

LACF/AF – Precursor Questions and Flow

Shelf Stable Food Guidance, Compliance & Regulatory Information Guidance Documents

Food

Introduction

The purpose of these questions is to assist you in determining if your product is governed by 21 CFR Part 113 (low-acid canned foods¹), 21 CFR Part 114 (acidified foods), or neither. Please note that products that are governed by 21 CFR Parts 113 or 114 must also comply with the relevant requirements in 21 CFR Part 108.

Please be advised that these questions might not cover every product and every scenario. 21 CFR Parts 108, 113, and 114 set forth the relevant parameters for FDA's regulation of low-acid canned foods and acidified foods. You may consult FDA if you are unsure of the regulatory status of a specific product.

Precursor Questions

1. Is the product stored, distributed, and retailed under refrigerated or frozen conditions? If yes, go to 1(a). If no, go to 2.
 - a. The product is not covered by 21 CFR Part 113 or 21 CFR Part 114.
2. Is the product processed under the continuous inspection of the meat and poultry inspection program of the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act or the Poultry Products Inspection Act? (Such food contains a statement on the label that it has been inspected by USDA.) If yes, go to 2(a). If no, go to 3.
 - a. The product is not covered by 21 CFR Part 113 or 21 CFR Part 114.
3. Is the water activity of the finished product less than or equal to 0.85? If yes, go to 3(a). If no, go to 4.
 - a. The product is not covered by 21 CFR Part 113 and 21 CFR Part 114.

¹ 21 CFR Parts 108 and 113 use the phrase “low-acid foods packaged in hermetically sealed containers” instead of the phrase “low-acid canned foods.” Although some hermetically sealed containers (e.g., pouches and glass bottles) used to package thermally processed low-acid foods generally would not be viewed as “cans,” the term “low-acid canned foods” has been used for decades as a shorthand description for “thermally processed low-acid foods packaged in hermetically sealed containers,” and we continue to use that term for the purposes of this document.

4. Is the finished equilibrium pH of the product 4.6 or lower? If yes, go to 5. If no, go to 4(a).
 - a. Is the product an alcoholic beverage? If yes, the product is not covered by 21 CFR Part 113 or 21 CFR Part 114.
 - b. Is the product a tomato or tomato product with a finished equilibrium pH less than 4.7? If yes, the product is not covered by 21 CFR Part 113 or 21 CFR Part 114.
 - c. If you answered “no” to 4 and “no” to 4(a) and 4(b), your product is a low-acid food covered by 21 CFR Part 113.
5. Is the natural pH of the product 4.6 or lower without any added acid? If yes, go to 5(a). If no, the product is an acidified food covered by 21 CFR Part 114.
 - a. Does the product contain low-acid ingredients? If yes, go to 5(b). If no, the product is an acid food that is not covered by 21 CFR Part 113 or 21 CFR Part 114.
 - b. Is the product predominantly an acid or acid food that (1) contains only small amounts of low-acid food(s) and (2) has a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food? You may consult FDA if you need help with this evaluation. If yes, go to 5(b)-(i). If no, go to 5(b)-(ii).
 - i. The product is not covered by 21 CFR Part 113 or 21 CFR Part 114. However, you can voluntarily submit a process filing as referenced in Figure 1.
 - ii. The product is an acidified food covered by 21 CFR Part 114.

If the product is a fermented food with a finished equilibrium pH of 4.6 or lower, then the product is not covered by 21 CFR Part 113 or 21 CFR Part 114. However, you can voluntarily submit a process filing as referenced in Figure 1.

If the product is a fermented food with a finished equilibrium pH greater than 4.6 and a water activity greater than 0.85, then the product is a low-acid food covered by 21 CFR Part 113.

Figure 1 - Table for Voluntary Filing Permitted

Product Type	Voluntary Filing Permitted (Y/N)
Refrigerated or frozen.	N
USDA product under the continuous inspection of the meat and poultry inspection program of the Food Safety and Inspection Service of the U.S. Department of Agriculture (USDA) under the Federal Meat Inspection Act or the Poultry Products Inspection Act.	N
Low water activity.	N
Alcoholic beverage.	N
Tomato product finished equilibrium pH less than 4.7.	N
Acid food.	N
Product predominantly an acid or acid food that (1) contains only small amounts of low-acid food(s) and (2) has a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food.	Y
Fermented product with finished equilibrium pH 4.60 or less.	Y