IAS ACCREDITED FDA-Food Safety Certification Body

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

Nuevo escenario comercial y regulatorio de EE.UU en el contexto actual: FDA, aduanas, impuestos y oportunidades en el mercado

Dra. Tania Martínez, Demos Global Group, SL

5 de Febrero del 2026

Tendencias del mercado estadounidense

Innovación tecnológica y crecimiento

Estados Unidos lidera en innovación, con avances destacados en inteligencia artificial y desarrollo de energías renovables en el mercado.

Expansión del comercio electrónico

El comercio electrónico transforma los hábitos de consumo, impulsando nuevas formas de comprar y vender productos en línea.

Sostenibilidad y responsabilidad social

Las empresas adoptan prácticas sostenibles y priorizan la responsabilidad social para adaptarse a demandas y regulaciones ambientales.

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Key Regulatory Challenges for Exporters to the U.S.

1. Tighter Export Controls, Especially on Technology & AI

- The U.S. BIS (Bureau of Industry and Security) recently expanded their export control rules covering advanced computing items — **integrated circuits, related software, hardware etc. — and for the first time imposed controls on *AI model weights*.**
- There's been an expansion of the geographical reach of export controls. **Items that incorporate U.S. software/technology may now be controlled even if they are produced abroad.**
- Also, companies found on **2. Sanctions and FU.S. lists like the "Unverified List" or "Entity List" face stricter licensing, additional due diligence, and constraints on what can be shipped to them.**

Foreign Relations / National Security

- Export regulations are increasingly driven by geopolitical considerations. Countries deemed adversarial or of concern may face much stricter export licensing (or even presumptive denial).
- There's also more attention on end-use and end-user: ensuring that sensitive technologies don't end up in military, surveillance, or other controlled uses.

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Key Regulatory Challenges for Exporters to the U.S.

3. Increased Scrutiny of Supply Chains, Origin, and Inputs

- There is more attention to ***where components or software come from*, who produces them, and whether foreign subcontractors comply with U.S. rules.** For example, exporting a product may require disclosing all sources of certain inputs.
- Obligations regarding **"foreign direct product rules" or controls on items based on U.S. software/technology embedded in foreign-produced products.**
- The U.S. is generally very open to foreign investment.
- Most sectors allow 100% foreign ownership.
- There are **restrictions in sensitive industries** (e.g., defense, telecommunications, energy, and critical technologies).
- The **Committee on Foreign Investment in the United States (CFIUS)** reviews deals where foreign control might pose a national security risk.

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Key Regulatory Challenges for Exporters to the U.S.

4. "Know Your Customer / End-User" Obligations

- Exporters increasingly must ensure that recipients are legitimate, that they are **not on restricted or blacklists**, that the intended use is lawful. End-use/end-user checks are becoming more demanding.

5. Penalties and Enforcement

- Violations of U.S. export controls (or sanctions) come with high risk: large fines, loss of export privileges, reputational damage. The U.S. government is enforcing more aggressively.

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Situacion actual del mercado

- En 2024, el comercio bilateral entre España y EE.UU. (bienes + servicios) representó alrededor del **4,4 % del PIB** español.

  - ✓ Las exportaciones de bienes fueron unos **16.168 millones de euros** (≈ 1 % del PIB).
  - ✓ En servicios, España tiene un superávit frente a EE.UU.: exporta más servicios no turísticos que importa.

- **Sectores fuertes en exportaciones hacia EE.UU.**
  - ✓ **Maquinaria y aparatos**: uno de los productos principales.
  - ✓ **Productos farmacéuticos** también tienen peso importante.
  - ✓ **Agroalimentarios**: aquí hay varios "hits":
    - Aceite de oliva (virgen) → líder dentro del sector.
    - Vino y bebidas relacionadas.
    - Conservas de frutas, hortalizas, aceitunas.
  - ✓ También se exportan bienes de equipo, semimanufacturas, productos energéticos, etc.

