

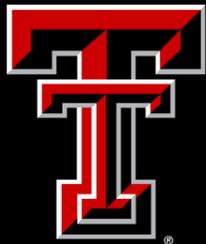
REQUISITOS **PROPUESTOS** FSMA

PROTECCIÓN DE ALIMENTOS CONTRA ADULTERACIÓN INTENCIONAL

DR. MARCOS X. SÁNCHEZ-PLATA, PHD.

marcos.x.sanchez@ttu.edu

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PROPUESTOS

FEDERAL REGISTER

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16 and 121

Focused Mitigation Strategies To Protect Food Against Intentional
Adulteration; Proposed Rule

**ESTRATEGIAS DE
MITIGACIÓN
ENFOCADAS EN LA
PROTECCIÓN CONTRA
LA
ADULTERACIÓN
INTENCIONAL**

**REGLA PROPUESTA
21 CFR PARTES 16 Y 121
DICIEMBRE 24, 2013**





ADULTERACIÓN INTENCIONAL

Tipos de **Intentional Adulteration**

1. Actos con la intención de causar **daño masivo** a la salud publica
2. Actos de **empleados descontentos, consumidores o competidores**
3. **Adulteración** motivada **económicamente**



AMENAZAS LATENTES 1. DAÑO MASIVO A LA SALUD PUBLICA

Algunos de los virus y bacterias que, por su peligrosidad, podrían emplearse como armas.

PRINCIPALES VIAS DE INFECCIÓN

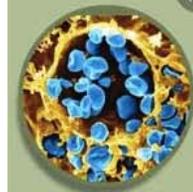


VIRUELA

Virus con dos variantes: mayor y menor.



TULAREMIA (Francisella tularensis) Bacteria



MELIOIDOSIS (Burkholderia pseudomallei) Bacteria. También conocida como "bomba de tiempo de Vietnam".



BOTULISMO (Clostridium botulinum) Bacteria



ÁNTRAX (Bacillus anthracis) Bacteria clasificada en tres tipos: carbunco cutáneo, pulmonar y digestivo.



GLANDERS (Burkholderia mallei) Bacteria



EL PRIMER CASO DE BIOTERRORISMO



Centro médico JKK
Robert Steven, editor fotográfico del diario Sun de Miami, se convirtió en la primera víctima del ataque bioterrorista de ántrax que se inició el 18 de septiembre de 2001.

MARBURG (Fiebre hemorrágica) Virus



ÉBOLA (Fiebre hemorrágica) Virus con cinco subtipos: Zaire, Sudán, Costa de Marfil, Bundibugyo y Reston.

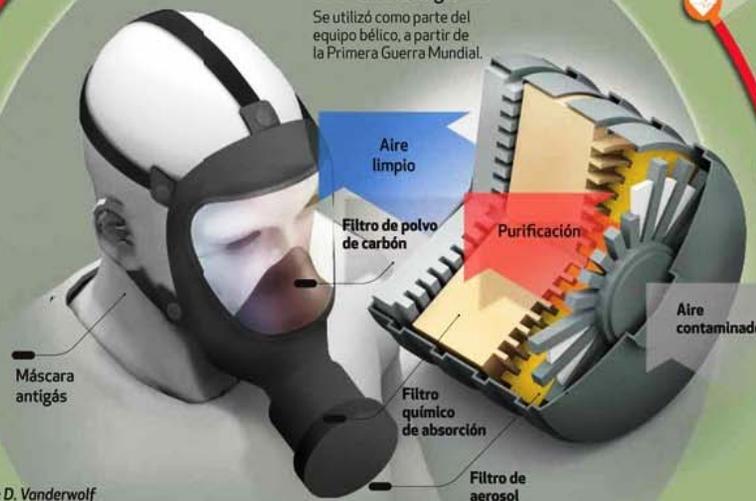


PESTE/PLAGA (Yersinia pestis) Cocobacilo: también conocido como "la muerte negra".



¿Cómo funciona una máscara antigás?

Un invento del siglo XX. Se utilizó como parte del equipo bélico, a partir de la Primera Guerra Mundial.



Existe vacuna Letal No letal

Infografía: D. Vanderwolf



1. DAÑO MASIVO A LA SALUD PUBLICA



The Bhagwan Shree Rajneesh Cult

Ataque de Bioterrorismo

Dalles, Oregon, 1984

Primer caso confirmado de bioterrorismo en los EEUU

Salmonella en barras de ensalada

Fines políticos para suspender una elección

Interés en asignación de terrenos para su Culto



Naranjas Jaffa con Mercurio

Ataque de Bioterrorismo

Holanda, 1978

Mercurio en Naranjas de Israel

Fines políticos para causar disrupción económica

Grupo extremista Palestino Armada

Revolucionaria Árabe

MEHR





2. EMPLEADOS DESCONTENTOS, CONSUMIDORES, COMPETIDORES



Empleados imprudentes
Despedidos vengativos
Consumidores con agenda
Competidores en busca de
ventajas y efectos
económicos

T 3. ADULTERACIÓN MOTIVADA ECONÓMICAMENTE



Melamina en alimentos de bebe y mascotas, China.

