

Recall Readiness – A Primer for Manufacturers Before An Event

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Manufacturers of products strive to produce safe and effective products for many reasons, such as public responsibility and safety, customer expectations, contractual specifications, brand protection, liability avoidance, profit, and compliance with government regulations. However, as diligent and well-intended manufacturers typically are, there is always the possibility of a product defect or danger arising that can threaten those important goals. To mitigate or eliminate any negative impact on such goals, manufacturers need to be ready to expeditiously stop the continuing distribution of potentially defective products and evaluate regulatory, contractual, and other legal reporting and recall obligations.

If necessary, manufacturers may need to timely report a problem to an applicable regulatory body or bodies and possibly others and, potentially, plan and implement a recall. Due to the need for speed when a defect or danger becomes apparent, manufacturers must know in advance which regulatory bodies/regulations may apply to their products. Manufacturers must be mindful of any related contractual obligations, know when reporting or a recall may otherwise be required under statutory, regulatory, or common law, and know the applicable reporting and recall substantive and timing requirements.

Product manufacturers need to understand in advance which regulations or standards might apply to their products. Many federal, state, and local government entities regulate products depending on the nature of the product. Some of the more obvious examples include, but are not limited to, the [U.S. Consumer Product Safety Commission](#), the U.S. Federal Aviation Administration, the U.S. Environmental Protection Agency, the U.S. National Highway Traffic Safety Administration, the U.S. Occupational Safety and Health Administration, and the U.S. Food and Drug Administration. See www.standardsportal.org for a non-exhaustive list of examples. It should be noted that it is typical for a product to be regulated from several different sources.

It is, of course, important to know which regulations or standards apply to your product in the first instance so that your company can comply with them up-front. Moreover, understanding the applicable governing bodies' regulations, timing, reporting, and recall requirements in advance of a problem is critical, given that some require rapid action once a problem is identified. To avoid penalties and maximize mitigation, a manufacturer must know its corresponding responsibilities in advance, so it doesn't waste time determining them once a problem occurs. In this regard, the

appointment of a knowledgeable company point person to handle such events can be a game-changer.

There are additional reasons to expeditiously consider recall other than avoiding regulatory fines and liabilities. Safety, customer expectations/relationships, and contractual obligations are a few. An early, targeted voluntary recall shows manufacturer diligence and responsibility, concern for customer safety and relations, and can head off lawsuits and bad will. The faster one acts, the less the offending product gets distributed, and the easier the recall. A recall protocol employing advance knowledge of obligations can avoid fines and liabilities and save your company's reputation. Don't wait until it is too late to have a plan in place.

Here is a short, non-exhaustive check-list to consider to be ready for a potential recall event:

- Know the regulations and standards that apply to your product in the potential areas of distribution and use.
- Comply with them in the first instance; and
- Make sure you are well versed in advance concerning the timing and circumstances where the applicable regulatory bodies may require defect/injury reporting and/or recall.
- Have a point person in place that can track requirements and help you in the event of an issue.
- Consider whether recall insurance makes sense. A recall is often a warranty type of issue; typical insurance may not cover the expenses of a recall.
- Monitor your products with acceptable quality and distribution control/tracking to:
- Identify batch/lot problems early; and
- Have the data to quickly find and selectively terminate distribution, notify distributors, retailers, and users, and/or target potentially defective products for recall or retrofit.
- Cover recall obligations in your contracts.
- Once a potential defect is identified, expedite an investigation, consult the applicable regulations and laws, contractual obligations, and other recall duties to determine the proper actions, timely reporting requirements, and expedite a plan.
- Consider user and bystander safety, compliance with laws and regulations, contractual obligations, customer relations, company reputation, brand protection, liability mitigation, public relations, and public company reporting issues, among other things.
- Provide official notices to all potential insurance carriers.
- Determine the source of the problem and remediate it.
- Consider careful proactive communications to get ahead of the issue, and whether the applicable regulatory bodies must first approve them.

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