Applying HACCP Strategies to Pathogen Detection Methods

The development of effective Hazard Analysis and Critical Control Points (HACCP) is crucial to enhancing quality and mitigating risk within food manufacturing. With increasing regulations, new technology and greater demand, more scrutiny is being placed on the implementation and monitoring of these HACCP strategies.

One tool in developing a HACCP plan is the failure mode and effect analysis (FMEA), which provides a weighted metric to apply to a HACCP strategy that analyzes potential error and provides a roadmap for implementing effective risk mitigation strategies.

By combining a solid HACCP plan with FMEA, and diligently monitoring program effectiveness, a higher quality product is achievable with lower risk. Incorporating the correct monitoring tool such as a pathogen detection test is as important as the program itself.

However, pathogen detection methods vary considerably in their complexity (number of steps), requirements for manual manipulation (touches) and analytical performance. It is critical to incorporate a pathogen test that upholds similar, if not greater, rigor than that of the HACCP program it is being utilized to monitor.

What is FMEA?

Failure mode and effect analysis is a method that identifies and quantifies method constraints and steps with potential process variation to quantify risk in each test method. It is a calculation of the total number of steps in a process, the total times the sample (or equivalent) is touched by an operator and a weighting of the risk associated with the failure mode. The weighting includes factors such as severity of the risk to the overall outcome of the result, the frequency at which the error may occur as well as the likelihood of an operator detecting the error or defect and intervening. These are all calculated to determine a risk priority number (RPN), where a lower number indicates a lower risk related to that particular method.

RPN = Severity • Frequency • Detection

Total RPN = SUM (RPN)

Applications to Pathogen Detection Methods

For example, let's use something as seemingly innocuous as a heat block, which can represent a single failure mode in an assay that requires its use. The protocol may state, "Place lysis tube in a heat block at 37°C (1±2°C) for 30 minutes." The potential risk is that the heat block is out of the 37°C specification, with an outcome of insufficient lysing that could lead to a false-negative result. The current controls in place are a thermometer and temperature dial on the apparatus.

Severity = 9: If cells do not lyse, there is a high risk for error.

Frequency = 1: It does not occur that often.

Detection = 5: Thermometer and heat block must be frequently and properly calibrated, and operator review is required each time samples are added.

RPN = 9 • 1 • 5 = 45

The above is an example of a single step in a protocol. As the protocol becomes more complex, requiring more steps and more operator interventions, the quality and consistency of the result suffer. Ultimately, the result may provide a skewed and erroneous view of the effectiveness of the control plan it is being used to monitor.

Differences in Current Methods

A recent review of different pathogen detection methods was recently published for *Salmonella* and *Listeria* spp. detection for a number of different vendors. This study reviewed the product inserts of 16 different kits, identified potential failure modes and developed an RPN as discussed above for each assay.

The study showed that minimizing the number of process steps as well as the number of touches per sample, and

Method: *Salmonella*	Number of Process Steps	Number of touches per "sample"	Number of defect opportunities	RPN
Method A	16	13	34	1002
Method B	28	21	77	2557

including automation that incorporates process control features, significant improvements of the overall quality of the final result were obtained.

Summary

In summary, quality and safety are the highest priorities of the food industry. Considerable investment and effort are taken to develop and implement effective HACCP plans. However, many of these plans are being monitored by methods that may not meet the same level of rigor being applied to the manufacturing process and therefore are not providing the accuracy in monitoring that the manufacturer may require.

By applying similar tools as those used to develop HACCP strategies, such as FMEA and Lean Six Sigma, to the laboratory for pathogen testing, a scale for risk impact can be applied to these methods. This scale of risk impact enables a manufacturer to make an informed choice as to which methods best meet the criteria of its facility. The results of this analysis prove that when FMEA is applied, those methods that incorporate the proper automation with reduced operator intervention will provide the highest quality data, enabling the clearest understanding of the effectiveness and changes occurring within the HACCP process.

The full report can be found at www.foodsafetymagazine.com/signature-series/fmea.

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