Pasta de Maní con Salmonella detectada por laboratorios, pero escondidos los resultados por procesador, EEUU



Carne de caballo en vez de res en Europa

Adulteración de leches e ingredientes lácteos en India





ADULTERACIÓN INTENCIONAL

Enfocado en **Sección 121** de FSMA

Prevención de actos con la intención de causar daño a la salud pública en gran escala

Considera las vulnerabilidades relacionadas a la adulteración intencional

Basado en riesgos y flexible

Propone los siguientes **mecanismos clave**:

1. Pasos Accionables de Proceso
2. Estrategias de Mitigación Enfocadas



ADULTERACIÓN INTENCIONAL

Requisitos Propuestos:



Plan de Defensa por Escrito



Pasos de Proceso Accionables



Estrategias de Mitigación Enfocadas



Monitoreo



Acciones Correctivas



Verificación



Entrenamiento





ADULTERACIÓN INTENCIONAL



Plan de Defensa por Escrito

Desarrollar y Mantener un Manual del Plan de Defensa de la Instalación

Tener disponible el manual para Inspección

Revisar el estatus periódicamente

Incluir:

- Componentes del Plan de Defensa

- Documentos de monitoreo y acciones correctivas

- Actividades de verificación y validación



ADULTERACIÓN INTENCIONAL



Pasos del Proceso Accionables

Identificación de Pasos del Proceso donde se puedan tomar acciones usando “tipos de actividad claves” o una **Evaluación de Vulnerabilidades**

Determinar la presencia de “**tipos de actividades clave**”, similar al Análisis de Peligros asociados con cada alimento y sus etapas de proceso

Los **Pasos de Proceso Accionables** son similares a los Puntos Críticos de Control



ADULTERACIÓN INTENCIONAL



Pasos del Proceso Accionables

Opción 1:

Determinar si la instalación se dedica a uno de los “**tipos de actividades clave**” identificados por el FDA:

1. Recepción y llenado de liquido en bulto (bulk)
2. Almacenamiento y manipulación de líquidos
3. Manipulación de ingredientes secundarios
4. Actividades de mezclado y similares

Identificar **Pasos del Proceso Accionables** para cada **Tipo de Actividad Clave**



ADULTERACIÓN INTENCIONAL



Pasos del Proceso Accionables

Tipos de Actividades Clave:

Evaluadas por el FDA en base a estudios de vulnerabilidades de mas de 50 tipos de productos y procesos

Estos tipos de actividades comúnmente se clasifican como de alta vulnerabilidad basado en factores como:

- Habilidad para poder acceder físicamente al alimento o al proceso

- Potencial de adulterar una cantidad suficiente de producto en orden de causar daño masivo a la salud publica



ADULTERACIÓN INTENCIONAL



Pasos del Proceso Accionables

Opción 2:

1. Desarrollar una **Evaluación de Vulnerabilidad** utilizando métodos e individuos cualificados apropiados
2. Identificar y priorizar puntos en la operación de alimentos que sean vulnerables a la adulteración intencional
3. Identificar Pasos del Proceso Accionables para Vulnerabilidades significativas



ADULTERACIÓN INTENCIONAL



Estrategias de Mitigación Enfocadas

Identificación e implementación de Estrategias de Mitigación Enfocadas en los Pasos del Proceso Accionables

Similares a los Controles Preventivos



ADULTERACIÓN INTENCIONAL



Monitoreo

Establecer e implementar procedimientos para el monitoreo de Estrategias de Mitigación Enfocadas



ADULTERACIÓN INTENCIONAL



Acciones Correctivas

Establecer e implementar procedimientos para la aplicación de Acciones Correctivas SI las Estrategias de Mitigación Enfocadas no son adecuadamente implementadas



ADULTERACIÓN INTENCIONAL



Verificación

Verificar que el Monitoreo esta siendo conducido

Verificar que decisiones apropiadas sobre Acciones Correctivas se cumplen

Verificar que las Estrategias de Mitigación Enfocadas son consistentemente implementadas y son efectivas

Conducir Re-evaluaciones del Plan de Defensa de Alimentos cuando sea necesario



ADULTERACIÓN INTENCIONAL



Registros

Mantener ciertos registros:

Plan de Defensa por Escrito

Pasos de Proceso Accionables

Estrategias de Mitigación Enfocadas

Monitoreo

Acciones Correctivas

Verificación

Entrenamiento



ADULTERACIÓN INTENCIONAL

A quién le aplica:

Instalaciones que manufacturan, procesan, empacan o almacenan alimentos humanos

En general, instalaciones que están requeridas de registrarse con el FDA bajo la Sección 415 de la FD&C Act

Aplica a productos domésticos e importados

Se proponen algunas exenciones y requisitos modificados





ADULTERACIÓN INTENCIONAL

Exenciones

Manufactura, procesamiento empaque y almacenamiento de alimentos para animales

Granjas

Almacenamiento de alimentos, excepto líquidos en bulto (bulk)

