



EXPORTING TO THE USA

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F.S.M.A.

The US **FDA's Food Safety Modernization Act** is the most exhaustive reform of US food safety laws in >70 years. Signed into law by Obama in January 2011.

- Primary aim is to ensure the US food supply is safe by shifting the focus from **responding** to contamination to **preventing** contamination.
- Gives FDA important new tools to **hold imported foods to the same standards as domestic foods.**
- Directs FDA to build an integrated national food safety system in partnership with state and local authorities.

F.D.A. or U.S.D.A. ??

Almost everything Americans eat has been vetted by one of these government agencies - but their roles and responsibilities are different and not always logical.

MEAT: USDA regulates almost all meat **BUT** FDA regulates “meat from exotic animals,” including venison & other game like wild boar. USDA inspects sausages, but FDA inspects sausage casings.

POULTRY: Domesticated poultry is inspected by USDA; & also inspects canned chicken products.

FISH: FDA regulates fish, shellfish, & all seafood — except farmed catfish, which is inspected by USDA

EGGS: USDA inspects egg products, e.g. powdered eggs, while FDA regulates whole shell eggs.

DAIRY: FDA regulates dairy, including yogurt, sour cream, cheese, & ice cream that does not contain eggs.

PRODUCE: Raw fall under USDA, but processed - into applesauce or bottled juice - become FDA's problem.

PACKAGED FOODS: All subject to FDA inspection & regulation. **BUT** when meat shows up on packaged sandwiches & pizza, exceptions emerge. Open-faced meat sandwiches, where the ratio of meat to bread & other ingredients is >50%, are regulated by USDA. But closed sandwiches, which have 2 slices of bread, are regulated by FDA because ratio of meat to other ingredients is <50%.

Extracted from: <https://www.eater.com/2017/3/24/15041686/fda-usda-difference-regulation>

Foreign Supplier Verification Program (FSVP)

So the next step logically, if control what is happening inside the USA, should also control what is brought in.

20% of food consumed in USA is imported (*UK is 50% imported, 30% from rest of EU*)

- 97% of fish/shellfish imported
- 50% of fresh fruits

Between 1996–2014, 195 outbreak investigations implicated an imported food, resulting in 10,685 illnesses, 1,017 hospitalizations, and 19 deaths.

Outbreaks associated with an imported food increased from an average of 3/year 1996–2000 (1%) to average of 18/year 2009–2014 (5%)

Gould L, Kline J, Monahan C, Vierk K. Outbreaks of Disease Associated with Food Imported into the United States, 1996–2014. Emerg Infect Dis. 2017;23(3):525-528. <https://dx.doi.org/10.3201/eid2303.161462>

So, clearly imported food is important and needs attention

Foreign Supplier Verification Program (FSVP)

- **Importer accountability:** Importers have an explicit responsibility to verify that their foreign suppliers have adequate **preventive controls** in place to ensure that the food they produce is safe.
- **Third Party Certification** – see later
- **Certification for high risk foods** – see later
- **Voluntary qualified importer program** – see later
- **Authority to deny entry:** FDA can refuse entry into USA of food from a foreign facility if FDA is denied access by facility or country in which facility is located.
Note they refuse entry so is blocked on arrival not before departure
- **When?** Already in place for majority
 - apart from suppliers categorized as very small businesses (<\$1m annual sales) which is 18 Mar 2019, and same date for qualified facilities – see later.
If fresh produce then also different dates

Foreign Supplier Verification Program (FSVP) What records are needed by the importer

Any record requested by the FDA must be available within 24 hours and could go two years back. If you don't have an automated system, it's likely time to consider one, as it's really the only way to manage the range of documents required by FSMA across your supplier base. Here are the records that should make up your FSVP:

- Hazard Analysis
- Foreign supplier Approved list
- Foreign supplier performance evaluation
- Foreign supplier approval procedures
- Procedures assuring only approved foreign suppliers are used
- Verification activities & their frequency used to determine approved foreign suppliers
- Performance of verification activities
- Identified corrective actions needed
- Re-evaluation of FSVP by cause, or at least every 3 years

If you are exporting, expect these questions, and requests for evidence, and to have to move quickly

Preventive Controls – what are they? 1

Importer accountability: *Importers have an explicit responsibility to verify that their foreign suppliers have adequate **preventive controls** in place to ensure that the food they produce is safe.*

- Preventive Controls are
 - Controls at CCPs if there are any CCPs
 - **Controls other than those at CCPs which are appropriate for food safety**
- So, not just CCPs, and may include Prerequisite Programmes (PrPs), which are currently “missed off” HACCP – i.e. PrPs are managed separately
- May be better/easier to use a risk matrix than a decision tree
- Four types of Preventive Controls (next slide)
 - Supply chain
 - Allergen
 - Sanitation
 - Process
- Supplier needs to use a Preventive Controls Qualified Individual (can be a consultant)

Preventive Controls – what are they? 2

Sanitation

Zoning assessment - identify your zones. Open product, Open product with no further process, packed product etc. same as you would do for BRC etc.

