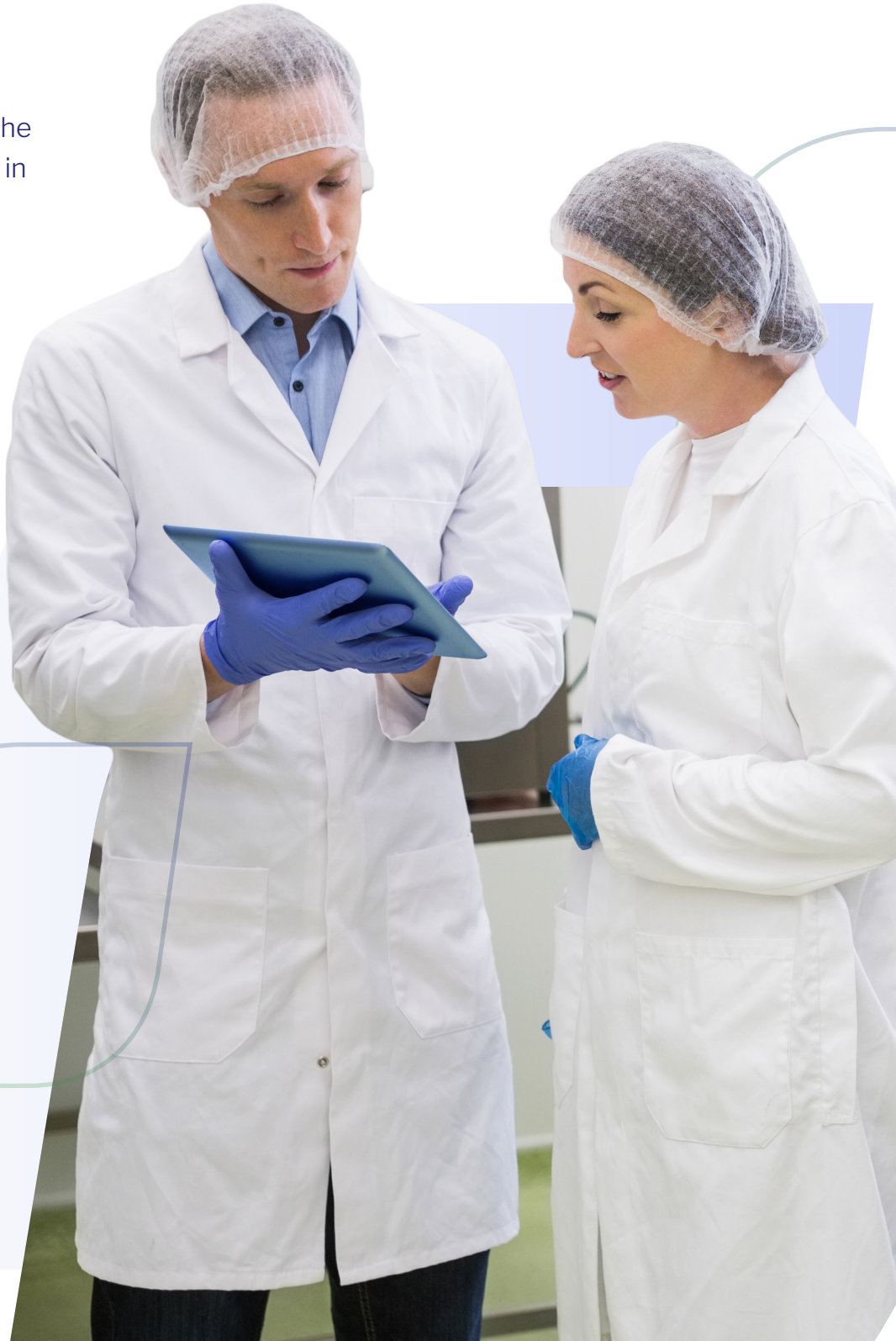
Novolyze

Environmental Monitoring Programs

OBTAINING VALUE FROM DATA

This whitepaper outlines why digitalizing environmental monitoring programs (EMPs) is the key to unlocking their true value in ensuring safe quality products.