Empacado, re-empacado, etiquetado o re-etiquetado de alimentos donde el envase que contacta directamente al alimento se mantiene intacto

Bebidas alcohólicas en ciertas instalaciones (bajo condiciones específicas)



ADULTERACIÓN INTENCIONAL

Requisitos Modificados

Instalaciones “Calificadas”:

Negocios muy pequeños (menos de \$10 millones en ventas totales anuales)

O

Ventas de alimentos que promedien menos de \$500,000 por año durante los últimos 3 años Y

Las Ventas a usuarios finales calificados DEBE exceder las ventas a otros



Es Usted el Dueño, Operador o Agente de la Instalación domestica o Extranjera que debe registrarse con el FDA?

SI

Le aplica lo siguiente?:

Esta su instalación involucrada en el almacenamiento de alimentos otros a alimentos que no sean alimentos en tanques de almacenamiento liquido?

Esta su instalación involucrada en el empaque, re-empaque, etiquetado, o re-etiquetado de alimentos, donde el envase en contacto directo con el alimento permanece intacto?

Esta su instalación involucrada en actividades sujetas a los Estándares de Inocuidad de Frutas y Vegetales (21 CFR Parte 112)?

Su instalación produce bebidas alcohólicas?

Esta su instalación involucrada en la manufactura, procesamiento, empackado o almacenamiento de alimentos para animales?

SI

La Regla propuesta 121 NO aplica a estas actividades en su instalación.
Su instalación esta involucrada en actividades de manufactura, procesamiento, empackado o almacenamiento de otros alimentos

NO

NO.

La Regla Propuesta de Adulteración Intencional No aplica

SI

Es su instalación "cualificada":

1. Una "Muy Pequeña empresa": menos de \$10,000,000 en ventas totales anuales de alimentos O
2. Una instalación que cumple:
a) Valor monetario promedio anual de alimentos vendidos directamente a usuarios finales cualificados durante los 3 años anteriores excede lo vendido a otros compradores, Y
b) Valor anual promedio de alimentos vendidos durante dicho periodo es menos de \$500K

SI

Usted estará exento, excepto que deberá proveer para revisión oficial, cuando sea pedido, la documentación que utiliza para demostrar que es una instalación cualificada.
Tendrá 3 años para cumplir

NO

NO

Usted ESTARA sujeto a la Regla Propuesta



ADULTERACIÓN INTENCIONAL

Fechas de vigencia formales:

60 días luego de publicación de Regla Final

Abierta a comentarios hasta Noviembre 26 2013

Fechas de Cumplimiento:

Luego de publicar la Regla Final

Empresas Pequeñas: menos de 500 personas, DOS años

Empresas Muy Pequeñas: menos de \$10 millones en ventas anuales de alimentos, TRES años para cumplir requisitos modificados

Empresas Muy Pequeñas son consideradas instalaciones calificadas y sujetas a requisitos modificados

Otras empresas: que no califican a exenciones, UN año



CURSO DE FOOD DEFENSE 101

Home > Food > Food Defense > Tools & Educational Materials

Food Defense

Tools & Educational Materials

Food Defense Acronyms, Abbreviations & Definitions

▶ [Food Defense 101 \(including ALERT\)](#)

[Food Defense Plan Builder](#)

[Food Related Emergency Exercise Bundle \(FREE-B\)](#)

[Employees FIRST](#)

[See Something, Say Something Campaign](#)

[Vulnerability Assessment Software](#)

[Mitigation Strategies Database](#)

Food Defense 101 (including ALERT)

Be a part of the team to protect our nation's food supply.

The food industry plays an integral part in protecting the nation's food infrastructure. Food Defense 101 provides training in preparedness against an intentional attack against our food supply. The courses provide an understanding of and guidance for developing a Food Defense Plan(s) based on a common sense approach.

Food Defense 101 is comprised of four courses:

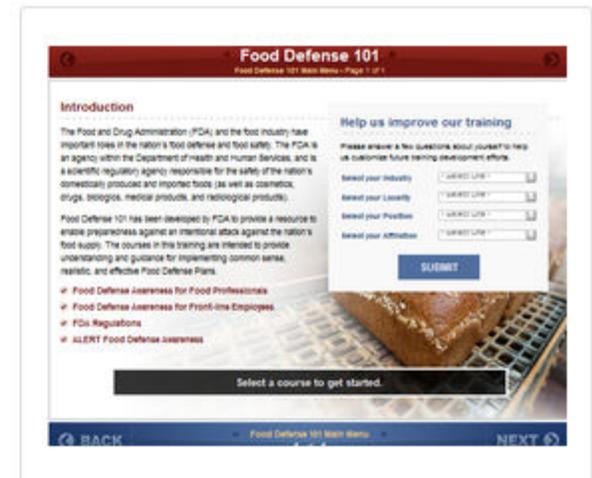
- Food Defense Awareness for the Food Professional;
- Food Defense Awareness for the Front-line Employee;
- Food Defense Regulations; and,
- ALERT, for owners and operators of food facilities

They are designed to stimulate discussion of food defense within the industry. Get started today and become a part of the team to protect our nation's food supply.

