

All Sandwiches Should Be Regulated by the USDA

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INTRODUCTION

There are many inconsistencies in how regulations are written for different types of food and even similar types of food are regulated differently. Normally common sense can be used when determining if the United States Department of Agriculture (USDA) or the Food and Drug Administration (FDA) regulates a product. With sandwiches common sense rules don't apply. New York Senator Hillary Rodham Clinton highlighted the difference of closed face sandwiches versus open-faced sandwiches during a speech, "A ham and cheese sandwich on one slice of bread is the responsibility of the U.S. Department of Agriculture, which inspects manufacturers daily. But a ham and cheese sandwich on two slices of bread is the responsibility of the Food and Drug Administration, which inspects manufacturers about once every five years."¹ The USDA defines a closed faced sandwich as:

Product must contain at least 35 percent cooked meat and no more than 50 percent bread. Sandwiches are not amendable to inspection. ... Typical "closed-faced" sandwiches consisting of two slices of bread or the top and bottom sections of a sliced bun that enclose meat or poultry, are not amendable to the federal meat and poultry inspection laws. Therefore, they are not required to be inspected nor bear the marks of inspection when distributed in interstate commerce.²

An open faced sandwich is defined by the USDA as "Must contain at least 50 percent cooked meat. Sandwiches are amendable only if they are open faced sandwiches."³

Does placing a slice of bread on top of a sandwich make it significantly different in a

¹ St. Petersburg Times "Ham and Cheese, but hold the bureaucracy" by Bill Adair Dec. 11, 2007

² United States Department of Agriculture, Food Standards and Labeling Policy Book, August 2005

³ United States Department of Agriculture, Food Standards and Labeling Policy Book, August 2005

consumer's eye, or have different food safety concerns? Loopholes in regulations like this need to be addressed; all sandwich type products containing meat should be regulated by the USDA.

The following sections are provided to assist in understanding the complexity of sandwich regulations and safety. The initial section will discuss the current practices in the United States regarding sandwich production. The second section will review federal and state procedures and regulations regarding sandwiches. The next section will provide recall history. The final section will provide possible solutions to the creation of a unified and comprehensible sandwich production regulation.

CURRENT PRACTICE

This section will provide information on current practices in sandwich production and Ready to Eat (RTE) status. Additional information on deli meat regulations is provided. This information is necessary to understand the basis of the complexity of the sandwich regulation issue.

The majority of sandwiches are eaten cold or without heating them to a microbial lethality temperature. Since the majority of purchased sandwiches are eaten right out of the package I consider them RTE. With RTE products microbiological issues need to be addressed by the manufacturer to assure safe food is provided to the consumer. Consumers identify sandwiches by their meat types, not by the bread or even the vegetables on the sandwich. As the world has become smaller with the free market, products are now mass-produced and widely distributed. Food outbreaks are now larger and affecting more consumers than ever before. The small sandwich producers that only

supply your local convince stores are becoming a thing of the past. Food safety of sandwiches should have increasing importance.

We are taught at an early age about food safety; make sure the mayonnaise salad doesn't get warm, keep cold foods cold, and wash your hands after handling raw meat. We are taught this to help prevent food born illness. Raw meat inherently contains many microorganisms that can lead to food born illness such as *E. coli* O15:H7, *Salmonella*, *C. perfringens*, and *Campylobacter*. The USDA addresses the issue of microorganisms on products that a consumer eats right out of the package by creating a category called RTE. A deli meat, the type you find in a closed faced sandwich is considered RTE since it has been fully cooked to kill or reduce the pathogens found in the meat so it is safe to eat.

The USDA defines RTE as

A meat or poultry product that is in a form that is edible without additional preparations to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purpose. RTE product is not required to bear a safe-handling instructions (as required for non-ready to eat products by 9CFR 317.2(1) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.⁴

The manufacturer provides the last food safety steps before the consumer eats the product.

Deli meat is a deli product and must be processed as an RTE item. The USDA defines a deli product as “A RTE meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.”⁵ Since the USDA has defined a deli product as a RTE meat it requires manufacturers to monitor the product to ensure safety.

⁴ 9 CFR 430.1

⁵ 9 CFR 430.1

Manufacturers and the government monitor the cook temperatures and times, audit facilities for cleanliness, and sample the product and environment for microorganisms to ensure they are meeting the definition and safety requirements for RTE.

FOOD REGULATIONS AND SAFETY

The information below is a review of federal regulations and guidelines related to sandwich production. It will include Hazard Analysis Critical Control Point Plan (HACCP) history, information about prerequisite programs including sanitation and environmental programs, as well as Good Manufacturing Practices (GMP's) information.

For a USDA plant to produce food they must address the safety of the food in a HACCP plan. HACCP was originally created for NASA to ensure safe food for the astronauts while in space. If an astronaut was to get food illness in space the situation could easily become serious or even fatal for the astronaut. HACCP requires the manufacturing facility to assess the product and production of the food to determine where critical points for food safety are, create scientifically determined limits for these points, monitor them, and when limits are not met create corrective action plans to prevent recurrence. HACCP was a mandated implementation by the USDA to help prevent food born disease outbreaks in the general population. HACCP is a systemized, scientifically addressed way of reviewing your food production process for food safety.