- **Efectos de aranceles y barreras comerciales**
  - ✓ Productos agroalimentarios como **aceite de oliva**, **vino**, **jamón serrano** y **aceitunas negras** están enfrentando un arancel del ~15 % en EE.UU. Esto afecta su competitividad.

  - ✓ Las empresas exportadoras están cargando con costes logísticos, arancelarios, variaciones en precios y márgenes más estrechos.

Sector	Variación 2024 vs. 2023	Nota / Fuente
Agro-alimentario (alimentos y bebidas)	**+22%**	Aumento motivado por anticipación a aranceles; dato citado para "alimentos y bebidas" españoles hacia EE. UU. en 2024.
Vinos (HS 2204)	**+7%**	Crecimiento en valor y volumen de las exportaciones españolas de vino a EE. UU. en 2024 (datos de aduanas compilados por OIVE).
Maquinaria (HS 84–85 aprox.)	**s/ cifra inmediata**	Sector con peso relevante y bajo presión por aranceles; la cobertura oficial reciente es por composición/riesgos más que por crecimiento exacto.
Equipos médicos / instrumentos de precisión (HS 90)	**s/ cifra inmediata**	No hay porcentaje sectorial público inmediato al destino EE. UU.
Fármacos	**Tarifa M/N vigente**	No hay datos exactos.

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Key Regulatory Challenges for Exporters to the U.S.

- **Spain-specific advantage**:

- Spain (EU member) is not itself restricted, so the main risks come from **foreign inputs** (Chinese components, Middle Eastern raw materials, U.S. technology/software).
- Spanish exporters often need to prove **traceability back to EU production** to avoid being caught in U.S. restrictions on third-country components.

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Key Regulatory Challenges for Exporters to the U.S.

- **1. Agricultural Machinery and other machineries:**
- **Product Classification**: Ensure machinery is properly classified under HTSUS codes. Some items (e.g., tractors, irrigation systems) may be dual-use if equipped with sensors or electronics.
- **Technology Origin**: If machines use U.S.-origin control systems, GPS, or semiconductors, check for **EAR export license requirements**.
- **End-Use Restrictions**: Get certificates from U.S. buyers that machinery won't be re-exported to embargoed countries or military use.
- **EPA / USDA Compliance**: Machines with engines must comply with **EPA emission standards** (Tier 4 regulations). Importers may require certificates.
- **Supply Chain Risk**: Audit suppliers of electronics/engines to ensure no **restricted Chinese components** are used (increasing U.S. scrutiny).

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Key Regulatory Challenges for Exporters to the U.S.

- **3. Medical Equipment**

- **FDA Registration**: All medical devices must be registered with the **U.S. FDA** Some need prior FDA clearance (510(k)).
- **Quality Systems**: Must comply with **FDA Quality System Regulation (QSR,**– supply chain audits required.
- **Technology Controls**: Devices with AI, chips, or encryption may trigger **U.S. export controls**.
- **End-Use Verification**: Strong documentation required to ensure products aren't diverted for military or prohibited uses.
- **Supply Chain Checks**: Screen component suppliers (electronics, sensors, batteries) against U.S. Entity Lists.
- **Forced Labor Compliance**: U.S. Customs has detained **medical gloves and devices** linked to labor abuses — document supply chain transparency.

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Key Regulatory Challenges for Exporters to the U.S.

4. Pharmaceuticals/drugs:

- **FDA Approval & Compliance** – Strict requirements for drug approval (NDA/ANDA), clinical trial data, GMP inspections, and ongoing pharmacovigilance.
- **Supply Chain Transparency** – Compliance with the Drug Supply Chain Security Act (DSCSA) mandating serialization and track-and-trace by 2027.
- **Quality & Manufacturing Standards** – Need to meet U.S. GMP and Quality Standards.
- **Trade & Tariffs** – Risk of new tariffs (up to 15%) unless exempt; uncertainty around "Buy American" policies for essential medicines.
- **ESG & Sustainability** – Growing scrutiny on environmental impact, labor practices, and reporting from both regulators and investors.

