# HACCP for Not Shelf Stable Ready-to-Eat/Not Ready-to-Eat (NSS RTE/NRTE) Products

**(03G, 03H, and 03I)**

## Objectives

To demonstrate mastery of this module, the Consumer Safety Inspector will

1. Understand the regulatory processing categories (03G, H, I).
2. Determine which of the regulatory processing categories are covered in the NSS NRTE/RTE products.
3. List the pathogens of concern in RTE products.
4. Understand biological/chemical/physical food safety hazards.
5. Understand the significance of performing the hazard analysis.
6. Understand the components of a HACCP plan and HACCP system.
7. Describe monitoring and verification activities.
8. State the difference between a HACCP noncompliance and a deviation.
9. Describe the plant's responsibility concerning a HACCP noncompliance and a deviation.
10. State where FSIS HACCP responsibilities are outlined.
11. List the 4 responsibilities for the CSI under the FSIS HACCP methodology.
12. Describe linkages and to what they may lead.
13. Describe the two components of HACCP 01 and 02 procedures.
14. Describe HACCP 01 and 02 procedures in relationship to the five regulatory requirements that will be verified.
15. Understand the difference between validation, verification, and pre-shipment review.
16. Understand the regulatory requirement for reassessment.
17. Understand the recordkeeping regulatory requirements.
18. Explain the pre-shipment review.

## Module Overview

This module is divided into content areas.

1. Product process categories and familiarization – a brief overview
2. RTE Product Sanitation – an industry perspective
3. *Listeria Monocytogenes* verification procedures in FSIS Directive 10,240.4
4. Sampling RTE products
5. Establishment responsibilities, including the 7 HACCP principles
6. Regulatory Process for HACCP – verifying the plant's implementation of HACCP by using the FSIS Directive 5000.1, Revision 1
   a. Applying inspection methods (knowing how and when to perform the 01 and 02 HACCP procedures)
   b. Using regulatory decision making (using questions outlined in FSIS Directive 5000.1)
7. Documentation and enforcement (including inadequate system determinations)
   a. Issuing noncompliance documentation using the NR and completing sampling forms
   b. Taking regulatory actions which encompass all the enforcement actions covered by the ROP and, when necessary, contacting the District Office

The attachments to the module include 9 CFR §417, and an example of using the random number generator.

# Abbreviations Used in this Module

§ - Section
01 procedure- verification procedure performed by CSI in 03 HACCP ISP Activity
02 procedure – verification procedure performed by CSI in 03 HACCP ISP Activity
03G – Fully cooked- not shelf stable HACCP regulatory process
03H – Heat-treated – not shelf stable HACCP regulatory process
03I – Product with Secondary Inhibitor – not shelf stable HACCP regulatory process
9 CFR – Title 9 Code of Federal Regulations
CCP – Critical Control Point
CL – Critical Limit
CSI – Consumer Safety Inspector
*E. coli* – *Escherichia coli*
EIAO – Enforcement, Investigations and Analysis Officer
EPA – Environmental Protection Agency
FDA – Food and Drug Administration
FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act
FSIS – Food Safety Inspection Service
HA - Hazard analysis
HACCP-Hazard Analysis and Critical Control Point
ISP – Inspection System Procedure Guide
*Lm* – *Listeria monocytogenes*
NACMCF-The National Advisory Committee on Microbiological Criteria for Food
NRTE – not ready-to-eat
NSS – not shelf stable
RTE – ready-to-eat
USDA – United States Department of Agriculture

# Introduction

Hazard Analysis and Critical Control Point, or HACCP, is a systematic approach to the identification, evaluation, and control of food safety hazards. The HACCP plan is the written document which is based upon the principles of HACCP and which delineates the procedures to be followed by the official establishment. The HACCP system is the result of the implementation of the HACCP plan.

HACCP is an establishment management's system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from all steps in production, including raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product. For successful implementation of a HACCP plan, an establishment management must be strongly committed to the HACCP concept sustaining a sense of the importance of producing safe food.

HACCP is designed for use in all segments of the food industry from growing, harvesting, processing, manufacturing, distributing, and merchandising to preparing food for consumption. Food safety systems based on the HACCP principles have been successfully applied in food processing plants, retail food stores, and food service operations. The seven principles of HACCP have been universally accepted by government agencies, trade associations and the food industry around the world.

### Consumer Safety Inspector Role

As a regulatory official at the in-plant level, your duties will focus on verifying that the official establishment has met its regulatory obligation to produce a safe, wholesome properly labeled product in a sanitary environment.

