

Tips para la implementación del plan de inocuidad alimentaria en tu empresa, de acuerdo con la Ley FSMA



V&N Solutions
#pasionporlainocuidad

Andrea Varón García

IL-Controles Preventivos
Alimentos para humanos

#f0934fc0

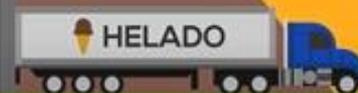


2 Controles preventivos para alimentos para el consumo humano

Plan de inocuidad de los alimentos

Análisis de peligros

Controles preventivos basados en riesgos



Definiciones

- **Plan de Inocuidad Alimentaria**
 - Conjunto de documentos escritos que se basan en los principios de la inocuidad alimentaria; incorpora el análisis de peligros, los controles preventivos, el programa de la cadena de suministro y un plan de retiros del mercado, y delinea los procedimientos que se deben seguir para el monitoreo, las medidas correctivas y la verificación.
 - Adaptado de 21 CFR 117.126
- **Sistema de inocuidad alimentaria**
 - Es el resultado de implementar el Plan de Inocuidad Alimentaria y sus elementos de apoyo.

PCQI: Individuo Calificado en Controles Preventivos



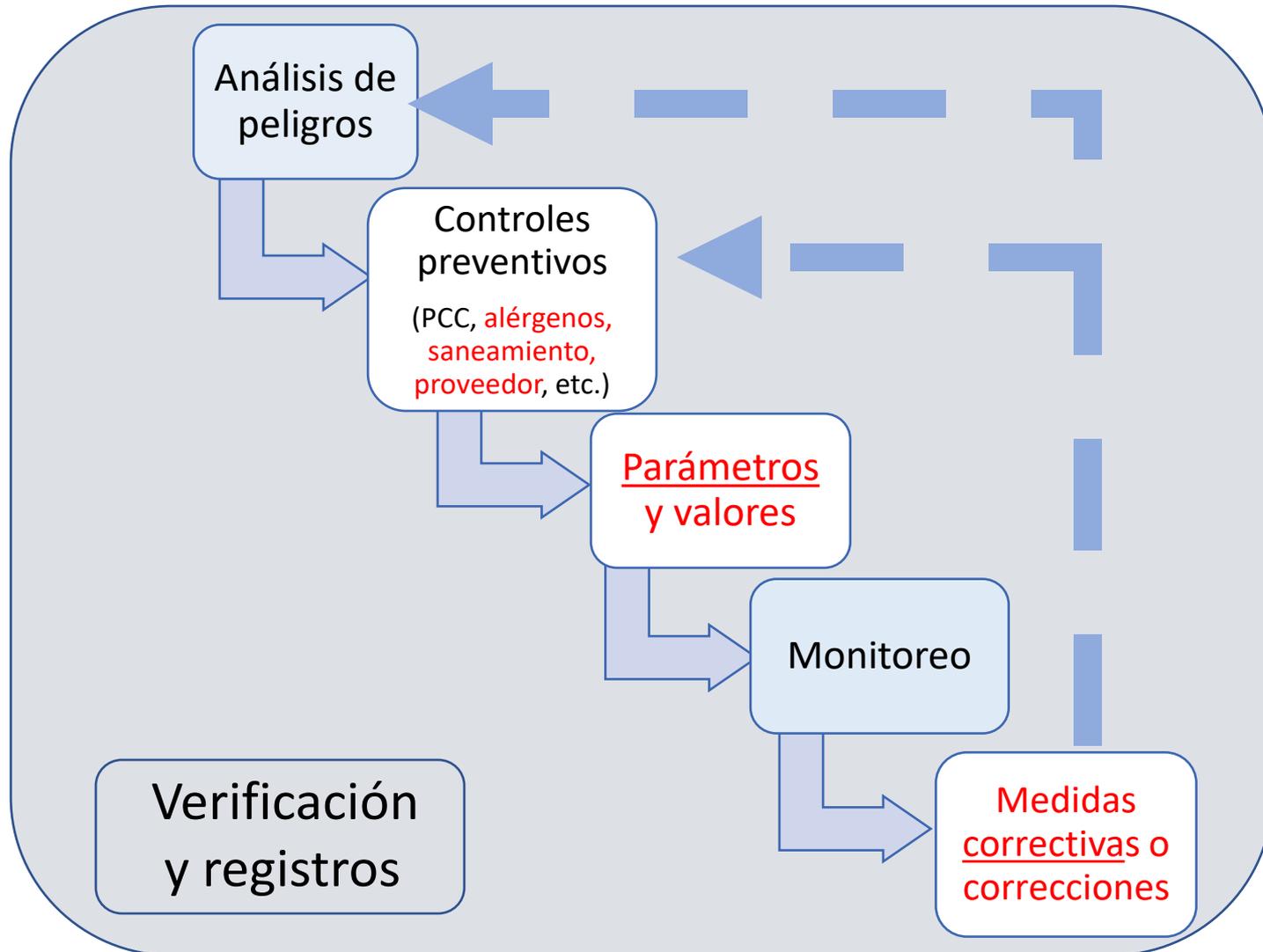
1. Preparación Plan de Inocuidad Alimentaria