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4. Cosmetics & Personal Care Products

•FDA treats cosmetics differently than the EU; U.S. is now tightening requirements under the **Modernization of Cosmetics Regulation Act (MoCRA, 2022)**, with stricter deadlines coming into force now.

Mandatory **facility registration & product listing with FDA**.

•**Safety substantiation** and supply chain traceability for all ingredients.

•Watch for **PFAS bans** and allergen disclosure requirements (U.S. rules differ from EU).

5. Chemicals & Industrial Inputs

Pre-approval of chemicals, even if already approved in the EU under REACH.

Some chemicals banned or restricted under U.S. TSCA but still legal in EU.

•Must maintain **substance origin traceability** and notify EPA.

•Possible **tariffs on fertilizers, plastics, coatings** linked to energy policy.

6. Furniture, Ceramics & Home Goods

•U.S. Customs has raised **anti-dumping and countervailing duties (AD/CVD)** on some categories (tiles, furniture, aluminum).
Detailed **origin documentation** required to avoid anti-dumping penalties.
•California **Prop 65** requires warning labels for products with trace heavy metals, formaldehyde, or certain glazes (e.g., in ceramics).

7. Renewable Energy Components (Solar panels, Wind, Batteries)

•Trump administration pushing **energy security / America First** means higher tariffs and stricter origin rules
•Solar panels/components often face **Section 201 tariffs** and additional duties.
•Batteries and rare-earth materials are **strategic goods** — expect more licensing requirements.
•Traceability required for minerals (cobalt, lithium, rare earths).

8. Luxury Goods (Jewelry, Watches, Leather)

•High-value items are targets for **tariffs and sanctions enforcement** because of dual-use (value transfer, money laundering risk).

•Customs requires detailed proof of **origin of precious metals and stones**.

•Gold and diamonds linked to certain African or Russian suppliers may trigger seizures under sanctions.

•Leather goods must meet **labeling and species protections**

Cross-Cutting Risks Across These Sectors and others:

•**Forced labor rules (UFLPA)**:

•**Section 301 & 232 tariffs**: applied unpredictably on goods from allies when U.S. seeks leverage.

•**Labeling divergence**: EU vs. U.S. standards (allergens, safety warnings, sustainability claims).

•**Supply chain traceability**: increasingly digital — CBP wants verifiable records of origin and material flow.

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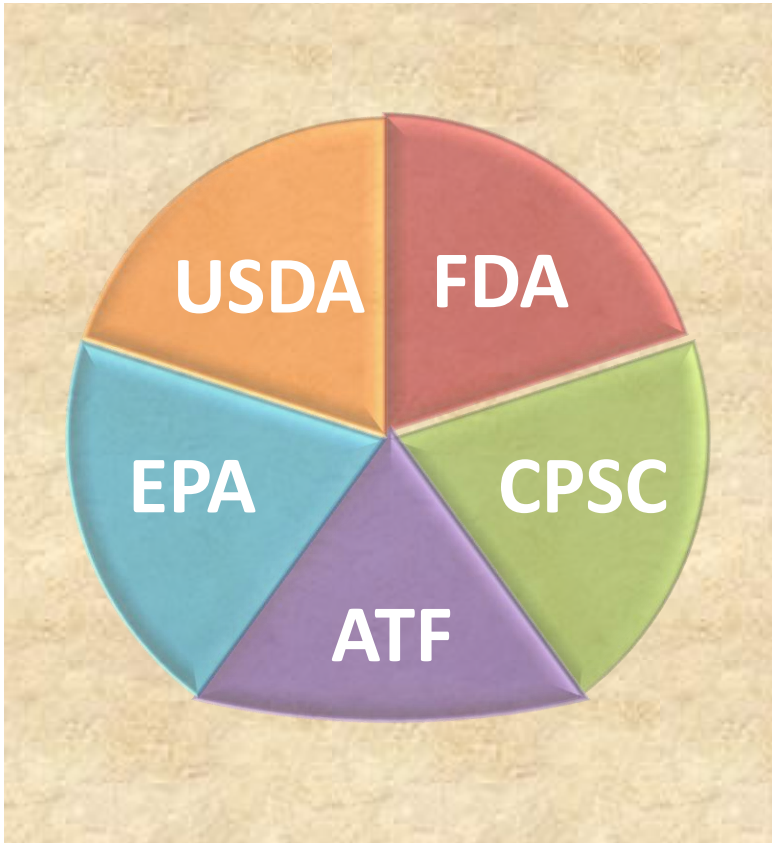
AGENCIAS DE GOBIERNO INVOLUCRADAS

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.

