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HEATHER RUSSINKO, ELIZABETH CIBOTARIU, MARTHA RABELLO, and the NEW JERSEY HOME BAKERS ASSOCIATION,

Plaintiffs,

v.

THE NEW JERSEY DEPARTMENT OF HEALTH and SHEREEF M. ELNAHAL, in his official capacity as Commissioner of the New Jersey Department of Health,

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MERCER COUNTY

DOCKET NO.: MER-L-505-18

CIVIL ACTION

EXPERT REPORT OF THOMAS J. MONTVILLE, Ph.D.

Prepared by Thomas J. Montville, Ph.D., F.A.A.M., F.I.F.T.

November 16, 2018

The Institute for Justice has retained me to proffer an opinion as to four issues: (1) whether baked goods that are considered to be not-potentially hazardous can pose a risk of foodborne illness to the public, (2) whether baked goods that are considered not-potentially hazardous that are prepared in home kitchens would present a greater risk of foodborne illness than such goods prepared in licensed and inspected commercial-grade kitchens, (3) if other not potentially-hazardous foods, such as chocolates, hard candies, dried herbs and spices, dried cookie and cake mixes, and dried pastas, can pose a risk of foodborne illness to the public, and (4) whether not potentially-hazardous foods prepared in home kitchens would present a greater risk when made for profit than when made for charity.

I. Summary

I have four main conclusions: (1) not potentially-hazardous baked goods[1], such as cakes, cookies, breads, and muffins, are perfectly safe, (2) there is no evidence or reason to think that not potentially-hazardous baked goods prepared in home kitchens would present a greater risk of foodborne disease than those prepared in licensed and inspected commercial-grade kitchens,[2] (3) other not potentially-hazardous foods, such as chocolates, hard candies, dried herbs and spices, dried cookie and cake mixes, and dried pastas, are also perfectly safe, and (4) there is no evidence or reasonable basis for concluding that not potentially-hazardous foods prepared in home kitchens would present a greater risk when made for profit than when made for charity.

II. Credentials

I am currently Professor *Emeritus* in the Department of Food Science at Rutgers—the State University of New Jersey. My scholarly achievements include seven books, more than 100 papers in peer-reviewed journals, and 14 book chapters. My expertise in food science and food microbiology is also reflected in my elections as Fellow of the Institute of Food Technologists (F.I.F.T.) and Fellow of the American Academy of Microbiology (F.A.A.M.), and appointments

[1] Baked goods are defined as "a food (such as a bread, cake, or cookie) made from a dough or batter that is baked." Definition of Baked Goods, Merriam-Webster Dictionary, http://www.merriam-webster.com/dictionary/baked%20good (accessed 11/16/18). This report does not address pastries, pies, and other items that are filled with creams, custards, or other ingredients that would require refrigeration because they are potentially hazardous and thus support the growth of foodborne pathogens.

[2] In this report, I use the term "commercial-grade kitchen" to mean a kitchen meeting the requirements set forth in Chapter 15 of Title 24 of the New Jersey statutes and Chapter 24 of the State Sanitary Code, codified at N.J.A.C. 8:24-1.1 to 8:24-10.2.

as Editor, *Journal of Food Safety*, Co-editor, *Food Microbiology: Fundamentals and Frontiers*, co-author of the textbook *Food Microbiology—an Introduction*, and Editorial Board member of the *Journal of Food Protection*. In addition, I have an advanced degree in food science (Ph.D., M.I.T.).

I have also served as a Special Government Employee (Food Advisory Committee member) of the U.S. Food and Drug Administration, Washington, D.C., and as Panel Manager for the U.S. Department of Agriculture Cooperative State Research Service National Research Initiative Competitive Grants Program in Food Safety, Washington, D.C. The Institute of Food Technologists recognized my dedication to food safety by honoring me as the 2008 laureate of the Bernard Oser Award for Food Ingredient Safety. I have also received the President's Lifetime Achievement Award from the International Association for Food Protection.

In preparing this report and forming the opinions expressed in it, I relied on my knowledge of food science and microbiology and the reference material listed at the end of this report. I reserve the right to revise this report if additional material is uncovered during discovery.

III. The Safety Of Not Potentially-Hazardous Baked Goods.

Below I discuss the safety of not potentially-hazardous baked goods. I address biological hazards caused by bacteria and viruses, physical contaminants, and allergens.

