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Opportunities for More Effective and Efficient Microbiological Monitoring in Food Production Operations

About the Author

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O'Brien holds/has held non-executive directorships of several technical organisations including ILSI (Washington), IFSH (Chicago), ILSI Europe (Brussels, as Chair), and Campden BRI (UK). He currently serves as a member of the Science Council of the Food Standards Agency (London), where he Chaired the Working Group on Global Food System Risks, and is a Visiting Professor and Chair of the Advisory Board at the Nutrition Innovation Centre for Food & Health (NICHE) at Ulster University, Northern Ireland. He has a PhD in Food Chemistry (University College, Cork) and an MSc in Toxicology with Distinction (University of Surrey).

About Creme Global

Creme Global is a scientific modelling, data analytics and computing company based in Dublin, Ireland with fifteen years of experience in food safety data and modelling. Creme Global was founded in 2005 as a spin out from an EU research programme based in Trinity College Dublin.

With a mission to enable better decision making in our complex world, the company helps organisations to understand the context of their data and provides expert scientific modelling, data analytics and reporting services as well as new model development and robust computing solutions.

The company works with the top food, beverage and chemical companies and government agencies worldwide, with a primary focus on the US and Europe.

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Purpose

The purpose of this white paper is to underline the importance of proactive and preventive strategies for industrial food safety management, to emphasize the value of combining genomic data analytics and machine learning with conventional microbiological monitoring and the potential pathways to securing both improved operational performance and better regulatory compliance/public health outcomes using such approaches.

2

Background

Industry is facing a number of new and unprecedented food safety challenges. The drivers of such challenges can be broken down as follows:

a) **Demographics**

In the developed world, the aging boomer population is increasing the number of consumers with weakened immune systems.[1] Such consumers are generally more at risk of food borne infections compared with young healthy individuals. If food standards and consumer behaviour remain the same, demographic trends point to a risk of increased foodborne illness.

b) **Consumption Trends**

Consumers are demanding fresher, minimally processed products, preservative-free, lower in salt and sugar (active preservatives). Recent evidence points to changes in consumption patterns such as increased demand for ready to eat foods as a driver of foodborne infections (e.g. listeriosis in Europe).[2]

c) **Non-traditional risk sources**

Recent investigations have revealed foodborne disease outbreaks associated with products that were not traditionally considered as "at risk" (e.g. cantaloupes and other fruit, bean sprouts, spices, nuts, etc.).[3]

d) **Changing supply chains**

Food supply chains are becoming more complex with the globalization of supplies of raw materials, ingredients and finished products. While global supply chains have delivered many benefits to both suppliers and consumers, they also necessitate awareness and management of risks that vary according to geography, regulatory landscape, supplier, etc.

e) **Climate Change**

Climate change is already changing how and what we eat.[4] [5] Consumers are responding by demanding products that minimize environmental impacts. Altered weather patterns can change the potential for crop contamination via several routes. The prevalence of some animal diseases is changing in response to a number of factors including climate change and intensification of production. Circular economies designed to make agri-food systems more sustainable will challenge the management of existing food safety hazards and may introduce new hazards. Freshwater systems are also becoming stressed in many parts of the world which impacts both agriculture and food manufacture.

f) **Costs**

Operating costs are not falling and margins are under constant pressure. This is at a time when the cost and reputational damage caused by food safety incidents is increasing.

g) **Technology**

Technology advances have delivered new laboratory tools to support the investigation of foodborne infections and to characterize the behaviour of microorganisms in food systems[6]. It is not the goal of this paper to outline the potential of the new technologies. The uptake of new tools by food companies has lagged behind that of regulators and the scientific community. Whole genome sequencing is proving to be an invaluable tool in foodborne disease investigation. As the technique becomes more widely used, it is likely that more of the sources of infection will be identified. Careful interpretation will be needed, as improved detection and identification of sources may even give the impression that the number of outbreaks is increasing. It is also likely that the tools will reveal how pathogenic organisms are moving throughout the food chain including within production environments.