ADUANAS/ TARIFAS

FIRST GROUP OF TARIFFS:

- **Beginning April 5, 2025:** The ad valorem duty on all imports from all trading partners shall start at 10 percent and shortly thereafter, the additional ad valorem duty shall increase for trading partners enumerated in Annex I.

SECOND GROUP OF TARIFFS: (SUSPENDED UNTIL JULY 9, 2025)

- APRIL 9, 2025: AT 12:01 a.m. eastern daylight time, all articles from trading partners imported into the customs territory of the United States entered for consumption, or withdrawn from warehouse for consumption, on or after 12:01 a.m. eastern daylight time on April 9, 2025.

- In the case of the European Union the reciprocal tariff adjusted is an additional 20%.

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What is important to know:

1. Tariffs are accumulative.
2. Tariffs are based on country of origin, not shipping location. Be careful with this!!
3. For example, Mexico and Canada are currently exempted from the 10% and 20% tariffs
4. See your options to determine if you can do a “strategic tariffs enginnering process”.
5. Determine if you falls under any of the 300 exemptions.

- **What can you do:?**

- 1. Classification under the Harmonized System Harmonized Tariff Schedule of the United States ("HTSUS"), taking into account what is the term "essential character," as used in the GRIs. Essential character of a good will vary as between different kinds of goods (i.e., must be determined on a case-by-case basis). Potential reclassification?
- 2. See your options to determine if you can do a "strategic tariffs enginneering process".
- 3. Determine if you falls under any of the 300 exemptions.

4. Study the possibility og engaging in what is called "Strategic Tariff Enginering". For this some of the aspects are:

a. Determine entire composition/formulation of the product origin of the ingredients, % of each of the parts. Tariffs are paid upon the foreign parts of the product. The ad valorem rates of duty set forth in this order shall apply only to the non- U.S. content of a subject article, provided at least 20 percent of the value of the subject article is U.S. originating.

b. Use substantial transformation rules to establish a new origin

c. Determine to who do you sell. First sale rule…. How can we structure this?

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c. Source domestically if posible, even temporarily, to avoid the 25% Steel tariff and accumulative 55% or 104% from China. This means US based suppliers or joint ventures to minimize exposure.

For example in a equipment or a product check what components is subject to 25% (SS) and what are not (wiring, motors, plastics knobs, etc.)

d. Assembly in a low tariff country?? For example Mexico? For example modular equipments?

b. Determine to who do you sell. First sale rule…. How can we structure this?

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d. Determine **the real value of the merchandise**. For example the term **"price actually paid or payable"** means the total payment exclusive of any costs, charges, or expenses incurred for transportation, insurance, and related services incident to the international shipment of the merchandise from the country of exportation to the place of importation in the United States).

- You should include in the declared value any money paid for selling commissions, assists, royalties, production costs, packing, proceeds and these items should be noted on the commercial invoice. Others are: post import charges (training, assembly, installation), buying commissions to your own agent, financing costs, royalties, licenses.

e. **Request an exclusion because the product is critical or has non-viable US alternative?**

To finish, after analyzing your ways and possibilities, request una "opinion vinculante". This is how the process should be concluded it to avoid surprises.

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¿Qué es un opinion vinculante de aduanas?

•Es una **decisión vinculante emitida por Aduanas** sobre la clasificación arancelaria (HS code) o el país de origen de una mercancía.
•Tiene **carácter legalmente vinculante** para la aduana: si se concede el ruling, debe aplicar la tarifa que allí se determina.