When HACCP was implemented prerequisite programs were also made mandatory. Prerequisite programs support your HACCP plan, without them HACCP would not work. One essential prerequisite program for HACCP is the plant sanitation program. Without proper sanitation of processing equipment and facilities the environment product is made in will never be in sanitary control. A sanitation program

addresses the cleanliness and monitoring of the cleanliness. A sanitation program requires specific chemicals be used to ensure the harmful micro flora in the facility be reduced to a safe level.

Environmental programs go hand in hand with a plant sanitation program. The plant environment is monitored to measure the microbial levels in different areas of the plant. Areas of the plants are set up in zones. In a RTE facility there are usually three zones: product contact surfaces, incidental product contact surfaces, and non-product contact surfaces. Daily these surfaces are swabbed before and during a RTE production. These swabs are analyzed to review the microbial load as well as detect if pathogens are present in the production environment.

A deli product in a sandwich goes through many obstacles before it is used in a closed faced sandwich. The deli product must be produced meeting the guidelines outlined by the USDA before it can be distributed. A USDA inspector is present in the manufacturing facility daily to monitor production to ensure HACCP and prerequisite programs are being followed. If the deli product doesn't meet these hurdles the product can be placed on hold before distribution or recalled. The deli product is only one component in the sandwich. The FDA monitors the remaining components of a sandwich.

Sandwich components, such as vegetables, cheese, condiments and bread, are held to different standard than the deli product since the FDA monitors them. The FDA has different guidelines for their items. The FDA has not mandated HACCP in these types of products. The FDA does not classify products based on how they are consumed, in other words they don't classify products as ready to eat or not ready to eat. Recent

recalls have provided evidence that lettuce, cheese and tomatoes are at the same risk as deli products to cause food born illness outbreaks.

The FDA has set up GMP's for product safety. The GMP program is very specific and doesn't have as much flexibility as the HACCP program. A USDA facility is required to follow GMP's as well as HACCP. With the HACCP program the manufacturer determines critical control points by scientific evaluation, there is flexibility for the manufacture to enhance their plans as science evolves. For the GMP's to be altered a docket has to be issued, reviewed and then enacted into law. Due to the amount of products the FDA has jurisdiction over they rely heavily on state inspection. States determine the regulations as well as the frequency of their inspections. Since the states are determining the regulations a closed faced sandwich made in Texas can have different regulations to meet than a closed faced sandwich made in Ohio. It becomes obvious that FDA regulated items can remain a risk to consumers.

RECALL HISTORY

The sandwich industry is not invincible to recalls. This section will provide a brief history of recalls specific to this industry. It is not all-inclusive; however, it is offered as examples of the complexity of the product and the related regulations.

Wrap sandwiches have become a popular form of sandwich that contains the same essential ingredient found in a closed faced sandwich. Since the product is wrapped in a tortilla instead of having two slices of bread to hold in the ingredients the USDA supervises it. In September 30, 2008 a ready to eat turkey burrito wrap was recalled due

to *Listeria Monocytogenes* contamination⁶. Producers and consumers should anticipate future recalls.

Products are increasingly being distributed across the country with trains, planes, and trucks available with refrigeration. Products can be made in California but sold in New York. Due to this many people can become sick nationally if food is contaminated, making tracking the product as well as the source of the outbreak cumbersome and time consuming. Recently an outbreak of *Salmonella St. Paul* occurred in jalapenos.⁷ It took over two months for the FDA to track down the cause of the outbreak, since the original source of the contamination was thought to be tomatoes. By the end of the investigation the jalapeno that was found to be the source, it had reached 43 states and Canada. The jalapenos were traced to specific fields in Mexico. It took several months to find the cause of the outbreak, during this time people continued to get sick from contaminated food. A recall issued in August 28, 2008 for Fresh from the Deli American Sub sandwiches affected multiple states; the product was made in Illinois but was distributed in Indiana, Kentucky, Ohio and Pennsylvania.⁸ Only 812 sandwiches were recalled but they affected numerous states due to distribution of the product. With the pressures to make food faster and cheaper we will continue to see major factories supplying our food with smaller factories starting to disappear.

Recently there has been recalls for sandwiches because they contained *Listeria Monocytogenes*. The USDA declared *Listeria Monocytogenes* as an adulterant in RTE

⁶ USDA Food Safety and Inspection Services, September 30, 2008, http://www.fsis.usda.gov/News_&_Events/Recall_034_2008_Release/index.asp

⁷ Center for Disease Control and Prevention, August 28, 2008, Press Briefing Transcripts, <http://www.cdc.gov/media/transcripts/2008/t080829.htm>

⁸ U.S. Food and Drug Administration, August 28, 2008, http://www.fda.gov/oc/po/firmrecalls/landshire08_08.html

meat in 1989. *Listeria* is found in a manufacturing facility in drains, walls, in sub floors and even drip pans. The bacteria are challenging to control because it adapts well to cold and heat. According the Center of Disease Control (CDC) 2,500 cases of Listeriosis are reported, of these cases there are 500 deaths⁹. The industry has addressed *Listeria* by trying to control and monitor it in their facility. The industry has not found a way to eliminate it permeantly from a production facility. In a sandwich *Listeria* would be of concern in the lunchmeat and the cheese. Often these items are cross-contaminated during slicing, after the lethality treatment has occurred.

