Lessons Learned from the Hydrolyzed Vegetable Protein Incident

Jenny Scott
FDA CFSAN Office of Food Safety
The Beginning

- FDA was notified on 2/5/10 (Company A) and 2/6/10 (Company B) of *Salmonella* Tennessee in HVP produced by Company C.
  - Positive initially found in 2 lots of finished product made by Company A
  - Investigation of the raw materials indicated the source was HVP
  - Other products made with the same lot of HVP had been shipped to Company B
Findings of Company C

- Environmental samples were positive for \textit{Salmonella}
  - collected 1/13/10, reported 1/21/10
  - collected 1/26/10, reported 2/8/10
  - collected 2/8/10, reported 2/18/10
- Subsamples of the implicated lot were positive for \textit{Salmonella} (2/19/10)
FDA Inspection of Company C
(2/12/10 to 3/4/10)

1. Failure to manufacture, package and store foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination. (Company C testing)

2. Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food-contact surfaces. (Residues on “cleaned” equipment)
3. The plant is not constructed in such a manner as to allow floors to be adequately cleaned and kept clean and kept in good repair. (Cracks, crevices; environmental positives)

4. Plumbing is not adequately installed and maintained to provide adequate floor drainage. (Standing water; environmental positives)
FDA Sampling

- Environmental samples (numerous) were positive (including food contact surfaces) for multiple serotypes of *Salmonella*, including *Salmonella* Tennessee with the same PFGE pattern as detected by Company A.
- FDA recovered *Salmonella* with the same PFGE pattern from HVP on 3/2/10.
Company C Actions

• Stopped distribution of HVP on 2/15/10
• Stopped manufacturing HVP on 2/20/10
• On 2/24/10, sent letter to customers to quarantine HVP with production dates of 9/17/09 and later
• After receiving FDA environmental results on 2/25/10, voluntarily recalled all HVP products manufactured since 9/17/09
FDA Considerations

- Hydrolysis step (heat, acid, pressure) would inactivate *Salmonella*.
- The drying step may also be lethal to *Salmonella*, but it had not been validated.
- *Salmonella* contamination was widespread in the facility.
- The positive HVP, manufactured 9/17/09, had a shelf life of 2 years.
- Multiple HVPs were made on the same production line and could have been contaminated.
FDA Considerations

• The PFGE pattern of the *Salmonella* Tennessee was new in the PulseNet database.
• There were no reports of illness associated with the HVP.
• HVP is used in a wide variety of products.
• HVP is used in many products that undergo heat treatments that would mitigate the risk from *Salmonella*. 
FDA Industry Calls
(2/26/10 and 3/1/10)

- Noted Company C recall and explained recall timeframe.
- Advised industry that the recalled bulk HVP product should be destroyed or reconditioned according to FDA-approved procedures.
- Noted that many uses of HVP will mitigate the risk, but others would not.
- Firms should consider recall of food not subjected to validated kill step. FDA to provide support for assessing adequacy.
- Firms should assess whether introduction of recalled product could have contaminated the environment.
Other FDA Actions

- FDA press release; posted company press releases
- Searchable database of recalled products
- Q&A for consumers
- Q&A for industry
FDA Advice to Industry

• Could not continue to use the HVP, but could use an ingredient containing the HVP if the ingredient or product would receive a validated kill step for *Salmonella* (e.g., cooking by the manufacturer, a food service operator, or the consumer).

• Recommended that ready-to-eat products be recalled if the products have not been subjected to a validated *Salmonella* kill step (e.g., a 5-log reduction, or the equivalent).
FDA Advice – Ready-to-Cook Products

• FDA believes cooking instructions validated for killing Salmonella will reduce to negligible levels or eliminate the risk from Salmonella, given the small levels of HVP typically present in these types of food products. Therefore, the agency does not believe at this time that recall of these products is necessary to protect public health. FDA will continue to assess the risk of illness through targeted surveillance, testing and risk modeling with respect to these products and will take further action if warranted.
HVP Recalls

- Searchable database of products recalled as a result of HVP from Company C lists 177 entries as of April 1, 2010.
  - Bouillon Products
  - Dressing and Dressing Mix Products
  - Flavoring Base and Seasoning Products
  - Frozen Food Products
  - Gravy Mix Products
  - Prepared Salad Products
  - Ready-to-Eat Meal Products
  - Sauce and Marinade Mix Products
  - Snack and Snack Mix Products
  - Soup/Soup Mix and Dip/Dip Mix Products
  - Spread Products
  - Stuffing Products
Reportable Food Submissions & Entries (Sept 8, 2009 – Sept 7, 2010)

March 2010: 1001 of the submissions were due to Salmonella in HVP
What did we learn?

- The benefits to FDA of the RFR portal in making the agency aware of contamination events and documenting the distribution of contaminated ingredients
- The utility of finished product testing in uncovering contamination events
- The importance of root cause analysis in identifying the source of contamination
What did we learn?

• The benefits of a good environmental testing program in identifying environmental contamination that could potentially lead to product contamination

• The importance of good supplier control programs

• The importance of firms knowing the impact of pathogen inactivation steps for their products (validation), including those to be delivered by the customer or consumer
Final Points

- Ingredient contamination events can be complicated.
- Adulterated ingredients should not be used unless they have been reconditioned.
- When contaminated ingredients have already been used in products, processes that have been validated to eliminate the contaminant may mitigate the need for a recall.
- As general policy, FDA believes that manufacturers should not rely on consumers to deliver a kill step.
- Ingredients are food and may be RTE; they should be produced under GMPs, applying appropriate preventive controls and verifying the adequacy of controls.
Lessons Learned

• The lessons learned from this incident have broad implications for the entire food industry, but food safety will be enhanced if appropriate actions are implemented as a result.
Thank You