🎯 ¿Para qué sirve en el caso de exportaciones españolas a EE.UU.?

1.Clasificación correcta (HS Code)

❖ Muchos productos pueden clasificarse en más de un código HS (ej. maquinaria agrícola con componentes electrónicos → ¿va como agrícola, como eléctrica o como "otros aparatos mecánicos"?).
❖ La diferencia entre códigos puede ser un arancel del **0 %**, del **5 %** o del **15 %**.
❖ Con **una opinion vinculante**, aseguras que tu producto quede clasificado en el código más favorable y evitas disputas en aduana.

2. **Reglas de origen**

❖ Si tu producto combina insumos de varios países, CBP puede cuestionar si realmente es "originario UE/España".
❖ Un ruling de origen te da **certidumbre legal** de que tu producto entra en la categoría correcta (y por tanto si aplica el 15 % o una exención).

3. Evitar retrasos y costes adicionales

❖ Si CBP tiene dudas en el puerto, puede **retener el cargamento** hasta que se resuelva la clasificación.
❖ Con un ruling, se minimizan los riesgos de retención, multas o recargos.

4. Base de negociación con clientes

❖ Al tener el documento oficial, puedes decirle a tu importador en EE.UU. exactamente qué tarifa pagará, lo que da más seguridad en contratos de suministro.

- 📌 **Ejemplo práctico**

• Un exportador español de **equipo médico** (ej. un dispositivo que combina electrónica y materiales plásticos).

• Según el HS code usado, puede tributar como:

• Aparato eléctrico (arancel MFN distinto),

• Instrumento médico (sujeto al 15 %),

• Parte de un dispositivo mayor (con exención).

• Con una **opinion vinculante** , determina de forma vinculante que el producto entra en el HS de “instrumento médico”, con su tarifa exacta → y esa será la que se aplique siempre, sin sorpresas.

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•**Plásticos españoles = sujetos a 15 %** bajo el nuevo acuerdo.
•**No tienen exenciones directas** (como sí ocurre con corcho o fármacos).
•La clave está en: correcta clasificación arancelaria, explorar producción en EE.UU./México, y apostar por productos diferenciados (eco, reciclables).

Marmoles/ Piedras:

Estrategias de mitigación
•**Revisar la clasificación arancelaria (HS codes)**:
•Ej. piedra en bruto vs. piedra trabajada tienen aranceles distintos.
•Una **opinion vinculante** de CBP puede asegurar la clasificación más favorable.

•**Producción o acabado en EE.UU.**: enviar bloques semiacabados y terminarlos en plantas locales para reclasificar como producto "U.S. origin".

•**Alianzas con importadores y mayoristas**: compartir el impacto del arancel en la cadena de valor.

•**Promoción del valor añadido**: diseño, tradición, exclusividad → no competir solo en precio.

1. Equipos Agricolas:

•Los **equipos agrícolas (HS 84.32, 84.33, etc.)** quedaron **exentos de los aranceles adicionales de represalia de 2019** (caso Airbus-Boeing).

•Gran parte de la maquinaria agrícola **no entró en los listados de productos gravados con tarifas extra** y se mantiene en **MFN normal (0-5 % según subpartida)**.

•La **mayoría de los equipos agrícolas españoles pagan aranceles bajos (0-5 %) y no el 15 % generalizado**, salvo excepciones muy específicas.

2. Retos adicionales

•**Normativa técnica distinta**:

•Emisiones de motores agrícolas → normas EPA más estrictas que las europeas.

•Seguridad laboral → OSHA exige adaptaciones en diseño.

•**Competencia estadounidense**: John Deere, AGCO, CNH tienen fuerte presencia local y lobbying.

•**Coste del dólar/euro**: la fortaleza del dólar puede favorecer, pero la volatilidad cambiaria añade riesgo.

3. Estrategias de mitigación

•**Certificaciones anticipadas**: homologar equipos según estándares EPA y OSHA antes del envío.