h) **Evolving science and the identification of new hazards**

It is worth recalling that the pathogen Listeria monocytogenes was not recognized as a food hazard 40 years ago. Scientific advances happen continuously and inform food safety management priorities. For example, more recently, the growth of antimicrobial resistance (AMR) has been recognized as a global emergency necessitating radical changes to the use of antibiotics in agriculture and intensive research on the movement of AMR genes in agri-food chains.[7]

Changes to the management, regulation and responsibilities for the microbial safety of foods are underway [1]. This is at a time when there is little change in the reported rates of some foodborne infections, whereas in some advanced economies there has been marked progress (e.g. decrease in Salmonella contamination of eggs in Ireland). The food industry has little control over some contributors to foodborne disease such as demographics, consumer health status and social trends in consumption behaviour. However, new regulations and standards have placed more responsibility in the hands of food businesses.

Against the backdrop of changing standards and regulations, the unprecedented advances in laboratory technology and market demands, business as usual is not an option. More testing, per se, while generating additional costs, may generate a false sense of security without contributing to a safer product and without an increase in operational resilience. A more strategic approach is required.

It is now recognised that pathogens (e.g. Salmonella) can persist in food processing and preparation areas for long periods of time. This has led to the term "resident" to describe pathogens that have been associated with specific facilities.[8] Two recent disease outbreaks highlighted the risks. In both cases the organisms were "resident" in the facilities for periods of years seemingly without the knowledge of the operators. From an operational point of view the facilities had little in common: Listeria in an ice cream factory [9] (a wet environment) and Salmonella in an infant formula factory[10] (a largely dry production environment). Significantly in both examples, official investigations concluded that controls in facilities were already failing to control pathogens months or years before illnesses were linked in consumers. Time is no longer a barrier to tracking sources of foodborne illness; having a clean product today does not imply you had a clean product in the past or will have in the future. More robust management measures are required.

3

Current approaches to environmental monitoring

Microbiological testing and monitoring programmes are verification tools used in conjunction with food safety management preventive controls such as HACCP and prerequisite programmes such as hygienic design and plant zoning.[8] Without the latter, monitoring has little value.

Conventional indicator organisms are selected based on ecological principles (co-existence) and relative abundance compared with the pathogens to be controlled. Examples include E. coli as an indicator of faecal contamination of water and other matrices and the use of Enterobacteriaceae in infant formula manufacturing environments and finished products.[8 11] If the indicators are present at above threshold levels, this triggers the need for further investigations to ensure freedom from pathogens.

Traditional approaches depend on bacterial cultures that target the organisms of interest/concern. As such, they provide simple feedback on the conditions in the manufacturing facility including information on the effectiveness of hygienic controls.

Well-designed environmental monitoring is a powerful tool to avoid product contamination and to understand the conditions that can lead to product contamination. It can determine whether a pathogen is transient or “resident”. Spatial mapping of the location of potential contaminants can help point to weaknesses in zoning or controls. It is an indispensable tool in root cause analysis once an incident or non-conformity has occurred; i.e. to look at the underlying conditions that contributed to a problem so that effective preventive actions can be put in place.

Evolving regulatory environment and international food standards

Official controls tend to evolve slowly as there is a need to embed the principles of good regulatory practice, notably proportionality (i.e. risk based) and consistency. Official analytical methods take time to develop as strict standards cover validation in the test matrix and verification that methods work as expected in routine laboratories. Nonetheless, we can expect a wave of future regulatory changes aimed at improving consumer protection while taking into account the quality of food safety management in food businesses (including at the level of the manufacturing facility). At present some proposals seem onerous and may have the unintended consequence of discouraging operator proactivity (e.g. suggestion in a French Senate report for mandatory disclosure of the results of in-house test results that indicate a food safety risk along with proposed corrective actions).[12]

The US Food and Drug Administration (FDA) has embarked on routine sequencing of pathogen isolates recovered from environmental swabs. The huge amount of data generated in this approach are at the heart of GenomeTrakr program, which aims to cut the number of foodborne disease outbreaks and to limit the number of cases per outbreak.[13] Inevitably, operators who fail to apply effective controls and who do not keep abreast of the scientific developments may find out they have a contamination problem when contacted by the regulatory authorities! New approaches present operators with an opportunity to deepen knowledge of what's going on in their premises, to reinforce due diligence and to take proactive steps to deal with early warning signals.

