



JAMES J. BOYLE & CO.
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The Current

6/10/2011 • The Current Volume 2011 – Issue 3

FDA Requires New Food Prior Notice Element on Other Country Refusal Effective July 3, 2011

Dear Valued Customer,

The Food and Drug Administration (FDA) recently issued an interim final rule, effective July 3, 2011, to require persons submitting prior notice (PN) of imported food, including food for animals, to report the name of any country to which the article has been refused entry. The requirement to submit this additional data element is mandated by the Food Safety Modernization Act (FSMA).

FDA will amend its regulations 21 CFR 1.281(a), (b), and (c) to require a person submitting PN of imported food, including food for animals, to report, in addition to other information already required, the name of any country to which the article has been refused entry. FDA will be able to use the additional information to better identify imported food shipments that may pose a safety or security risk to U.S. consumers.

The FSMA (Public Law 111-353) was signed into law on January 4, 2011. The law provides FDA with new enforcement authorities to help it achieve higher rates of compliance with prevention and risk-based food safety standards and to better respond to and contain problems when they do occur. The law also gives FDA new tools to better ensure the safety of imported foods and directs FDA to build an integrated national food safety system in partnership with State and local authorities.

JJB Request to Food Importing Customers

In order to comply with this new requirement, beginning with food shipments imported into the USA on or after July 3, 2011, JJB requires our customers to provide information on your commercial shipping documents or by instruction in writing for each shipment, as to whether or not the food shipment had been previously refused entry by another country prior to importation or return to the USA. An acceptable example of such indication could be a simple positive or negative statement on the commercial invoice or other commercial document, for example:

- ✓ Shipment has not been refused entry by any other country prior to importation into the USA.
- ✓ Shipment was refused entry by (NAME OF COUNTRY) prior to importation into the USA.

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If your documentation does not contain a positive or negative statement, JJB will not file the PN for the shipment until confirmation can be obtained and JJB will not be responsible for any filing delays.

If a shipment was refused entry, please also provide an explanation on your letterhead as to the reason it was refused by any other country as FDA will require it at the time entry is filed for shipment release.

We thank you very much for your time and should you require any assistance or if you have any questions, please consult with your local James J. Boyle & Co. office listed below.

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