A. What is a not potentially-hazardous baked good?

This report addresses only baked goods that are "not-potentially-hazardous," as defined by the State of New Jersey.[3] In layman's terms, not potentially-hazardous foods are foods that do not allow growth of bacteria, do not require refrigeration, and are shelf-stable. Not potentially-hazardous baked goods include most common baked goods such as breads, cakes, and cookies, and exclude items such as cream pies, cheese-filled danishes, and other similar products that require refrigeration and are of limited shelf-life.

[3] New Jersey defines "not-potentially-hazardous" food as food that does not "require[] temperature control" and cannot support "[t]he rapid and progressive growth of infectious or toxigenic microorganisms." N.J.A.C. 8:24-1.5 (giving the definition of both "potentially hazardous food" and the definition of what is not considered to be a "potentially hazardous food").

B. Not potentially-hazardous baked goods are not biological hazards from bacteria or viruses.

Not potentially-hazardous baked goods are considered to be inherently safe. A risk assessment conducted by the U.S. Food and Drug Administration (2015) considers "baked goods from milled grain products (e.g., breads and cookies)" to be low-risk[4] (i.e., unlikely to cause serious health consequences). Below I evaluate any risk of bacteria to these foods and then any risk of viruses.

1. Not potentially-hazardous baked goods are not microbiological hazards.

Not potentially-hazardous baked goods are not microbiological hazards because cooking to an internal temperature of 168-179^{o}F kills the bacteria that cause foodborne illness, including *Bacillus, Campylobacter, Escherichia (e.g., E. coli), Listeria monocytogenes, Salmonella, Shigella, Staphylococcus.* (International Commission for Microbiological Specifications of Food, ICMSF, 1980). For example, the internal temperature of bread during baking is well above 179^{o}F and approaches 212^{o}F. It is likely that other baked goods such as cookies and cakes reach similar internal temperatures, and probably higher, since they are smaller. In addition, it is unlikely that baked goods would be undercooked because the poor quality of the resultant product would cause them to be rejected by the baker and consumer. The heat treatment provided by baking kills all bacteria except spores,[5] as discussed below (International Commission for Microbiological Specifications of Food, ICMSF, 1980).

The ability of baking to kill injurious bacteria would be equally true for baked goods prepared in home kitchens and for those prepared in licensed and inspected commercial-grade kitchens. Therefore, baked goods prepared in home kitchens would not present a greater risk than those prepared in licensed and inspected commercial-grade kitchens.

As noted above, some spores survive the baking process. However, heat-resistant spores are not a safety concern in baked goods. There are only three types of disease-causing foodborne

[4] FDA categorizes foods as low-risk, medium-risk, or high-risk, defining low-risk foods as: "Low-risk foods are foods that 'are unlikely to contain pathogenic microorganisms and will not normally support their growth due to food characteristics.' Examples are grains and cereals, bread, carbonated beverages, sugar-based confectionery, alcohol, and fats and oils." FDA, 2015. ("Low-risk" is the FDA's safest category, as FDA does not consider any food to be "no risk.")

[5] Spores are heat-resistant bodies formed by some types of bacteria. Under certain conditions, spores can turn back into bacteria.

bacteria that produce spores: *Clostridium botulinum, Clostridium perfringens*, and *Bacillus cereus*. Air is toxic to *Clostridium botulinum* and *Clostridium perfringens.* Thus, *Bacillus cereus*, which produces toxins that cause a minor self-limiting illness (i.e., resolves without medical attention), is the only bacteria of potential concern that can survive baking. But the survival of its spores is minimal and has only been demonstrated in the laboratory when bread is artificially contaminated with spore levels much higher than that which might be naturally occurring. When bread was artificially contaminated with an unnaturally high level of one million *Bacillus cereus* spores in the laboratory, 99.9% were killed by baking (Rizk, 1989). Other studies (Kaur, 1986) also showed that some *Bacillus cereus* spores survived when inoculated in artificially high amounts into large loaves of bread in the laboratory, but concluded that "the risk of food poisoning due to the presence of *B. cereus* in bread is minimal." In the laboratory where conditions have been manipulated to allow *Bacillus cereus* to grow in a bread-like environment, toxins are not produced (Sharma and Dogra, 1983). A definitive ICMSF chapter on *Bacillus cereus* (ICMSF, 1996) makes no specific mention of illness from *Bacillus cereus* as being associated with baked goods. The International Commission on Microbiological Specifications for Foods also states "there appears to be no reports of food poisoning attributable to this source."[6] (International Commission on Microbiological Specifications for Foods, ICMSF, 2000).

