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Know your post-sale risks and opp

Food-borne contamination and bioterrorism threats present many challenges to our food supply. While biological attacks have been rare, several points of vulnerability from farm to fork make it difficult to secure the entire chain.

In addition, certain production stages are highly concentrated, which may hasten the disease or contamination transmission.

Aside from the serious consumer health risks, food-borne illnesses from any source put the pork industry at risk legally and financially, and could damage a company's reputation. Companies, and individual employees, may be subject to criminal charges for processing, transporting or selling adulterated (unwholesome, unfit) food under various federal and state laws. Affected consumers also may file civil lawsuits, claiming adverse health consequences.

So the question is: How can a pork producer protect the health of consumers, his business and the industry as a whole?

Recall Decisions

If a food-safety issue arises, every company along the food chain should consider whether a post-sale warning and/or recall are appropriate. Voluntarily withdrawing food products from the market may suffice. But if a food product is "adulterated," the Food and Drug Administration or the Food Safety and Inspection Service may request a recall, particularly in urgent public-health situations where the firm has not voluntarily withdrawn the product.

While FDA and FSIS typically cannot order a recall, they may pursue legal actions, including court-enforced product seizure and/or plant closure if a company ignores a recall request.

Any recall strategy must consider the following:

- 1) The recall's depth, meaning how far along the distribution chain it will extend;
- 2) Whether and to what extent a public warning should be issued and how to disseminate key information to others in the food chain;
- 3) How to confirm that the recall is effective.

Executing a recall is a company's responsibility. Close cooperation with relevant agencies is expected before, during and after a recall to ensure that it and any necessary investigation is effective. This close cooperation also carries a benefit in civil litigation. Punitive damages are often the most damaging aspects of product liability lawsuits. Careful and responsive work with a federal agency to execute a recall can be a critical defense to plaintiffs' allegations that a company's actions were "willful and wanton."

Before the Recall

The most effective way to prevent food dangers, and identify and limit them quickly is through cooperation, coordination and accountability within a company and by each production-chain member. Agency guidelines encourage food companies to develop contingency plans for product recalls. Customer safety and business continuity are best protected if a written recall plan is drafted long before problems arise.

A typical plan identifies recall team members, the person designated to coordinate efforts with federal agencies, and the individual(s) responsible for communicating the recall to others in the food chain and the public. Still, a plan is only as good as its execution.

In addition to a recall plan, companies can protect consumers through proper manufacturing practices, education, training, testing and careful contingency planning.

Pork producers can protect themselves externally, as well. Vendor and supplier contracts should clarify liability, duties, insurance coverage and defense costs, which may help protect you if a problem arises somewhere else along the food chain. These contracts and relationships can result in better operating practices throughout the chain. In turn, this creates a safer end product for consumers and a better business environment.

Just as a recall plan's execution is critical, failure to ensure that quality and testing specifications are spelled out clearly in vendor and supplier contracts can leave you

holding the bag during a recall.

For example, materials that cannot be fed to ruminant animals due to the danger of BSE must be clearly labeled — 21 C.F.R. 589.2000(d)(1). Moreover, careful measures must be taken to avoid ruminant materials from commingling or cross-contaminating ruminant feed — 21 C.F.R. 589.2000(e)(1). Any company that manufactures, uses or disposes of animal feed can protect itself best by ensuring that all other companies along the food chain comply with these regulations.

If a food-safety issue surfaces, the ability to trace it to its original source will allow targeted investigations, health warnings or recalls. Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, companies that manufacture, process, pack, transport, distribute, receive, hold or import food must have records that identify the immediate previous sources and subsequent recipients of human or animal food products. Upon information that food is adulterated and poses serious health consequences, the FDA can request access to these records within 24 hours. Failure to provide such records can result in civil or even criminal liability.

After the Recall

Retaining documents that are relevant to a suspected contamination, as well as to sanitation and safety procedures, previous agency inspections and the recall itself is critical because FDA, FSIS, the Centers for Disease Control and Prevention or plaintiffs pursuing product liability claims may want the documents. Failure to retain them can be costly during litigation.

It's best to have a comprehensive electronic-discovery and document-retention plan in place before you ever need one. A good records-management policy is realistic, practical and tailored to the company's circumstances. It should address the creation, identification, retention, retrieval and destruction of information and records. It needs to outline how and when to suspend

ordinary record-destruction practices in order to comply with any anticipated or pending litigation, government investigations, audits and business needs.

News stories about people getting sick from everyday food items can damage a company's or industry's reputation for years. Implementing protective measures across the food chain before a food-safety issue surfaces will protect consumers, as well as your company's and the industry's reputations. Once an industry loses its goodwill with the public, the rules of regulation and litigation may be forever changed. Reputation is a valuable asset and should not be taken for granted. Every action may affect it.

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Checking off post-sale considerations

Here's a rundown of items that you need to address in order to best protect yourself, your business, the food chain, the industry and the consumer.

- Identify issues that warrant consideration as part of your strategic issues-management plan.
- Craft practical, cohesive strategies to address emerging issues.
- Strive for impeccable corporate conduct and best practices.
- Coordinate efforts internally and externally through carefully drafted contracts and close cooperation.
- Understand every part of the food chain that affects your product.
- Develop meaningful corporate compliance, education, investigation and enforcement programs.
- Develop a recall plan and identify key personnel internally and externally.
- Develop effective electronic-discovery and document-retention plans.
- Honor and protect the company's reputation and that of the U.S. pork industry.

The natural way.

Biomim

Which mycotoxins affect your pigs?

ZON, T2, DON

- Irregular heats
- Abortion
- Pseudo pregnancy
- Low conception rates
- Ovarian cysts
- Embryonic Loss
- Tail necrosis
- Nymphomania

AFB₁, T2, OTA

- Diarrhea
- Blood in faeces and urine
- Inflammation of bladder and kidneys

T2, DON, AFB₁, OTA, FUM

- Intestinal hemorrhages
- Damage of the kidneys
- Pale and fatty liver
- Porcine pulmonary edema (PPE)
- Increased water consumption

T2, DON

- Decreased feed intake
- Dermal and oral lesions
- Feed refusal
- Vomiting

T2, DON, AFB₁, OTA, FUM

- Decreased performance
- Immunosuppression
- Pancreatic necrosis

T2

- Dermal lesions

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