This portion of the training covers your regulatory duties in relation to products that fall into three of the nine processing categories

- (03G) Fully cooked – not shelf stable,
- (03H) Heat treated, but not fully cooked – not shelf stable, and
- (03I) Products with secondary inhibitors – not shelf stable.

Products produced in these three processing categories share the feature that they are not shelf stable products (NSS). Products produced in these three processing categories differ in that they include either Not Ready-to-Eat (NRTE), Ready-to-Eat (RTE) or both NRTE and RTE products.

To fulfill your role in protecting public health, you must not only understand the establishment's responsibilities and the processes used to produce these products, but also your responsibilities in performing your verification activities as a federal regulator of these NRTE/RTE products under the HACCP system.

The organization of this portion of the training is intended to assist you in your development of a logical, critical thought process defining your role as a regulator of the

establishment's food safety system. Included in the discussion will be a brief overview of the three mentioned processing categories, a review of the official establishment's responsibilities and the establishment's processes used to produce NRTE/RTE products in these processing categories. This section will include information on the public health concerns associated with the production of these finished products. Finally, the role of in-plant inspection personnel in protecting public health will be discussed with details related to the performance of Agency verification procedures. These Agency verification procedures will include the inspection methodology, basis for supportable regulatory decisions, graphic documentation of noncompliance, and legally defendable enforcement as prescribed by the rules of practice.

## Not Shelf Stable Processing Categories and Products

Following is a brief overview of the three regulatory HACCP processing categories included in this portion of the training: 03G, 03H, and 03I and examples of products that may be produced under these Inspection System Procedure (ISP) Guide HACCP elements. The 03G, 03H, and 03I HACCP elements will be presented together in this portion of the training due to the similarities with pathogens of concern during the production of these not shelf stable finished products.

### *03G - fully cooked-not shelf stable* (RTE)

This processing category includes all meat and poultry products that have been fully cooked, but are not shelf stable. ***Fully cooked*** means that these products have been sufficiently cooked so that they are safe to eat as they are, with no further preparation required by the consumer. This is also known as "***ready-to-eat***." Please note, however, that many of these products are customarily eaten hot, and cooking instructions may be included on the label. This does not affect the classification of these products into this processing category. An example is the hot dog. This product receives sufficient heat treatment to be fully cooked, and does not necessarily need to be reheated by the consumer. Most consumers do, however, heat this product, and cooking instructions may be included on the label of the product. Another parameter that defines this category is that the products are not shelf stable. ***Shelf stable*** means that the product has received a treatment that renders it safe to store without refrigeration. This does not apply to this category. These products, although fully cooked, are **not** shelf stable, and must be kept refrigerated or frozen in order to maintain safety and quality. Again, the hot dog is a great example. It must be kept refrigerated by the consumer until it is eaten.

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 frozen RTE products produced in this processing category require reheating for palatability. These frozen products are still safe to eat without this further preparation by the consumer and are therefore still considered RTE. Some examples of finished products produced under this process category that may fall under the ISP 03G Element include: fully cooked hams, cooked beef, roast beef, pastrami, corned beef, hot dogs, meat

loaves, meat and poultry salads, sliced luncheon meats, baked chicken, frozen entrees, and poultry rolls. These finished products are labeled in a manner that identifies them as RTE by the consumer. Product standards, processing methods, and labeling are all factors that must be considered in determining the regulatory processing category for 03G RTE products.

**Examples**:

**Cooked and smoked sausage:** A major product group in this category is the cooked and smoked sausage. There are many different types of these sausages made; some common examples are bologna, cooked salami, polish sausage, and hot dogs.

**RTE fresh or frozen entrees:** These range from pre-cooked chicken pieces, barbecue beef, to prepared dinners with meat or poultry along with rice, pasta, sauce, vegetables, etc. Fully cooked meat or poultry portions are combined with fully cooked sauces, vegetables, pasta, or other ingredients. These products are designed to be re-heated by the consumer, and may include instructions for re-heating. If these products are considered fully cooked, they must be safe to eat without the re-heating step.

