"CERTIFICATION BODY OFFICIALLY ACCREDITED UNDER THE FDA-FSMA FOOD SAFETY MANAGEMENT PROGRAM"

Taller

Nuevas regulaciones y programas para Exportar a los EE.UU

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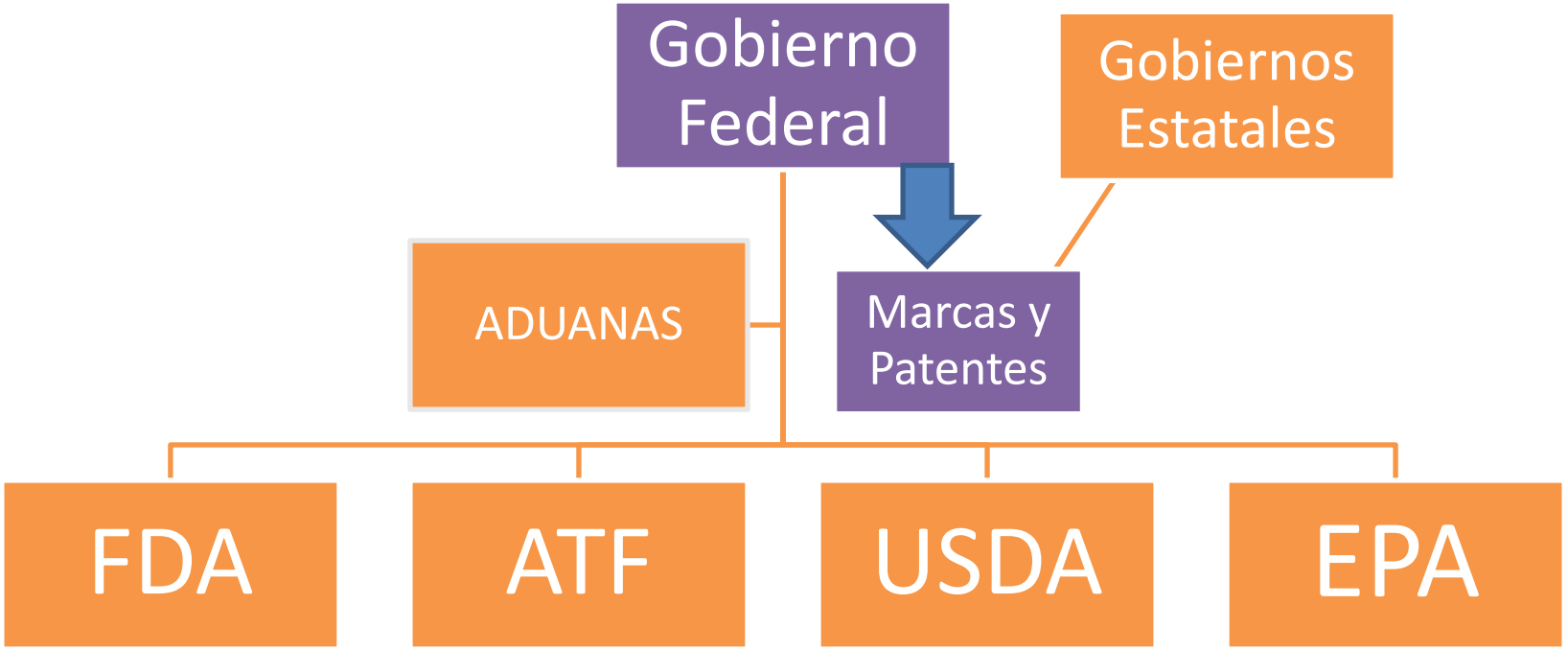
1 de Octubre del 2024

Entidades de gobierno importantes del gobierno Federal



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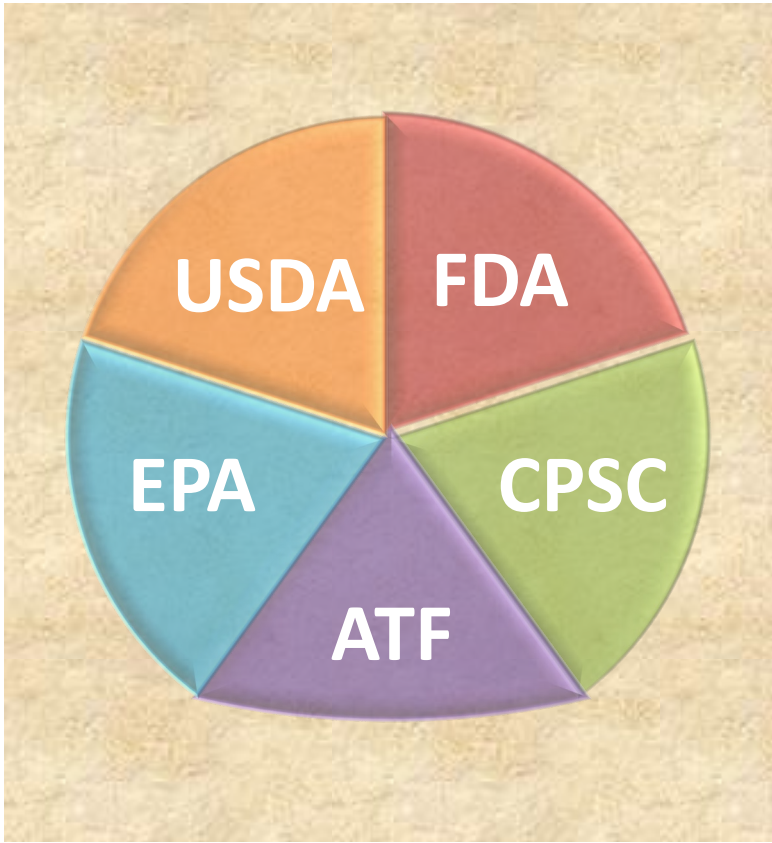
AGENCIAS DE GOBIERNO INVOLUCRADAS

FDA regulates all **foods** and **food** ingredients introduced into or offered for sale in interstate commerce, with the exception of meat, poultry, and certain processed egg products regulated by the **U.S.** Department of Agriculture (USDA).

Food imported into the United States must meet the same laws and regulations as food produced in the United States. It must be safe and contain no prohibited ingredients, and all labeling and packaging must be informative and truthful, with the labeling information in English (or Spanish in Puerto Rico).