Download the [Food Defense 101 brochure \(PDF: 3MB\)](#).

Additional Information:

- [Courses](#)
- [Course Completion Certificates](#)
- [Navigation](#)
- [System Requirements](#)





CURSO DE FOOD DEFENSE 101

Food Defense 101

Food Defense 101 Main Menu • Page 1 of 1

Introduction

The Food and Drug Administration (FDA) and the food industry have important roles in the nation's food defense and food safety. The FDA is an agency within the Department of Health and Human Services, and is a scientific regulatory agency responsible for the safety of the nation's domestically produced and imported foods (as well as cosmetics, drugs, biologics, medical products, and radiological products).

Food Defense 101 has been developed by FDA to provide a resource to enable preparedness against an intentional attack against the nation's food supply. The courses in this training are intended to provide understanding and guidance for implementing common sense, realistic, and effective Food Defense Plans.

- ✓ **Food Defense Awareness for Food Professionals**
- ✓ **Food Defense Awareness for Front-line Employees**
- ✓ **FDA Regulations**
- ✓ **ALERT Food Defense Awareness**

Help us improve our training

Please answer a few questions about yourself to help us customize future training development efforts.

Select your Industry	<input type="text" value="Manufacturer/Food Proc"/>
Select your Locality	<input type="text" value="Florida"/>
Select your Position	<input type="text" value="Production Supervisor"/>
Select your Affiliation	<input type="text" value="Industry"/>

SUBMIT



CURSO DE FOOD DEFENSE 101



Food Defense Awareness for Food Professionals



Food Defense Awareness for Food Professionals - Introduction • Page 1 of 2

Food Defense Awareness for Food Professionals





CURSO DE DEFENSA DE ALIMENTOS 101

FDA Home » Food Defense 101 Menu » ALERT Food Defense Awareness » ALERT

◀ Conciencia acerca de la defensa de los alimentos ALERT ▶

Menú Principal • Página 1 de 1

INTRODUCCIÓN

ALERT

QUÉ VIENE DESPUÉS

Ahora en Español

Seleccione Siguiente para continuar o seleccione un tema

◀ VOLVER

• Menú Principal •

SIGUIENTE ▶





FOOD DEFENSE ... DEFENSA, PROTECCIÓN



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- [Science](#)

Food Defense and Emergency Response

Food Defense is the protection of food products from intentional adulteration by biological, chemical, physical, or radiological agents. It addresses additional concerns including physical, personnel and operational security.



[Food and Drug Administration \(FDA\) Food Defense Plan Builder](#)

FDA's Food Defense Plan Builder is a user-friendly software program designed to assist owners and operators of food facilities with developing personalized food defense plans for their facilities.

- Also at www.FDA.gov: [Food Defense 101 Training](#)



[Food Defense Plan Survey Results](#)

The seventh food defense plan survey was completed in August 2012. The survey measured the status of industry's voluntary adoption of food defense plans. Read a summary of the results.



[General Food Defense Plan \(PDF Only\)](#)

Document defense measures for your FSIS-regulated small and very small plants to protect food and food production processes from intentional harm.



CONSTRUCTOR DE PLANES DE DEFENSA

Food Defense Plan Builder

The Food Defense Plan Builder is a user-friendly software program designed to assist owners and operators of food facilities with developing personalized food defense plans for their facilities. This user-friendly tool harnesses existing FDA tools, guidance, and resources for food defense into one single application.

The Food Defense Plan Builder guides the user through the following sections:

- Company Information
- Broad Mitigation Strategies
- Vulnerability Assessment
- Focused Mitigation Strategies
- Emergency Contacts
- Action Plan
- Supporting Documents

[DOWNLOAD](#) the Food Defense Plan Builder
(view [system requirements](#))

[WATCH](#) the training videos

[Workshops](#) available introducing the Food Defense Plan Builder

Frequently Asked Questions

What is Food Defense?

Food Defense is the effort to protect the food supply against intentional contamination due to sabotage,





FOOD DEFENSE PLAN BUILDER



<https://collaboration.fda.gov/p7d584u2378/?launcher=false&fcsContent=true&pbMode=normal>



U.S. Food and Drug Administration
Protecting and Promoting Public Health

www.fda.gov

Food Defense Plan Builder

Julia Guenther

Policy Analyst

Food Defense and Emergency Coordination Staff

FDA/Center for Food Safety and Applied Nutrition



Clase de 30 minutos





PLAN GENERAL DE FOOD DEFENSE

Plan de protección alimentaria
Medidas de seguridad para la protección
alimentaria

[http://www.fsis.usda.gov/wps/wcm/connect/3df365ba-b26e-4795-b2d5-4c352aafffeb/Spanish General Food Defense Plan 092309.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/3df365ba-b26e-4795-b2d5-4c352aafffeb/Spanish_General_Food_Defense_Plan_092309.pdf?MOD=AJPERES)