***03H – heat treated but not fully cooked - not shelf stable*** **(NRTE)**

The products included in this category vary quite a bit from each other. What they have in common is that **they have received some type of heat treatment, but not sufficient heat treatment to result in ready-to-eat 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)). These products also require safe handling instructions (9 CFR §317.2(l) and §381.125(b)). Some finished products in this processing category may be prepared with both meat/poultry components that have received a lethality treatment in combination with non-meat/poultry components that need to receive a lethality treatment. These multi-component products, e.g., meals, dinners, and entrees, have labeling features which are conspicuous so that intended users are fully aware that the product must be cooked for safety. The principle display panel on the label will define these products, e.g., “Cook and Serve,“ Must be thoroughly cooked,” “Cook before eating”, and the product will have cooking instructions. Some examples of finished products produced under this process category that may fall under the ISP 03H Element include: bacon, char-marked patties, partially cooked nuggets, frozen entrees or dinners, and low temperature rendered products. In the case of bacon, the heat is used to aid the smoking and curing process. For the char-marked patties, the heat is applied to sear grill marks on the meat, but is not meant to cook the product. Nuggets are partially cooked to help set the breading and give it a more appealing color. All of these products must be thoroughly cooked before consumption.

One of the key elements in determining if an establishment is producing products that fall under the regulatory 03H processing category is the finished product label.

However, product standards, processing methods, as well as labeling are all factors that must be considered in determining the regulatory processing category for 03H NRTE products. Finished products in this category would *not* have received heat in combination with other treatments that change the product characteristics to promote microbial inhibiting qualities that are enhanced by antimicrobial agents, acidulants, salt, etc.

**Examples**:

**Partially cooked battered, breaded poultry products** are another product in this category. The raw poultry pieces are coated with ***batter***, a liquid mixture of flour, egg, milk, or water, etc; or with ***breading***, a granular mixture of cereal products, like breadcrumbs; or they are both battered and breaded. The pieces are then heat treated to "set" or precook this coating, usually in hot oil. The poultry product inside is still uncooked. The products are cooled, usually in a special **IQF (*individually quick frozen)*** freezer, and packaged.

**Char-marked patties** are included in this category. These products received a heat treatment on the outside surface that produces a "char-mark" which imitates the marks created from cooking product on a grill. The product is still essentially uncooked, and it is important that product labeling distinguish this product from ready-to-eat products. It is crucial that this product be fully cooked by the final user, to ensure safety.

**Low temperature rendered products** are derived from the low temperature rendering of fresh meat. The products are usually ground, heated, then treated to a process that separates some of the fat from the lean portion. The temperature used must not exceed 120° F. The product is then cooled quickly to limit potential growth of bacteria at these warm temperatures. The heat treatment is not sufficient to eliminate pathogens or to result in a cooked appearance. The rendered product is frozen and used in further processing operations. If the raw meat trimmings had at least 12% lean meat prior to rendering, the resulting product is called ***partially defatted chopped (species)***. If the fatty trimmings used as raw materials contain less that 12% lean meat, the resulting products are called ***partially defatted (species) fatty tissue***.

There are, of course, many other products that you may encounter that fall into this category. The common characteristic is that these products receive some heat treatment, but not enough to result in a fully cooked, ready-to-eat product

***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.

**Water activity ($a_w$) -** Microorganisms in food need water in order to live and grow. The water must be in a form that is available to the microorganisms. Water activity is a measurement of how much water is available in a product. The water activity can be reduced by removing water (drying) or by increasing the concentration of solutes dissolved in the water (adding salt or sugar). The water activity is a measure of the amount of water that is available to support bacterial growth in different foods. Bacteria require a certain amount of "free" water in order to grow. The more available the water, the faster the bacteria will grow. Water activity is lowered by the addition of solutes, such as salt or sugar. These food constituents bind water molecules together, making it unavailable for use by microorganisms.

**Acidity** - Most bacteria grow best in a medium that is neutral or slightly acidic, and the growth of most bacteria are significantly inhibited in very acidic foods. pH is measured on a scale from 1 to 14, with 7 being neutral. pH levels from 7 to 14 are basic, or alkaline, while those below 7 are acid. Most bacteria do not thrive in high pH (basic mediums) or low pH (acidic mediums), but prefer pH ranges close to neutral. Adding acid lowers the pH level of the product. Citric acid is a common food acidulant. Lactic acid is also used, but it imparts a fermented flavor, which may not always be a desired quality in the end product. Many foods are acidified to prevent the growth of undesirable microbes. This may be done by adding acidic ingredients, like tomatoes, or by adding the acid directly, like vinegar. The acidity of products may also be increased by the process of fermentation.

**Fermentation** - During this process, the pH level of the product is reduced by starter culture activity and by appropriate time/temperature factors. The starter culture is added to the meat or poultry mixture, and held in an environment optimum for their growth. The temperature and humidity are carefully monitored. The starter culture bacteria actively reproduce, and as they do they give off lactic acid, which lowers the pH of the product. It is important that lactic acid is produced quickly, because it inhibits undesirable bacteria, like the toxin-producing *Staphylococcus*. The pH is monitored over time to determine when the process is complete. During fermentation, the establishment will probably want to achieve a pH of 5.0 or less within a certain time.

