an NRLC spokesperson said Nov. 29.

Majority Leader Steny Hoyer, D-Md., said during a press call with reporters that the House will begin debate on the bill at 9 a.m. on Nov. 30. He said the Democrats are still counting votes, but that he hopes the bill will get broad bipartisan support. “We want to get it to the Senate as soon as possible,” he said. He said he’s sympathetic to the issue of sick leave for railroad workers, but that a functioning freight rail system is “absolutely essential” for the economy.

But some rail workers were hoping for a better deal and were preparing to begin a strike next week. John Feltz, rail division director for the Transport Workers Union of America, said he doesn’t think Congress should be involved in the negotiations, adding that workers have a right to strike under the Railway Labor Act. He also said he’s concerned about the precedent this sets for future disagreements between rail companies and workers, who don’t receive paid sick days.

“To me, this gives the railroads a superpower,” Feltz said in an interview Nov. 29. “That allows them to dominate that negotiating table knowing that, you know what? You’re not allowed to strike.”

Feltz said he doesn’t believe rail workers will agree to again postpone their strike—currently set for Dec. 9—to try to work out a better deal with railroad companies. “We’ve done that already,” said Feltz, who has worked for 48 years in the rail industry. “How much more can we push it out and push it out?”

Biden this week said he’s “pro-labor” and is “reluctant to override the ratification procedures and the views of those who voted against the agreement.” But “in this case—where the economic impact of a shutdown would hurt millions of other working people and families—I believe Congress must use its powers to adopt this deal.” More than 400 trade associations warned Congress that a strike would severely disrupt freight movement and back up supply chains (see [ITT 11/28/2022](#)).

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Pelosi also said Congress has little choice, adding that the U.S. needs to avoid a rail shutdown. She said the strike would cause more than 750,000 workers to lose their jobs in the first two weeks, and “millions” of families would lose access to groceries, medications and other goods.

“We are reluctant to bypass the standard ratification process for the Tentative Agreement—but we must act to prevent a catastrophic nationwide rail strike, which would grind our economy to a halt,” Pelosi said. “Under the Commerce Clause of the Constitution, Congress has both the authority and the responsibility to prevent this outcome and ensure the uninterrupted operation of critical transportation services.”

Pelosi said the House will take up a bill adopting the tentative agreement this week and send it to the Senate “with no poison pills or changes to the negotiated terms.” Although Biden said some lawmakers want to “modify the deal to either improve it for labor or for management,” Congress can’t afford to spend time on revisions. “However well-intentioned, any changes would risk delay and a debilitating shutdown,” he said. “The agreement was reached in good faith by both sides.” — *Ian Cohen and Mara Lee*

### FMC Releases Draft Finding of No Significant Impact for D&D Proposed Rule

The Federal Maritime Commission issued a draft “Finding of No Significant Impact” for its recent proposed demurrage and detention billing requirements (see [ITT 10/07/2022](#)), the agency said in a [notice](#) released last week. The finding will become final within 10 days of the notice’s publication in the *Federal Register* “unless a petition for review is filed,” the FMC said. Petitions for review must be submitted on or before Dec. 9.

### Compliance Officials Say Forced Labor Enforcement Will Continue to Climb

NEW YORK—The standard of proof for cotton importers is tremendously high, compliance officials said during a panel at the Nov. 10 [Apparel Importers Trade and Transportation Conference](#).

Janet Labuda, head of compliance at Maersk customs services and a former director of CBP’s Textile Enforcement and Operations Division, gave the example of a manufac-

turer that bought organic cotton from India but ginned it in China. She said a CBP official asked: “How do you know there wasn’t one thread of [Xinjiang] cotton caught in the machine?”

The importer spent \$500,000 in storage, legal and demurrage fees, but did not prevail, and lost \$10 million in sales, as well as an entire season’s worth of products.

Labuda said that when she worked at CBP, she asked if the agency could give more direction on what “clear and convincing evidence” is, but her colleagues said that if they were to give 10 examples of steps to take, a company would say, “Well, I did nine, is that good enough?”