The recently published eighth issue of the BRC Global Standard for Food Safety (2018)[14] has added requirements (Clause 11.8) for risk-based environmental monitoring programmes for pathogens or spoilage organisms covering: design of the monitoring programme; control limits; and periodic review. Of all of the current regulations and standards that specify a requirement for environmental monitoring, the BRC GS is probably the most prescriptive. While there is a minimum set of requirements, it leaves scope to design programmes that are optimal for each processing environment/product type. Clause 11.8.3 specifically allows for, among others, new scientific developments; failures of the programme to identify a significant issue; and consistently negative results (to offset the possibility of complacency in the face of flaws in the design of the programme).

5

New Approach Actionable Insights from Combining Microbiological Monitoring and Predictive Analytics

A smarter approach is required that combines traditional tried and tested approaches with new scientific tools to deepen insights and knowledge of microbial ecology in the production environment in a cost-effective way. Applied effectively, such approaches have the potential to move responses from a reactive footing to a proactive approach based on data capture and computer machine learning to generate early warning signals that have the potential to:

1. Prevent incidents and non-conformities.
2. Avoid excessive waste as food safety management is shifted upstream facilitating early management and avoiding out-of-spec finished product that would be either reworked or destroyed.

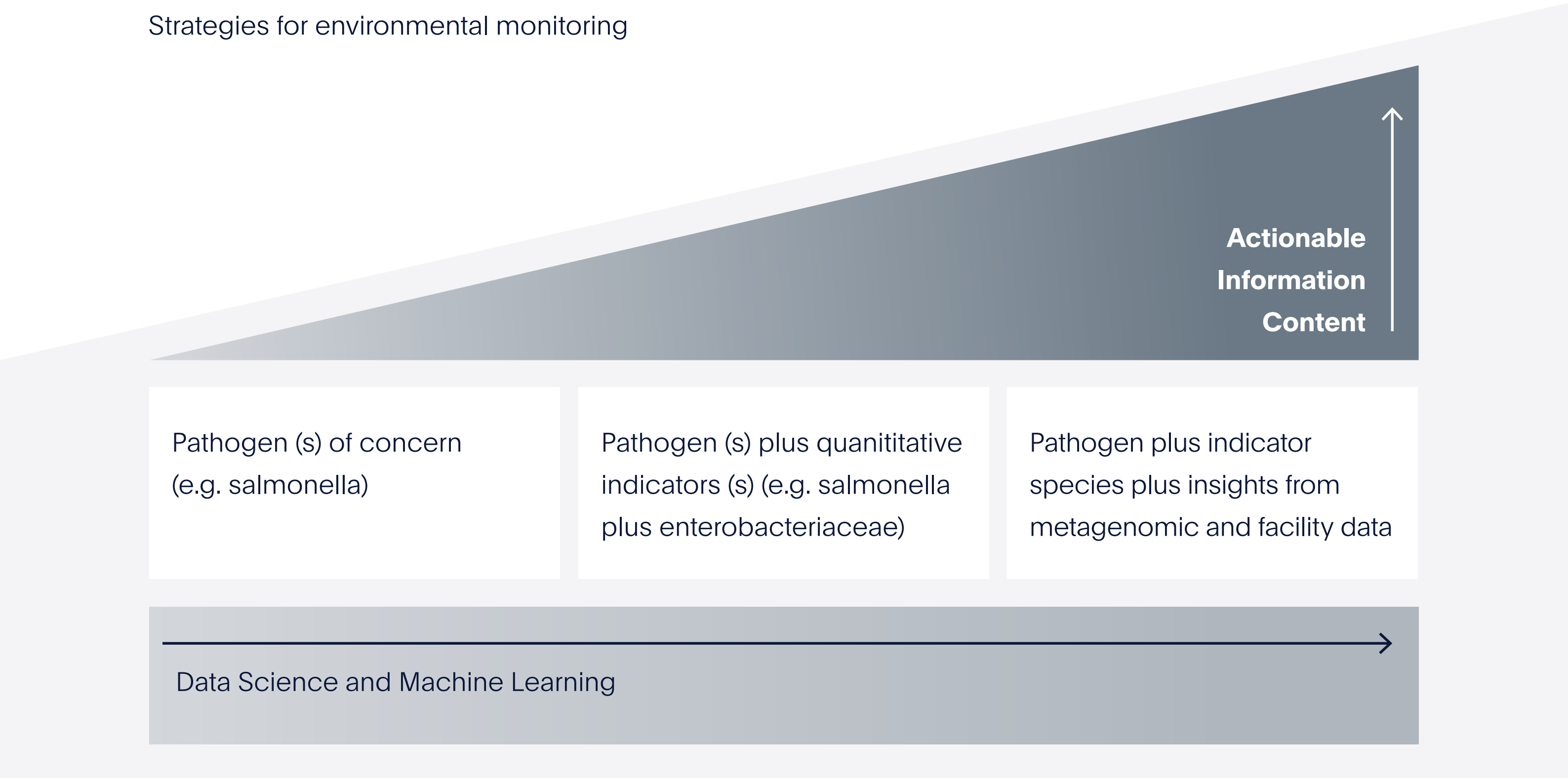
End–product tests are lagging performance indicators. As such, they can be used to verify that the controls in place are working. However, the disadvantage is that the results are only available after the problem has emerged. Equally, the results of traditional environmental monitoring act as lagging performance indicators, but can serve as early warning signals before product contamination takes place. A fundamental shift is now required in the approach to microbiological testing in food safety management. Many millions of tests are conducted annually that confirm the absence of target microorganisms and yet nonconformities and foodborne disease outbreaks continue.

