

White Paper-Legal Threats

Abstract

The white paper explores the use of technology to protect food manufacturers from legal challenges.

Problem Statement

Where there are laws – litigation is sure to follow. The Food Industry is no different as FSMA becomes more mainstream. Unexpected legal costs can come from many sources and food suppliers need to find ways to protect themselves by covering all their bases.

Introduction

The records of food manufacturers need to match all the requirements for records by FSMA. Missing, partial or incomprehensible records can leave organizations unable to provide detailed records to prove that the requirements are met.

According to the Specialty Foods Association the following are the records

Records required as part of the Food Safety Plan include:

- Hazard analysis
- Preventive controls
 - Process preventive controls
 - Allergen preventive controls
 - Sanitation preventive controls
- Supply chain program requirements
- Recall plan
- Monitoring procedures
- Corrective action procedures
- Verification procedures

Required Implementation Records include, but are not limited to:

- Monitoring records for preventive controls
- Corrective actions taken

- Verification records: validation, verification of monitoring, ^[L]_[SEP]product testing, environmental monitoring, records review, etc.
- Supply chain program and supporting documentation
- Training records
- Monitoring records document that a food safety hazard has been controlled.
- Deviation from the Food Safety Plan, there must be a corrective action to make sure the food is safe.
- . Verification records must document that the Food Safety Plan is working properly.

These could include

- logs that verify the accuracy of thermometers and other measurement devices,
- results of finished product testing,
- audit records of suppliers responsible for the preventive controls, and so on.
- Each facility will have different verification records based on its Food Safety Plan’.

If these are not addressed completely, the following types of legal and other instances can create issues for food manufacturers.

1.1 Product Liability

The Food Safety Modernization Act (FSMA) is a legal requirement for the food industry; sooner or later, there will be case law relating to the practice of food safety responsibility. The operational records will be subjected to the same scrutiny as financial records.

According to Life Sciences decoded, “We believe that in addition to its intended effects, the FSMA may have some unintended consequences. For example, some new regulatory requirements may give plaintiffs’ lawyers and the consumers a comprehensive set of blueprints for bringing successful product liability and unfair trade practices lawsuits against food companies.’

1.2 The Whistle Blower

The whistleblower laws re section 402 of the statute with provisions borrowed from Sarbanes Oxley (Husch Blackwell) applies to any person or entity engaged in manufacturing, processing, packing, transporting, distribution, reception, holding or the importation of food. Husch Blackwell believes that the employer must prove that

defense with clear and convincing evidence. February 9, 2017, Case # 17-cv-01046 was filed against Mead Johnson Nutrition Company by a whistleblower.

1.3 Insurance Liability

At least one insurance company provides Food manufacturing insurance related to FSMA for Specialty Foods. The basis of claims needs to be made on reliable evidential records, which are verifiable and auditable to the strictest scrutiny. Insurance companies will look for reasons not to pay. Therefore, records must be pristine without gaps. Conversely, insurance premiums can become competitive if the 3000 FDA citations of 2019 are reduced.

FSMA Reanalysis of the food safety plan

117.170 informs a reanalysis must be completed every three years or

1.3.1 Significant changes to the process or product

1.3.2 Unanticipated problem

1.3.3 Ineffective preventive control

1.3.4 New information about potential hazards

Any of these can occur along a continuum from zero to 3 years; therefore, pristine formatted records are required for retrieval to conduct the reanalysis. The date of the original food safety plan must be recorded so that the three-year reanalysis is triggered during the scheduling. A non-conformance is triggered for ineffective preventive control or unanticipated problem. Changes to the process, product or hazards, drive retraining, part of which is a record of retraining. It is an opportunity to verify standard product identity is current. How traceable are the records to prove the reanalysis is conducted? In the 2019, the three thousand 117.xxx onsite audits citations, none of the preventive control issues indicated whether reanalysis was completed. If not stated in the records, the outcome of a future court matter can hinge on these details.

1.4 FDA Inspection Citations

In 2019 FDA Inspection records indicate 7000 Food citations^{iv}. The citations were across several 21 CFRS, 111,117,123 etc. The 3000 FSMA citations are limited by the number of annual inspections that can be conducted. What is the status of the non-audited companies? Seven thousand instances of audit issues suggest that there are

gaps in the Management control of the audited companies. Companies need the type of media that places the requirements of each process step in front of the operator and controls the operations to provide the records to avoid the situations. The point is, technology baked into the requirements will significantly reduce citations and protect companies from potential future threats.

Notwithstanding automated equipment for production rates, it is the Management controls for managing FSMA, that differentiates production automation from management controls automation for Management by Exception. Production automation does not facilitate all FSMA requirements such as training records for duties; for the most part, production automation may trigger exceeded values within Lower and Upper control levels, but it does not facilitate the corrective action, when values are outside the prescribed range.

1.5 Supply chain liability

Supplier products for inputs into receiving facility product requires confidence that the supplier preventive controls were adequate. Real-time records of date and auto time-stamped providing such confidence from the supplier for verification by receiving facilities in real time. Evidence is created by the supplier that the Receiving facility can see the production details, reducing conflict between suppliers and receiving facilities, including PCQI verification of Preventive Controls and corrective action responses within the 7-day requirement.

Conclusion

The technology bars the acrimonious side and legal issues, because the organizations are compliant to all the FSMA legal requirements. Maintaining ongoing compliance with appropriate records helps to ensure that organizations are protected from legal challenges.

All the records stated by the Specialty associations are paperlessly available electronically and found at fsmafoodsafety.com

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