Introduction

Every year in the United States, one out of six Americans gets sick from foodborne disease, resulting in approximately 128,000 hospitalizations and 3,000 deaths, according to the Center for Disease Control (CDC, 2011). These surprising numbers are often the result of *Salmonella* and *E. coli* O157:H7, two microorganisms that have been the causative agents for foodborne outbreaks worldwide. Although the presence of *Salmonella* and *E. coli* in a variety of raw ingredients is well understood, many are unaware of the risks of these microorganisms in one of the most common ingredients of all: flour.

Low-moisture foods and ingredients haven’t traditionally entered the discussion in terms of food safety, primarily because these products don’t offer welcoming environments for microorganism growth. Yet, *Salmonella* has been implicated in several foodborne outbreaks in low-moisture foods, including chocolate, powdered infant formula, raw almonds, toasted oat breakfast cereals, dry seasonings, paprika-seasoned potato chips, infant cereals and peanut butter, according to the Grocery Manufacturers Association (GMA, 2004).

Flour, a low-moisture ingredient, has also been associated with foodborne outbreaks. While most flour-based products undergo a validated kill step at the point of production, such as baking or cooking, many other products may be at risk.

In 1952, an outbreak of *Salmonella* Paratyphi B phage type 1 occurred in New South Wales, Australia, in which flour was suspected, however, the microorganism was not isolated from the flour (Dack, 1961).

In 2005, 25 people in the United States were sickened with salmonellosis due to cake batter ice cream. In this case, a dry cake mix that was designed to be baked was added to a pasteurized sweet cream base. Although flour was not the determined ingredient of contamination, the Food and Drug Administration (FDA)
Foodborne Outbreaks
(continued)

The effects of flour milling and the microbiological quality of flour have been investigated both in the United States and abroad to better understand the potential food safety risks. Studies have shown that the milling process has little effect on the microbiology of wheat flour other than removing the outer bran of the wheat kernel (Richter et al., 1993). Typically, the dry milling process concentrates in excess of 90% of aerobic bacteria present on wheat into the bran and germ fractions (Sperber et al., 2007). Flours with lower bran or ash content typically have the greatest reduction in microbial populations.

Over the 1997-98 and 1998-99 wheat seasons, raw wheat, in-process wheat flour and finished wheat flour in Australia were analyzed for various microbiological populations (Berghofer et al., 2003). E. coli was not recovered in raw wheat; however, tempered wheat was contaminated at 14% and finished wheat flour was contaminated at 1%. The level of E. coli in finished wheat flour was 9 MPN/g.

In 1989, a total of 4,796 flour samples from various wheat types and seasons of milling were analyzed for indicator microorganisms (aerobic bacteria, coliforms, E. coli, yeast and mold) and Salmonella. In general, there were little differences in populations of aerobic bacteria, coliforms, yeast and mold across wheat types and season of milling. The overall average incidence of E. coli and Salmonella was 12.8% (n=3,350) and 1.32% (n=3,040), respectively (Richter et al., 1993).

A microbiological survey of milled cereal grains was also conducted (mostly from 2003 to 2005) using routine data from North American dry-milling operations (Sperber et al., 2007). For wheat flour, the average levels of microbiological populations were: aerobic bacteria at 4.41 log CFU/g, coliform bacteria at 3.64 log CFU/g (Petrifilm method), E. coli at 0.84 log CFU/g (Petrifilm method), mold at 2.58 log CFU/g, and yeast at 1.79 log CFU/g. Levels of coliform bacteria and E. coli were lower when MPN methods were reported. Salmonella was present in 0.14% of wheat flour (n=4,358).

Microbiological Quality of Flour

warned food manufacturers, retail and foodservice operators that Salmonella is known to be present in flour and other ingredients that might be listed on the dry cake mix label. The FDA also commented that dry cake mix should not be considered ready-to-eat (RTE) if it has not been processed to ensure it is safe to consume without further cooking (FDA, 2005).

In 2008, flour traced back to the retail shelf was implicated in a Salmonella outbreak in New Zealand. The evidence was not conclusive, but the results of the investigation indicated that individuals with the infection (especially children) were more likely to have eaten the uncooked flour in homemade play dough, and raw cake and batter mixes. Sixty-six cases of illness were reported, of which eight patients were hospitalized (Egelezos, 2010).

