

Salmonella Tennessee Contamination Causes Major HVP Recall

On February 26, 2010, Basic Food Flavors ("Basic Food") of Las Vegas, Nevada, initiated a recall of its hydrolyzed vegetable protein (HVP) in powder and paste form produced since September 17, 2009 due to Salmonella Tennessee contamination. The FDA was made aware of the contamination when a third-party company tested the ingredient and reported its contamination finding through FDA's Reportable Food Registry (RFR). The RFR is an electronic portal for industry to report when there is reasonable probability that an article of food will cause serious adverse health consequences.

Working with the FDA, Basic Food has notified its customers that it is recalling its affected HVP. In turn, Basic Food customers are recalling food products manufactured with the recalled ingredient.

What products are affected?

HVP is a common ingredient used most frequently as a flavor enhancer in many processed foods, including soups, sauces, chilis, stews, hot dogs, gravies, seasoned snack foods, dips and dressings. So far, over 200 products manufactured in North America have been recalled by a number of companies. This recall has the potential to be as large as the peanut paste recall in 2009.

According to the FDA as of March 24, 2010, no illnesses are known to be associated with the contaminated HVP. In coordination with the Centers for Disease Control and Prevention, the U.S. Department of Agriculture, other federal agencies, and state health departments, FDA is closely monitoring and assessing the potential risks of illness from affected products. The Canadian Food Inspection Agency (CFIA) continues to monitor the situation and to assess the risks related to HVP in Canada.

What should a company do if it manufactured, processed, packed, or held products affected by the recall?

The first step, if a facility has manufactured, processed, packed, or held food affected by the recall, as per Section 417(d) of the Federal Food, Drug, and Cosmetic Act (21 USC 350f), would be for the responsible party to submit a report as soon as possible, but no later than 24 hours, after determining that an article of food is reportable. A responsible party is the person who submits the registration under section 415(a) of the FD&C Act (21 USC 350d) for a food facility that is required to register, where such article of food is manufactured, processed, packed, or held. Companies will then need to determine, depending on whether they are a manufacturer, processor, packer, or holder of products containing the recalled HVP or the bulk HVP itself, if they need to institute a recall and/or render the Salmonella Tennessee bacteria inactive.

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What does a manufacturer, distributor, or food service establishment do if it possesses the recalled bulk HVP?

According to FDA, bulk HVP from Basic Food may be reconditioned using validated procedures to inactivate Salmonella. Companies should submit their reconditioning packages for review to the Center for Food Safety and Applied Nutrition and their local FDA District Office Recall Coordinator with:

- An explanation of how and where the reconditioning will take place;
- Type of process;
- Processing parameters, including all critical factors that inactivate Salmonella; and
- Procedures to prevent recontamination of the reconditioned HVP.

All reconditioning must be conducted under applicable current Good Manufacturing Practices (cGMP).

Manufacturers, distributors, and food service establishments with recalled HVP that has not been incorporated into other products should discontinue distribution or use of the HVP unless it has been reconditioned by a process reviewed by the FDA.

The FDA expects establishments to take responsibility for ensuring that their processes are appropriately validated. If a firm has a concern about unique circumstances regarding specific products it may consult with FDA by contacting the Center for Food Safety and Applied Nutrition and local FDA District Office Recall Coordinators.

When is it appropriate for a manufacturer to continue to use or distribute an ingredient or product that has already incorporated the recalled HVP?

Per the FDA, it is appropriate for a manufacturer to use or distribute an ingredient or product received that contains the recalled HVP if the ingredient

or product will receive a validated kill step for Salmonella (e.g., cooking by the manufacturer, a food service operator, or the consumer). However, if the kill step or labeling with the kill step is not applied, the company should obtain a guarantee from its customers that the kill step will be applied.

Any ready-to-eat products should be recalled if the products have not been subjected to a validated Salmonella kill step (e.g., a 5-log reduction, or the equivalent). Conversely, if these products have been subjected to a validated Salmonella kill step, FDA does not believe at this time that a recall of these products is necessary. Products cooked in food service establishments to the minimum temperatures and times specified in the 2009 FDA Model Food Code 3 would be considered to have met this level of kill.

For manufacturers of ready-to-cook products with the recalled HVP, the 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 at this time, the FDA does not believe at that recall of these products is necessary to protect public health. The 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. The FDA expects establishments to take responsibility for ensuring that the cooking instructions provided on their products are validated.

What is meant by a "validated kill step for Salmonella"?

With respect to this situation, according to the FDA, a validated kill step is one that has been shown to adequately reduce Salmonella if it is present in a food containing the affected HVP. The FDA explains the meaning of "adequately reduce" to mean capable of reducing the presence of Salmonella to an extent sufficient to prevent illness. The extent of reduction sufficient to prevent illness usually is determined by the estimated extent to which Salmonella may be present in the food combined with a safety factor

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to account for uncertainty in that estimate. For example, if it is estimated that there would be no more than 1,000 (i.e., 3 logs) Salmonella organisms per gram of food, and a safety factor of 100 (i.e., 2 logs) is employed, a process adequate to reduce Salmonella would be a process capable of reducing Salmonella species by 5 logs. (From the FDA's "Guidance for Industry: Measures to Address the Risk for Contamination by Salmonella Species in Food Containing a Peanut-Derived Product as an Ingredient," March 2009.)

How Marsh Risk Consulting Can Help

Marsh Risk Consulting's (MRC's) Global Product Risk Practice can assist HVP-affected clients with managing and administering possible product recall actions and complying with any relevant regulatory requirements. MRC can help an organization:

- Understand accidental or intentional product tampering/contamination risks
- Understand risks associated with suppliers, licensees, and third-party manufacturers
- Evaluate the application of quality assurance processes and procedures throughout the supply/distribution chain
- Develop and implement consistent and tailored product recall processes and procedures, including the establishment of a product recall task force
- Train the product recall task force members
- Institute product loss accounting procedures
- Understand regulatory compliance demands and support related activities
- Assess risk mitigation and risk transfer mechanisms already in place and their applicability to the current situation

- Create and rollout internal and external communications plans
- Develop and implement financial and brand recovery plans, including claims management and litigation support, following a product recall

Contact Us

The Global Product Recall team, comprised of global regulatory compliance, supply chain, legal, and product traceability experts, has participated in over 5,000 product safety and product recall projects in 122 countries, including some of the largest global product recalls. We have helped numerous food and beverage companies and their suppliers reduce the likelihood of recalls, minimizing the financial effects as well as brand and reputational damage.

For further information about the HVP recall or how MRC can provide assistance, please speak with your local Marsh representative or contact:

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You can find additional information about our Global Product Risk Practice and related services on www.marsh.com or www.marshproductrecall.com.

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