The avoided and potentially avoided food safety risks addressed by FDA’s import alert program

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¹ These views are solely those of the author and are not the official views of FDA
Objective

Estimate the food safety risks addressed by FDA’s import alert program

Use estimates of lab test accuracy found in the literature to estimate the avoided risks as well as the additional food safety risks that go undetected by the program

Use a tool developed for FDA to estimate the number of illnesses from poor food handling practices at the retail and household levels, to estimate avoided illnesses

Highlight the connection between tests used as an enforcement tool and safety practices by all food suppliers potentially subject to being tested
FDA’s import alert program and lab tests

- At least 16,682 food shipments that were refused entry over 2005-2013 were associated with an import alert (J. Bovay)

- During FY 2017 FDA reports there were 243 import alerts (ORA Accomplishments)

- Import alerts may apply to products, countries, manufacturers, packers, and importers.

- Import alerts allow FDA to detain shipments of potentially contaminated products without physical examination

- Owners of detained food provide negative lab test findings for the food to be released

- Negative findings from tests of five consecutive shipments are generally required to be removed from the import alert

- We estimate 96 - 98 percent of these test findings are negative
How accurate are lab tests? Quite accurate!

The **sensitivity** of a test reflects its ability to detect a contaminant when the contaminant is present. The more sensitive the test the lower the probability of a false negative – which would mistakenly result in allowing an unsafe shipment of food to enter the US.

The **specificity** of a test reflects its ability to exclude non-contaminants from triggering a positive result. The more specific the test the lower the probability of a false positive – which would mistakenly result in rejecting a safe shipment of food at the border.

Zweitering and den Besten report the sensitivity and specificity for 11 alternative test method–pathogen combinations when compared to a gold standard method.

The mean sensitivity was 97.4 percent (false negative = 2.5 percent), and the mean specificity was 90.9 percent (false positive = 9.1 percent).
Framework used to measure the avoided and potentially avoided illness

- Apply rates of false negatives and false positives estimated from Zweitering and den Besten to internal FDA data
- From OASIS we calculate the mean and variance of kg/shipment for 26 food product categories
- Apply the serving sizes reported in the Serving Size Final Rule to the kg/shipment from OASIS
- Apply information from the Investigations Operations Manual (IOM) on the no. of sub-samples in a full sample to estimate the no. contaminated servings in a shipment given that the full sample tests positive
- Calculate the numbers of observed positive servings, unobserved false positive servings and unobserved false negative servings
- Input the no. of contaminated servings into FDA’s Food Handling Practices Model to convert to illnesses
- Value the number of illnesses by applying the value of a QALD loss from a foodborne illness found in the literature
Use OASIS data to estimate the kg per shipment and $ per shipment

We cleaned 2016 OASIS data which contained over 12 million observations of food shipments to account for observed systematic data entry errors

• Observed systematic errors made by importers when filling out entry forms include conflating the number of kg per shipment with the number of kg per package (e.g., 1,000 kg per shipment versus 1,000 kg per package for the same shipment)

• This type of data entry error leads to reporting some not credible large shipment sizes

• We considered as outliers any observation that lay outside the interval $0.01 per kg to $100 per kg

• Assumed a lognormal distribution and estimate the 90 percent range in kg per shipment to be 13 kg to 26,000 kg, with mean of about 8,500 kg
The mean $/kg by OASIS product category
Estimate the no. of food servings in a shipment

• We applied the average Reference Amount Customarily Consumed reported for 21 food categories in the Serving Size Final Rule to the means and variances of kg per shipment found for the corresponding OASIS product categories

• We assumed a lognormal distribution and estimate the no. of servings per shipment is 950 to 1,800,000, with a mean 580,000 servings per shipment
Estimate the no. of contaminated servings given a positive test result

- A sample may comprise, say, 10 to 60 sub-samples (~ 2.5 lbs.), depending on food and contaminant of interest (IOM)
- Parts of each sub-sample are combined to form a composite sample which is tested by the lab

We assume:
- The full sample (including all sub-samples) is representative of the entire food shipment, and
- The composite sample is representative of the full sample

If the test of a composite sample is found to be positive, then we estimate the percent of contaminated servings in the sample is between 2 percent and 71 percent, with a mean of 27 percent.
We estimate the annual no. of contaminated servings of food subject to an import alert