PLAN GENERAL DE FOOD DEFENSE

Medidas de seguridad para el exterior

Seguridad física

Seguridad de áreas de envío y recepción

Seguridad en el manejo del correo

Medidas de seguridad en el interior

Medidas generales

Seguridad en matadero y procesamiento

Seguridad en bodegas/ almacén

Seguridad de ingredientes, agua, hielo

Seguridad de materiales peligrosos

(químicos)

Seguridad de la información

Medidas de seguridad del personal

Seguridad de empleados

Seguridad de NO empleados

Capacitación de seguridad

Medidas de seguridad de respuesta

Investigación de situaciones de seguridad preocupantes

Contactos de emergencia

Otros planes de seguridad



EMPLEADOS PRIMERO (FIRST)

Employees FIRST

Food Defense Awareness for front-line food industry workers

Employees FIRST is an FDA initiative that food industry managers can include in their ongoing employee food defense training programs. Employees FIRST educates front-line food industry workers from farm to table about the risk of intentional food contamination and the actions they can take to identify and reduce these risks.

Follow company food defense plan and procedures.
Inspect your work area and surrounding areas.
Recognize anything out of the ordinary.
Secure all ingredients, supplies, and finished product.
Tell management if you notice anything unusual or suspicious.

Employees FIRST Learning Objectives:

- Increase food defense awareness;
- Define and explain the five parts of the Employees FIRST initiative.

Employees FIRST Tools

- Employees FIRST Poster - a 4-color poster that can be hung in work areas to reinforce the initiative
 - [English Employees FIRST Poster](#)
 - [Chinese Employees FIRST Poster](#)
 - [French Employees FIRST Poster](#)
 - [Japanese Employees FIRST Poster](#)
 - [Korean Employees FIRST Poster](#)





EMPLEADOS PRIMERO (FIRST)

EMPLEADOS
SON LA
PRIMERA
Linea de Defensa
de los alimentos

FOLLOW. SEGUIR EL PLAN DE DEFENSA Y LOS PROCEDIMIENTOS DE LA EMPRESA
INSPECT. INSPECCIONAR SU ÁREA DE TRABAJO Y LAS ÁREAS ALREDEDOR
RECOGNIZE. RECONOCER CUALQUIER COSA FUERA DE LO NORMAL
SECURE. ASEGURAR TODOS LOS INGREDIENTES, SUMINISTROS Y PRODUCTOS TERMINADOS
FIRST
TELL. AVISAR A LA GERENCIA SI NOTA ALGO INUSUAL Ó SOSPECHOSO



ANÁLISIS DE VULNERABILIDADES CARVER+

Criticality, Accessibility, Recognizability, Vulnerability, Effect, Recuperability

FDA's Vulnerability Assessment Software tool

Quick Instruction Guide

The FDA's Vulnerability Assessment Software tool uses the CARVER + Shock methodology. The software tool is a user-friendly, interactive application developed by the Food and Drug Administration's Center for Food Safety and Applied Nutrition. The software tool assists users to conduct vulnerability assessments of food products and processes to intentional contamination and support user's efforts at mitigating contamination threats to food products.

CARVER is an acronym for the following six attributes used to evaluate the attractiveness of a target for attack:

- **Criticality:** Assesses the public health and economic impacts of an attack.
- **Accessibility:** Ability to physically access and egress from a target undetected.
- **Recuperability:** Ability of a system to recover from an attack.
- **Vulnerability:** Ability to accomplish a successful attack.
- **Effect:** Amount of direct loss from an attack as measured by loss of production.
- **Recognizability:** Ease of identifying a target.

Shock, a seventh attribute, has been added to the original six to assess the combined health, economic and psychological impacts of an attack within the food industry.

The FDA's Vulnerability Assessment software tool uses all seven attributes to develop a total score for each point in the process. NOTE: Attribute scores are presented only for Criticality, Accessibility, Recuperability, and Vulnerability. The software incorporates Effect, Recognizability, and Shock attributes into the scores of the other four attributes.

During the CSVA Workshops, we will provide instruction to industry users on the functionality, capabilities, and usability of the software tool. This Train the Trainer Info Sheet provides at-a-glance



ANÁLISIS DE VULNERABILIDADES CARVER+

Criticality, Accessibility, Recognizability, Vulnerability, Effect, Recuperability

Overview Help Dialog

Getting Started, Screen 1 of 2: Overview. Use Tab key to move to navigation buttons.

CARVER + Shock (Manufacturing) allows you to assess the potential for an attacker to be successful in contaminating a manufactured product, or a piece of equipment, in your food operation.

1. Each assessment consists of three steps.

1a) Build a Diagram for one product of your operation.

1b) Answer questions about the operation and product in the Interview.

1c) Look at the results of the analysis in the Scoring.

For a first-time user of the software, this might take 4 to 6 hours.