In 9 CFR 430.4 it states ready to eat deli product facilities are required by law to use post lethality treatments the prevent *Listeria* cross contamination or use a sanitation monitoring program to show control. The sanitation program has the most risk associated with cross-contaminated product. With the use of sanitation program the USDA has set specific testing programs of the finished product as well as the environment to detect *Listeria*.

In the case of cheese there are no control points that take place to prevent the growth of *Listeria*, which are mandated by the FDA. The FDA does not have the same requirements since they don't define products as ready to eat. A FDA plant is not mandated to swab the environment for *Listeria* or test finished product for contamination. Listeriosis is known to cause miscarriages in pregnant women. The CDC recommends pregnant women to not consume soft cheeses due to the possibility of *Listeria* contamination.

⁹ Center for Disease Control, accessed on November 29, 2008, http://www.cdc.gov/nczved/dfbmd/disease_listing/listeriosis_gi.html

Salmonella is another concern in a sandwich product. Over 40,000 cases of Salmonellosis is diagnosed a year in the United States.¹⁰ *Salmonella* can be found in lettuce, tomatoes, lunchmeat, and cheese. *Salmonella* is found in the digestive track of animals and humans and is transferred to food from cross-contamination. *Salmonella* is of concern in vegetables due to them being grown outside and exposed to bird feces as well as cross contamination from animal run off. *Salmonella* is addressed in a HACCP or prerequisite program in USDA plants. Again everything except the meat is held to a different food safety standard.

POSSIBLE SOLUTIONS

When a consumer orders a sandwich they refer to the type of meat in the sandwich. It might be assumed that USDA regulated pre-made closed faced sandwiches since they contained meat. When Senator Clinton highlighted this in a speech reporters had to research the topic because it wasn't instantly clear who should regulate closed faced sandwiches. Since the general public refers to closed faced sandwiches by the meat type it might be assumed that the USDA governs it when it does not. Confusion appears inevitable for both consumers and food manufacturers. The information below is provided in an effort to address possible solutions to the confusion in sandwich regulations by reviewing arguments against changes in regulations.

In November 7, 2005 the USDA introduced Docket 05-013N for review and public comment. In this docket the issue of who should regulate all sandwiches was opened for discussion. A change was not made to amend the regulations; however the industries response to the docket was made public. Many manufacturing companies,

¹⁰ Center for Disease Control, accessed November 29, 2008, http://www.cdc.gov/nczved/dfbmd/disease_listing/salmonellosis_gi.html

trade organizations and government employees were in favor of changing the regulation to have USDA jurisdiction over all sandwich type products that contain meat. This would help to eliminate confusion over who has jurisdiction since the category of sandwiches is expanding.

Opposition to the changing of the regulation brought up the following points: lack of inspectors for the increase in inspection, labeling requirements changing, and updating the plants to USDA standards. These items are of concern due to the possible change in regulation affecting the small manufacturing facility. The stated concerns appeared to be surmountable; however no action was taken on Docket 05-013N.

The potential problems cited above do not seem to be sufficient to slow or stop improved food safety. The size of the facility or the amount of closed faced sandwiches made should not make food any less safe for the consumer. All products should be manufactured in safe facilities. Bringing a facility to USDA standards should not be an issue if you are currently producing using the FDA's GMP's. In no circumstance should a food be made in unsanitary conditions. If closed faced sandwiches were changed to USDA governance labels would have to be submitted for review before use. With any changes affecting numerous products labels a time extension is given to help the industry comply with the change. When the Nutrition Labeling and Education Act (NLEA) was passed in 1990, full compliance was not expected till 1994. Time can be given for full compliance for facilities. A shortage of inspectors can be addressed by increasing the availability of inspectors by hiring more employees. The bottom line of the argument was concern about profit for the manufacturer, it costs money to re-create labels and

ensure the safest food is being made. If you asked any consumer they would put food safety first over a profit for the manufacturer.

CONCLUSION

The USDA should regulate all types of sandwiches. The programs that have been put in place for RTE products would ensure safe sandwiches to consumers. HACCP and prerequisite programs don't completely prevent recalls but they have reduced them. We as a nation are moving from locally made product distributed within our states to a global approach. When Richard Raymond the USDA's undersecretary for food safety was asked why this regulation exists he responded that "there is no rationale or logic that I can explain to anybody"¹¹. If there is a regulation that doesn't have rationale should it not be changed to be logical to provide our society safe food? The food industry should not continue to allow irrational oversight but should promote adequate government oversight. Safety is a key goal for all stakeholders in food production.

¹¹ St. Petersburg Times "Ham and Cheese, but hold the bureaucracy" by Bill Adair, December 11, 2007

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