Venta en plataformas online: requerimientos, precauciones, consecuencias fiscales.

LEYES ESTATALES

- Cada estado exige un requerimiento diferente
- El Sales tax cambia p/condado en cada estado

No cambia la ley por la forma de realizar la venta

- Se exige registros de empresas en los estados
- Numero fiscal federal y estatal

→ No cumplir con las regulaciones aplicables fiscales conlleva penalidades comerciales pudiendo llegarse a considerar FRAUDE FISCAL.

CTPAT DE ADUANAS

This is a program from Customs to strengthen international supply chains and improve United States border security.

It is address to importers, carriers, consolidators, licensed customs brokers, and manufacturers. oversight requirements. What are the benefits:

- Reduced number of CBP examinations
- Front of the line inspections
- Shorter wait times at the border
- Assignment of a Supply Chain Security Specialist to the company
- Access to the Free and Secure Trade (FAST) Lanes at the land borders
- Eligibility for other U.S. Government pilot programs, such as the Food and Drug Administration's Secure Supply Chain program
- Business resumption priority following a natural disaster or terrorist attack

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Nuevo Foreign Producer Number

- It is a registration for the foreign company to assign tax benefits to importers under (CBMA). The Benefit is a substantial reduction in the alcohol taxes to be paid when the producto is imported to the USA.

ALIMENTOS:

- ADITIVOS INDIRECTOS DE ALIMENTOS: ADHESIVOS Y COMPONENTES DE COATINGS
- ADITIVOS INDIRECTOS DE ALIMENTOS: COMPONENTES DE PAPEL Y PAPERBOARD
- COMPONENTES BASICOS DE SUPERFICIES DE CONTACTO DE ALIMENTOS DE USO SOLO Y REPETIDO
- ADITIVOS ALIMENTARIOS INDIRECTOS: ADYUVANTES, AYUDAS A LA PRODUCCIÓN Y DESINFECTANTES
- IRRADIACION EN LA PRODUCCION, PROCESAMIENTO Y MANEJO DE ALIMENTOS
- SUSTANCIAS DE CONTACTO CON ALIMENTOS; es una sola sustancia, como un polímero o un antioxidante en un polímero. Como sustancia, es razonablemente pura (la definición de sustancia del químico). A pesar de que un polímero puede estar compuesto de varios monómeros, todavía tiene una composición bien definida.
- El material de contacto con alimentos (FCM) se fabrica con el FCS y (generalmente) con otras sustancias. A menudo (pero no necesariamente) es una mezcla, como un antioxidante en un polímero. La composición puede ser variable.
- ARTICULO DE CONTACTO DE ALIMENTOS (FCS + OTRAS SUSTANCIAS): la película terminada, botella, gancho de masa, bandeja, o lo que se forme a partir del FCM. Una sustancia utilizada en un artículo de contacto con alimentos (por ejemplo, envases de alimentos o equipos de procesamiento de alimentos) que migre, o que pueda esperarse que migre, a los alimentos estará exenta de regulación como aditivo alimentario porque se convierte en un componente de los alimentos en niveles que están por debajo del umbral de regulación si no se ha demostrado que la sustancia es un carcinógeno en seres humanos o animales , y no hay ninguna razón, basada en la estructura química de la sustancia, para sospechar que la sustancia es un carcinógeno

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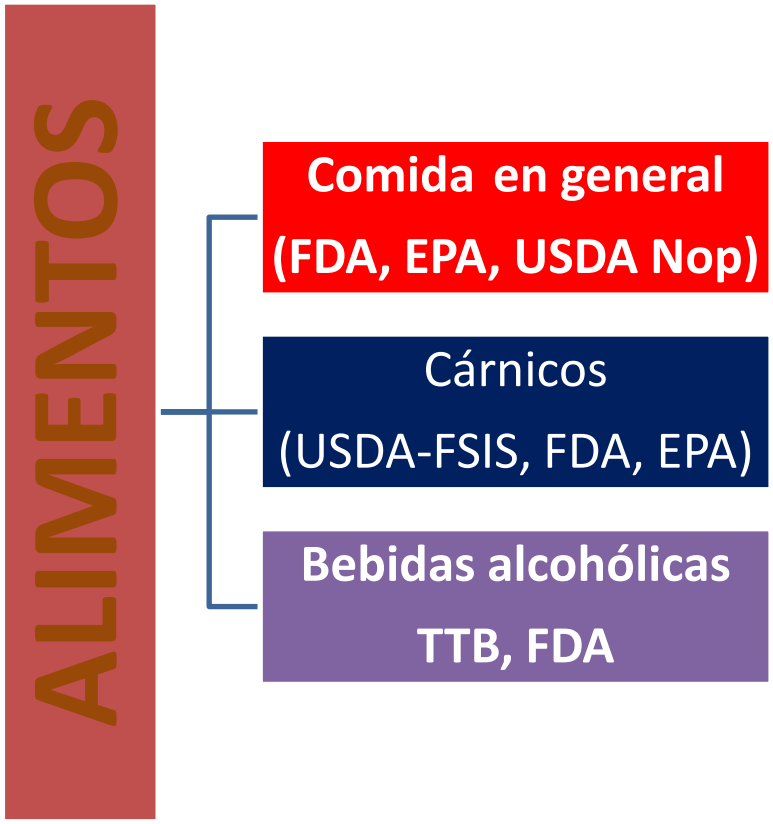
- **Bases de la Clasificación de los Alimentos y sus Regulaciones**



- Los alimentos son:
- suplementos dietéticos
- agua embotellada
- aditivos alimentarios
- fórmulas infantiles
- otros productos alimenticios (USDA. juega un papel principal en los aspectos de regulación de un poco de carne, aves y productos de huevo)