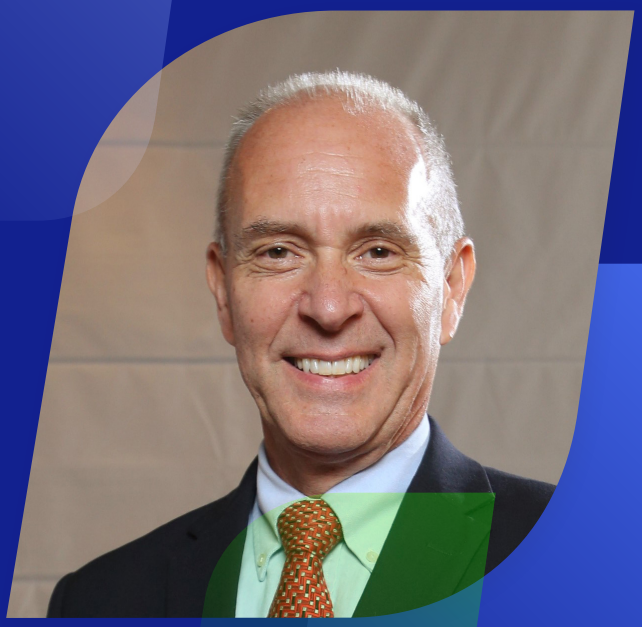
Introduction

One of the greatest risks for the food industry today is the post process contamination of ready to eat (RTE) foods.

Contamination of RTE food with *Listeria monocytogenes* or *Salmonella* has resulted in significant outbreaks, serious illness, deaths, recalls and massive financial and even judicial consequences to the food industry. Controlling the risks in the RTE area requires robust environmental control programs that are designed to keep unwanted pathogens away from the RTE areas. Only by supporting your control program with an aggressive environmental monitoring program (EMP) that is driven by a seek and destroy mentality can you properly control the risks.

A properly leveraged EMP is a powerful risk reduction tool and one of the most effective ways to fully leverage your EMP is through data digitalization. Data must be tracked, trended, reacted to and documented. Failure to fully leverage your data creates risks that may have massive regulatory and financial consequences. Data digitalization is a powerful tool that will allow your EMP data to be transformed into actionable management strategy. Such actions will save you money, reduce risks, enhance your operational efficiency and most importantly send a strong message to your customers and regulators that you are operating with best-in-class systems. Anything less than that today exposes you to unnecessary risk that can be easily avoided.

DR. DAVID ACHESON • M.D., TAG LLC & former U.S. Food & Drug Administration Associate Commissioner for Foods



Importance of EMPs in Food Safety

According to the World Health Organization, one in 10 people fall ill and 420,000 people die from eating contaminated food globally each year.[1]

The global economic burden of foodborne diseases is considerable as they affect individuals of all ages, particularly children under five years of age and persons living in low-income regions of the world. In addition, costs resulting from outbreaks and recalls can be enormous for food manufacturers -estimated to be in the region of $10 million[2]- damaging both their bottom line and reputation.

The task of tackling this public health issue is a shared responsibility between governments, industry, academia and consumers. Food processors play an important role. Food Safety and Quality (FSQ) teams must implement food safety plans, including Hazard Analysis Critical Control Point (HACCP) systems, which identify pertinent hazards and the critical control points to manage them. However, despite the value of HACCP-approach and other similarly structured food quality systems, it has become clear that many food safety and quality issues experienced around the world are due to failures in prerequisite programs.

In 1998 a *Salmonella* Agona outbreak was traced back to a toasted oat cereal, which resulted in 209 cases of Salmonellosis. The source of the contamination was found to be the processing plant environment. Ten years later, in 2008, another *Salmonella* Agona outbreak caused 28 Salmonellosis cases. These cases were linked to a puffed rice cereal. The strains implicated in both outbreaks were of the same subtype and it was determined that — *Salmonella* had survived in the processing plant for a decade.[3] This highlights the tenacity of bacteria and why it is vital to control the movement of pathogens in the processing areas and to thoroughly monitor hygiene and track pathogens.

The purpose of an Environmental Monitoring Program is to facilitate the 'oversight and management' of FSQ issues and to take corrective actions as fast as possible. This is achieved through continual monitoring of indicator organisms, pathogens, spoilage organisms and potential allergen contamination.

Yet continual monitoring is only the first step.

In order to obtain meaningful information from the data, a number of documents from regulatory agencies and institutions consistently highlight the importance of not only testing samples at regular intervals but, perhaps more importantly, evaluating these results on a regular basis. Routinely assessing the data can provide an overview of pathogen trends, leading to valuable insights.

For example, the U.S. Department of Agriculture's Food Safety and Inspection Service's Compliance Guideline: Controlling *Listeria monocytogenes* in Post-Lethality Exposed Ready-to-Eat Meat and Poultry Products — January 2014[4] states that establishments should track their sampling results over time to identify *Listeria* trends to determine if there are increases in positive samples over a particular period (eg, weekly, biweekly, monthly, quarterly, or semi-annually) or in particular sites or areas. Similarly, FDA's Draft Guidance: Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry,[5] specifically requires the analysis of environmental monitoring data over time to observe trends.