•**Alianzas locales**: distribuidores y concesionarios agrícolas en EE.UU. son clave para la postventa.

•**Explorar FTZ (Foreign Trade Zones)**: ensamblar componentes en EE.UU. para reclasificar como producción local.

•**Segmento de nicho**: equipos para viticultura, fruticultura intensiva o riego de precisión → España tiene ventaja tecnológica.

d. Determine **the real value of the merchandise**. For example the term **"price actually paid or payable"** means the total payment exclusive of any costs, charges, or expenses incurred for transportation, insurance, and related services incident to the international shipment of the merchandise from the country of exportation to the place of importation in the United States).

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e. **Request an exclusion because the product is critical or has non-viable US alternative?**

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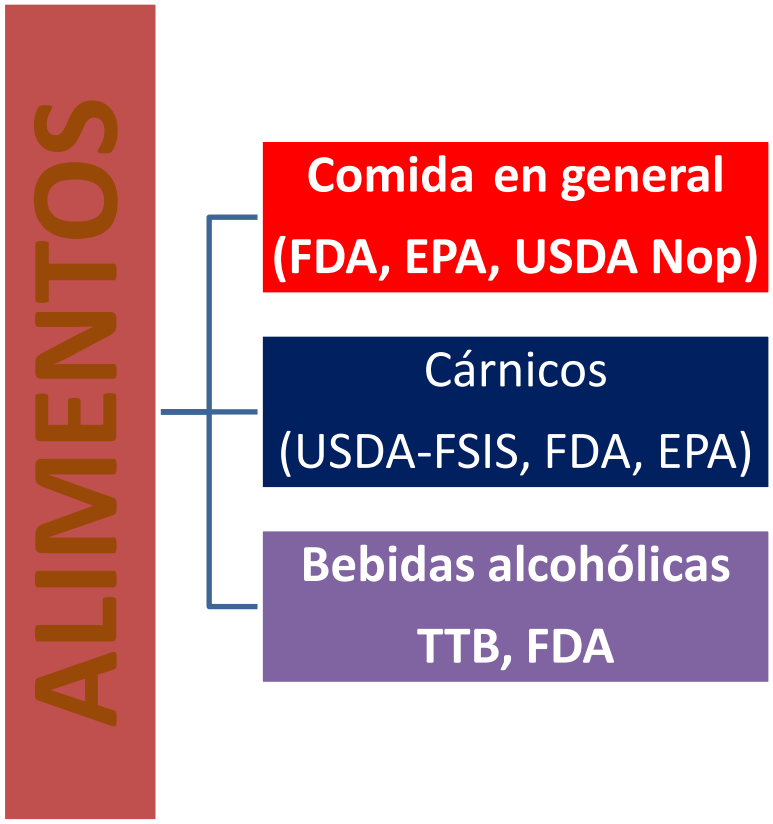
- **Bases de la Clasificación de los Alimentos y sus Regulaciones**



- 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)