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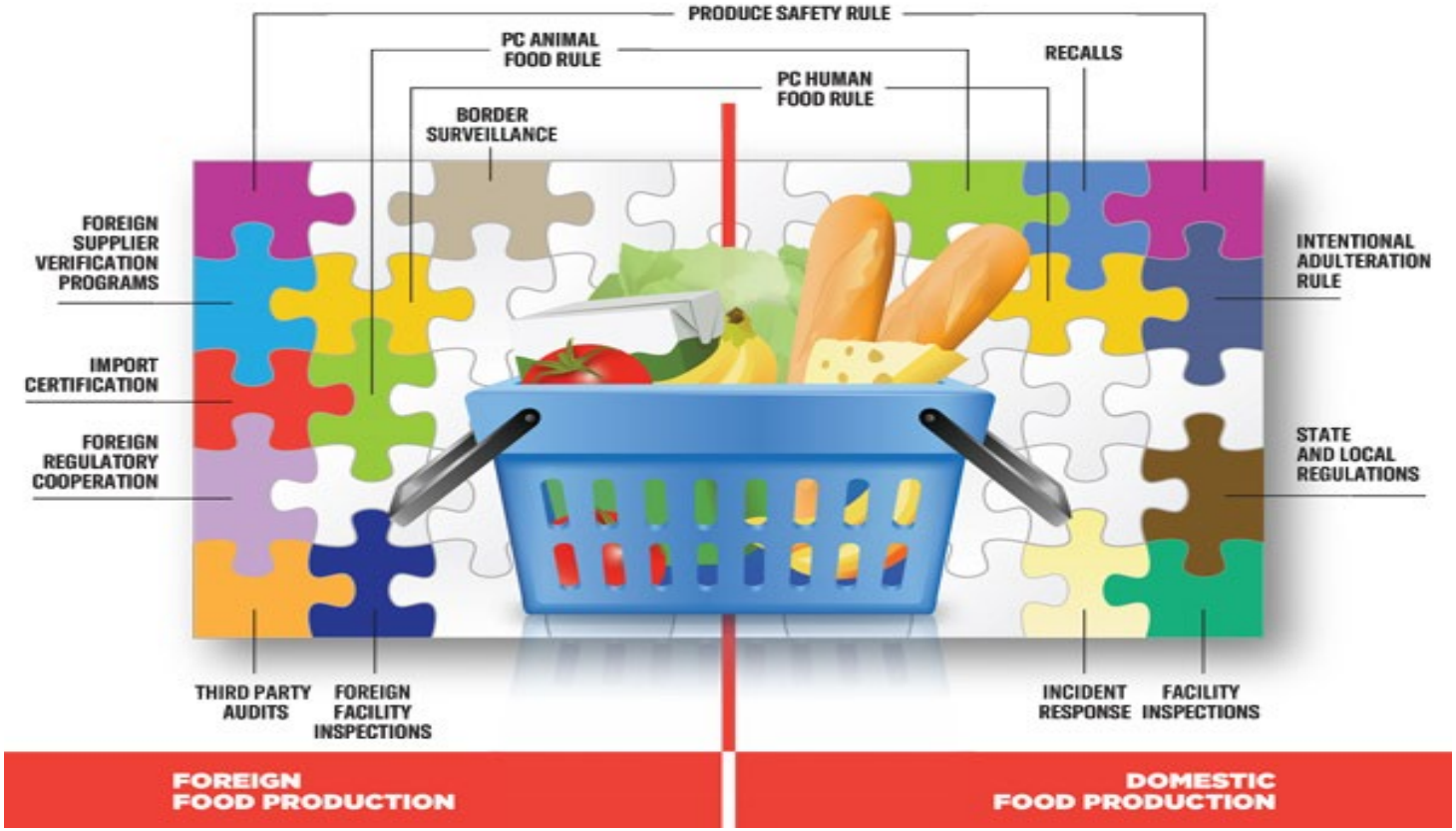
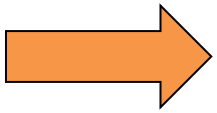
Aspectos regulatorios- FSMA

PIECING TOGETHER THE PUZZLE OF IMPORTED FOOD SAFETY

The FDA oversees the safety of most of the human and animal food consumed in the United States. An overarching goal of the agency is to ensure that Americans can be confident that food imported from other countries is held to the same safety standard as food produced domestically. To that end, the agency brings together many elements to help ensure that our food is safe to eat, no matter where in the world it is produced. You'll see in the graphic below that despite some differences, many of the same regulations and tools impact both foreign and domestically produced foods.

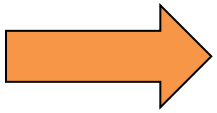


Empresa



- ✓**Registro de Bioterrorismo y**
- ✓Registro de Establecimiento, (cadena).
- ✓Registro FCE
- ✓Registro APHIS/FSIS (USDA)
- ✓ **Numero fiscal (importador).**
- ✓**Registro de notificaciones previas a envío**
- ✓Registro ante FWS (pescados y mariscos)
- ✓Ley de Trazabilidad alimentaria
- ✓Ley de Food Defense – FDA- FSMA
- ✓Ley de Laboratorios Autorizados.

Del Producto:



- ✓ Etiquetado con agencia corres.
- ✓ (Cuadro nutricional, ingredientes y sub., colorantes, porcentajes).
- ✓ SID (LACF)
- ✓ Revisión disclaimers/ aseveraciones
- ✓ Marca registradas
- ✓ Numero de licencia si aplica
- ✓ Certificación (orgánico, natural, etc.). Otros
- ✓ Nuevos alergenos: sesame seed y coco
- ✓ Cambios en estándares de los alimentos
- ✓ Foreign producer number (para alcohol)

Registros de FDA

(1) Bioterrorism Act, FDA established regulations requiring that: Food facilities register with FDA, and FDA be given advance notice on shipments of imported food.

(a) Quien se tiene que registrar: owner, operator, or agent in charge of either a domestic or foreign facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States.

(b) Categorías de alimentos:

- Acidified Food and Low Acid Canned Food (LACF) Products
- Baby (Infant and Junior) Food Products Including Infant Formula;
- Cheese and Cheese Product Categories: Soft, Ripened Cheese; Semi-Soft Cheese; Hard Cheese; Other Cheeses and Cheese Products;
- Dietary Supplement Categories: Proteins, Amino Acids, Fats and Lipid Substances; Animal By-Products and Extracts; Herbals and Botanicals;
- Fishery/Seafood Product Categories: Fin Fish, Whole or Filet; Other Shellfish; Ready to Eat (RTE) Fishery Products; Processed and Other Fishery Products; Molluscan Shellfish*
- Fruit and Fruit Products: Fresh Cut Produce; Raw Agricultural Commodities; Other Fruit and Fruit Products; • Fruit or Vegetable Juice, Pulp or Concentrate Products;
- Nuts and Edible Seed Product Categories: Nut and Nut Products; Edible Seed and Edible Seed Products;
- Shell Egg and Egg Product Categories: Chicken Egg and Egg Products; Other Egg and Egg Products;
- Vegetable and Vegetable Product Categories: Fresh Cut Products; Raw Agricultural Commodities; Other Vegetable and Vegetable Products; and
- If none of the human food categories listed in the registration form apply, print the applicable food category or categories.

