Factors Contributing to Incidences of Foodborne Illness from Manufactured Foods:

2015 – 2018

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Author Note

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FOODBORNE ILLNESS FACTORS IN MANUFACTURED FOODS

Abstract

Foodborne illness factors specifically tied to manufactured food products are not well known. Seven states that participate in the Manufactured Foods Regulatory Program Standards (MFRPS) and one that does not were surveyed to determine the contributing factors and outcome of environmental assessments performed in response to foodborne illnesses resulting from ready-to-eat (RTE) manufactured foods between September 2015 and September 2018. Contributing factors fell into one of five categories: cross-contamination of ingredients, unsanitary conditions, improper processing (including lack of a kill step), improper holding temperature, and improper labeling. The study found that improper processing was the most common contributing factor in the 16 investigations where at least one contributing factor was identified. Of the 14 improper processing occurrences, six were for unpasteurized dairy products. The study concluded that environmental assessments and factor identification is rarely performed by regulators in response to foodborne illness attributed to manufactured foods. Of the eight states that did report data over the three-year period, half of them only conducted one environmental assessment in response to a suspected manufactured food related illness. The limited amount of data precluded definitive recommendations. However, the study did recommend that states should conduct environmental assessments in support of foodborne illness investigations implicating a manufactured food and follow-up on any investigations handed over to regulators in other jurisdictions. The study also recommended that this study be repeated on a national basis for a five-year period as well as analyzing Rapid Response Team (RRT) program Capability Assessment Tools data.
Keywords: foodborne illness, manufactured foods, contributing factors.
Factors Contributing to Incidences of Foodborne Illness from Manufactured Foods

**Background**

The CDC estimates that each year 48 million people get sick from a foodborne illness, 128,000 are hospitalized, and 3,000 die (Scallan, Griffin, Angulo, Tauxe, & Hoekstra, 2011). Based on investigation data analyzed by the CDC and FDA, the FDA Food Code identifies five risk factors that directly relate to food safety concerns within food service and retail food stores: food from unsafe sources, poor personal hygiene, inadequate cooking, improper holding/time and temperature, and contaminated equipment/protection from contamination (FDA, 2013). These risk factors are addressed in the Food Code, which is used as a basis for food safety inspections throughout the nation at retail and food service establishments. The FDA Food Code does not address food safety concerns specific to manufactured foods or the food manufacturing environment. No similar risk factor identification and rank exists on the manufactured food side.

Foodborne illnesses are usually initiated at the retail or food service link to the consumer. Only by an investigation involving traceback can a regulator determine if a manufactured food product is implicated. Manufactured foods, such as ice cream and peanut butter, have been linked to high profile outbreaks that have sickened hundreds and resulted in several deaths. In each of these outbreaks, an investigation was conducted that identified possible contributing factors that could have led to product adulteration.

The Manufactured Food Regulatory Program Standards (MFRPS) established a uniform basis for measuring and improving the performance of manufactured food
regulatory programs in the United States. The MFRPS are “a critical component in establishing a national integrated food safety system” (FDA, 2016). Standard 5, Food-related Illness and Outbreaks Response, requires state programs to correlate and analyze environmental assessment data to identify contributing factors and antecedents that led to food contamination or adulteration causing illness, injury, or outbreak in order to be in compliance (FDA, 2016).

During a foodborne illness investigation, regulatory agencies may conduct an environmental assessment in coordination with other local, state and federal public health agencies to try to identify the root cause of the contamination. “An environmental assessment is an investigation to learn what factors may have contributed to an outbreak of foodborne illness or a food contamination event” (FDA, 2019). Environmental assessments are not routine regulatory inspections of a facility but rather focus on determining the contributing factors that lead to product adulteration. An examination of multiple foodborne illness investigations, all related to manufactured food products, may allow for the identification of the most common contributing factors identified during environmental assessments. Once these are identified, food safety regulators and industry can determine the course of actions to mitigate them.

**Problem Statement**

The types and prevalence of contributing factors to foodborne illness specific to manufactured foods is not well understood.

**Research Questions**
1. What are the contributing factors identified during environmental assessments carried out as part of foodborne illness investigations linked to ready-to-eat manufactured foods?

2. What implications can be drawn from the patterns found in contributing factors identified during environmental assessments carried out as part of foodborne illness investigations linked to ready-to-eat manufactured foods?

**Methodology**

Of the 42 states with MFRPS programs, 16 were selected for this study: California, Florida, Georgia, Indiana, Iowa, Maryland, Massachusetts, Michigan, Minnesota, New York, North Carolina, Pennsylvania, Texas, Virginia, Washington, and Wisconsin. Oregon, while not a MFRPS state, was also contacted. These states were chosen both due to their MFRPS participation as well as their size, as their population constitutes about 63% of the total U.S. population.

