US Food Safety Modernisation Act (FSMA) Compliance Information for New Zealand Suppliers and United States Importers

Overview

The US Food and Drug Administration (FDA) recently promulgated a series of rules (regulations) under the Food Safety Modernisation Act (FSMA) that have various implications for US importers of food and food ingredients intended for human or animal consumption in the USA, including those imported from New Zealand. The rules cover all food regulated by FDA including animal food, however there are exemptions relating to foods already covered by HACCP-type rules prior to FSMA including seafood, fruit juices and low acid canned food. Also excluded from coverage are foods regulated solely by the United States Department of Agriculture (USDA) Food Safety Inspection Service (FSIS), i.e. meat, poultry, egg products and catfish.

The FSMA rules place a number of obligations on US importers to undertake certain activities and document these to demonstrate that foods (and food ingredients) imported into the USA meet the same food safety standards as foods produced domestically. The primary mechanism for importers to be able to demonstrate compliance with the FSMA is through the development a foreign supplier verification programme as required under the Foreign Supplier Verification Program rule.

Food producers are also required to register with the FDA as a Foreign Food Facility and must renew this registration every 2 years (ref for more information https://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm)

The following links provide useful information on the FSMA:

FSMA Rules &
Guidance https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm253380.htm
FSMA FAQ
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm
FSMA Technical Assistance
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm

Foreign Supplier Verification Program (FSVP) and Food Safety Systems Recognition (FSSRA)

The Foreign Supplier Verification Programme (FSVP) is the framework established within FSMA to ensure that importers have systems in place to "verify that their foreign suppliers are producing food in a manner that provides the same level of public health protection to ensure

that the supplier's food is not adulterated and is not misbranded with respect to allergen labelling". It requires that importers perform certain risk-based activities and establish written procedures to verify that food imported into the US has been produced in a manner that meets applicable safety standards. Further information on what is expected of US importers of food can be found at
https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm593060.htm

Within the FSVP rule, FDA have established modified requirements (under section 1.513) for importers of food from countries such as New Zealand that have entered into a **Food Safety Systems Recognition Agreement (FSSRA)** with the FDA. The FSSRA between MPI and FDA allows FDA to rely on the administration and oversight of NZ's food safety systems by MPI as the means of providing many of the assurances needed to satisfy the requirements of the FSMA. This enables FDA to reduce the requirements for US importers importing most forms of food from NZ as part of the modified requirements of the FSVP rule

MPI's FSSRA with FDA accounts for all food regulated by the two competent authorities with the exception of Grade A dairy products, infant formula, petfood and dietary supplements regulated by Medsafe.

While the majority of foods within the scope of the FSSRA are permitted to be imported under modified FSVP requirements (provided that certain conditions are met), it is important to note that even for countries with a FSSRA, the modified FSVP requirements only apply to food that is "**not intended for further manufacturing / processing**" which includes "packaged food products and raw agricultural commodities that will not be commercially processed further before consumption".

The full text of the MPI-FDA Food Safety Systems Recognition Arrangement (FSSRA) can be found at
https://www.fda.gov/InternationalPrograms/Agreements/MemorandaofUnderstanding/ucm331907.htm

Exemptions from the Foreign Supplier Verification Program Rule
Some food categories under FDA jurisdiction are exempt from the FSVP rule, these are:

1. Juice, fish, and fishery products that are imported from a foreign supplier under the requirements in part 120 (Hazard Analysis and Critical Control Point (HACCP) Systems) or part 123 (Fish and Fishery Products) of 21 CFR. Importers must comply with the requirements applicable to importers of these products under §120.14 or §123.12 of this chapter, respectively. Juice or fish imported as raw material or ingredients are similarly exempt.
2. Food imported for research or evaluation, provided such food-
    a. Is not intended for retail sale and is not sold or distributed to the public,
    b. Is labeled with the statement "Food for research or evaluation use",

c. Is imported in a small quantity that is consistent with a research, analysis, or quality assurance purpose, the food is used only for this purpose, and any unused quantity is properly disposed of, and
d. Is accompanied, when filing entry with U.S. Customs and Border Protection, by an electronic declaration that the food will be used for research or evaluation purposes and will not be sold or distributed to the public.

3. Foods imported for personal consumption.
4. Alcoholic beverages and raw material and ingredients for alcoholic beverages.

For countries with a FSSRA in place such as NZ, FDA has notified US importers that when importing food (excluding that intended for further manufacturing/processing) they **need only comply** with the following FSVP requirements:

1. Document that the foreign supplier is located in a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent, and the supplier is under the regulatory oversight of that country (21 CFR 1.513(b)(1)).
2. Document that the food you import is within the scope of the official recognition or equivalency determination (21 CFR 1.513(b)(1)).
3. Determine and document whether your foreign supplier is in **good compliance standing** with the food safety authority of the country in which the supplier is located (21 CFR 1.513(b)(2)). For example, you might document your supplier's good compliance standing by saving a screen shot from the Web page of a food safety authority to which FDA's Web page is linked showing your supplier's appearance on a list of food producers in good compliance standing (or your supplier's absence from a list of food producers not in good compliance standing). Alternatively, you might obtain from your foreign supplier documentation that it is in good compliance standing with the relevant food safety authority.
4. Continue to monitor whether the foreign supplier is in good compliance standing and promptly review any information obtained (21 CFR 1.513(b)(2)). We recommend that you check FDA's Web site or contact your foreign supplier at least every 6 months to determine whether your supplier remains in good compliance standing. To meet the requirement to monitor your supplier's status, you might require your supplier to notify you if it is no longer designated as being in good compliance standing with the relevant food safety authority.
5. If the information indicates that food safety hazards associated with the food are not being significantly minimized or prevented, you must take prompt corrective action (21 CFR 1.513(b)(2). For example, if you learn that your foreign supplier recalled a food for food safety reasons, you should determine whether any food you are importing from that foreign producer is subject to the recall or may be similarly affected. You should determine whether the foreign supplier has taken sufficient corrective actions to ensure that the identified food safety hazard is now being controlled. The appropriate corrective action you take will depend on the circumstances but could include discontinuing use of the foreign supplier (21 CFR 1.513(b)(2)).
6. Ensure that you are identified as the FSVP importer at entry (21 CFR 1.509).
7. Maintain applicable FSVP records (21 CFR 1.510).

When importing food (excluding that intended for further manufacturing/processing) from countries like New Zealand that have a FSSRA importers **are not** required to undertake any of the following activities normally required under the FSVP.

1. Conduct a hazard analysis of the food (21 CFR 1.504).
2. Evaluate the potential foreign supplier and the risk posed by the food (21 CFR 1.505)
3. Determine and conduct appropriate supplier verification activities (e.g. audits or inspection activities) based on the evaluation of the food and foreign supplier (21 CFR 1.506).
4. Comply with the requirements for foods that cannot be consumed without application of an appropriate control or for which the hazards are controlled after importation (21 CFR 1.507).
5. Take corrective actions under 21 CFR 1.508.

FSVP - Suppliers in Good Compliance Standing and Regulatory Good Standing

Under the FSVP rule importers must ensure that when sourcing food from countries with a FSSRA the food business is in current "**good compliance standing**" (section 1.513). The concept of regulatory good standing is covered in the FSSRA.

Being in good compliance / regulatory standing means US importers knowing that the goods have come from a NZ registered establishment, and the products that are exported to the USA are not subject to active recalls as made publicly available on the following web link: https://www.mpi.govt.nz/food-safety/food-safety-for-consumers/food-recalls

Products produced and business operating in accordance with either the Food Act 2014 or the Animal Products Act 1999, can be found in the following links:

1. Registered Animal Products Act businesses:
Dairy
Other animal products

2. Food Act Regulated businesses:
Food Control plans and National Programmes
Food Safety Programmes (registered before 1 March 2016)

In addition to being in good compliance standing in accordance within section 1.513 of the FSVP rule, the FSSRA between MPI and FDA requires operations to be in "regulatory good standing". This is defined as: "an establishment for which FDA, or its delegate, or MPI, or its delegate, has performed an inspection, where required, and for which the establishment has no pending judicial enforcement or regulatory action such as seizure, injunction, or prosecution." Exporters should ensure they are not sourcing products from operators which are known to be subject to these regulatory actions.

Verification Letters for New Zealand Suppliers of Ingredient Products and Other Products to be Further Processed* in the USA

For companies producing **food or ingredients intended for further manufacturing/processing** that do not qualify for the modified requirements under section 1.513 of the FSVP, MPI can provide an annual letter that can be used by US importers to satisfy verification requirements in section 1.506 of the FSVP rule. Specifically, these letters provide an appropriate form of verification to US importers that "The written results of an inspection of the foreign supplier by the food safety authority of a country whose food safety system FDA has officially recognized as comparable or determined to be equivalent to that of the United States" has occurred in the past 12 months and that the "the foreign supplier is in, and under the regulatory oversight" of MPI as required under the FSVP rule.

Letters are issued on request in the MPI AP E-cert system https://sancrt.mpi.govt.nz/ecert/main/login. The letter must be supported by an assurance letter from the MPI recognised verifier of the food business confirming that over the preceding year the operator was verified at least once and the operator was in compliance with applicable regulatory requirements under the Food Act 2014 and / or the Animal Products Act 1999. The operator of the food producing business must apply to MPI Verification Services for the letter either by raising an E-cert submission directly or arranging to have one raised, and submit the recognised verifier assurance at the time of applying. Food business operators will need to notify MPI verification services (freesalesapplications@mpi.govt.nz) once the letter submission has been raised in E-cert in order for the letter to be issued. The below verifier assurance example template is not compulsory, but any alternative letter must cover the same information in order for a MPI verification letter to be issued.
Further guidance and instructions on issuing annual verification letters is given below.