2. Validación de los controles Preventivos

3. Examen de los Registros
(Tempo: 7 días)

4. Nuevo análisis del Plan de Inocuidad Alimentaria

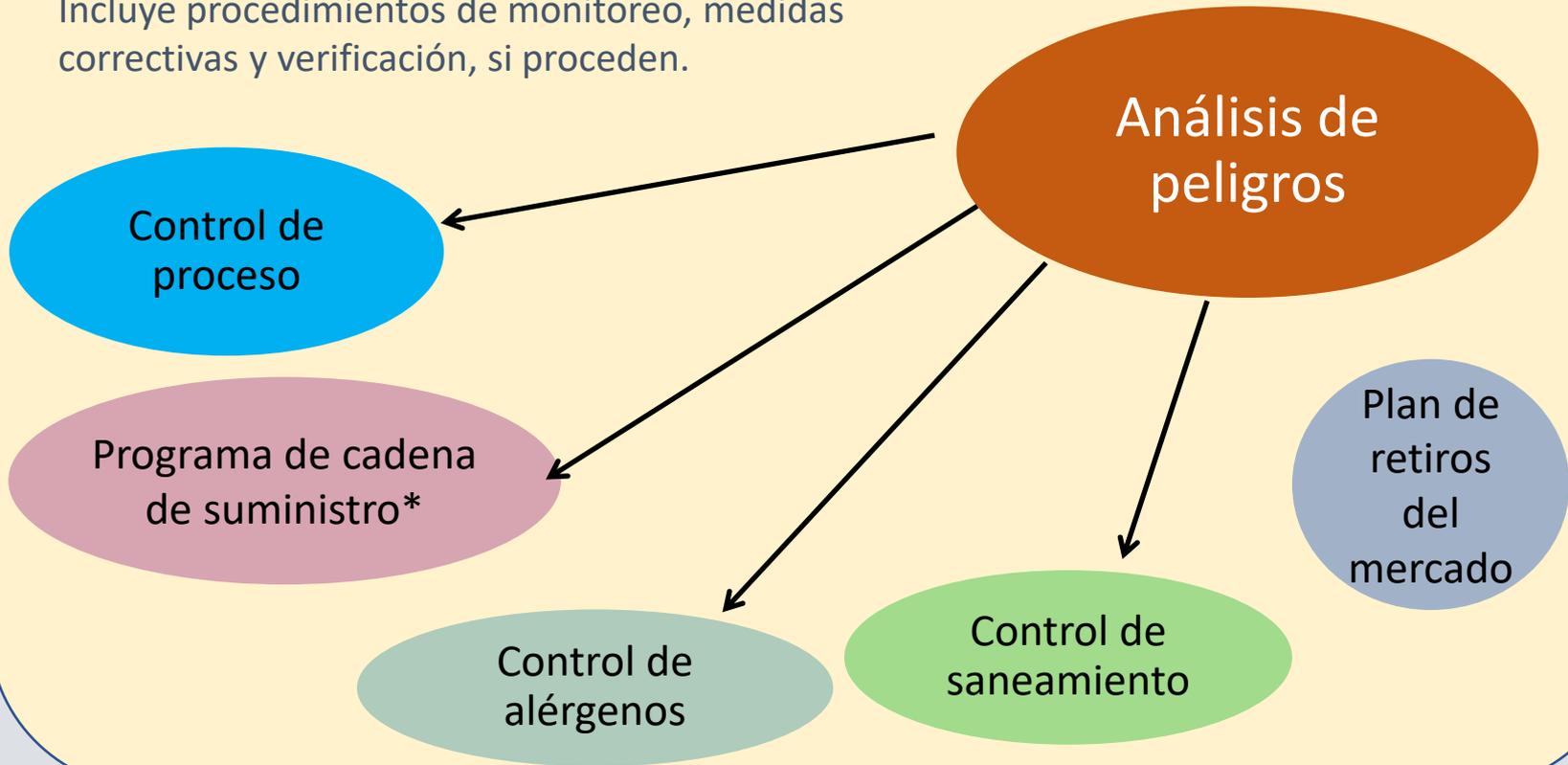
Los controles preventivos incluyen más que el HACCP



Sistema de Inocuidad Alimentaria

Plan de Inocuidad Alimentaria

Incluye procedimientos de monitoreo, medidas correctivas y verificación, si proceden.



