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Legal Update

Voluntary Recalls Protect Risk In Two Ways

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Within the last two weeks, three major recalls have taken place by manufacturers of popular food products. Initially, Blue Bell ice cream imposed a recall as a result of eight cases of Listeria in Texas. This was followed by a recall by Sabra as a result of an inspection of hummus in a Kroger market in Port Huron, Michigan, which revealed potential for Listeria.

Listeria is a bacteria found in soil and water that can be tracked into a plant or carried by animals. It is difficult to get rid of since it contaminates a processing facility, partly because it grows well in refrigeration.

As recent as last week, Blue Bell Creameries issued a voluntary recall all of their products as a result of two samples of chocolate chip cookie dough ice cream testing positive for Listeria.

Recalls by companies are an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration (FDA). Both Blue Bell and Sabra have undertaken voluntary recalls as a result of the potential findings for Listeria. The FDA has put in measures such as voluntary notifications which are necessary to eliminate the unreasonable risk of potential harm and in cases where there is no practical means available to eliminate the risk[1]. Both these food companies are required to maintain written procedures for recalls of any of their food products, which must specify how the company will decide whether to conduct product recall and how the company will affect the recall should it decide that one is necessary.

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Both Sabra and Blue Bell's recent recalls are not unusual specifically in the food industry since both companies have protocols for randomly testing their food for multiple conditions including Listeria. This is simply another example of how food manufacturers and the FDA have multiple protocols in monitoring dangerous conditions in their product and protecting the public.

For companies to effectively determine whether recall is appropriate they must conduct a health – hazard assessment, plan a course of action, contact the FDA, and keep accurate records[2].

Conducting a health hazard assessment is a way of determining whether a recall may be necessary, and the impact that the failure may have on the health and safety to the public. The companies that are performing an assessment should retain outside experts to assist them on whether there is a true hazard to the public. The retaining of an independent expert will further insulate the company from potential liability.

If it is determined that the recall is necessary the company should take decisive action immediately. There should be in place a procedure for removing the product especially if it could cause the injury to the public. The timing is more important if there is a potential for harm.

After the health hazard assessment has been completed, the FDA should be contacted and documentation should be prepared containing all the details are necessary for the FDA to evaluate the product failure, how it will affect consumer safety, and whether the course of action is adequate.

It is imperative that the recall is well documented internally. All departments that are affected by the recall must documents that are consistent with the planned course of action. This is especially true if the recall has a significant effect on public health and is large in scope.

[1] 13 Fed. Proc. L. Ed §35:309
[2] Pharmaceutical Technology, January 2, 2011, Vol. 35, Issue I

***Mike Foley**'s practice focuses on commercial litigation, government contracting, construction, product liability, and municipal government liability. He has extensive trial experience in both state and federal courts prosecuting and defending contract disputes, defective product claims, municipal liability claims, and construction claims.*