*further processed does not include simple re-packing without changing the form, nature or constituents of the food product as exported from New Zealand

FSVP – Annual Verification Report to Meet the Requirements of the FSVP for Further Manufacture/Processing

Food intended for further manufacture/processing prior to sale to the final consumer / food service (i.e. food not subject to the modified import requirements under section 1.513 of the FSVP rule) must be subject to verification for compliance with the relevant New Zealand food regulatory requirements at least annually. Verification can be carried out directly by the importer, or by a qualified 3rd party auditor, or in accordance with the New Zealand's competent authority (MPI) "inspection" requirements. Where the competent authority (MPI or MPI recognised agencies or local territorial authority) is carrying out food business verifications / inspection the importer may rely on an annual statement issued by the competent authority that verification / inspection of compliance with New Zealand regulation has taken place. This includes for manufacturers of food products intended for further

processing to which the FSMA rules apply as long as they are within the scope of the FSSRA between the US FDA and the exporting MPI.

The issuing of an annual inspection letter is not mandatory and US importers are free to elect the form and content of their FSVP. However, FSMA rules do permit US importers to utilise annual inspection letters issued by MPI as the means to satisfy FSVP requirements when sourcing product from New Zealand suppliers, including ingredients intended for further manufacture/processing in the US.

Consumer and food service products are not required to be subject to an annual FSVP verification by US importers, therefore an annual verification letter is not available for these products. As noted previously, for finished products the US importer is only required to confirm that the New Zealand manufacturer is in good compliance standing, which can be achieved by checking the appropriate MPI websites (refer above).

To obtain an annual inspection letter from MPI the food business must:

1. Ensure their food business is subject to official verification (by a recognised verifying agency under the APA, or Food Act, or by the Local Territorial Authority) at least once per year.

2. Request the agency who carried out the at least annual verification to issue a verification summary report as provided below on the agency's letter head.

3. Submit this letter to MPI Verification Services certification office (Email: freesalesapplications@mpi.govt.nz, ph: 09-9092701, fax: 09-9092707. Email is preferred) and request that a US810 "New Zealand Ministry for Primary Industries (MPI) Annual Inspection Result Report" be issued.

> a. Where a food business is a registered animal products business under the Animal Products Act they will need to sign up (if not already) for access to the Animal Products (AP) E-cert system, and submit the US810 application in AP E-cert with the verifying agency letter attached electronically.
>
> b. Where a food business is not registered under the Animal Products Act and otherwise has no access to AP E-cert. The Food business must submit the letter to MPI VS (per the above contact details) and request in writing that a US810 be issued.

4. MPI VS will send the signed original to the food business. MPI recommends that the signed original be kept by the food business, and that US importers are provided with a notarised copy of the original. MPI also recommends that the signed original be kept on file for at least 5 years for possible future FDA audit purposes.

5. MPI recommends the US810 be issued as soon as possible after the food business's annual verification takes place, or as soon as possible after the verification immediately preceding

the 1 year anniversary of the previous year's US810 passes in the case of food businesses that are verified more than once per year.

There is no legal requirement to use the US810 "New Zealand Ministry for Primary Industries (MPI) Annual Inspection Result Report". However, if the US importer elects to meet their FSVP requirements by utilising an annual verification statement by the "exporting country competent authority" the US810 is the only document that US FDA has recognised as meeting this requirement, and is the only document MPI will issue.

The administration and issuing of a US810 is an entirely discretionary activity, which is carried out on request of the New Zealand food business. Therefore all costs associated with obtaining a US810 falls on the food business, and costs should be agreed with all parties in advance. This includes verification costs where a food business is not already subject to a mandatory minimum annual verification in accordance with the Food Act or Animal Products Act. Where a food business is already subject to a mandatory minimum annual verification no additional verification activity is required for issuing a US810.

If the food business is verified by MPI VS, and the food being exported to the USA is within the scope of the MPI VS verification the local MPI VS verifier may directly issue the US810 without having to complete the below verification summary report.

Template Verifier Annual Verification Summary Report

[Verifying agency letter head]

XX Date

Annual US Foreign Supplier Verification Summary report to Ministry for Primary Industries (MPI) Inspection

RMP/FCP/NP [confirm which type of registration applies so the US810 can be verified as correctly raised in E-cert] operator [……] [RMP/FCP/NP ID] was verified onsite by [recognised agency / Territorial Authority name] on [date(s) less than 1 year prior to the date of issue of this letter (including all verification dates since the last FSV annual report, or if the first FSV report the most recent verification date)] for the following [food types]. The operator's [RMP / FCP / NP] is registered for the following processes and product groups that are intended for export to the United States of America:

- [Product/process]
- [Product/process]
- [Product/process]

This is to confirm that, as of [date of the letter], the findings of the abovementioned onsite verification audits indicate this operator is in substantial compliance with applicable regulatory requirements under the [APA 1999 / Food Act 2014]. The operator should be regarded as being in Regulatory Good Standing[#] according to the terms of the New Zealand – USA Food Safety Systems Recognition Arrangement.

Yours sincerely,

[signature]

[Name and title of accountable person for the RA / LTA]
[Name of RA / LTA]

[#Regulatory Good Standing means a food business for which MPI (or a delegated agency) has performed an inspection/verification and for which the food business has no pending judicial enforcement, or regulatory action such as seizure, injunction or prosecution.]