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Numero DUNS-UFI nuevo para registros de FDA ya vigente

1. You may comply with FDA's requirement to provide a unique facility identifier (UFI) recognized as acceptable by FDA when you submit your food facility registration or renewal in the Food Facility Registration Module (FFRM).

2. Food facilities that manufacture/process, pack or hold food for consumption in the United States are required to register with the FDA, and this final rule adds new provisions to the current regulations to codify certain provisions of FSMA that were self-implementing and effective upon enactment of FSMA.

Web entry / prior notices

- **Prior Notice:** Notification to the US Food and Drug Administration (FDA) of imported shipments of articles of food prior to their arrival in the United States.

  Includes information about the product, quantity, and packaging, and related facilities, such as the manufacturer, shipper, owner, and ultimate consignee. Information required varies by entry type.

- **Web Entry:** The information that applies to one or more Articles subject to prior notice requirements in one shipment.

  Includes information such as the anticipated arrival port, date, and time, the submitter, importer, and the carrier. Information required varies by entry type.

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Standards of Identity

- The FDA began establishing Standards of Identity (SOI) in 1939, and since then, the agency has established more than 250 SOIs. Products like milk, milk chocolate, various breads, peanut butter, and ketchup have a SOI.
- SOIs often describe in detail what a food must contain and what is optional and sometimes describe the amount or proportion of ingredients or components.
- Many SOIs also prescribe a method of production or formulation.

Standards of Identity

- **Frozen Cherry Pie.** The agency issued a final rule to revoke the SOI and standard of quality for frozen cherry pie.
- **Canned Tuna.** FDA issued a proposed rule to revise the standard of identity and standard of fill of container for canned tuna.
- **Pasteurized Orange Juice.** a citizen petition is asking the FDA to amend the standard of identity for pasteurized orange juice by lowering the minimum soluble solids content, known as the Brix level.
- **Salt Substitutes and Standards of Identity.** The FDA issued a proposed rule in April 2023 to amend the standards of identity (SOIs) to permit the use of salt substitutes in foods for which salt is a required or optional ingredient. The proposed rule would provide manufacturers with flexibility and facilitate industry innovation to reduce sodium in standardized foods.
- **French Dressing.** The FDA issued a final rule in January 2022 revoking the SOI for French dressing because it is outdated.
- **Cheeses and Ultrafiltered (UF) Milk.** Proposed rule to permit the use of fluid UF milk and fluid UF nonfat milk in the production of standardized cheeses and related cheese products.
- **Partially Hydrogenated Oils**. The FDA previously determined that PHOs, which are the primary dietary source of artificial trans fat in processed foods, are no longer generally recognized as safe.

IMPORT LICENSES

- **(1) For all animal or animal by products: (2% or more);**
- **(2) For all siluriformes fish;**
- **(3) For all egg and egg products;**

  Unpasteurized Egg Products (currently permitted from Canada only) are not required to present for FSIS reinspection at an official import inspection establishment. All unpasteurized egg products shipments must proceed directly to an official FSIS egg product plant in the United States and be presented for FSIS reinspection

- **(4) Fruits and vegetables (fresh/ refrigerated)**

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Nueva Ley de Food Defense de los EE. UU. ya vigente.

1. Food Defense is the effort to protect food from acts of **intentional adulteration** intended to cause public health harm or economic disruption. In May 2016 FDA issued the final rule on Mitigation Strategies to Protect Food Against Intentional Adulteration with requirements for covered facilities to prepare and implement food defense plans.

2. Food Safety - the protection of food products from **unintentional contamination**

Ley IA

- FSMA rule 21 CFR Part 121 (IA Rule): **Mitigation Strategies to Protect Food Against Intentional Adulteration requires facilities to create and enact a food defense plan that protects from acts of intentional adulteration intended to cause harm to consumers. Food defense activities are often confused with food fraud mitigation,** but the two topics are mutually exclusive. How can you tell the difference and prepare for both?

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Food Fraud vs Food Defense

- **Food Fraud**
- **Food Fraud happens at the supplier level**. It is the need to protect against adulteration and verify that the ingredients you are buying are truly what they should be and not altered accidentally or intentionally.
- The intentional adulteration, substitution or mislabeling of food ingredients can pose serious health risks for consumers and permanently damage the reputation of producers and suppliers around the globe.
- The new food fraud requirements with GFSI benchmarked standards (SQF, BRC, FSSC 22000) are aimed at minimizing the risk for food fraud by reducing opportunities for fraudsters to reach consumers through monitoring, corrective actions, training and recordkeeping, and evaluation. **However, in no way or form these meets the requirements of FSMA-FDA**

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Obligaciones de las empresas bajo la Ley de IA

Obligatoriedad y contenido del Plan de Food Defense:

Un plan de defensa alimentaria es funcional cuando cumple las cuatro condiciones siguientes:

- Desarrollado: el plan está documentado y firmado
- Implementado: se implementan prácticas de defensa alimentaria
- Verificado : las medidas de defensa alimentaria se controlan y validan
- Revisado y mantenido: el plan se revisa al menos una vez al año y se revisa según sea necesario
- Formar al equipo de food defense bajo los estándares del FDA

FOOD DEFENSE: ESPAÑA-USA

- Concepto original de los EE.UU
- Enfoque totalmente distinto. Se protégé al consumidor y el ataque esta intencionalmente hecho para matar o producer daños graves en los consumidores.
- Las medidas generals de Seguridad de planta NO SON ESTRATEGIAS DE MITIGACIÓN.
- Las consecuencias de los actos de adulteración intencional son SIEMPRE CRIMINALES

- Actualmente ningún país de la Unión Europea ha legislado sobre ningún requisito en materia de Food Defense.
- La intencionalidad no está necesariamente dirigida al consumidor, sino tambien a ocasionar otros daños como consecuencia del ataque.
- Las medidas generals de Seguridad de planta se consideran estrategias de mitigación.
- No necesariamente las consecuencias de los actos de adulteración intencional son SIEMPRE con consecuencias CRIMINALES

Nueva Ley de Trazabilidad aplicable a industrias reguladas por el FDA (alimentos y suplementos dietéticos)

- Establishes traceability recordkeeping requirements, beyond those in existing regulations, for persons who manufacture, process, pack, or hold foods included on the Food Traceability List (FTL) ad the **Trazability Lot Code.**

- FTL, maintain records containing **Key Data Elements (KDEs)** associated with specific **Critical Tracking Events (CTEs)**; and provide information to the FDA within 24 hours or within some reasonable time to which the FDA has agreed.