The most recent Labor Department [report](#) on child and forced labor said there are 158 goods from 77 countries that are made with either child labor or forced labor.

“I think that is going to be a blueprint for the forced labor task force,” Labuda said. “Once we have the new calendar year kick in, I think we’re also going to see more enforcement.”

Altana AI, a company that sells artificial intelligence software that attempts to penetrate deeper into supply chains, also participated in the panel. Kristen Daniels, Altana’s business development lead, said the company is working both with private companies and regulators, and has identified a million companies tied to forced labor across 590 industries. — *Mara Lee*

### CBP Adds New Forced Labor Benefits to CTPAT Trade Compliance Program

CBP is adding three new benefits related to forced labor in its Customs-Trade Partnership Against Terrorism Trade Compliance program, CTPAT Director Manual Garza said in a [message](#) to the trade community posted to the CBP website Nov. 18. Effective immediately, CBP will provide “to the greatest extent possible and practical,” front-of-line admissibility review, the ability to hold instead of redeliver goods suspected of forced labor and the ability to move shipments detained under a withhold release order to a bonded facility.

The new benefits follow CBP’s announcement in August of six new forced labor requirements to its CTPAT Trade

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Compliance program, including risk-based mapping, code of conduct, evidence of implementation, due diligence and training, remediation planning and sharing of best practices (see [ITT 08/22/2022](#)). The new benefits “are provided in exchange for compliance with the recently updated Trade Compliance program forced labor requirements,” CBP said.

The front-of-line admissibility review benefit will give CTPAT Trade Compliance members who have shipments detained due to forced labor priority for review by the relevant CBP Center of Excellence and Expertise, Garza said in the message. “The importer must assert that they are an active member [in the] CTPAT Trade Compliance program and request prioritized review at the time that supporting documentation is submitted to CBP,” he said. The Center will then process the package above non-CTPAT Trade Compliance member packages received by the Center team or division.

In another benefit, CTPAT Trade Compliance members who have shipments arrive at their facility that are later determined to have ties to forced labor also will be able to hold the shipment intact at their facility, instead of redelivering the merchandise, until an admissibility determination is made or an inspection is required. Members who have a shipment detained by CBP due to a withhold release order also will be allowed to move the goods to a bonded facility to be held intact until a CBP admissibility determination is made, Garza said. — *Brian Feito*

### CBP Updates CTPAT Trade Compliance Handbook With Forced Labor Requirements

CBP on Nov. 1 posted the latest version of its Customs-Trade Partnership Against Terrorism (CTPAT) Trade Compliance program [handbook](#). Version 2 updates the initial release of the handbook in July by revising language on the disclosure benefit and adding new sections of program requirements, including those related to forced labor announced in August (see [ITT 08/22/2022](#)).

### Trade Analyst Doesn't Expect Much Difference in Biden's Trade Policy Post-Midterms

Simon Lester, president of China Trade Monitor and WorldTradeLaw.net, said he doesn't expect any large changes in the Biden administration's trade policy follow-

ing the midterm elections. In a [blog post](#) Nov. 15, Lester wrote that while the administration could look at the election results as not provoking too much of a backlash to its trade policy, it's more likely that the election cycle was favorable to Democrats, due to the Supreme Court's *Dobbs* decision and “terrible” GOP candidates.

“I don't expect them to make big changes in trade policy,” Lester said. The Indo-Pacific Economic Framework, the U.S.-EU Trade and Technology Council, “etc. will go forward; the Section 301 tariffs will be reviewed as required by statute, but there will be no big changes to the U.S.-China trade relationship; and [World Trade Organization] reform will meander along.”

Lester similarly doesn't expect a big swing in trade policy in Congress. Retiring Sen. Pat Toomey, R-Pa., “was a strong free trader,” but given the similarities of Democrat John Fetterman, who won the election, and his challenger, Republican Mehmet Oz, on trade, Lester said he suspected for some time that there “wasn't going to be much of a voting difference.” With Sen. Rob Portman, R-Ohio, also retiring, Lester also doesn't see much of a difference between Republican J.D. Vance, the ultimate victor, and Democrat Tim Ryan on trade. However, Sen. Mark Kelly, D-Ariz., triumphing over his Republican challenger, Blake Masters, “is fortunate for trade,” Lester said. In Georgia, where incumbent Sen. Raphael Warnock faces a run-off against Republican Herschel Walker, Warnock “would probably be more pro-trade,” Lester said in the post.