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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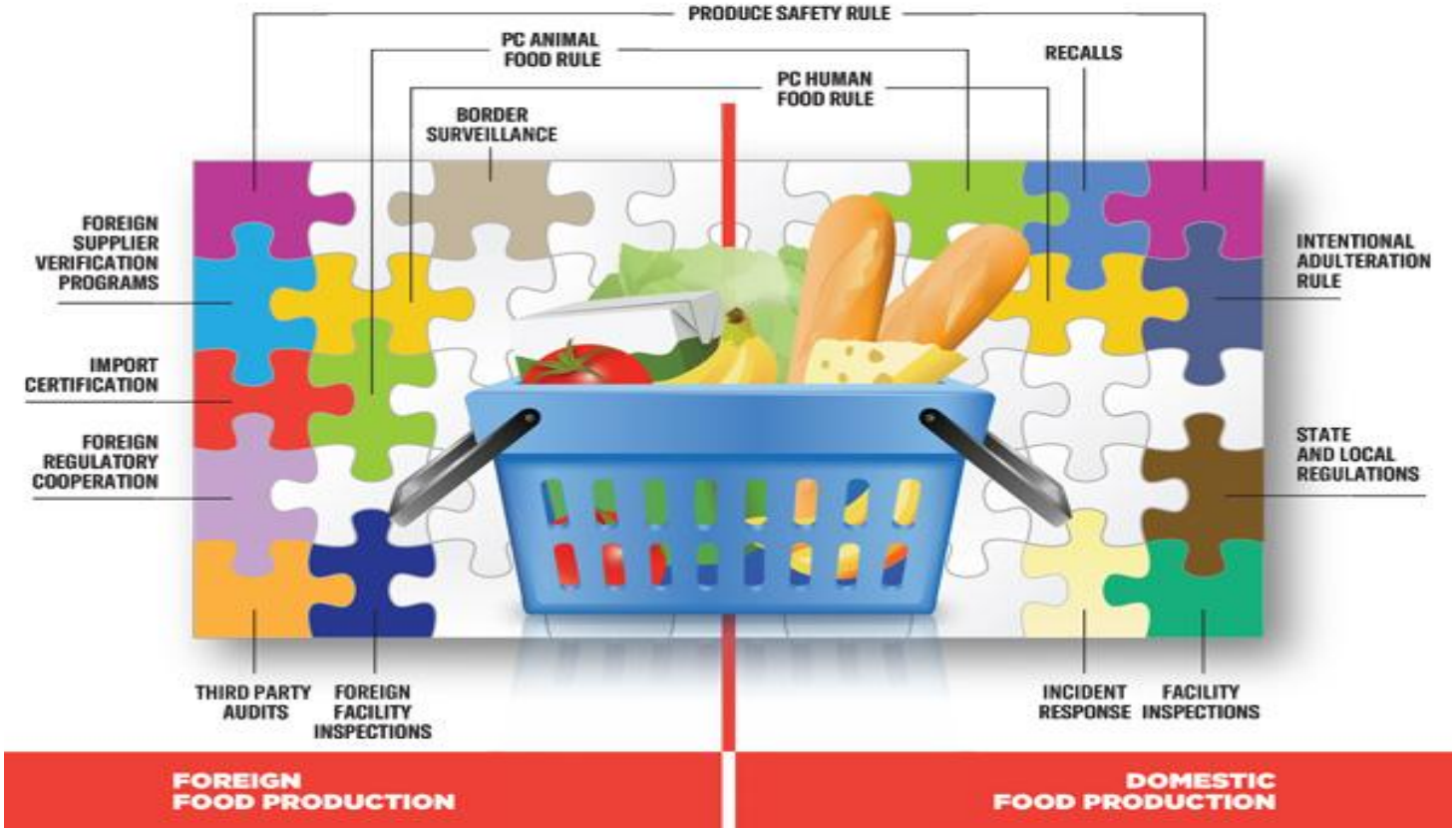
Aspectos regulatorios- FSMA

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.

- 5. **GRAS:** ingredientes que son seguros en base a: las opiniones de expertos calificados por formación científica y experiencia para evaluar la seguridad de las sustancias añadidas directa o indirectamente a los alimentos o (2) en el caso de una sustancia utilizada en alimentos antes del 1 de enero de 1958, a través de la experiencia basada en el uso común en alimentos. El reconocimiento general de la seguridad requiere el conocimiento común de **toda la comunidad científica conocedora de la seguridad de las sustancias añadidas directa o indirectamente a los alimentos de que existe una certeza razonable de que la sustancia no es dañina en las condiciones de su uso previsto**

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?

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)

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

4. **Ending the $800 "low-value" import exemption for regulated products**
As of July 9, 2025, the FDA requires full screening of *all* imported FDA-regulated products, regardless of value. This removes a prior exemption of shipments valued at $800 or less. This affects food, drugs, cosmetics, medical devices, and other items under FDA jurisdiction.