The symbol **pH**, which stands for the hydrogen-ion concentration of a product, is an expression of the degree of acidity or alkalinity of a substance.

**pH**

**0 1 2 3 4 5 6 7 8 9 10 11 12 13 14**
**Acidity Neutral Alkalinity**

Most microorganisms thrive on pH near neutral, 7.0, although there are exceptions. Meat and poultry processors can control pH to limit microbial growth and give meat and poultry a longer shelf life. A pH below 7 indicates the degree of acidity, whereas a pH above 7 indicates the degree of alkalinity. The pH of fresh meat ranges between 5.3 and 6.4. Higher pH meat (6.0 to 6.4) spoils faster than meat in the lower pH range (5.3 to 5.7), because the spoilage bacteria are more active at the higher pH.

**Drying** - Drying is the process of dehydration in which osmosis withdraws water from the cell of the spoilage organisms, shriveling or inactivating the cells. The product must be dried to the point at which bacterial growth is slowed or the bacteria are inactived or destroyed in order to create a shelf stable 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.

You, as the CSI, must take ***all*** factors into account – all processing steps, labeling, etc. – to determine if a product is RTE. The RTE designation is especially crucial when you determine which products to select for Agency directed sampling verification activities. Based on your evaluation of all the factors associated with an establishment's production of finished products, you will select the regulatory processing category which you will use to regulate the establishment's compliance with 9 CFR Part 417.

# Process Familiarization for Fully Cooked-Not Shelf Stable (03G) Product – Cooked and Smoked Sausage (Hot Dogs)

## *Cooked and Smoked Sausage (Hot Dogs)*

One of the major product groupings that fall under this category is the cooked and smoked sausage. There are many different types of these sausages made; some common examples are bologna, cooked salami, polish sausage, and hot dogs. Let's take a closer look at hot dogs as an example of how these products are produced.

The first steps are the same as we have previously covered: meat and/or poultry, other ingredients, and packaging materials are received and stored in the establishment until ready to use. Many establishments carefully control the quality of the incoming ingredients through purchasing specifications. Meat ingredients may have quality specifications such as percent fat, moisture, and protein. These are parameters that will effect the final quality of the product.

***Raw meat ingredients*** used in these products will depend on the type of finished product desired. Not long ago, most hot dogs were either a combination of pork and beef, or they were all beef. Today, establishments still make these products, but many more combinations of ingredients are used. Many formulations include at least some ***poultry*** products (turkey or chicken), and some products are made exclusively with poultry.

The first step in the formulation process is weighing or measuring the meat and/or poultry ingredients. They are ground and mixed or blended with the non-meat ingredients. Often establishments will ***pre-blend***, that is, they will grind and mix the meats with water and salt, and sometimes with the nitrite, and let it stand for a period of time in a cooler.

***Antimicrobial agents,*** are substances such as acetates, diacetates, and lactates, added to an RTE product to reduce or eliminate a microorganism, including a pathogen such as *L. monocytogenes*, or suppress or limit growth of *L. monocytogenes* in the product throughout the shelf life of the product.

***Binders and extenders***, such as dry milk powder, cereal flours, and soy protein, have a number of uses in a sausage formulation. They increase the overall yield, improve binding qualities, and add certain flavor characteristics.

***Cure accelerators,*** such as ascorbates and erythorbates, are used to speed up the curing process. They also stabilize the color of the final product.

***Phosphates*** are used to improve the water-binding capacity of the meat, and contribute to the flavor and color of the product.

***Spices and flavorings*** are used to add flavor to the sausage. The wide range of available spices, seasonings, and flavorings is a primary reason for the variety available in sausages in the marketplace.

- **Spices** are any aromatic vegetable substance that is intended to function as contributing flavor to food, rather than as a nutritional substance. The active aromatic or pungent properties of spices that contribute the most to the flavoring effect are present in the volatile oils, resins, or oleoresins of the spice. Spices may be used whole or ground. White pepper, paprika, and nutmeg are common spices used to produce the characteristic flavor of the hot dog. Because paprika also adds color and makes meat look brighter red, it must be listed as “paprika” on labels.
- **Flavorings** are substances that are extracted from a food, and contribute flavoring, such as spice extracts.

