Updates

On November 1, 2023, the U.S. Food and Drug Administration (FDA) published a proposed rule to amend Prior Notice requirements for imported human and animal food in two key ways:

1. Prior notice for human food and animal feed arriving by international mail must include the name of the mail service and a mail tracking number; and
2. Prior notice and food facility information must be submitted within a certain timeframe after FDA has issued a refusal or hold notice.

Additionally, on October 13, 2023, FDA published guidance clarifying how to best comply with the current FDA Prior Notice rule.

This Update summarizes FDA's Prior Notice requirements, the agency's November 1 proposed rule seeking to amend these requirements, and FDA's recently published final guidance (its fourth edition) on compliance.

What Is Prior Notice?

Prior Notice is the requirement to provide advance information to FDA regarding human food and animal feed being imported into the United States. FDA has required prior notice since 2003. 68 Fed. Reg. 58974 (Oct. 10, 2003). Depending on the mode of shipment, prior notice must include, for example, information on the submitter, shipment, arrival, and details regarding the origins, manufacture, and identity of the food. 21 C.F.R. § ?1.281. Importers currently submit prior notice via either FDA's Prior Notice System Interface (PNSI) or U.S. Customs and Border Protection's (CBP) ABI/ACE Interface.

Consequences. FDA may refuse food arriving at the port of entry if it considers prior notice inadequate (21 C.F.R. §?1.283) or it may hold food if it is from an unregistered foreign facility (21 C.F.R. §?1.285). Importers may correct these violations in responses to FDA.

Proposed Rule

FDA's November 1 proposed changes would amend prior notice requirements by:

- Requiring prior notice of foods arriving by international mail to include (1) the name of the mail service and (2) a mail tracking number. FDA aims to improve food tracking, identification, inspection, emergency response times, and agency coordination during investigations and surveillance operations.
- Removing the requirement that food arriving by international mail may only be reported on FDA's PNSI. This is because CBP's new system, the ABI/ACE Interface, can now accept submissions for such foods. Submissions for food arriving by international mail can be reported via either FDA's or CBP's system.
- Setting response deadlines for importers if their food has been subject to an FDA prior notice refusal or hold. First, importers would have 10 calendar days to provide FDA with adequate notice, from the date of an FDA prior notice refusal. Second, importers would have 30 calendar days from the date of receiving an FDA prior notice hold to obtain a food facility registration. FDA aims to lower the cost of holding food at the port of entry by expediting corrective submissions.

Interested parties may submit comments on FDA's proposed rule through January 30, 2024.

FDA's Final Guidance

FDA's October 13 Guidance clarifies that submitters must provide prior notice to FDA only, not both FDA and CBP, and submitters can do so through either FDA's PNSI or CBP's ABI/ACE interface. (Question D.3.2).

The Guidance also clarifies:

- Food imported from a country that has a Systems Recognition Arrangement (SRA) with FDA or an equivalence determination from FDA requires prior notice. (Question C.1.4). An SRA is an agreement between FDA and a foreign regulatory counterpart concluding that they operate comparable regulatory programs. Similarly, FDA makes an equivalence determination if it concludes that a country's safety controls achieve at least the same level of public health protection as those mandated under corresponding U.S. requirements.
- FDA requires prior notice for food that is imported from a country that is a signatory to a free trade agreement with the United States. (Question B.10.3).

Lastly, the Guidance clarifies the procedure for FDA prior notice refusals or holds.

- FDA will send notice of prior notice refusals or holds first to CBP and then to the relevant party (i.e., submitter or transmitter of the prior notice). (Question E.1.6).
- FDA must receive requests for review of the refusal or hold within five calendar days from the day that FDA notified the relevant party (i.e., submitter or transmitter of the prior notice). (Question E.1.7).

FDA welcomes stakeholder comments on the Final Guidance (and no timeline applies).

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Taken together, the proposed amendments to FDA's Prior Notice Rule on the heels of the agency's publication of Final Guidance on Prior Notice compliance may indicate heightened attention at FDA to come in the short term on imports of human and animal food. Notably, on September 29, FDA additionally posted a video to its Importing Human Foods page highlighting applicable FDA requirements that FDA verifies/enforces at the time human foods are imported into the United States. In light of these developments, affected stakeholders should confirm compliance with FDA's import requirements and anticipate a potential increased focus from FDA on imports of both human and animal food.

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