The screenshot displays the CARVER+ software interface, divided into three main sections:

- Diagram (1a):** Shows a process flow diagram with components like 'Perimeter Fence', 'Factory', 'Production Floor', 'Nuts', and 'Shipping'.
- Interview (1b):** A 'Question List' panel with a 'Status 100% Complete' indicator. It includes a question: 'Does the company have questions?' with 'Yes' and 'No' radio buttons.
- Scoring (1c):** A 'Score Detail for Water soluble modest h' panel. It shows a table of scores for various items, with blue bars for 'Importance: Criticality + Recuperability' and red bars for 'Ease of Attack: Accessibility + Vulnerability'. A 'TOTAL SCORE FOR SELECTED BAR - 28 of 40 possible' is displayed at the bottom.

Item	Importance: Criticality + Recuperability (Score range)	Ease of Attack: Accessibility + Vulnerability (Score range)
Blender	11.5	1.3
Softer	11.5	1.0
Nuts	11.4	1.1
Shipping	11.3	1.0
Packager	11.5	1.6
Roaster	11.3	1.0
Blancher	11.4	1.6

Getting Started, Screen 1 of 2: Overview.

Do not show me these help slides again

Back Next Close



ANÁLISIS DE VULNERABILIDADES CARVER+



**AN OVERVIEW OF THE CARVER PLUS
SHOCK METHOD FOR FOOD SECTOR
VULNERABILITY ASSESSMENTS¹**

Template Wizard

Select the choice in the list below that best describes your operation. Use up and down arrows to select a file. Select the Open button to open the selected template file.

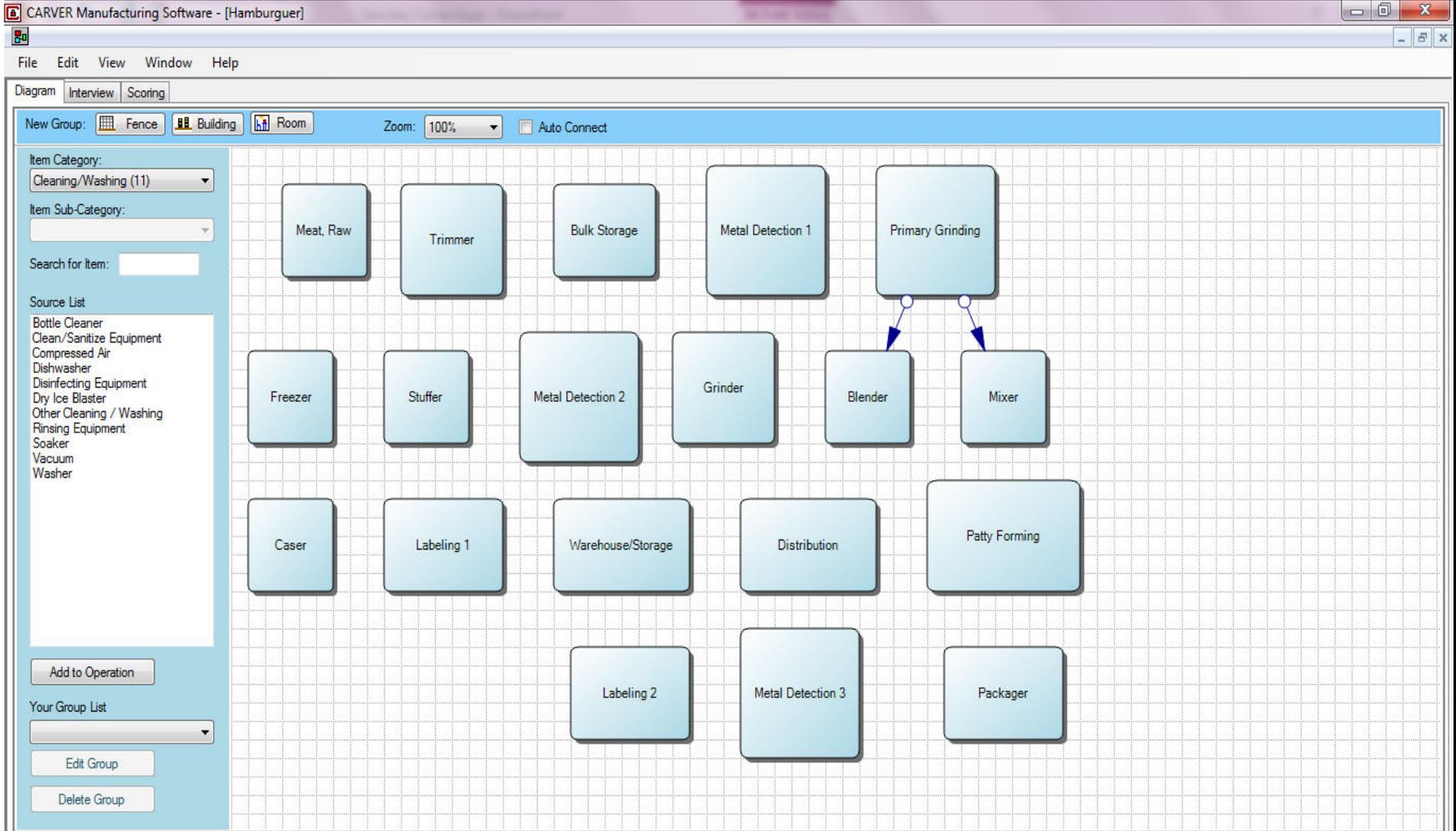
Template Name	Template Description
All Beef Hotdogs Template	Template All Beef Hotdogs Template Description
Animal Feed Mill Template	Template Animal Feed Mill Template Description
Animal Slaughter Template	Template Animal Slaughter Template Description
Apples Template	Template Apples Template Description
Baby Food (Hot Fill) Template	Template Baby Food (Hot Fill) Template Description
Bottled Water Template	Template Bottled Water Template Description
Cereal Template	Template Cereal Template Description
Chocolate Candy Bar Template	Template Chocolate Candy Bar Template Description
Fish Stick Template	Template Fish Stick Template Description
Fluid Milk Template	Template Fluid Milk Template Description
Fresh Vegetable Template	Template Fresh Vegetable Template Description
Fruit Canning Template	Template Fruit Canning Template Description
Fruit Juice Template	Template Fruit Juice Template Description
Hamburger Template	Template Hamburger Template Description
Ice Cream Template	Template Ice Cream Template Description
Peanut Butter Template	Template Peanut Butter Template Description
Pet Food Template	Template Pet Food Template Description
Pizza Assembly Template	Template Pizza Assembly Template Description
Pizza Bakery Template	Template Pizza Bakery Template Description
Potato Chip Template	Template Potato Chip Template Description
Shelled Nuts Template	Template Shelled Nuts Template Description
Soda Template	Template Soda Template Description
Veggie Burger Template	Template Veggie Burger Template Description
Whey Template	Template Whey Template Description