BPM y otros programas de prerrequisitos

* proveedores

Plan de Inocuidad Alimentaria



Análisis de Peligros

IMPORTANTE



Biológico

Importante:
Patógenos

No confundir con los
indicadores



Físico

Pueden Causar:

Fractura –
Perforación –
Cortada - Asfixia



Químico

Peligros radiológicos
Residuos de
medicamentos y de
pesticidas - Toxinas
naturales - Aditivos o
colorantes no
aprobados - Alérgenos
alimentarios

Recordemos: Productos serán comercializados en Estados Unidos



FALCPA: La Ley de Protección al Consumidor y Etiquetado de Alérgenos Alimentarios

Análisis de Peligros

(1) Ingrediente / paso de procesamiento	(2) Identifique <u>peligros potenciales</u> para la inocuidad alimentaria introducidos, controlados o potenciados en este paso.	(3) ¿Requiere un control preventivo alguno de los <u>peligros potenciales</u> para la inocuidad alimentaria?		(4) Justifique su respuesta de la columna 3	(5) ¿Qué medida(s) de control preventivo se puede(n) aplicar para minimizar significativamente o prevenir el peligro para la inocuidad alimentaria? <i>Control preventivo de proceso, incluidos los PCC, alérgenos, saneamiento, cadena de suministro u otros</i>	(6) ¿Se aplica en este paso el control preventivo?	
		Sí	No			Sí	No
	B	<div style="border: 2px solid black; padding: 10px; text-align: center;"> <p>Ejemplo de formulario para análisis de peligros- Se pueden usar otros formatos</p> </div>					
	Q						
	F						

Análisis de Peligros

Peligro conocido o razonablemente previsible

Un peligro biológico, químico (incluidos los radiológicos) o físico que es conocido por estar, o **tiene la posibilidad de estar, asociado con la instalación o con el alimento.**

Contains Non-binding Recommendations
Draft-Not for Implementation

Hazard Analysis and Risk-Based Preventive Controls for Human Food: Draft Guidance for Industry¹

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact FDA's Technical Assistance Network by submitting [your question](https://www.fda.gov/oc/your-question) at <https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm>.

Appendix 1: Potential Hazards for Foods and Processes

Appendix Organization

This appendix contains information on the potential biological, chemical, and physical hazards that are food-related and process related. The potential hazard information presented covers the following 17 food (including ingredients and raw materials) categories:

Draft-Not for Implementation

Category	#	Subcategory	Storage Conditions	<i>Bacillus cereus</i>	<i>Clostridium botulinum</i>	<i>C. perfringens</i>	<i>Brucella</i> spp.	<i>Campylobacter</i> spp.	Pathogenic <i>E. coli</i>	<i>Salmonella</i> spp.	<i>L. monocytogenes</i>	<i>Shigella</i> spp.	<i>S. aureus</i>	<i>Giardia lamblia</i>	<i>Trichinella spiralis</i>	Example Products
Powdered Beverages	18	Instant Tea	Shelf-Stable							X						Lemon-flavored powdered tea
Powdered Beverages	19	Coffee Creamer - Non-Dairy	Shelf-Stable							X						Non Dairy Coffee Creamer
Liquid Beverage Mixes	20	Base mix, Concentrated	Shelf-Stable													Cola Base, Root beer Base, Flavored Drink Syrups, Tea Concentrates, Coffee Concentrates
Liquid Beverage Mixes	21	Dairy-based mixes	Shelf-Stable							X						Breakfast Cocoa, Chocolate Dairy Mix, Cocoa Dairy Mix, Cappuccino Mix
Liquid Beverage Mixes	22	Mixes intended for alcoholic beverages	Shelf-Stable							X						Mohito Mix, Bloody Mary Mix, Margarita Mix, Cocktail Mix, Pina Colada Mix

Análisis de Peligros

Peligro que requiere un control preventivo

Peligro conocido o razonablemente previsible para el cual una persona conocedora de la manufactura, el procesamiento, el envasado o la conservación de alimentos inocuos establecería, **con base en el resultado de un análisis de peligros** (que incluye una evaluación de la severidad de la enfermedad o la lesión, si ocurriera el peligro o la probabilidad de que el peligro **ocurra en ausencia de controles preventivos**),



FOOD SAFETY PLAN BUILDER

<https://www.cfsanappsexternal.fda.gov/scripts/foodSafetyPlanBuilder/>

FSPB User Guide

3.2 Download/Installation Instructions

3.2.1 UNINSTALL

If you have a previous version of the application, uninstall completely from your computer and continue with step 2.

