Implementing GFSI Requirements
in Non-Traditional Food Production Environments

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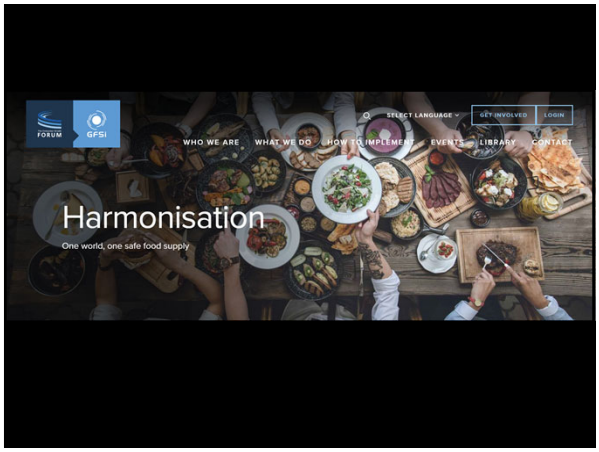

Non-traditional food production environments?

U.S. FOOD & DRUG ADMINISTRATION

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FDA 101: Dietary Supplements

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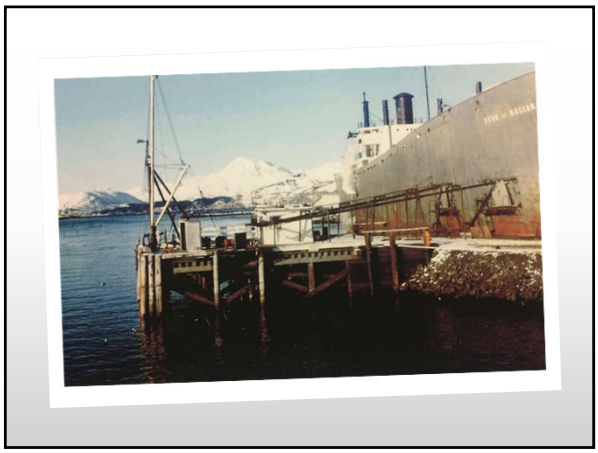
The law defines dietary supplements in part as products taken by mouth that contain a "dietary ingredient." Dietary ingredients include vitamins, minerals, amino acids, and herbs or botanicals, as well as other substances that can be used to supplement the diet.

Dietary supplements come in many forms, including tablets, capsules, powders, energy bars, and liquids. These products are available in stores throughout the United States, as well as on the Internet.



On-site Audit

- Opening meeting
- Production facility inspection
- Document review
- Traceability challenge
- Label review
- Review of production facility inspection
- Final review of findings by auditor
- Closing meeting – review audit findings and confirm any non-conformities

The vessel MUST be in active production so that all of the requirements of the Standard can be assessed by the auditor.

What does it mean when a GFSI Standard says we need a "Risk Assessment"?

CLAUSE	REQUIREMENTS
4.8.1	Designated changing facilities shall be provided for all personnel, whether staff, visitor or contractor. These shall be sited to allow direct access to the production, packing or storage areas without recourse to any external area. Where this is not possible, a risk assessment shall be carried out and procedures implemented accordingly (e.g. the provision of cleaning facilities for footwear).
4.8.2	Storage facilities of sufficient size to accommodate personal items shall be provided for all personnel who work in raw material handling, preparation, processing, packing and storage areas.
4.8.3	Outdoor clothing and other personal items shall be stored separately from production clothing within the changing facilities. Facilities shall be available to separate clean and dirty production clothing.
4.8.4	Suitable and sufficient hand-washing facilities shall be provided at access to, and at other appropriate points within, production areas. Such hand-washing facilities shall provide, at a minimum: • advisory signs to prompt hand-washing • a sufficient quantity of water at a suitable temperature • water taps with hands-free operation • liquid/foam soap • single-use towels or suitably designed and located air driers.

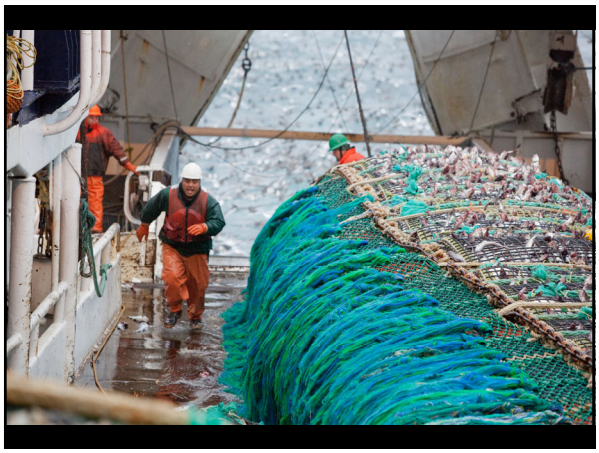
Risk assessments play a key role in the GFSI accreditation schemes.

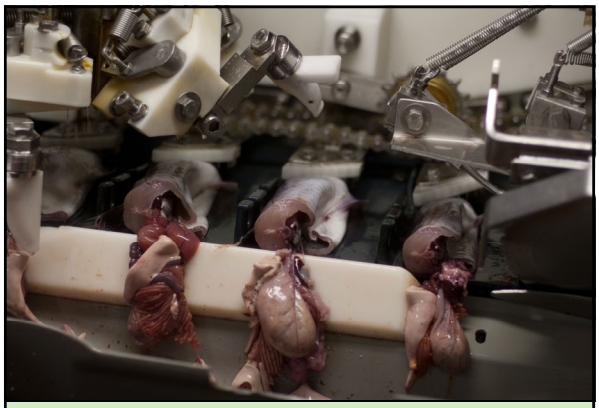
The standards have been written to cover all types of food processing. Risk assessments determine how these standards are to be applied in your facilities.