Select and click Open or Double click to open a template.

Open Cancel

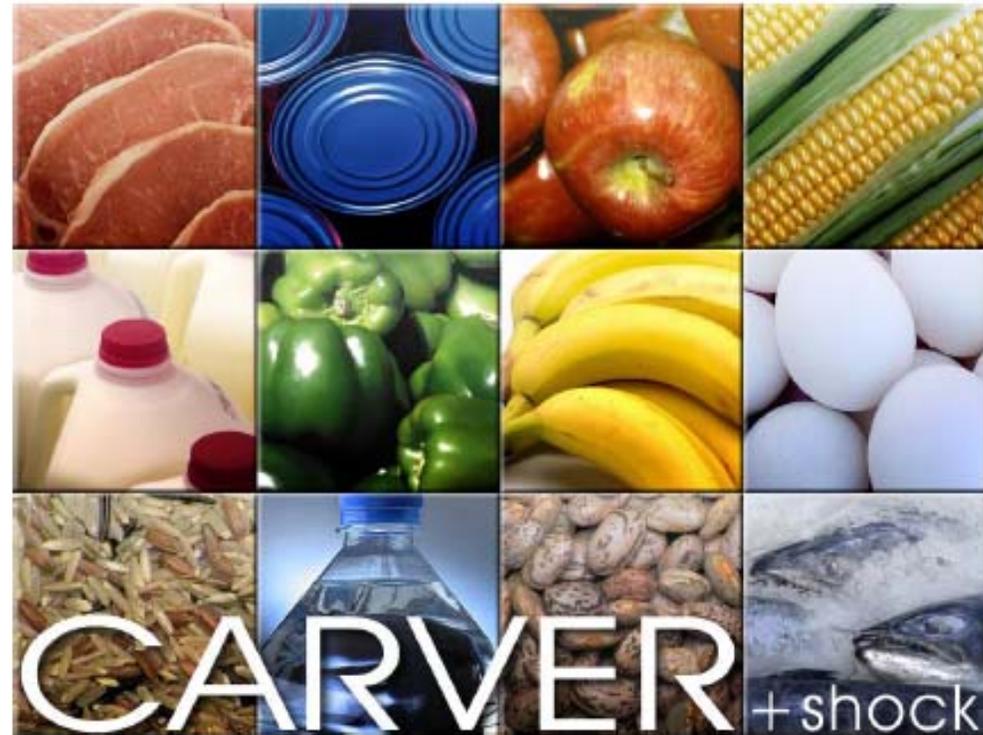


ANÁLISIS DE VULNERABILIDADES CARVER+





ANÁLISIS DE VULNERABILIDADES CARVER+



CARVER + Shock (Manufacturing) User's Manual

Version 2.0, January 27, 2010

Abstract

CARVER + Shock (Manufacturing) Version 2.0 is designed to assess the potential for an attacker to successfully contaminate a food product after harvest and prior to its sale to retail outlets. This user's manual describes the scope, assumptions, and some details of operation of the of the software tool. It is intended for use primarily by food-processing operations.



