



Mitigation Strategies to Protect Food Against Intentional Adulteration (IA)

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Contamination

unintentional and intentional

- Food Safety
- Unintentional contamination
- Biological, chemical and physical hazards (agents)
- Food Safety Plan
- Food safety (defense)
- Intentional contamination
- Biological, chemical, radiological, physical agents
- Food defense plan
- Economic fraud: adulteration for economic purposes.
- Quality: shelf life, consumer perception, standards



Objective of the regulation (21CFR121)

- Prevent deliberate (intentional) adulteration through acts **intended to cause large-scale harm to public health**, including acts of terrorism directed at the food supply.
- They can cause illness, death, and economic disruption to the food supply **in the absence of mitigation strategies.**



Agents Used

- "Biological "weapons
 - Pathogens
 - Toxins (*C. botulinum*)
- Chemicals
 - Cyanide
 - Methanol
- Radiological substances
- Physical Substances



Some reported incidents



Over 600 farmers were forced to dump tons of strawberries due to the finding of needles in some boxes in Australia (2018)



6 million packages of frozen food were recalled due to contamination with pesticide in Japan (2014)



Bottled water was contaminated with ammonium, injected by means of syringes, in Italy (2003)

Source: Arthur D. Little



One of the largest US egg producers recalled more than 206 millions eggs potentially contaminated with salmonella (2018)



A major US food company recalled millions of snacks from 55 countries due to potential contamination with plastics (2017)



A major french retail company recalled coffee pods due to high levels of ochratoxin (2016)

Source: Arthur D. Little



Adulterated canola oil

- 1981, Spain
- Canola (rapeseed) oil adulterated with aniline (for industrial use and not for human consumption) triggered the toxic oil syndrome
 - 20.000 cases (affected)
 - 800 deaths



Salad bars

- 1984, Oregon, USA.
- *Salmonella* Typhimurium introduced on salad bars in 10 restaurants by the Rajneeshee cult in order to influence a local election
 - 751 cases (affected)



Malathion added to frozen foods

- October 2013, Japan
- Malathion (2.6Xmillion MRL) added to frozen foods by disgruntled production line employee
 - ≤ 2.800 sick
 - Recall of millions of product packages



Sewing needles in strawberries



- 2018- Sewing needles in strawberries by disgruntled employee
- Affected the supply chain (consumer demand) and the strawberry industry
- Disgruntled Supervisor
- ~180 strawberries with needles





Who is subject to regulation?

- In general, **both U.S. and foreign businesses** are required to **register with the FDA**
- **Small business** - a business that employs fewer than 500 people.
- **Other businesses**- a business that is not small or very small and does not qualify for the exemptions

<https://www.fda.gov/media/102250/download>



EXEMPTIONS

- **Very small business-** one business (including subsidiaries and affiliated companies) with an average of less than \$10,000,000; adjusted to inflation, per year (\$11,424,271 per by 2018 2020) in sales of human food plus the market value plus the market value of processed human food processed, packaged, or packaged human food, processed, packaged, or stored (in inventory).



EXEMPTIONS

- The storage of food, **except** holding food in liquid storage tanks.
- The packaging, repackaging, labeling, or relabeling of food where the packaging that comes in direct contact with the food remains intact





EXEMPTIONS

- Activities falling under the definition of "farm" (farm, field, orchard)
- Manufacture, processing, packaging, or storage of animal feeds
- Alcoholic beverages under certain conditions (methanol in alcoholic beverages)
- Farms where certain foods identified with low-risk production practices (jams) are manufactured, processed, packaged, or stored (mixed-type establishment) by a small or very small business.



KEY PROVISIONS

- Vulnerability assessment
- Mitigation strategies



Vulnerability assessment

- Identification of vulnerabilities and actionable process steps for each type of manufactured, processed, packaged or stored food



Vulnerability assessment

- The following elements should be evaluated at each point, step or procedure in the process:
 - ✓ Severity and
 - ✓ Magnitude of potential public health impact
 - ✓ Product volume,
 - ✓ # of servings,
 - ✓ # of exposures,
 - ✓ speed with which the food transits through the distribution system, potential agents of concern (and the infectious/lethal dose of each); and
 - ✓ possible number of people affected (illnesses and deaths)



Vulnerability assessment

- The following elements should be evaluated at each point, step or procedure in the process:
 - ✓ The degree of physical access to the product
 - ✓ (gates, railings, doors, covers, seals and protections)
 - ✓ The ability to successfully contaminate the product.



Actionable process steps

- Identification of the highest risk points, i.e., actionable process steps

Key activity types (**KAT**) ID by FDA:

1. Receiving and filling of bulk liquids
2. Storage and handling of liquids
3. Handling of secondary ingredients
4. Mixing and similar activities

Identify Actionable Process Steps for each Key Activity Type

- By company personnel
- By someone who does not work for the company





Three fundamental elements

1. Potential impact on public health public health,
2. Degree of physical access to the product,
3. Ability of an attacker to successfully the product successfully



Possible actionable steps that could be applied? If farms were to relapse, these could be actionable steps

- Washing
- Waxing
- Mixing



CARVER + Shock

- Criticality: measure of the economic and public health impacts of an attack.
- Accessibility: ability to physically access and egress from the target
- Recuperability: ability of the system to recover from an attack.
- Vulnerability: ease of attack
- Effect: amount of direct loss from an attack measured by loss of production.
- Recognition: facility to identify the target.
- "Shock", to assess the combined health, economic and psychological impacts of an attack within the food industry.