For each operation, e.g. assembly table, there is most likely to be a preventive control which will detail

- Purpose – why clean – remove potential allergens, reduce microbial number
- Frequency – of cleaning and sanitising
- Who
- How and using what
- Monitoring
- Corrections (corrective actions are different)
- How record
- Verification

There will be another section which will detail the control of the environment of the assembly table – so the legs and the table underside and the edges

Under existing UK/EU, this would all be within a cleaning/sanitising programme as a pre-requisite, separate from HACCP, but in FSVP/FSMA is brought within one process.

3rd Party Certification – I have BRC so I'm OK??

Third Party Certification: FSMA establishes a program through which qualified 3rd parties can certify that foreign food facilities comply with U.S. food safety standards. This certification may be used to facilitate the entry of imports.

This is not recognition of BRC, or IFS or any GFSI standards. Having a GFSI-benchmarked standard is an excellent start especially if you have the FSMA module, but it is not recognized as a “Get out of jail free” card by the FDA. Same as UK retailers would not give any credence to an FDA approval instead of BRC.

However the process is similar to what happens with GFSI audits. FDA will recognize Accreditation Bodies, who will accredit Certification Bodies who will audit and certify the suppliers, certification is valid for 1 year. The first 2 Accreditation Bodies have been approved and both are US (ANSI and ANAB).

Certification Bodies: 1 has been approved so far, on 23rd August.

Watch this space, but don't hold breath. Could be a useful option if rolls out



Certification for high risk foods – I have BRC so I'm OK??

Certification for high risk foods: FDA can require that high-risk imported foods be accompanied by a credible 3rd party certification or other assurance of compliance as a condition of entry into the U.S.

There has been no clarification of what this means and what certification would be acceptable

VQIP – what is that?

VQIP (Voluntary Qualified Importer Program) is a fee-based program (\$16,400 p.a. estimate) that will provide expedited review & import entry of human and animal foods into US for participating importers.

They will be able to import with greater speed & predictability, avoiding unexpected delays at the point of import. To participate, importers must meet eligibility criteria and pay a fee that covers costs associated with the FDA's program administration.

Applications opened 31 Jan 2018. see

www.fda.gov/Food/GuidanceRegulation/ImportsExports/Importing/ucm490823.htm

Early days, sounds promising BUT -> FDA announced in June, that would not launch this until October 2019 – because need certification bodies accredited.

VQIP – what is that?

To be eligible for VQIP, you must:

- Have a 3-year history of importing food into the U.S.
- Have a DUNS number.
- Use paperless filers/brokers who received an acceptable rating during their [last FDA Filer Evaluation](#).
- Have no foods you import (including those not in the VQIP application) that are subject to an [import alert](#) or Class 1 recall at the time the application is submitted.
- Not be subject to an ongoing FDA administrative or judicial action or have a history of significant food safety non-compliances without documentation of appropriate corrective actions.
- Be in compliance with the supplier verification and other importer responsibilities and regulations if you are the FSVP or HACCP importer (relevant for Juice and Seafood) for a VQIP food. *Or* – if you are not the FSVP or HACCP importer for a VQIP food – you must identify the FSVP or HACCP importer and ensure they are in compliance with the applicable regulations.
- Have a current facility certification for each foreign supplier of a VQIP food.
- Develop & implement a VQIP Quality Assurance Program (QAP) and submit QAP documentation with your application.
- Have not been the subject of any U.S. Customs and Border Protection penalties, forfeitures, or sanctions within the past 3 years related to the safety and security of any FDA-regulated product that you imported or offered for import.
- Pay the user fee before October 1, the start of VQIP fiscal year, each year that you are approved to participate in the VQIP.

The end – nearly!

At moment, no short cut, although some opportunities in the pipeline.

If you are exporting to US, key is choice of the importer you will use – how knowledgeable they are about FSVP, how well staffed, and familiar with the process. **Get a PCQI**

Some US companies are still not aware (or claim not to be aware) of the onset of FSMA.