1. Click the Start button, type Programs and Features in the search box, and then select Programs and Features.
2. Under Programs and Features, select "Food Safety Plan Builder" and then click Uninstall.
3. Delete the "FoodSafetyPlanBuilderInstall_V(old version)" folder from your local C: Drive and continue with the next step.

For more detailed instructions in how to remove a program from your computer on different version of Windows, you can visit the following links: [Uninstall Programs in Windows 7](#); [Uninstall Programs in Windows 8](#); [Uninstall Programs in Windows 10](#).

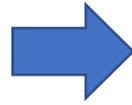
3.2.2 DOWNLOAD

Click the Download Food Safety Plan Builder button.



Figure 3: FSPB Tool Download

ENTREMOS



Food Safety Plan Builder - Huevo líquido

File Edit View Tools Help

Facility Information Preliminary Steps GMP & Other Prerequisite Programs **Hazard Analysis & Preventive Controls Determination** Process Preventive Controls Food Allergen Preventive Controls Sanitation

Hazard Analysis

- List of all process steps
- 1. The hazard analysis process b

Pasteurización

- Identifying known or reasonably fore
- 1a. For each process step, identif
- Determining if preventive controls ar
- 2a. For each known or reasonabl
- Identifying appropriate preventive co
- 2b. For each hazard requiring a p
- Identifying at which processing step t
- 2c. For each preventive control id

Recepcion MPI

- Identifying known or reasonably fore
- 1a. For each process step, identif
- Determining if preventive controls ar
- 2a. For each known or reasonabl
- Identifying appropriate preventive co
- 2b. For each hazard requiring a p
- Identifying at which processing step t
- 2c. For each preventive control id

Pasteurización: Identifying known or reasonably foreseeable hazards

1a. For each process step, identify all known or reasonably foreseeable hazards introduced, controlled or enhanced at this step. If there is no hazard for a specific category, indicate "No" for that category. If no hazards are introduced, controlled or enhanced at this step, indicate "No" for all three categories and proceed to the next process step.

Hazard Categories

Biological hazard(s) Chemical hazard(s) Physical hazard(s)

Yes No Yes No Yes No

Process Step Hazards

Hazard: Name:

(1a) Hazard	Name
Biological	Salmonella

Changes from the Hazard Analysis and Preventive Controls Determination tabs are reflected in the Process Preventive Controls, Food Allergen Preventive Controls, and Sanitation Preventive Controls tabs once you select the 'Import Hazard(s) requiring Process Preventive Control(s)', 'Import Hazard(s) requiring Allergen Preventive Control(s)', and 'Import Hazard(s) requiring Sanitation Preventive Control(s)' buttons respectively.

Supplementary Information:

The rule defines the term "known or reasonably foreseeable hazard" as a biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

The three major categories of hazards that must be considered are biological, chemical (including radiological), and physical hazards.

"A biological hazard" would be microbiological hazards such as parasites, environmental pathogens, and other pathogens.

"A chemical hazard" includes substances such as pesticide and drug residues, natural toxins, decomposition, unapproved food or color additives, food allergens, and radiological hazards.

"A physical hazard" would include hazards such as stones, glass, and metal fragments.

If any known or reasonably foreseeable hazards are introduced, controlled or enhanced at this step, please enter the name(s) of the hazard(s) in the appropriate comment boxes for each hazard category.

Additional information and resources regarding various types of hazards that must be considered can be found in the User Guide.

Zoom(-) Zoom(+)

12:04 a. m. 7/06/2021

Link de Interés

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-hazard-analysis-and-risk-based-preventive-controls-human-food>

<https://www.cfsanappsexternal.fda.gov/scripts/foodSafetyPlanBuilder/>

<https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts>

<https://www.epa.gov/laws-regulations>

<https://www.fda.gov/food/food-allergensgluten-free-guidance-documents-regulatory-information/food-allergen-labeling-and-consumer-protection-act-2004-questions-and-answers>



- *Andrea Varón García*
- *Consultora.*
- *+573212419629*
- [*apvaron@gmail.com*](mailto:apvaron@gmail.com)
- [*www.vynsolutions.com*](http://www.vynsolutions.com)