- The compliance date for all persons subject to the recordkeeping requirements is Tuesday, January 20, 2026.

Nueva Ley de Trazabilidad aplicable a industrias reguladas por el FDA (alimentos y suplementos dietéticos)

Table 1. Commodities on the Food Traceability List and commodity risk scores

Commodity Category	Commodity	Commodity Risk Score
Dairy - Cheese and Cheese Products	Cheese (made from pasteurized milk), fresh soft or soft unripened	430
Dairy - Cheese and Cheese Products	Cheese (made from pasteurized milk), soft ripened or semi-soft	490
Dairy - Cheese and Cheese Products	Cheese (made from unpasteurized milk), other than hard cheese	410
Eggs	Shell Eggs	450
Nuts and Nut Products	Nut Butters	420
Prepared Food - Refrigerated and Ready-to-Eat Salads	Ready-to-eat Deli Salads	330
Produce - Fresh Cut	Fruits (fresh-cut)	370
Produce - Fresh Cut	Leafy Greens (fresh-cut)	390
Produce - Fresh Cut	Vegetables other than leafy greens (fresh-cut)	430
Produce - RAC	Cucumbers	430

Nueva Ley de Trazabilidad aplicable a industrias reguladas por el FDA (alimentos y suplementos dietéticos)

Commodity Category	Commodity	Commodity Risk Score
Produce - RAC	Herbs (fresh)	240
Produce - RAC	Leafy Greens	430
Produce - RAC	Melons	430
Produce - RAC	Peppers	370
Produce - RAC	Sprouts	420
Produce - RAC	Tomatoes	430
Produce - RAC	Tropical Tree Fruits	370
Seafood - Finfish	Finfish, species not associated with histamine or ciguatoxin	370
Seafood - Finfish	Finfish, histamine-producing species	430
Seafood - Finfish	Finfish, species potentially contaminated with ciguatoxin	330
Seafood - Finfish	Smoked Finfish	360
Seafood - Invertebrates	Crustaceans	430
Seafood - Invertebrates	Molluscan Shellfish, bivalves	380

Nueva Ley de Trazabilidad aplicable a industrias reguladas por el FDA (alimentos y suplementos dietéticos)

Plan de trazabilidad (párrafo 1.1315)

Si está sujeto a los requisitos de la norma final, tiene que establecer y mantener un plan de trazabilidad que contenga la siguiente información:

1. **Una descripción de los procedimientos que utiliza para mantener los registros** que debe mantener según esta norma, incluidos el formato y la ubicación de estos registros.
2. **Una descripción de los procedimientos utilizados para identificar los alimentos** de la Lista de trazabilidad de los alimentos que fabrica, procesa, empaca o guarda;
3. **Una descripción de la forma en la que asigna los códigos de lote de trazabilidad** a los alimentos de la Lista de trazabilidad de los alimentos, si corresponde;
4. **Una declaración que identifique un punto de contacto para preguntas relacionadas con su plan de trazabilidad y registros**; y

Nueva Ley de Trazabilidad aplicable a industrias reguladas por el FDA (alimentos y suplementos dietéticos)

5. Si produce o cría un alimento de la Lista de trazabilidad de los alimentos (aparte de huevos), **un mapa de la finca que muestre las áreas en las que produce o cría dichos alimentos.**

1. **El mapa de la finca tiene que mostrar la ubicación y el nombre de cada campo** (u otra área de cultivo) en el que cultiva un alimento de la Lista de trazabilidad de los alimentos, incluidas las coordenadas geográficas y cualquier otra información necesaria para identificar la ubicación de cada campo o área de cultivo.
2. **Para las fincas acuícolas, el mapa de la finca tiene que mostrar la ubicación y el nombre de cada contenedor** (p. ej., estanque, piscina, tanque, jaula) en el que cultiva los mariscos de la Lista de trazabilidad de los alimentos, incluidas las coordenadas geográficas y cualquier otra información necesaria para identificar la ubicación de cada contenedor.

Nueva regulación sobre Laboratorios autorizados bajo el Programa de FSMA- FDA

Under the new proposed program, only laboratories accredited by an Accreditation Body (AB) recognized by the FDA will be able to conduct food testing in certain circumstances, which are outlined in the proposed rule. Further, the results will be required to be sent directly to the FDA by the accredited laboratories.

- Testing conducted to **identified or suspected food safety problem** (including certain tests of shell eggs, bottled water, and sprouts);
- Testing conducted to provide evidence **to support the admissibility of imported food into U.S. commerce;**
- Testing conducted **to support the removal of a food from an import alert through successful consecutive testing**;
- Testing conducted **to address an identified or suspected food safety problem before a mandatory recall order**, as part of a corrective action plan submitted after an order suspending the registration of a food facility,
- Testing conducted **in response to a food testing order**.