### Chamber of Commerce Calls for GSP, MTB Renewal

The U.S. Chamber of Commerce says “it's critical that legislation to renew the Miscellaneous Tariff Bill (MTB) and the Generalized System of Preferences (GSP) not get lost in the shuffle” during the lame duck session, as Congress tries to find a way to pass funding for the federal government.

John Murphy, senior vice president for international policy, [wrote](#) Nov. 18 that since past votes for MTB and the GSP benefits program had been nearly unanimous, “This shouldn't be hard.”

The MTB renewal proposed by the House Ways and Means Trade Subcommittee chairman would eliminate finished

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goods in the MTB in future cycles, which the Chamber suggested is the controversy holding up both bills.

MTB is defended as an aid to manufacturers, but includes tariff waivers on a number of consumer products, including scissors, leather belts, certain shoes, electric rice cookers, certain portable stoves, drip coffee makers, leather basketballs, table saws, certain sports rackets, swim goggles, plastic pet carriers, aquarium plastic plants, nail clippers, tweezers, curtain hardware, steam irons and certain microwave ovens.

Products covered by MTB must have no more than \$500,000 in annual tariffs in aggregate, and be administrable; otherwise, the only restriction is that no domestic producer or member objects. The last version included 1,655 duty suspensions.

While it's true that the Senate does not agree that the restriction is necessary, (see [ITT 06/17/2021](#)), given that any item can be barred from MTB when a member objects, the differences between the Senate and House versions of GSP and MTB are not the main obstacle; instead, it is the Democrats' desire to make sure that Trade Adjustment Assistance get renewed this year, which Republicans oppose (see [ITT 11/16/2022](#)).

Murphy argued that since the tariff reduction for any item has to stay under \$500,000, there's no harm in allowing finished goods. He also said that while it's good to have conditions for GSP, "setting overly strict criteria could lead foreign governments to conclude that GSP's compliance burdens outweigh its economic benefits. This would undermine the program's viability as a tool to foster trade-based economic development while also failing to advance the new criteria's goals. The Chamber encourages lawmakers to work together on any new GSP eligibility criteria under consideration and reach a balanced approach that will allow the program to be reauthorized this year."

And, Murphy said, if GSP cannot be renewed this year, Congress should refund the GSP tariffs paid during the 23 months the program has been gone—it estimated this at \$2 billion.

"Doing so would provide a critical lifeline to U.S. small businesses, many of which are owed hundreds of thousands or even millions of dollars, that have waited nearly two years for Congress to act on GSP," he said.

### USTR Extends 81 Section 301 Exclusions for COVID Goods Until February

Exclusions from Section 301 China tariffs for 81 medical care products related to COVID-19 will be extended until the end of February 2023, the Office of the U.S. Trade Representative said in a pre-publication [notice](#) released Nov. 23. The exclusions had been set to expire Nov. 30.

"In light of the continuing efforts to combat COVID, the U.S. Trade Representative has determined that a 3 month extension of the 81 COVID related product exclusions is warranted," USTR said in the notice.

The exclusions had originally been announced as a set of 99 exclusions, of which 81 were extended in November 2021 and June 2022. They are listed under U.S. Note 20(sss) to Subchapter III of Chapter 99 of the Harmonized Tariff Schedule of the U.S., and tariff subheading 9903.88.66. — **Brian Feito**

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**INTERNATIONAL TRADE TODAY**



The source for trade compliance news

(ISSN 1932-6289)

PUBLISHED BY WARREN COMMUNICATIONS NEWS, INC.

Warren Communications News, Inc. is publisher of International Trade Today, Export Compliance Daily, Trade Law Daily, Communications Daily, Communications Litigation Today, Consumer Electronics Daily and other specialized publications.

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