<table>
<thead>
<tr>
<th></th>
<th>5 percent estimate</th>
<th>mean</th>
<th>95 percent estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Observed positives (unsafe)</td>
<td>49,440</td>
<td>83,734,934</td>
<td>278,796,143</td>
</tr>
<tr>
<td>B. Observed positives + unobserved false negatives (unsafe) – unobserved false positives (safe)</td>
<td>60,853</td>
<td>125,807,941</td>
<td>418,766,764</td>
</tr>
<tr>
<td>Difference between A and B</td>
<td>-247,859</td>
<td>41,352,450</td>
<td>84,469,787</td>
</tr>
</tbody>
</table>
Use the Food Handling Practices Model to convert contaminated servings to illnesses

• The FHPM (ERG) computes the no. of illnesses from servings of food given baseline probabilities of contamination at the source, and growth and contamination at retail and household levels

• There are 7 categories of food used by the model - dairy, eggs, meat, poultry, produce, seafood, and water, and 17 potential microbial contaminants used by the model

• The model is calibrated so that baseline rates of contamination at the source and growth and contamination at retail and household levels yields the annual no. of foodborne illnesses reported in Scallan, et al. (47.8 million)

• We input the no. contaminated servings from import alerts, assume all are contaminated at the source with no further contamination, growth or cross-contamination at retail or household levels
FHPM estimates of the annual no. of illnesses avoided and potentially avoided from food subject to an import alert

<table>
<thead>
<tr>
<th>Annual illnesses from contaminated servings assuming:</th>
<th>5 percent estimate</th>
<th>Mean</th>
<th>95 percent estimate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoided illnesses (observed positives only)</td>
<td>1,931</td>
<td>6,672</td>
<td>12,116</td>
</tr>
<tr>
<td>Avoided and potentially avoided illnesses (observed positives + unobserved false negatives – unobserved false positives)</td>
<td>2,898</td>
<td>9,949</td>
<td>18,019</td>
</tr>
<tr>
<td>Difference</td>
<td>-5,942</td>
<td>3,276</td>
<td>12,600</td>
</tr>
</tbody>
</table>
Use Minor, et al. to value the QALD losses from foodborne illness

Minor, et al. estimate the average value of a QALD loss from a foodborne illness of between $528 (using a VSL of $4.6 million) to $1,723 (using a VSL of $15 million)

<table>
<thead>
<tr>
<th>Total avoided and potentially avoided QALD losses from:</th>
<th>5 percent</th>
<th>Mean</th>
<th>95 percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observed positives</td>
<td>$1,841,496</td>
<td>$7,509,480</td>
<td>$15,394,326</td>
</tr>
<tr>
<td>Observed positives + false negatives - false positives</td>
<td>$2,799,220</td>
<td>$11,196,740</td>
<td>$23,307,619</td>
</tr>
<tr>
<td>Difference in QALD loss estimates</td>
<td>-$6,755,425</td>
<td>$3,687,260</td>
<td>$15,833,914</td>
</tr>
</tbody>
</table>
Would better tests result in improved food safety practices?

• Better test accuracy increases the probability that unsafe food would be removed from the market

• This may reduce the supply of “safe” food in the short run and encourage safety practices by all food suppliers potentially subject to an import alert to where the expected marginal benefit from better safety practices is equal to the marginal costs

• Expected marginal benefit = $ per shipment x P(inspection) x ΔP(positive test), holding constant the effectiveness of the better food safety practice, where, ΔP(positive test) = ΔP(false negative) – ΔP(false positive)

• All else equal, better food safety practices would more likely result from better tests: a. the higher the $ per shipment, b. the more likely an inspection, and c. the more effective the safety practice
Some take-aways

- We estimate the avoided and potentially avoided food safety risks addressed by import alerts is between $2.8 million and $23.3 million annually.

- Tests are generally accurate: we estimate expected false negatives = 0.025, and expected false positives = 0.091.

- Food safety practices are generally of high quality: 96 - 98 percent test findings from food subject to an import alert are negative.

- Test inaccuracies may result in underestimates of the risks from foods.

- Tests are used as an enforcement tool and better test accuracy may affect long term food safety practices by all food suppliers potentially subject to being tested.
References

• Bovay, John; “FDA Refusals of Imported Food Products by Country and Category, 2005-2013;” USDA, ERS, Economic Information Bulletin Number 151, March 2016

• ORA Facts, [https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ora/ucm555525.htm](https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ora/ucm555525.htm)

• Zweitering, Marcel H, and den Besten, Heidy MW, “Microbial testing in food safety: effect of specificity and sensitivity on sampling plans – how does the OC curve move?” Current Opinion in Food Science, 2016 12:42-51

• 2016 OASIS information on imported lines for 26 food product categories

• FDA, Serving Size Final Rule 81 FR 34000, May 27, 2016

• FDA, “Modeling the Effects of Food Handling Practices on the Incidence of Foodborne Illness.” ERG Task No. 0193.16.004.001, March 18, 2009