Salmonella is not the only pathogen that has been related to an outbreak caused by a product containing flour. In 2009, prepackaged, ready-to-bake cookie dough was recalled due to E. coli O157:H7. The outbreak resulted in 77 consumers of unbaked dough becoming ill. Thirty-five patients were hospitalized, and ten developed life-threatening hemolytic-uremic syndrome. (Neil et. al., 2011). Flour suspected to be tainted with E. coli O157:H7 that was used in the cookie dough remains the prime suspect for this foodborne illness event. It should be noted that flour is typically purchased in very large quantities for commercial use in food products. If the flour contains pathogens, a single purchase can contaminate multiple lots of finished product, which is a distinct possibility in the cookie dough incident. CDC investigators issued a report after the outbreak that stated: “Foods containing raw flour should be considered as possible vehicles of infection of future outbreaks of STEC (Shiga toxin-producing E. coli) or Salmonella infections. Food processors should consider the use of pasteurized flour in ready-to-cook or ready-to-bake foods that are likely to be consumed without cooking or baking, even though label statements may warn against consuming uncooked product” (Neil et. al., 2011).
There are two popular misconceptions regarding flour and food safety risks. The first is that pathogens such as *Salmonella* are not of importance in low-moisture ingredients simply because these ingredients do not support the growth of the microorganism. On the contrary, *Salmonella* does not need to grow to cause illness; in some instances infection has occurred from consuming low-moisture products contaminated with less than 1 cfu/g depending on the host, the product, and the *Salmonella* strain (GMA, 2004). It’s also important to note that flour may be added to environments that are more receptive to growth, such as batters and mixes.

The second misconception is that sample testing is a reliable means to assure food safety. Microbiological testing of a production lot of a food product does not guarantee the whole of the lot to be pathogen free. Production lots are usually very large, so only a fraction of a lot can be tested. Pathogens generally are not homogeneously distributed throughout the lot; they tend to clump together in groups. Therefore, a sample that is tested for the pathogen can return a negative result, when indeed other areas in the lot may contain pathogens.

Accordingly, when testing for pathogens, the probability of acceptance based on incidence rate is important. For a lot where 5% of the samples are contaminated, analyzing one sample will yield a 95% chance that you are accepting a contaminated lot. Testing 300 samples would give a less than 0.5% chance of accepting a contaminated lot (Table 1). The challenge is that testing to this magnitude is not realistic because it’s cost-prohibitive.

### Table 1

<table>
<thead>
<tr>
<th>n</th>
<th>For lots with =.05 (5% of samples are contaminated)</th>
<th>For lots with =.01 (1% of samples are contaminated)</th>
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<tbody>
<tr>
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<td>Probability of Acceptance of lot</td>
<td>Probability of Rejection of lot</td>
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<td>0.05</td>
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<td>300</td>
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</table>

Probabilities of Acceptance of Lots Containing Indicated Proportions of Defective Sample Units.

Since microbiological testing does not guarantee a safe food product in all applications, it is important to understand how to mitigate the risk of pathogen contamination in flour for use in ready-to-cook or ready-to-eat foods.

Ardent Mills has developed a solution for flour: SafeGuard® Flour and the SafeGuard Treatment and Delivery System. SafeGuard’s lethality treatment maintains flour’s natural flavor, color, absorption, appearance and gluten functionality while achieving up to a 5-log validated pathogen reduction. Although treated flour options have existed for some time, the effects on the functionality and taste of flour have limited their applications. Because of its versatility, applications for SafeGuard flour include refrigerated biscuit and cookie dough, pizza crusts, frozen doughs, cereals, retail packaged flour, brownie/cake mixes and ready-to-cook meals. The SafeGuard Treatment and Delivery System can also produce flakes, whole kernels/seeds and custom grain blends for RTE products.

For manufacturers, it’s also important to consider how flour shipments will be received: in bag or bulk. Bagged SafeGuard flour is treated in the bag then shipped. Ardent Mills has also made SafeGuard flour available in bulk, a first for the industry. In designing the bulk SafeGuard Treatment & Delivery System, Ardent Mills took a holistic approach and considered all aspects of delivering SafeGuard flour products to the customer. Spouting and bins were designed for highly effective cleaning and sanitizing, using a process that exceeds common flour-milling standards. The SafeGuard fleet of trailers (See figure 1) contains fewer hatches, aerators and penetrators, and
To learn more about SafeGuard or to assess your product’s flour safety risk, contact your account manager, visit ardentmills.com or call (888) 685-2534.