Furthermore, in GMA's Control of *Salmonella* in Low-Moisture Foods guidance[6], the recommendation is that "sites may be sampled on a continuing basis to assess trends. Sampling data should be reviewed on a routine basis. The sampling program should be dynamic and refined according to the data generated."

1. *Who.int. 2021. Food Safety. [Internet] Available at: <https://www.who.int/news-room/fact-sheets/detail/food-safety> [Accessed 3 January 2021].*
2. *https://forms.consumerbrandsassociation.org//forms/store/ProductFormPublic/capturing-recall-costs*
3. *Cdc.gov. 2021. CDC - Salmonella Agona Infections - Salmonella. [Internet] Available at: <https://www.cdc.gov/salmonella/2008/rice-wheat-puff-cereal-5-13-2008.html> [Accessed 4 January 2021].*
4. *Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products [Internet]. Fsis.usda.gov. 2021 [cited 7 February 2021]. Available from: https://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/guidelines/2014-0001*
5. *Draft Guidance on Listeria monocytogenes in Ready-To-Eat Foods [Internet]. U.S. Food and Drug Administration. 2021 [cited 7 February 2021]. Available from: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-control-listeria-monocytogenes-ready-eat-foods*
6. *Control of Salmonella in low-moisture foods [Internet]. GMA. 2021 [cited 7 February 2021] Available from: https://forms.consumerbrandsassociation.org/forms/store/ProductFormPublic/SalmonellaControlGuidance*

So why digitalize EMPs?

Reducing Manual, Error-Prone Tasks

A recent survey commissioned by Novolyze, and contracted to an independent research institute, interviewed thirty-one quality managers from various food sectors, including meat, dairy, low-moisture foods, fruits and vegetables. The interviews showed that in over 70% of cases, tasks associated with EMPs were handled manually using paper or spreadsheets.

Digitalizing EMPs reduces the number of repetitive manual tasks that are not only very time consuming, but also prone to errors, leading to inappropriate food safety decisions being made. Laure Pujol, FSQ specialist with Novolyze, commented “Manual handling of EMPs often requires a significant number of double checking whether that be during planning and executing environmental sampling, or in managing corrective actions and preparing reporting activities. These procedures are sources of human errors that everyone can make. Today, it is even possible to automate the randomization of samples in EMPs. Digitalizing EMPs enables the quality team to streamline repetitive tasks and refocus on higher value-added tasks, including troubleshooting and the identification of priority pathways for improvement.”

While large plants that generate many thousands of environmental results a year have a need for digitalizing EMPs, medium and small operations can also benefit from the decrease in human errors.

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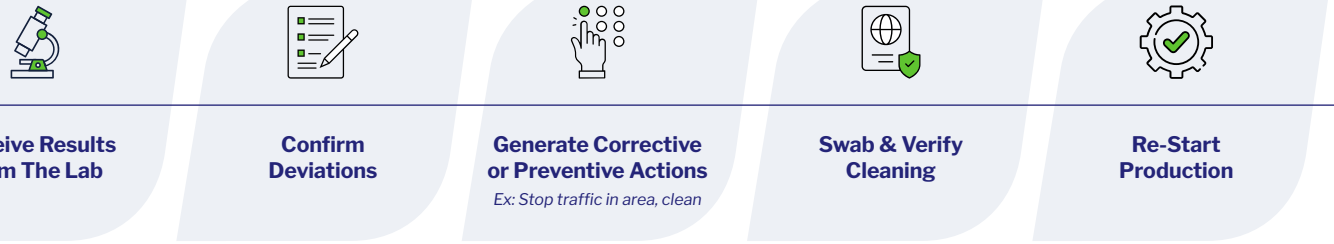
Making Remediation Activities Faster & More Reliable

In case of a deviation, the quality team is alerted in real-time, enabling them to take faster corrective actions that can be fully documented. Tasks can be organized and traced electronically, and workflows can be preconfigured to gain additional efficiencies. The following is an example of a simplified workflow:



As demonstrated through the workflow, EMPs typically involve several stakeholders: the FSQ team, the maintenance team, the cleaning and sanitation team, an inhouse or external lab and the production team itself. Digital transformation can streamline workflows between these stakeholders and makes the whole chain more efficient and less prone to errors or missing a key step.