US “Labeling” 1

Usual trip hazards associated with spelling and language; fibre/fiber; Cilantro/Coriander; etc., labelling is similar yet different in many ways. Here’s a label for a pizza

Nutrition Facts		Amount Per Serving	% DV*	Amount Per Serving	% DV*	*Percent Daily Values (DV) are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:		
Serving Size 1/3 pizza (133g)		Total Fat 10g	15%	Total Carbohydrate 36g	12%	Calories	2,000	2,500
Servings Per Container 3		Saturated Fat 5g	25%	Dietary Fiber 1g	4%	Total Fat	Less than 65g	80g
Calories 310		Trans Fat 0g		Sugars 6g		Saturated Fat	Less than 20g	25g
Calories from Fat 90		Cholesterol 40mg	13%	Protein 17g		Cholesterol	Less than 300mg	300mg
		Sodium 810mg	34%			Sodium	Less than 2,400mg	2,400mg
		Vitamin A 4% • Vitamin C 0%		Calcium 25% • Iron 15%		Total Carbohydrate	300g	375g
						Dietary Fiber	25g	30g

INGREDIENTS: ENRICHED WHEAT FLOUR (WHEAT FLOUR, NIACIN, REDUCED IRON, THIAMIN MONONITRATE, RIBOFLAVIN, FOLIC ACID), BARBECUE SAUCE (WATER, TOMATO PASTE, BROWN SUGAR, VINEGAR, MOLASSES, SUGAR, SALT, APPLE CIDER VINEGAR, CONTAINS LESS THAN 2% OF MODIFIED FOOD STARCH, MUSTARD BRAN, DRIED GARLIC, NATURAL HICKORY SMOKE FLAVOR, CARAMEL COLOR, SPICE, NATURAL FLAVOR), GRILLED WHITE CHICKEN MEAT (WHITE CHICKEN MEAT, WATER, SALT, SPICE EXTRACTIVES, SODIUM PHOSPHATES, MALTODEXTRIN, MODIFIED RICE STARCH), LOW-MOISTURE PART-SKIM MOZZARELLA CHEESE (PART-SKIM MILK, CHEESE CULTURE, SALT, ENZYMES), WATER, SMOKED GOUDA CHEESE (PART-SKIM MILK, CHEESE CULTURE, SALT, ENZYMES, ANNATTO [COLOR]), RED ONIONS, CONTAINS LESS THAN 2% OF SOYBEAN OIL, YEAST, SALT, SUGAR, MONO- AND DIGLYCERIDES, CILANTRO.

CONTAINS: MILK, WHEAT.

DISTRIBUTED BY: NESTLÉ USA, INC., NORTHBROOK, IL 60062 USA
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Allergens are called out. Nutritional is in g and per serving size which is defined, as well as not being per 100g, no traffic lights, no country of origin for meat (yet), no QUID. Beware of different date formats MM-DD, and expression of expiry date

US “Labeling” 2

Allergens (8 not 14)

Milk	Eggs	Fish*	Crustaceans*
Tree nuts*	Peanuts	Wheat	Soybeans

- species identification required for fish/crustaceans and nuts – so cod, walnut, shrimp
- EU nuts vs US nuts: Not the same. EU has defined list of nuts to be declared. US – **ALL TREE NUTS inc coconut and pine nuts**

E-numbers

- Although used less and less in UK, there are no e-number shortcuts for the USA, they mean nothing. Some colours do have short names e.g. Red 40, Yellow 6

What haven't I talked about?

- Trump
- Zero tolerance for some pathogens, e.g. no $<100/g$ for Listeria.
- Contracts – under which legislation would a dispute between companies be held?
- Insurance – may be implications for liability insurance because of US liability laws, leading to increased premiums
- Individual state laws (esp. California) –

May contain a moisture absorbing desiccant pack. Do not eat.

WARNING: This product contains a chemical known to the state of California to cause birth defects or other reproductive harm.

Acronym Atlas



FSMA	=	Food Safety Modernization Act
FDA	=	Food & Drug Administration
USDA	=	US Dept. of Agriculture
FSVP	=	Foreign Supplier Verification Program
HARPC	=	Hazard Analysis, Risk-based Preventive Controls.
PCQI	=	Preventive Controls Qualified Individual
QI	=	Qualified Individual
VQIP	=	Voluntary Qualified Importer Program

Sources of information

FDA: A wealth of information, being added to and updated all the time.

www.fda.gov/Food/GuidanceRegulation/FSMA/

BRC: Current edition 7 has an additional module on FSMA. Website has support documents inc quick guide, & a self-assessment tool. Edition 8 takes into account FSMA & has more US-aligned wording – e.g. food safety plan instead of HACCP plan

www.brcglobalstandards.com/brc-global-standards/food-safety/additional-modules/food-safety-modernization-act/

FSPCA: Do the training and support materials for the FSPCA Preventive Controls for Human Food. A number of training courses are available in the UK run by bodies such as SGS, Campden, LRQA etc. – Google PCQI training.

www.ifsh.iit.edu/fspca/fspca-preventive-controls-human-food

Techni-K: Good articles on FSMA – <https://techni-k.co.uk/FSMA-Articles> Sign up & get a range of articles on subjects as diverse as microbiology, High Risk Areas, Pest control etc.

Primority of course take a look at www.primority.com to see a software solution suitable for FSVP, and other standards such as BRC. It is in use by several US importers as well as UK companies such as Park Cakes and Weetabix.