BASE DE DATOS DE ESTRATEGIAS DE MITIGACIÓN

Mitigation Strategies Database



The [Food Defense Mitigation Strategies Database \(MSD\)](#) is one of several tools developed by the FDA for the food industry to help protect our nation's food supply from deliberate acts of contamination or tampering. This resource is designed for companies that produce, process, store, package, distribute, and/or transport food or food ingredients. The MSD provides a range of preventive measures that companies may choose to implement to better protect their facility, personnel, products, and operations.

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[Background](#)

The FDA is committed to improving the safety and security of the food and cosmetic supply. In 2007 FDA published [five guidance documents](#) detailing security preventative measures for all components of the food supply chain, including cosmetics processors and transporters. More recently, FDA has made available food defense tools which allow companies to conduct vulnerability assessments, and determine suitable mitigation approaches.

[3 Key Steps to Food Defense](#)

1. Conducting a vulnerability assessment

CARVER + Shock is one example of a vulnerability assessment tool which will help industries, States, and Multi-State Consortia build a safer, less vulnerable food supply chain.



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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate telephone number listed on the title page of this guidance.



HOW TO USE THIS TOOL

Welcome to the Food Defense Mitigation Strategies Database. This database is one of several tools developed by the FDA for the food industry to help protect our nation's food supply from intentional acts of contamination or tampering. Specifically, this resource is designed for companies that produce, process, store, package, distribute, or transport food or food ingredients. It provides a range of preventive measures that companies may choose to better protect their facility, personnel, and operations. These safety measures are specific to individual categories that impact every step of the food production and distribution process.

Not all measures are applicable or practical for all sizes and types of food production. It is the responsibility of the owner/operator/supervisor to choose those measures that may be helpful and appropriate for their facility.

Data can be accessed using two different methods.

1. **LOOKUP TOOL:** Data can be searched by a specific item, or *node*, commonly used within commercial food production and distribution. First, select a food industry category from the provided list. Once the category is selected, a list of nodes will be provided to choose from. Once the node is chosen, select "GO" to view its safety objective(s) and steps that can be taken to ensure safety.
2. **SEARCH ENGINE TOOL:** Data can be searched by a specific term or keyword. Similar to any search engine on the Web, type in the desired item to be found and select GO; a list of applicable items will be returned.

LOOKUP TOOL

To begin, select a category and node from the drop down menus shown below, then click on the "Go" button.

SEARCH ENGINE TOOL

You can access a specific Node Security Data Sheet by entering a keyword (i.e. mixing tank) into the text box. Then, select the "GO" button. The application will provide you with





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Ejemplo: Procesamiento de Frutas

Category: Processing

Node: Fruit Processing

Search:

Node pages: 1 | General Information

Fruit Processing

Process

Objective: Reduce the opportunities for intentional contamination

- Develop a policy and protocol for handling "suspect product"
- Develop and use a system to track fruit inventory throughout operations
- If appropriate, employ surveillance equipment at the dump, washing, and product incorporation areas for fruit
- Locate office windows to enable observation of production floor
- Purchase fruit from known and trusted suppliers
- Restrict handling of fruit to designated employees
- Maintain employee presence in produce area at all times
- Restrict access to and operation of processing equipment to authorized employees
- Upon receipt and prior to use verify the quality and general condition of the fruit delivered
- Secure storage areas with swipe cards, cipher locks, or biometric devices
- Secure cleaning supplies away from production operations
- Upon receipt immediately transfer to designated secure storage
- Use only suppliers that have an adequate employee security screening plan in place
- Use only suppliers that maintain chain of custody documentation





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Ejemplo: Jugos (Juice)

Category: Search:

Node:

Node pages: 1 | General Information

Juice Concentrate

Ingredients

Objective: Reduce the opportunities for intentional contamination

- Between uses, protect opened fruit concentrate containers utilized during the production process
- Conduct period checks of the fruit concentrate inventory to ensure integrity
- Develop a policy and protocol for handling "suspect product"
- Develop and use an inventory management system
- For bulk fruit concentrate shipments, require tamper evident seals on tankers/hoppers
- Handle fruit concentrate as you would any other food additive/ingredient
- If practical, add fruit concentrate using automated dispensing equipment
- Locate office windows to enable observation of the production floor
- Maintain employee presence in fruit concentrate storage and addition areas at all times
- Prior to use, employ industry standard testing procedures to ensure quality and safety of fruit concentrate
- Purchase fruit concentrate from known and trusted suppliers that maintain chain of custody documentation
- Reconcile seal breaches prior to delivery acceptance
- Restrict access to and operation of fruit concentrate incorporation equipment to authorized employees
- Secure storage areas with swipe cards, cipher locks, or biometric devices
- Use only suppliers that have an adequate employee security screening plan in place
- Restrict handling of fruit concentrate to designated employees
- Secure cleaning supplies away from fruit concentrate storage and incorporation areas
- Upon receipt and prior to use verify the quality and general condition of the fruit concentrate delivered
- Upon receipt immediately transfer fruit concentrate to designated secured storage
- Use surveillance equipment at the fruit concentrate incorporation areas of the production floor

GRACIAS

Dr. Marcos X. Sánchez-Plata



marcos.x.sanchez@ttu.edu