Reducing Plant Downtime

The resolution of issues related with environmental contamination is not only paramount to food safety; it has significant impact on plant performance indicators. Inappropriate actions may lead to increased downtimes and trigger heavy financial impacts. Digitalizing EMPs enables faster and more reliable corrective actions in case of a deviation and reduces the frequency and duration of unplanned plant downtime associated with environmental contamination issues.

Simplifying Learnings From the Past & From Other Locations

Digitally tracing problems, corrective actions and results strongly contributes to simplifying the corrective actions. Let's assume that Plant A faces a contamination issue with a pathogen. With a digitalized EMP, the FSQ team can easily find out:

> ***If a similar deviation occurred previously through a searchable database of current and past deviations.***
>
> ***What was the root cause of the past deviation?***
>
> ***What corrective actions were implemented?***
>
> ***Which ones worked/which did not work?***

> **Digitalizing EMPs enables faster and more reliable corrective actions in case of a deviation and reduces the frequency and duration of unplanned plant downtime associated with environmental contamination issues.**

Laure Pujol noted "a digital solution cannot replace human intervention for obvious reasons. But digital tools offer quality managers a robust and easy assistant when it comes to making decisions. There is one pertinent point when considering EMPs: There is a tremendous amount of data that is being generated, yet only a very small portion of it is used to make decisions. Digital EMP contributes to gathering and organizing data in a way that enables it to be used in a faster and more reliable way. The benefit is even higher for companies that have digitalized multiple sites because the translation of the learnings from one site to another site is greatly simplified and can be used as a training tool."

Visualization of Data on Maps

Going one step further, digital EMPs support the visualization of results directly onto a map of the plant. Digital maps enable the spread of risks to be viewed more dynamically, with zoom-in / zoom-out features and perspective over a certain time period. "Track & trace" activities become more dynamic and more thorough. This, combined with easier trend analysis features, not only facilitates identification of root causes, but also the identification of preventative actions and priority pathways for improvement.

Centralizing Data, Increasing Traceability

When it comes to FSQ, traceability is considered to be a cornerstone of most regulations. In 2020, Frank Yiannas, Deputy Commissioner for Food Policy and Response at the FDA, introduced a blueprint called New Era for Smarter Food Safety. On FDA's website one can read: "To keep pace with this evolution, FDA is taking a new approach to food safety, leveraging technology and other tools to create a safer and more digital, traceable food system".

One of the four core pillars of FDA's program is tech-enabled traceability, which brings digital to the fore. Although EMPs are by no means the only component addressed in the program — indeed, the FDA's remit is far broader — considering the large number of FSQ issues associated with environmental contamination, implementing a robust traceability framework for EMPs has become a "no-brainer" for ensuring the highest level of compliance.

Fast & Measurable Payback

Digitalization of EMPs usually pays itself back by an increase in the plant's Key Performance Indicators (KPIs), whether that be overall equipment effectiveness (OEE), cost of quality or any kind of tracked indicator. Major gains are usually expected from the reduction of unplanned plant downtimes and product waste associated with environmental contamination issues. Some paybacks are harder to quantify from a financial perspective, such as potential recalls and withdrawals associated with environmental contamination issues.

However, given how costly such recalls can be and how detrimental to a brand's reputation, EMPs are a multi-stakeholder activity that can bring significant efficiencies to a team by saving time and achieving more with a lower level of resources. Laure Pujol adds that "even in factories already equipped with the first bricks of digitalization, like a LIMS system, the payback of adding an EMP digitalization layer is high".

Beyond EMP Digitalization

Transforming EMPs into digital programs provides most food companies with a fast return on investment means of experiencing the benefits of digital transformation of their FSQ operations. Yet this is only the tip of the iceberg; there are broader silos that can be removed, expediting the realization of the true value of digitalization in safety and quality. If spreadsheets and paper are most frequently the rule for EMPs, quality teams must deal with numerous heterogeneous sources of information including ERPs, service providers, etc. Superposing data from different types of food safety initiatives and establishing correlations quickly affords companies full access to the value of digital transformation.

About Novolyze

Novolyze empowers food and beverage companies to enhance food safety and quality performance and compliance in a rapidly changing environment.

We offer application-driven, tech-enabled solutions to activate a groundbreaking, holistic approach to food safety and quality. We leverage the power of IoT and cloud-computing to unify food safety and quality data, transform them into actionable insights, and enable real-time decision-making.

Novolyze

Do not hesitate to
contact our team at

NOVOLYZE.COM
contact@novolyze.com

USA

1875 K St NW, 4 Fl,
20006 Washington DC

+1 (301) 241-6261

FRANCE

50 Rue de Dijon
21121 Daix

+33 (0) 983 694 213