Thus, there is no realistic risk of not potentially-hazardous baked goods causing illness because of bacteria, regardless of whether they are made at home or in a licensed kitchen. I next turn to whether not potentially-hazardous baked goods could cause illness from a viral hazard.

2. ***Not potentially-hazardous baked goods are not viral hazards.***

The risk of ill food-handlers contaminating baked goods with a virus is for all practical purposes zero. A virus is a small submicroscopic organism that, unlike bacteria, cannot grow in food. It instead needs to infect a host cell (i.e., human cells "catch" a virus) where the virus can use that cell's machinery to produce more viruses. The virus can be excreted by a food handler and contaminate a food through poor hygienic practices. Norovirus is the most common virus that can contaminate food.[7]

[6] "This source" specifically refers to *Bacillus cereus* in baked goods.

[7] Hepatitis rarely causes foodborne illness and has not been reported to cause any outbreaks in cookies, cakes, or bread over the period 1998-2016 (Centers for Disease Control, 2018).

Noroviruses are a specific type of virus that are transmitted by a fecal-oral route and cause more than eight million cases of foodborne illness per year. Noroviruses cause acute diarrheal disease after an incubation period of one or two days and can be shed in feces for several weeks after the illness has abated (Montville, et al., 2012).

The risk of norovirus contaminating home-baked goods is for all practical purposes zero. That is because normal baking temperatures, as discussed above, kill norovirus in the oven. As a result, norovirus can only be transmitted to the baked good after it has already been baked. Such transmission is rare.

There were 158 outbreaks caused by norovirus in bread, cookies, or cakes over an eighteen-year period (CDC 2018).[8] This equates to 8.8 outbreaks per year. None of the outbreaks resulted in fatalities. To provide context, 8.8 outbreaks per year should be considered relative to the number of servings per year. Even if all of these outbreaks were caused by home-baked goods (which they realistically would not have been), the probability of a home-baked good causing a norovirus outbreak would be approximately one outbreak in 1.9 billion servings.[9] One outbreak per 1.9 billion servings represents a negligible risk. A person is significantly more likely to be struck by lightning *twice* in his or her lifetime, the chances of which are reported at one in 9 million.[10]

In addition, there is no reason to believe that the incidence of ill workers would be any different in non-licensed facilities compared to licensed ones. The FDA Model Food Code

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[8] I intended this estimate to cover only not potentially-hazardous baked goods. To determine how many norovirus outbreaks involved not potentially-hazardous baked goods, I did a search for all norovirus reports involving "cake," "cookie," and "bread." I then excluded from these reports all foods that were obviously potentially hazardous, (i.e., crab cake and cheesecake). I included all reports for foods that could possibly be not-potentially hazardous, even if there were not enough details to conclusively make this determination. For example, I included many outbreaks involving foods that were described only as "unspecified cake" or "unspecified bread." As a result, my estimate of 158 number of norovirus outbreaks involving not potentially-hazardous baked goods is conservative and cautiously overinclusive.

[9] The population of the United States is 325.7 million people. If each person consumed one serving of a baked good per week (i.e., 52 servings annually) this would result in 16,936,400,000 servings of baked goods per year. 8.8 outbreaks caused by noroviruses per 16,936.4 million servings equates to one outbreak per 1,924,590,909 servings.

[10] Rodney Overton, *Odds Of Winning Powerball Jackpot Less Than Being Hit By Lightning—Twice*, CBS 17 (Jan. 12, 2016), *available at* https://www.cbs17.com/news/odds-of-winning-powerball-jackpot-less-than-being-hit-by-lightning-twice/1082701256.

(2009) puts forth policies that bar ill food-handlers from working. But a recent survey (Carpenter, et al., 2013) reports that these policies are ineffectual; almost 60% of food workers recalled working while ill. In addition, carriers of norovirus can be infectious and contagious without showing symptoms.

Thus, norovirus is not a genuine risk in home-baked goods, and in any event, there is no reason to believe that the incidence of ill workers would be any different in home kitchens compared to licensed and inspected commercial-grade kitchens.