OTRAS REGULACIONES

1. Labeling of plant based milk alternatives

2. Nuevos requerimientos para poder usar la palabra "Made in USA".

3. FDA Announces Qualified Health Claim for Cocoa Flavanols in High Flavanol Cocoa Powder and Reduced Risk of Cardiovascular Disease

4. Propuesta de Ley para restricciones en el uso de la palabra "Healthy" en alimentos y suplementos dieteticos

EXPORTACIÓN DE COSMÉTICOS Y OTC

EMPAQUE Y ETIQUETADO
EE.UU

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1. Principios básicos de la nueva Ley
2. Sectores regulados
3. En que cambia la Ley y que tenemos que saber para cumplir con ella.
4 . Cumplimiento de las regulaciones

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Generalidades

- 1. La ley y las costumbres es lo que determina la categoría. No el fabricante según le convenga;
- 2. NO SE PUEDEN USAR NINGUN INGREDIENTE QUE NO ESTE EXPRESAMENTE AUTORIZADO EN LA BASE DE DATOS DEL FDA Y LAS NORMAS APLICABLES.
- 3. Los ingredientes se escriben por su nombre científico o común, no de fantasía;
- 4. El tema de los COLORANTES
- 5. TODA LA INFORMACIÓN OBLIGATORIA DEBE IR EN INGLÉS;
- 6. No debemos olvidarnos de la Ley de Empacados que aplica en su totalidad a ambas categorías de productos.

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- **QUE ES UN COSMÉTICOS?**

La Ley Federal de Alimentos, Medicamentos y Cosméticos (FD & C Act) define los cosméticos por su uso previsto, como "objetos destinados a **ser frotado, vertidos, rociados, o que de lo contrario se aplica al cuerpo humano ... por limpiar, embellecer, la promoción de atracción, o alterar la apariencia** "[Ley de FD & C, sec. 201 (i)]. Entre los productos incluidos en esta definición son hidratantes de la piel, perfumes, lápices labiales, esmaltes de uñas, preparaciones de ojos y maquillaje facial, champú de limpieza, permanentes, tintes para el cabello y desodorantes, así como cualquier sustancia destinados a ser utilizados como componente de un cosmético producto.

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- **DRUGS. OTC.**

- La Ley de FD & C define las drogas, en parte, por su función original, como **"artículos destinados a ser utilizados en el diagnóstico, cura, mitigación, tratamiento o prevención de enfermedades" y "artículos (que no sean alimentos) cuyo propósito es afectar la estructura o cualquier función del cuerpo del hombre u otros animales "**[Ley de FD & C, sec. 201 (g) (1)].

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- **CUANDO UN PRODUCTO ES: cosméticos y medicamentos**.

- Cuando un producto tiene dos usos previstos. Por ejemplo, un champú es un cosmético debido a que su uso previsto es para limpiar el cabello. Un tratamiento anticaspa es una droga, ya que su uso previsto es para tratar la caspa. En consecuencia, un champú anticaspa es a la vez un cosmético y un fármaco.
- Dentífricos que contienen fluoruro,
- Desodorantes que también son antitranspirantes,
- Las cremas hidratantes y maquillaje comercializados con las reclamaciones de protección solar. Estos productos deben cumplir con los requisitos para ambos cosméticos y medicamentos.

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- **COMO SE SABE SI ES UNA CATEGORÍA U OTRA??**

1. **En base a su uso real; y simultáneamente;**
2. **En base a los ingredientes y como están autorizados en los EEUU para su uso;**
3. **Por la percepción del público respecto a esos productos en general;**
4. **Publicidad de los productos: internet, brochures, medios de comunicación**

Diferencias entre Cosméticos y OTC

- **Cosméticos.**
- En virtud de la Ley de FD&C, ingredientes y productos cosméticos, con la excepción de los aditivos de color, no requieren aprobación de la FDA antes de que salgan al mercado.

- Los etiquetados deben estar acorde a la Ley federal del FDA

- **OTC**
- Las drogas, sin embargo, deben generalmente o recibir la aprobación previa a la comercialización por la FDA a través del proceso de solicitud de nuevo fármaco (NDA) o ajustarse a una "monografía" para una categoría de medicamento en particular, según lo establecido por Over-the-Counter (OTC) Revisión de Drogas de la FDA.

- Dentro de la revisión de etiquetados: se debe verificar cada uno de los ingredientes (si estan permitidos o no). El mismo ingrediente puede estar aprobado para distintos usos en distintas proporciones.
- La etiqueta es totalmente distinta a la de un OTC

- Algunos medicamentos de venta libre pueden permanecer en el mercado:

i. Si hay una monografía: sin una aprobación NDA ; o

ii. Un "nuevo", un "nuevo fármaco" puede haber estado en uso durante muchos años Si un producto está destinado para su uso como un medicamento, debe cumplir con los requisitos señalados más arriba).

- Verificacion de etiquetado tambien igual que un cosmetico.

- Pudiera un producto tener etiquetado de cosmetico y OTC a la vez.
- Por ejemplo, los componentes de los medicamentos deben ser listados alfabéticamente como "ingredientes activos", seguido de ingredientes cosméticos, en orden descendente de predominancia como "Ingredientes inactivos".

- La etiqueta lleva unos “Drugs Facts”
- Es obligatorio obtener un ¨New Drug Code¨¨ para su comercialización

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EJEMPLOS DE MONOGRÁFICOS

- 1. ANTIÁCIDOS
- 2. GRIPE, RESFRIADOS, TOS, ANTI ALÉRGICOS;
- 3. ANTIREUMÁTICOS, ANO RECTAL.
- 4. ALGUNOS PRODUCTOS TÓPICOS
- 5. ANALGÉSICOS
- 6. PROTECTORES SOLARES
- 7. ANTICARIES
- 8. GOTAS OFTALMOLÓGICAS
- 9. WART REMOVER (VERRUGAS)

Empresa

- ✓Registro de FDA. Obligatorio para OTC
- ✓Registro de productos (OTC)
- ✓Listings

Del Producto:

- ✓ Etiquetado con agencia corres.
- ✓ Revisión disclaimers/ aseveraciones
- ✓ Marca registradas

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- **COSTES:**

Respecto al FDA a partir del día 10/1 comenzó a cobrar una tasa determinada por los registros de empresas de OTC y por las notificaciones de productos dependiendo de la monografía y su características

REQUISITOS OBLIGATORIOS DE TODAS LAS EMPRESAS FABRICANTES DE OTC

CUMPLIMIENTO CON:

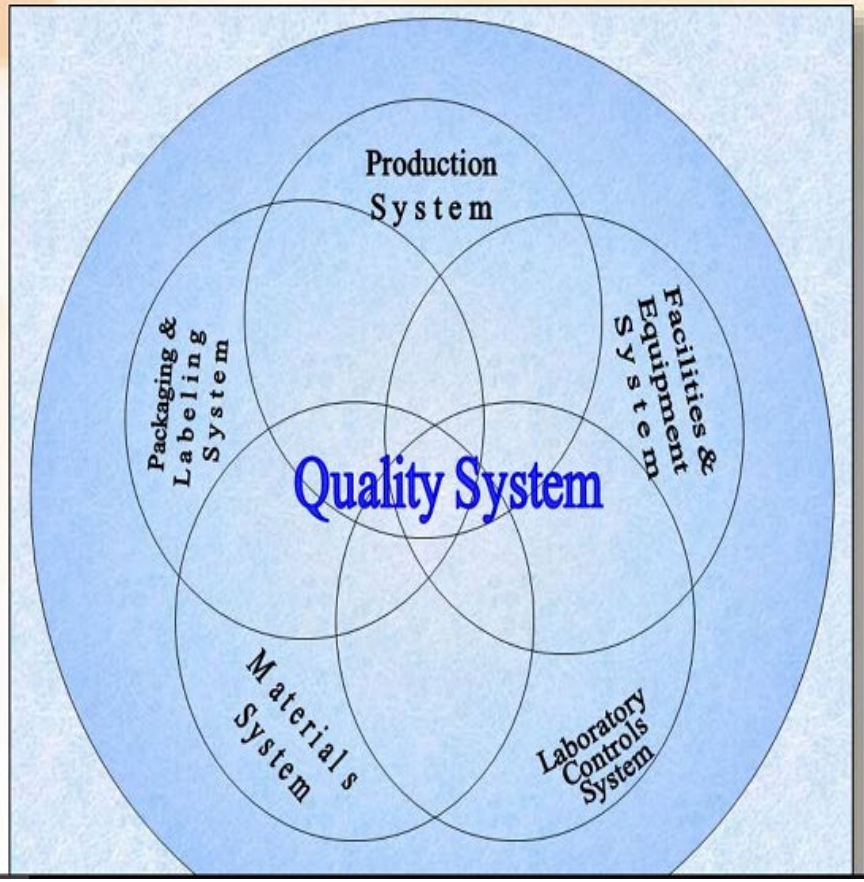
- Standards& Expectations
- Regulations & CGMPs •
- QS Elements / Framework –
- Registro de la empresa
- Obtención de un PIN y PUC
- Listing de los productos ante el FDA.
- Identificación de los importadores (que deben tambien estar debidamente registrados)
- Tasa a pagar al FDA por el registro de la empresa

Drug Regulation Framework

Legal Regulatory Framework

The Six Components

- Quality
- Production
- Laboratory
- Materials
- Facilities & Equipment
- Packaging &



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Modernization of Cosmetics Regulation Act (MoCRA)

- Was signed into law on December 29, 2022,
- MoCRA is the first major update to the Food and Drug Administration's (FDA) cosmetics authorities since 1938, and amends Chapter VI of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to include new provisions for cosmetic products.
- MoCRA now requires cosmetic manufacturing **facility registration and product listing. It implements new labeling requirements, and imposes current good manufacturing requirements, adverse events reporting and record keeping compliance.**
- MoCRA directs the FDA to establish **good manufacturing practice regulations consistent with national and international standards.** Cosmetic products manufactured or processed under conditions that do not meet the CGMPs will be deemed adulterated.
- **Compliance programs in advance of MoCRA's December 29, 2023, effective date.**

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- **PROCEDIMIENTOS Y REQUISITOS:**

- **Requisitos:**

a. Respecto a los productos:

- Revisión del cumplimiento de los parámetros legales de la etiqueta y etiquetado de acuerdo a la Ley Federal de los EEUU;
- Adaptación de la etiqueta a dichos parámetros que apliquen según el tipo de producto; (tomar en cuenta principios activos, declaraciones y otros)
- Registro y Listing de cada producto

b. Respecto a la empresa fabricante o fabricante contratante:

- Que cumple con las Buenas Practicas de Manufactura de empresa fabricante de fármacos en los EEUU; cGMP.
- Registro de la empresa ante el FDA (contract manufacturer/manufacturer/ importador)

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- **PROCESO:**

A. Solicitar el DUNS de la empresa fabricante y fabricante contratante si es el caso;

B. Registrar la empresa fabricante y fabricante contratante;

C. Solicitar el numero de etiquetador de ambas empresas;

D. Registrar cada producto en cada formato para obtener el “Numero de Fármaco”

E. Se debe contar con un importador registrado ante el FDA en el registro de fármacos.

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ORGANIC COSMETICS:

FDA does not regulate organic claims for cosmetics under the authority of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA). The term "organic" is not defined in either of these laws or the regulations that FDA enforces under their authority.

The NOP regulations include a definition of "organic" and provide for certification that agricultural ingredients have been produced under conditions that would meet the definition. They also include labeling standards based on the percentage of organic ingredients in a product.

The USDA requirements for the use of the term "organic" are separate from the laws and regulations that FDA enforces for cosmetics. Cosmetic products labeled with organic claims must comply with both USDA regulations for the organic claim and FDA regulations for labeling and safety requirements for cosmetics.

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- **Expiration Dating**
- There are no regulations or requirements under current United States law that require cosmetic manufacturers to print expiration dates on the labels of cosmetic products, but cosmetic firms have a responsibility for the safety of their products. Here's where to learn more about shelf life and expiration dating.

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- **REQUIREMENTS FOR THE COMPANY**

- 1. **F**DA **REGISTRATION.** Voluntary if it is a cosmetic and mandatory if it is an OTC.
- 2. Manual of **Good Manufacturing Practice, or GMP, of the USA must be up-to-date and in accordance with Federal Law.**
- Example of the mandatory content of a GMP Manual:

Factory or establishment, personnel, process records, raw materials, laboratory controls, production, equipment, labeling, complaints, etc.

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- **“Soap"?**

- Soap is a category that needs special explanation. Section 201(i)(2) excludes soap from the definition of a cosmetic.
- FDA interprets the term "soap" to apply only when the bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the product's detergent properties are due to the alkali-fatty acid compounds, and the product is labeled, sold, and represented solely as soap.
- Products that meet this definition of soap are regulated by the Consumer Product Safety Commission (CPSC), not by FDA.

