

Informational Notice: FDA Requirements for Food-Contact Articles

Purpose

This notice explains **when FDA data must be included** in your entry filing for imported articles that come into **contact with food or beverages**, how to **identify such items**, and where to find **official references** for further review.

1. When FDA Data Is Required

The U.S. **Food and Drug Administration (FDA)** regulates not only food and beverages, but also **articles that come into direct contact** with them.

FDA data (the **PGA Message Set**) must be submitted through ACE for **all imported “food-contact substances (FCS)”**, as defined under **Section 409(h) of the Federal Food, Drug, and Cosmetic Act** and **21 CFR Parts 174–178**.

These items include, but are not limited to:

- Tableware (plates, bowls, cups, utensils, thermoses, straws)
- Food storage containers (plastic, glass, metal)
- Beverage bottles, tumblers, and lids
- Kitchenware and cookware that directly contacts food
- Packaging materials or liners that directly touch food (bags, wraps, films)

If an imported article **will contact food or beverages under normal use**, the entry must include an **FDA product code**, **intended use code**, and (if applicable) **Affirmation of Compliance (AofC)** references.

2. How to Identify a Food-Contact Item

Ask the following questions to determine if FDA data is required:

Question	If “Yes,” FDA data required
Does the product directly touch food or drink during use?	✓
Is the product intended for serving, preparing, or storing food or beverages?	✓
Does the product have any component (e.g., coating, gasket, liner) that touches food?	✓
Is the product a packaging material for food?	✓
Is the product a utensil, tableware, or kitchenware item?	✓

If the product only **indirectly supports** food operations (e.g., shelving, outer packaging, display racks), FDA data is **not required**.

3. What Data to Provide for Food-Contact Items

If the item qualifies as food-contact, the following information must be included in your **FDA PGA message set** at time of entry:

Data Element	Example
FDA Product Code	E.g., “LHA–99” (stainless steel tableware) or “MJY–99” (plastic container)
Intended Use Code	<i>081.006 – Food contact substance for direct food use</i>
Manufacturer Name & Address	As shown on invoice or manufacturer declaration
Country of Production	Country where item is made
Affirmation of Compliance (AofC)	E.g., “CFR: 21 CFR 177.2600 – Elastomeric materials for food contact”

Providing this data ensures FDA can electronically screen the entry without delay. Missing or incomplete PGA data often leads to **FDA “May Proceed” hold reviews** or entry delays.

4. Where to Research More Details

For more in-depth information and references:

1. **FDA Food Contact Substance Regulations:**

 <https://www.fda.gov/food/food-ingredients-packaging/packaging-food-contact-substances-fcs>

- Explains FCS definitions and approval pathways

2. **21 CFR Parts 174–178:**

 <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-174>

- Lists specific materials and coatings permitted for food contact

3. **FDA Product Code Builder Tool:**

 <https://www.accessdata.fda.gov/scripts/ora/pcb/>

- Helps identify correct product codes for ACE filings

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