FDA Foreign Supplier Verification Program Answers from CVM

Question:

If a firm is receiving imported products but is NOT the importer can they request a copy of the importer's FSVP?

Can the same firm also request a copy of the supplier's (out of country) physical address, DUNS number, primary contact person, and the name and qualifications of the person who conducted the hazard analysis?

Are there any requirements for the importer to provide this information to the US firms that they are sending product to?

Does any of this change if the ingredient received is one that has a hazard that requires a preventive control and the preventive control has been determined to be a Supplier Chain Applied Control?

Response:

Thank you for your inquiry. Under the FSVP rule, the importer is not required to provide any records or documentation to its customers; it is up to the importer's discretion.

Under the preventive controls requirements in 21 CFR Part 117, if the firm receiving a raw material or other ingredient is a "receiving facility" (a facility that is subject to subparts C and G of part 117 and that manufactures/processes a raw material or other ingredient that it receives from a supplier), the raw material or other ingredient has a hazard requiring a preventive control, and that hazard is controlled before receipt (a supply-chain-applied control) (see 21 CFR 117.3 for definitions of "receiving facility" and "supply-chain-applied control"), then the receiving facility must have a supply-chain program as described in 21 CFR part 117 subpart G. In that case, the receiving facility would need information to approve the supplier and determine the appropriate supplier verification activities, such as the supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients; the supplier's compliance with FDA food safety regulations; the supplier's food safety history relevant to the raw materials or other ingredients that the receiving facility receives from the supplier; and any other relevant factors (21 CFR 117.410). The receiving facility would be able to obtain some of that information online (e.g., through FDA's Firm/Supplier Evaluation Resources); however, other information would have to be obtained from the supplier (e.g., the supplier's procedures, processes, and practices related to the safety of the raw material and other ingredients). There is no requirement in subpart G to obtain the importer's FSVP, or the supplier's DUNS number, primary contact person, and the

name and qualifications of the person who conducted the hazard analysis. The receiving facility is responsible for conducting its own hazard analysis under 21 CFR 117.130.

Links:

21 CFR Part 117
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=117

21 CFR 117.3
https://www.ecfr.gov/cgi-bin/text-idx?SID=c9a475e96a80d48987650e54edec3a48&mc=true&node=pt21.2.117&rgn=div5#se21.2.117_13

21 CFR part 117 subpart G
https://www.ecfr.gov/cgi-bin/text-idx?SID=c9a475e96a80d48987650e54edec3a48&mc=true&node=pt21.2.117&rgn=div5#sp21.2.117.g

21 CFR 117.410
https://www.ecfr.gov/cgi-bin/text-idx?SID=c9a475e96a80d48987650e54edec3a48&mc=true&node=pt21.2.117&rgn=div5#se21.2.117_1410

FDA's Firm/Supplier Evaluation Resources
https://datadashboard.fda.gov/ora/fd/fser.htm

21 CFR 117.130
https://www.ecfr.gov/cgi-bin/text-idx?SID=c9a475e96a80d48987650e54edec3a48&mc=true&node=pt21.2.117&rgn=div5#se21.2.117_1130