

FDA notes that under its amendment proposal “topping off” with the article of food that is already the subject of a prior notice would be allowed. To the extent “topping off” with non-food items occurs, this practice would not be affected. FDA believes, however, that this limitation is dictated by the Bioterrorism Act’s requirements and moreover is necessary to ensure that FDA has adequate notice of all FDA-regulated food imports such that FDA can deploy its resources effectively. In this case, a separate prior notice would be required for these foods not already covered by a prior notice. FDA solicits comment how common “topping off” is and the quantities of food involved.

8. How Do You Submit a Product Identity Amendment or An Arrival Update to a Prior Notice? (Proposed § 1.292)

FDA is proposing to limit the way in which a prior notice may be amended or updated. FDA is proposing that a product identity amendment or an arrival update to a prior notice may be submitted only in the same manner as an initial prior notice; that is, electronically to FDA through FDA’s Prior Notice System. Only the information concerning product identity and grower identity can be electronically amended under proposed § 1.290. Only the information concerning the anticipated location, date, and time of arrival and grower identity can be electronically updated under proposed § 1.294.

FDA proposes to design its Prior Notice System to require identification of the type of submission (Initial, Amended, Updated) and to be capable of differentiating amongst them. If FDA’s Prior Notice System is unable to receive submissions electronically, amendments or updates may be communicated directly to FDA using a printed version of the Prior Notice Screen, and delivered either in person, by fax, or by e-mail to the FDA field office with responsibility over the geographical area in which the port of entry is located, as provided by proposed § 1.287(b). If the identification of the anticipated port of entry is being updated, and the FDA system is down, the updated printed version of the Prior Notice Screen should be delivered to the FDA field office with responsibility over the port covered by the initial submission. FDA intends to issue guidance for communication between the field office receiving the initial prior notice and the field office covering the updated port of entry.

9. What Are the Consequences If You Do Not Submit a Product Identity Amendment to Your Prior Notice? (Proposed § 1.293)

FDA is proposing that if a U.S. importer or U.S. purchaser, or their U.S. agent, informed FDA in a prior notice that the submission would be amended, but subsequently does not amend it appropriately and within the applicable timeframe, then the prior notice is inadequate for the purposes of proposed § 1.278(a). By telling FDA that the prior notice will be amended they are telling us that it is incomplete. We therefore will be waiting for complete information upon which to make our inspection decision. Without complete product identity, FDA cannot complete the assessment of whether to inspect or take other action when the food arrives in the United States. The consequences of inadequate prior notice are the same as the consequences for failing to provide prior notice; the food shall be refused admission and held at the port of entry unless FDA directs its removal to a secure facility. The consequences are more fully described previously in the discussion of proposed § 1.278.

10. What Must You Do If the Anticipated Arrival Information (Required Under § 1.288(k)(1)) Submitted in Your Prior Notice Changes? (Proposed § 1.294)

FDA is proposing to require the submitter to update anticipated arrival information submitted in a prior notice, if the anticipated information changes after the submission. The types of information FDA expects may change between submission of prior notice and actual importation are the date, time, and location of arrival. Although the statute requires only anticipated port of entry, accurate, up-to-date arrival information (if different) is necessary for FDA field offices to reschedule inspections. FDA thus believes that it has the authority to require this information.

If anticipated arrival information submitted in a prior notice changes, FDA is proposing that the submitter be required to provide the new port of entry (proposed § 1.294(a)(1)), and the new time of arrival in an update electronically filed in the Prior Notice System (proposed § 1.294(c)). FDA is proposing that if the time of arrival is expected to be more than 1 hour earlier (proposed § 1.294(a)(2)) or more than 3 hours later (proposed § 1.294(a)(3)) than the anticipated time of arrival, the time of arrival must be updated. FDA is proposing that, if the identity of the grower was not provided at the time the

prior notice was submitted and that identity is known at the time of the update, the amendment must include information that identifies growers (proposed § 1.294(b)).

The FDA Prior Notice System will be designed to accommodate updates. As stated above, FDA is proposing to design its Prior Notice System to require identification of the type of submission (Initial, Amended, Updated) and to be capable of differentiating amongst them.

FDA is proposing to limit the time within which a prior notice may be updated. The proposed regulation would require updated information to be submitted in accordance with the deadline for amendments under proposed § 1.291, that is, an update to a prior notice must be submitted 2 hours prior to arrival.

IV. Analysis of Economic Impacts

A. Preliminary Regulatory Impact Analysis

FDA has examined the economic implications of this proposed rule as required by Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including: having an annual effect on the economy of \$100 million, adversely affecting a sector of the economy in a material way, adversely affecting competition, or adversely affecting jobs. A regulation is also considered a significant regulatory action if it raises novel legal or policy issues. FDA has determined that this proposed rule is a significant regulatory action as defined by Executive Order 12866.

The Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121) defines a major rule for the purpose of congressional review as having caused or being likely to cause one or more of the following: An annual effect on the economy of \$100 million; a major increase in costs or prices; significant adverse effects on competition, employment, productivity, or innovation; or significant adverse effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. In accordance with the Small Business Regulatory Enforcement Fairness Act, OMB has determined that