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Aspectos regulatorios-
Seguridad Alimentaria

- **Current Good Manufacturing Practices (CGMPs)**[4]
- Métodos, equipos, instalaciones y controles para la producción de alimentos procesados y suplementos dietéticos. Siguiendo CGMPs garantiza la calidad de los alimentos procesados y suplementos dietéticos. También asegura que los alimentos procesados o suplementos dietéticos estén envasados y etiquetados según lo especificado en el expediente de fabricación principal.

EXPORTACIÓN DE COSMÉTICOS Y OTC

EMPAQUE Y ETIQUETADO
EE.UU

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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)].

Empresa

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

Del Producto:

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

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

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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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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 are subject to Consumer Product Safety Commission.

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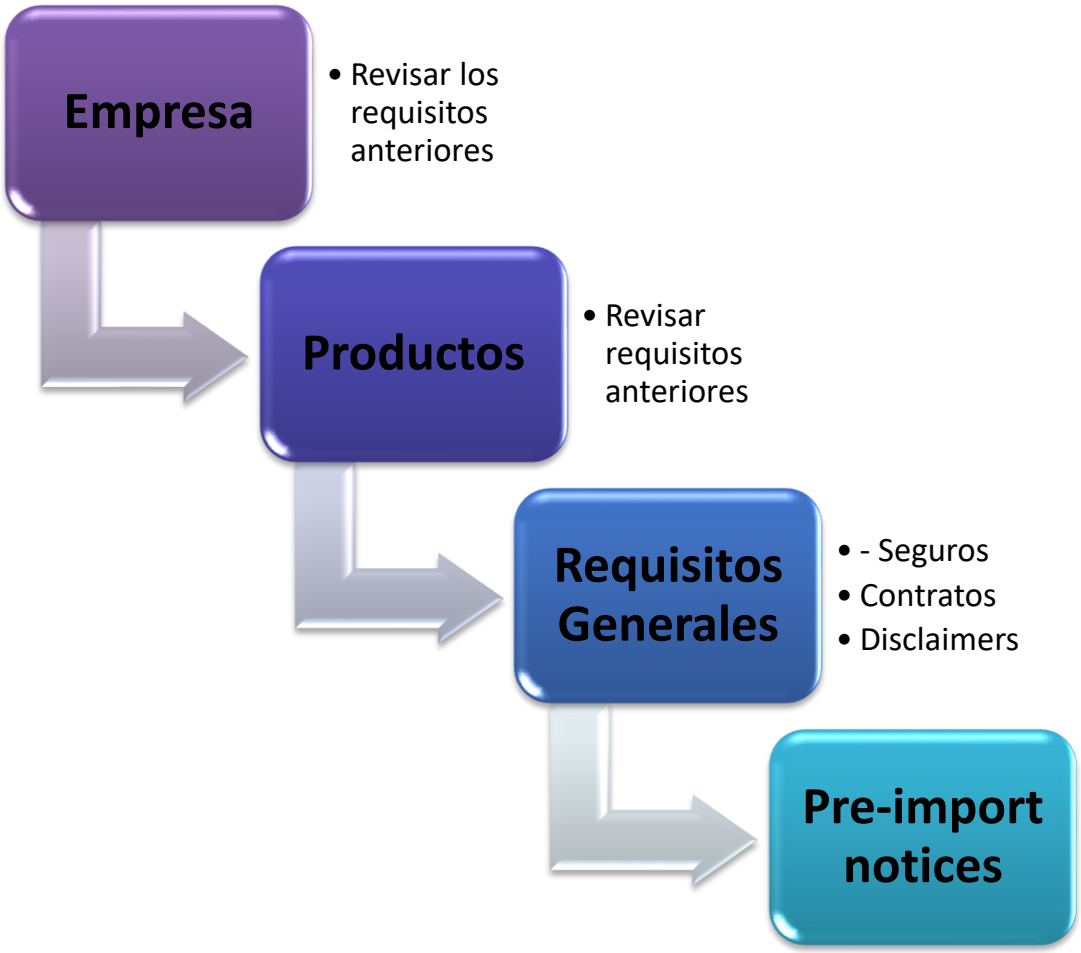

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