A properly conducted risk assessment will ensure the correct amount of control has been implemented … and will reduce unnecessary expense and efforts.

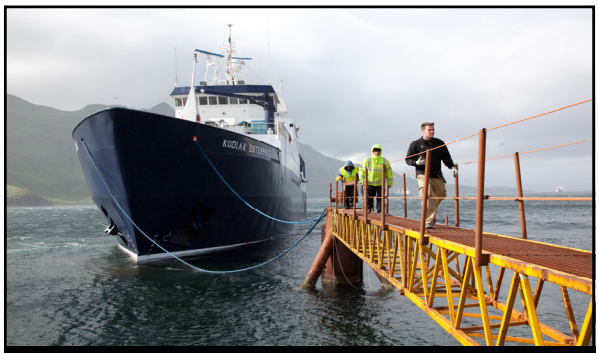
LIKELIHOOD OF DETECTION	LIKELIHOOD OF OCCURRENCE				
	Very unlikely	Unlikely	Fairly likely	Likely	Very likely/ certain
Very likely/ certain					
Likely					
Fairly likely					
Unlikely/remote					
Very unlikely					

FUNDAMENTAL
The company shall have an effective supplier approval and monitoring system to ensure that any potential risks from raw materials (including primary packaging) to the safety, authenticity, legality and quality of the final product are understood and managed.





All food-processing equipment shall be suitable for the intended purpose and shall be used to minimise the risk of contamination of product.



CLAUSE	REQUIREMENTS
4.1.2	The external areas shall be maintained in good order. Where grassed or planted areas are located near buildings, they shall be regularly tended and well maintained. External traffic routes under site control shall be suitably surfaced and maintained in good repair to mitigate the risk of contamination of the product.

FUNDAMENTAL
The factory layout, flow of processes and movement of personnel shall be sufficient to prevent the risk of product contamination and to comply with relevant legislation.

CLAUSE	REQUIREMENTS
4.5.1	All water (including ice and steam) used as a raw material in the manufacture of processed food, the preparation of product, hand-washing or for equipment or plant cleaning shall be supplied in sufficient quantity, be potable at point of use or pose no risk of contamination according to applicable legislation. The microbiological and chemical quality of water shall be analysed at least annually. The sampling points, scope of the test and frequency of analysis shall be based on risk, taking into account the source of the water, on-site storage and distribution facilities, previous sample history and usage.

CLAUSE	REQUIREMENTS
4.8.4	Suitable and sufficient hand-washing facilities shall be provided at access to, and at other appropriate points within, production areas. Such hand-washing facilities shall provide, at a minimum: • advisory signs to prompt hand-washing • a sufficient quantity of water at a suitable temperature • water taps with hands-free operation • liquid/foam soap • single-use towels or suitably designed and located air driers.

CLAUSE	REQUIREMENTS
4.8.6	Where smoking is allowed under national law, designated controlled smoking areas shall be provided which are both isolated from production areas to an extent that ensures smoke cannot reach the product and fitted with sufficient extraction to the exterior of the building. Adequate arrangements for dealing with smokers' waste shall be provided at smoking facilities, both inside and at exterior locations. Electronic cigarettes shall not be permitted to be used or brought into production or storage areas.

4.8.8	Where catering facilities (including vending machines) are provided on the premises, they shall be suitably controlled to prevent contamination of products (e.g. as a source of food poisoning or introduction of allergenic material to the site).

FUNDAMENTAL
Housekeeping and cleaning systems shall be in place which ensure appropriate standards of hygiene are maintained at all times and the risk of product contamination is minimised.

4.15 STORAGE FACILITIES

All facilities used for the storage of raw materials, packaging, in-process products and finished products shall be suitable for purpose.

4.14 PEST MANAGEMENT

The whole site shall have an effective preventive pest management programme in place to minimise the risk of infestation and resources shall be available to respond rapidly to any issues which occur to prevent risk to products.

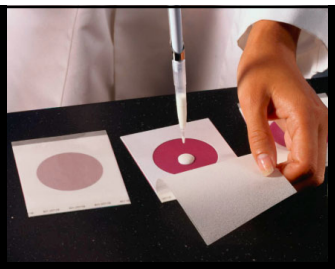
Pest management programmes shall comply with all applicable legislation.

SEATTLE ENTERPRISE

CLAUSE	REQUIREMENTS
4.16.1	Procedures to maintain product safety and quality during loading and transportation shall be developed and implemented. These may include, as appropriate: • controlling temperature of loading dock areas and vehicles • the use of covered bays for vehicle loading or unloading • securing loads on pallets to prevent movement during transit • inspection of loads prior to dispatch.

FUNDAMENTAL

The site shall have a system for the management of allergenic materials which minimises the risk of allergen contamination of products and meets legal requirements for labelling in the country of sale.



CLAUSE	REQUIREMENTS
5.6.2.2	Where routine testing laboratories are present on a manufacturing site, they shall be located, designed and operated to eliminate potential risks to product safety. Controls shall be documented, implemented and include consideration of: • design and operation of drainage and ventilation systems • access and security of the facility • movement of laboratory personnel • protective clothing arrangements • processes for obtaining product samples • disposal of laboratory waste.

FUNDAMENTAL

The company shall ensure that all personnel performing work that affects product safety, legality and quality are demonstrably competent to carry out their activity, through training, work experience or qualification.

Bottom-line: No matter how unusual or remote our food processing operation, we must strive to provide safe, quality products. GFSI certification is a great way to show our commitment to food safety.

Huge thanks to Tod Hall

Factory Manager, Master Photographer
& Miracle Worker