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- **ANTIBACTERIAL SOAP:**

- According to the U.S. Food and Drug Administration (FDA), there isn't enough science to show that over-the-counter (OTC) antibacterial soaps are better at preventing illness than washing with plain soap and water.
- FDA issued a final rule under which OTC consumer antiseptic wash products (including liquid, foam, gel hand soaps, bar soaps, and body washes) containing the majority of the antibacterial active ingredients—including triclosan and triclocarban—will no longer be able to be marketed.

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If a cleanser does not meet all of these criteria…

If a product intended **to cleanse the human body does not meet all the criteria for soap**, as listed above, it is either a cosmetic or a drug. For example:

- If a product
  - consists of detergents, or
  - primarily of alkali salts of fatty acids, and
  - is intended not only for cleansing but also for other cosmetic uses,

  it is regulated as a cosmetic. Examples of cosmetic uses include making the user more attractive, by acting as a deodorant, imparting fragrance to the user, or moisturizing the skin.

- If a product consists of detergents, or
  - primarily of alkali salts of fatty acids, and
  - is intended not only for cleansing but also to cure, treat, or prevent disease, or to affect the structure or any function of the human body,

  it is regulated as a drug, or possibly both a drug and a cosmetic. Examples include antibacterial cleansers and cleansers that are also intended to treat acne.

- If a product is intended solely for cleansing the human body,
  - has the characteristics consumers generally associate with soap, and
  - does not consist primarily of alkali salts of fatty acids,
  - it may be identified in labeling as soap, but it is regulated as a cosmetic.

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AROMATHERAPY

What's the "intended use"?

- Under the law, how “aromatherapy” products are regulated depends mainly on how they are intended to be used.
- FDA determines a product’s intended use based on factors such as claims made in the labeling, on websites, and in advertising, as well as what consumers expect it to do. We also look at how a product is marketed, not just a word or phrase taken out of context. Finally, we make decisions on a case-by-case basis.

- Some fragrance products are regulated by the Consumer Product Safety Commission (CPSC). These include products such as air fresheners, scented candles, laundry detergents, and household cleansers.

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- **If an "essential oil" or other fragrance is "natural" or "organic," doesn't that mean it's safe?**

- Even if the "essential oil" or other ingredient comes from a plant, it does not mean to be safe. Many plants contain materials that are toxic, irritating, or likely to cause allergic reactions when applied to the skin.
- FDA doesn't have regulations defining "natural" or "organic" for cosmetics. All cosmetic products and ingredients must meet the same safety requirement, regardless of their source.

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- 1. **Cleaning products for surfaces:**

  - Regulated by EPA, Not FDA

  - If it cleans surfaces that touches food: then it is regulated by EPA and FDA under FCS

  - If the Cleaning product is a Simply clearning product or antibacterial, fungicide, anti-virus, etc. Registration, Scientific validation, and many other requirements are needed. Same for aereosols.

  - All these products ar subject to Consumer Product Safety Commission

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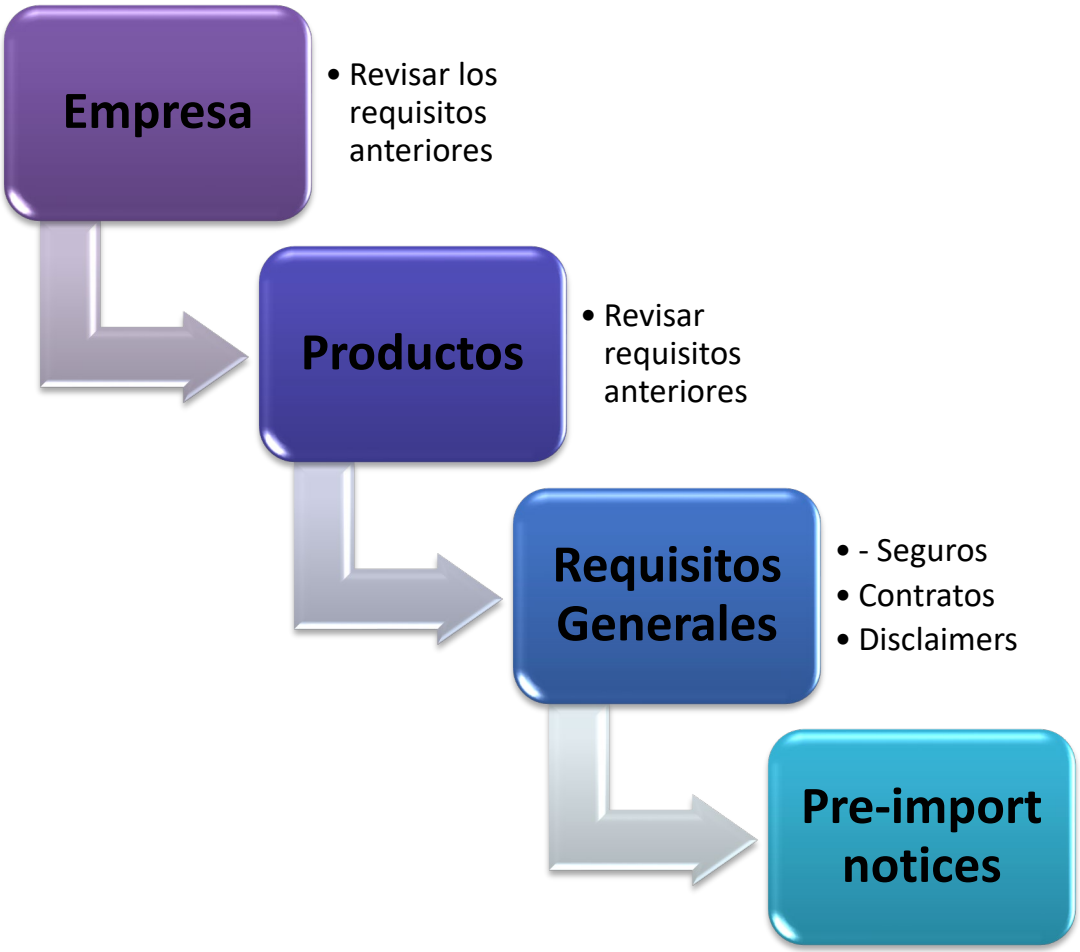

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