

03I – Products With Secondary Inhibitors - Not Shelf Stable (NRTE or RTE)

Finished products produced under this regulatory processing category can be NRTE or RTE meat and poultry products that have been processed in a manner that utilizes strategies which produce results that will inhibit secondarily the growth of pathogenic bacteria. Finished products in this regulatory processing category may or may not have had heat applied to the product. The finished products in this category are not shelf stable products and require special handling to maintain their wholesome condition, i.e., labeling that states the product must be kept refrigerated or kept frozen (9 CFR §317.2(k) or §381.125(a)). Some of these products also require safe handling instructions if they are NRTE (SHI) (9 CFR §317.2(l) and §381.125(b)). However, some products may omit statements in conflict with the product's specific handling instructions from the SHI and replace it with statements such as "refrigerate leftovers" (9 CFR §317.2(l)(3)(i)). In other words, the product may be heat treated, but not fully cooked, and a secondary inhibitor gives a cumulative effect (heat plus a food additive that affects the product) so that the product is RTE, yet it would not be ready-to-eat in the absence of the secondary inhibitor. These 03I RTE products would not be shelf-stable. An example would be the addition of salt or sugar in quantities that effectively lower the water activity of the finished product.

The process of using secondary inhibitors is a very complex system. Often several different inhibitors are used, each depending on the others in order to result in a safe product. For example, preservation methods that use large amounts of salts or sugars work by reducing the water activity. An ingredient that changes the pH to a level that inhibits bacterial growth is another example of a secondary inhibitor. The added ingredient is the secondary inhibitor because it does not inhibit the growth, but changes the pH of the product to the level that the pH inhibits the growth. This regulatory processing category is only used when products do not fit into one of the other categories. The food safety system is designed around monitoring the secondary inhibitor for products to be regulated under the 03I HACCP element.

Some examples of products that may fall into this processing category include products that are uncooked, cured, fermented, dried, salted, or brine treated, which are not shelf stable but can be RTE or NRTE, such as sliced country style ham, salt pork, and semi-dry fermented sausage. The product standards, processing methods, and labeling are all factors that must be considered in determining the regulatory processing category for the 03I products.