The study began with a telephone survey to the 17 states. They were asked about the availability of information related to their foodborne illness investigations where environmental assessments were conducted and contributing factors were identified in illness/outbreaks implicating manufactured foods during a three-year period, September 2015 to September 2018. The states were requested to provide a summary of investigation information but not individual investigation reports, firm names, or consumer information. Eight states were able to provide the requested data, constituting about 36% of the U.S. population. In some cases, the state programs provided the information in the form of their Rapid Response Team (RRT) Capability Assessment Tool, (CAT) as these states activated their RRT for any foodborne illness investigation.
One state reported that a recent data breach had resulted in losing most of the pertinent data. The other states that did not provide data reported that they had not conducted any environmental assessments related to foodborne illness linked to manufactured foods due to lack of resources and/or jurisdictional boundaries, i.e., the implicated product was manufactured in another state/country; or no illnesses were linked to manufactured foods during the time period requested.

The data from the eight reporting states was examined for the three-year period and only information regarding illness investigations and environmental assessments into ready-to-eat manufactured food products was considered a qualifying investigation. Contributing factors identified during qualifying investigations by the states were recorded.

**Results**

There was a total of 16 qualifying investigations among the eight states that reported data. Of the eight states that did report data over the three-year period, half of them only conducted one environmental assessment in response to a suspected manufactured food related illness.

Some investigation summaries noted multiple contributing factors; all identified contributing factors were counted. Contributing factors were divided into five categories: cross-contamination of ingredients, unsanitary conditions, inadequate processing (including lack of a kill step), improper holding temperature, and improper labeling. These categories were not developed prior to the study but were identified while reviewing the data. All contributing factors identified by the state program environmental assessments
were counted in one of the above categories; and the total for each category was then summed.

The most prevalent contributing factor was *improper processing* with 14 occurrences. *Cross contamination* was identified as the second most prevalent factor with six occurrences, followed by *unsanitary conditions* with five (see Table 1).

**Table 1**

*Contributing Factors Found in Qualifying Investigations*

<table>
<thead>
<tr>
<th>Contributing Factor</th>
<th>Number of Occurrences</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of, or Improper processing</td>
<td>14</td>
</tr>
<tr>
<td>Cross Contamination</td>
<td>6</td>
</tr>
<tr>
<td>Unsanitary Conditions</td>
<td>5</td>
</tr>
<tr>
<td>Improper Temperature Holding</td>
<td>3</td>
</tr>
<tr>
<td>Improper Labeling</td>
<td>2</td>
</tr>
</tbody>
</table>

The contributing factor identified most often, *lack of or improper processing*, is primarily linked to the selling of raw dairy products. Six of the 14 occurrences were for raw—that is, unpasteurized—dairy products. While raw milk is prohibited in interstate commerce, it remains legal to sell in many states through various means (pet food loopholes, cow-shares, and in some states legal sale at retail.)

Three investigations included a lack of permitting/regulation as a factor. This factor was not considered as a contributing factor for this study as a lack of permit and/or inspection does not directly cause adulterated product. The other identified factors may have been mitigated with proper permitting and inspection; however, in and of itself proper permitting and inspection (or lack thereof) does not contribute to product adulteration.
Conclusions

Based on the low numbers of environmental assessments reported, the study concluded that environmental assessments and factor identification is rarely performed in response to foodborne illness attributed to manufactured foods; either through lack of resources, jurisdictional issues, or lack of opportunity (i.e., no applicable illnesses during the study period.)

There was some cross-over between the results from this study concerning foodborne illness implicating a manufactured food product versus the top five contributing factors to foodborne illness at retail as identified by the CDC. *Improper hot/cold holding* is directly identified in both retail and manufacturing as a contributing factor to foodborne illness. Likewise, *unsanitary conditions* and *cross contamination* are similar to the retail foods *contaminated equipment/protection from contamination* risk factor.

While improper processing was the most common risk factor identified the data was skewed by one product—unpasteurized milk—as well as the limited amount of data in general. These two conditions preclude any definitive recommendation regarding risk factors within a manufacturing environment.

The limited number of states that had the requested information, and the response from some states that jurisdictional and resource issues prevented them from conducting foodborne illness environmental assessments pertaining to manufactured foods, not only resulted in a small samples size but was also disconcerting. As such, any definitive conclusions pertaining to the trending of foodborne illness risk factors associated with manufactured foods is difficult to reach.
Recommendations

1. The Manufactured Foods Regulatory Program Alliance should consider encouraging states to conduct environmental assessments in support of foodborne illness investigations implicating a manufactured food. These assessments can directly address issues that relate to the root cause of the foodborne illness being investigated. These assessments should, also, be shared with any other regulatory agency involved in the investigation. Completing foodborne illness related environmental assessments is particularly important for states who wish to be in full conformance with Standard 5 of the MFRPS.

2. This study could be repeated on a national basis for a five- or ten-year period. As more states move toward full compliance with Standard 5 of the MFRPS, the data available for study will become more robust and thus better suited for recommendations.

3. Compiling data from all of the RRT program states over multiple years also could yield more robust data and thus offer the opportunity for recommendations. This data includes foodborne illness investigations for RRT programs that utilize their RRT for foodborne illness investigations. Acquiring this data may be easier than surveying states as RRT programs are required to submit their CAT annually to the FDA.

4. The incidences of foodborne illness tied to raw milk should be noted, and the appropriate intervention strategies should be applied as needed.

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References