Key activity types

- Coating / Mixing / Preparation / Reprocessing
- Staging / preparation / addition of ingredients
- Receiving / loading of liquids
- Storage tanks / liquid retention



Food defense plan





Mitigation strategies

- These must be identified and executed at each actionable step of the process to provide assurance that vulnerabilities will be minimized or prevented.
- Mitigation strategies should be tailored to the facility and its procedures.
- <https://www.fda.gov/food/food-defense-tools-educational-materials/mitigation-strategies-database>
- Guidance: <https://www.fda.gov/media/135122/download>



Mitigation strategies



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Food Defense Mitigation Strategies Database

The Food Defense Mitigation Strategies Database (FDMSD) is a tool designed to help owners and operators of a food facility with identifying mitigation strategies to protect the food against intentional adulteration, and may assist them with meeting some requirements of the Mitigation Strategies to Prevent Food Against Intentional Adulteration regulation (21 CFR Part 121).

The FDMSD contains a collection of potential mitigation strategies that could be implemented to significantly minimize or prevent significant vulnerabilities at actionable process steps. The FDMSD is intended as a starting point for facilities to consider when identifying potential mitigation strategies. Facilities can customize and tailor strategies listed in the FDMSD to apply to their specific circumstances. Use of the FDMSD is voluntary. The FDMSD is not an exhaustive list of potential mitigation strategies or associated points, steps, or procedures; facilities have the flexibility to identify and implement mitigation strategies that are not contained in the FDMSD.



- [How to use this Tool](#)
- [Full Disclaimer](#)

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Components of the management of the mitigation strategy

- Measures must be taken to ensure the proper implementation of each mitigation strategy.
- Flexibility to determine the most appropriate actions for your operation and product.



Components of the management of the mitigation strategy

- **Monitoring:** Establish and implement procedures for monitoring mitigation strategies, including the frequency with which they are to be carried out.
- **Corrective actions:** if mitigation strategies are not adequately implemented.
- **Verification:** Verification activities would ensure that monitoring is conducted and appropriate decisions on corrective actions are made.





Training and record keeping

- Facilities must ensure that personnel assigned to vulnerable areas receive appropriate **training**;
- Establishments should maintain **records** for food defense control, corrective actions, and verification activities.





Defense plan and management elements

- Food defense plan
 - Vulnerability assessment
 - Mitigation strategies
 - Food defense monitoring procedures
 - Food defense corrective action procedures
 - Food defense verification procedures
- Training records



Tools and resources

- <https://www.fda.gov/food/food-defense>

Tools & Resources

- Food Defense Plan Builder
- FREE-B
- Mitigation Strategies Database
- Food Defense Vulnerability Assessments and Identification of Activity Types



Education & Outreach

- Intentional Adulteration Rule Training
- Intentional Adulteration Webinar Series
- Intentional Adulteration Final Rule Video Presentation

Guidance/Regulations

- Supplemental Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration
- Draft Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration
- Final Rule: Mitigation Strategies To Protect Food Against Intentional Adulteration
- Guidance for Industry: Mitigation Strategies to Protect Food Against Intentional Adulteration - What You Need to Know About the FDA Regulation: Small Entity Compliance Guide
- All Food Defense Guidance and Regulations





FSPCA IA Rule Training Courses	Delivery Method	Intended Audience	Cost
Food Defense Awareness ¹	Available now 	<ul style="list-style-type: none"> Workers at Actionable Process Steps (e.g., front line food workers) Supervisors of Workers at Actionable Process Steps Satisfies requirement in § 121.4(b)(2) 	Free
Overview of IA Rule	Available now 	<ul style="list-style-type: none"> Any stakeholder interested in learning more about the IA rule requirements This course is not associated with any IA rule training requirement 	Free

FSPCA IA Rule Standardized Curriculum Recognized by FDA ²	Delivery Method	Intended Audience	Cost
Conducting Vulnerability Assessments using Key Activity Types	Available now 	<ul style="list-style-type: none"> Food professionals who conduct VAs using the KAT Method only This course is strongly recommended before taking the Conducting Vulnerability Assessments course 	\$159.00 USD
Identification and Explanation of Mitigation Strategies	Available now 	<ul style="list-style-type: none"> Food professionals who identify Mitigation Strategies to implement at Actionable Process Steps 	\$169.00 USD
Conducting Vulnerability Assessments	Available now 1-Day Course 	<ul style="list-style-type: none"> Food professionals who conduct VAs using the 3 Fundamental Elements This 1-day course must be taught by FSPCA VA Lead Instructors The VA/KATs online course is strongly recommended before taking this course 	Varies – price set by independent VA Lead Instructors
Food Defense Plan Preparation and Reanalysis	Available now 	<ul style="list-style-type: none"> Food professionals who prepare the Food Defense Plan and/or who conduct Reanalysis activities 	\$99.00 USD



Thank you very much

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