After the non-meat ingredients are blended with the ground meats, the mixture is ***emulsified***. This is done in an emulsifier, and further reduces the size of the meat particles to achieve a very fine texture. Fat, protein, salt, and water are mixed and combined into a semi-fluid emulsion. The meat muscle protein, myosin, is ***solubilized***, or released from the muscle fibers, by salt. The solubilized protein and water combine and surround the fat globules, and suspend the fat particles within the mixture.

Careful control of the amount of each ingredient is essential to the quality of the final product. The manufacturer must select a mix of raw meat materials with the appropriate binding characteristics. Different meats vary in their ability to bind. Lean beef, for example, bull, cow, and shank meat, have high binding ability. Regular pork or beef trimmings with more fat, and poultry, have medium binding ability. Low binding meats contain high levels of fat, such as jowls and briskets. Organ meats have no binding qualities. The binding capabilities are directly proportional to the myosin (red pigment) in the muscles. Thus, the paler the muscle, the less bind it contributes to the mixture.

Control of the emulsification process is also essential. Product defects result from too much chopping, or from an increase in temperature during the process. Over-chopping makes the protein fibers too short. It also creates heat from friction that melts fat. This results in product defects such as pockets of fat in the final product.

After emulsification, the mixture (or “batter”) is ***stuffed*** into casings, usually artificial plastic casings that allow moisture to cook out and smoke flavors to penetrate. Natural casings such as sheep small intestines may also be used.

Following stuffing, the product is ***linked*** by pinching and twisting the casing to form separate units of sausage. The sausages are still held together by the casing. These lengths of casings are then placed on racks or trees, and are ready to be loaded into the smokehouse. Some establishments load trees into individual smokehouses, however, some large volume establishments use continuous smokehouses.

The smokehouse parameters that must be controlled are temperature, time, and humidity. The product must be exposed to a high enough temperature in order to produce a fully cooked, ready-to-eat product. The temperature inside the smokehouse, and the internal temperature of the sausage, may be monitored by the establishment in order to verify that the critical limits are met. Cooking is a very important step, because it is here that any pathogens (e.g., *Salmonella*) that may be in the product will be eliminated and the numbers of spoilage bacteria will be lowered to an acceptable level. This is called a ***lethality*** treatment.

After product has reached the final temperature desired, the cooling process begins. This product is often showered with cold water inside the smokehouse. This removes some of the heat from the product, and immediately halts the cooking process. The shower is usually not sufficient to complete the cooling process. Usually product is moved to another chiller or cooler to finish cooling. Some establishments use very cold water as a chilling medium, sometimes with salt added to lower the temperature below the normal freezing point of water. This is called a ***brine chiller***. Other establishments may use cold air, and some use a combination of methods.

The cooling process is also known as ***stabilization***. There are two types of bacterial contamination that must be addressed by the stabilization process.

- **Spore-forming bacteria** (*Clostridium perfringens* and *Clostridium botulinum*) **can survive cooking** when in the heat-resistant spore form, and these organisms need to be considered as the products are chilled. Growth (sometimes referred to as **"*outgrowth*"**) of these bacteria is slowed by rapid cooling. Cooling rates, or time/temperature relationships, must be carefully controlled in order to ensure that product does not remain at warm temperatures that would support the outgrowth.
- **Recontamination with bacteria** (e.g., *Listeria monocytogenes*) must be considered as cooked products are exposed to the environment, food contact surfaces, or cross-contamination with raw product prior to final packaging. Proper chilling and cold storage temperatures are essential to limit the growth of these bacteria.

After product has been chilled to the desired temperature, it is removed from the artificial casings in a machine called a **peeler**. This equipment quickly runs the sausage through a tunnel that has a tiny blade that slices the casing. Steam or air is then used to blow the casing away from the sausage. The sausage links are now separate. If you closely examine the outside of a hotdog, you might see where the casing had been cut. This blade is a potential source of contamination, since it contacts every hot dog!

Sometimes a product that has partially or fully completed the production cycle is not sellable but is still wholesome, and can be used for food. For example, the casing of some sausages may split during the cooking or smoking cycle. Manufacturers may reuse these edible but unsalable products by removing the casing and adding the contents to the grinder to include in another run of the same product. This is called ***rework***. Since the proteins are coagulated from cooking, rework has no bind capabilities. Of course, the ingredients of the rework must be compatible with the ingredients of the batch to which they are added for labeling purposes.

The final steps are packaging, labeling, and storage. The product is ready for distribution to retail stores, restaurants, or institutions.

**FULLY COOKED - NOT SHELF STABLE (03G)** FLOW CHART
Example product: **Hot Dogs**