C. Physical contamination is not a genuine risk in home-baked goods.

Physical hazards (i.e., foreign matter) occur when extraneous materials, such as broken glass or metal from kitchen utensils, are accidentally introduced into a food. One common-sense way to prevent this is simply to know that there has been such an occurrence. A home-baker would certainly know if a glass jar had been broken, or a chunk of metal has been dislodged from a cooking utensil, and would be able to take corrective action. While some large commercial-baking factories have additional measures, such as metal detectors, in place, smaller baking establishments, such as "mom and pop" bakeries, would not. From my decades of experience, I conclude that physical contamination of food is no more likely to occur in home kitchens than it is in food prepared in commercially licensed bakeries.

D. Not potentially-hazardous baked goods prepared in the home are no more likely to cause allergenic reactions than those prepared in licensed and inspected commercial-grade kitchens.

The presence of undeclared allergens in not potentially-hazardous baked goods can cause adverse reactions in people with food allergies. There are two concerns here: (1) foods can be accidently contaminated with allergens, and (2) foods with allergenic ingredients may not be properly labeled to list these ingredients. However, neither occurrence is more likely for goods prepared in a home-kitchen than those prepared in a licensed and inspected commercial-grade kitchen.

Regarding the first concern, while inspection of large commercial factories that manufacture baked goods may include procedures to prevent contamination with unlabeled allergens, no such procedures are likely to exist in smaller retail bakeries. Regarding the second concern, commercially licensed bakeries are not required to label most of their goods, including labels indicating ingredients and allergens. N.J.A.C. § 8:24-3.6(d) (exempting from all labeling

requirements “bulk, unpackaged foods such as bakery products and unpackaged foods that are portioned to consumer specifications”).

Thus, it would be expected that baked goods prepared in home kitchens do not present allergen hazards when compared to those prepared in some retail bakeries.

IV. Not potentially-hazardous home-made goods prepared for profit are no more likely to cause illness than those prepared for charity.

It is my understanding from reading the legal documents in this case that New Jersey only allows the sale of foods made in a home-kitchen if it is both “not-potentially hazardous” and “prepared for sale or service at a function such as a religious or charitable organization’s bake sale.” N.J.A.C. 8:24-1.5. Below I discuss the safety of “not-potentially-hazardous” foods in general. I also discuss whether foods made for profit are more likely to cause illness than those prepared for charity.

A. Not potentially-hazardous goods are inherently safe.

Above, I discussed the safety of not potentially-hazardous baked goods, including those that are home-made. Other not potentially-hazardous foods are very safe as well, again including those that are home-made.

Other not potentially-hazardous goods include chocolate, hard candies, dried herbs and spices, dried cookies, and cake mixes.[11] All are considered not-potentially hazardous because they do not support the growth of bacteria, usually because these foods have insufficient available water.

There is also no indication that these foods are a safety risk when they are made in a home-kitchen. While it is impossible to prove a negative (i.e., that not potentially-hazardous homemade goods cannot cause foodborne disease), I am not aware of the involvement of any homemade not potentially-hazardous food being involved in an outbreak of foodborne disease.

B. Goods made for profit are as safe as those made for charity.

In addition, there is no reason that the safety of these goods would change depending on whether they were made for profit. Consider a batch of baked goods where half of them are sold at a church bake sale, and the other half is sold for profit. The method of distribution does not

[11] Honey and maple syrup are also examples of not potentially-hazardous foods. It is my understanding that the State of New Jersey allows the sale of these foods without licensure or other regulation, as long as they are sold directly to consumers and not at wholesale.

affect their safety. If foods made for profit use the same recipes and procedures used to make foods for sale for charities, they must be equally safe.

V. Conclusions

Based on the information reported above, I can state with a reasonable degree of scientific certainty that:

1. Not potentially-hazardous baked goods are safe.
2. There is no evidence or rational basis for concluding that not potentially-hazardous baked goods prepared in home kitchens would present a greater risk of foodborne disease than those prepared in licensed and inspected commercial-grade kitchens.
3. Not potentially-hazardous foods, such as cookies, breads, muffins, chocolates, hard candies, dried herbs and spices, dried cookie and cake mixes, and dried pastas, are safe.
4. There is no evidence or rational basis for concluding that not potentially-hazardous foods, such as those listed above, that are prepared in home kitchens would present a greater risk of foodborne disease when they are made for profit than when they are made for charity.

November 16, 2018

Thomas J. Montville, Ph.D.

Compensation

I am being compensated at the rate of $345 per hour.

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Chapter 24 of the State Sanitary Code, codified at N.J.A.C. 8:24-1.1 to 8:24-10.2.