The importance of the ecosystem in which organisms exist is being increasingly recognised. Microorganisms rarely exist as monocultures (except in the lab). Pathogens and spoilage organisms often have “fellow travellers” that can serve as early warning signals warranting preventive action. Microorganisms support and inhibit each other’s growth and activities. For example, a biofilm created by a group of innocuous organisms may enable the survival of organisms of concern (pathogens or spoilers). Conversely, some organisms may inhibit the growth of pathogens or spoilers in a production setting. As mentioned above, organisms may colonise a production environment and persist over months or years. Different production environments can be characterised as having different environmental microbiomes. The recognition that AMR genes may be disseminated by non-pathogenic bacteria[15] also underlines the need to take an ecosystem approach when developing management plans.

Mining upstream and environmental data that can steer managers toward preventive measures is seen as the way forward. Data science coupled with metagenomic and environmental data can improve the insights available from existing samples and electronic data sources. Careful design of monitoring programmes is still required as specified, for example, in BRC Global Standard Issue 814. In addition, there is a need to integrate different data streams (e.g. conventional microbial culture data, ambient meteorological conditions, time of year, equipment data, biochemical data, collection method and location, etc). Capturing such data has become much easier due to recent advances in sensing and communications technology as driven by advances in the industrial internet of things (IIOT) arena.

A pragmatic approach is to design a scalable programme based around an existing environmental monitoring programme (See Figure 1) combined with new data streams. Data-based insights can be achieved routinely and targeted investigations can be launched on an as-required basis.

Figure 1
Strategies for environmental monitoring



The value proposition of the above approach can be summarized as follows:

a) It proposes the extraction of more data from existing samples; it does not necessarily require a new sampling plan.

b) It makes use of available metadata that are currently exploited for a narrower management function but which can be reused to build data science models to explain and predict the genesis of food safety and quality defects.

c) The focus shifts from reacting to late signals toward proactive, preventive, and targeted measures to prevent quality and safety problems.

Emerging Trends

As mentioned above, there is increasing research investment dedicated to improved understanding of the behaviour of pathogens and spoilage microorganisms in foods. The outcome of such research will be to improve public health (by decreasing the incidence of foodborne infections) and to improve the sustainability and competitiveness of businesses (by developing tools to enable decisions that reduce waste and improve product quality and compliance). Understanding of microbial ecology is progressing rapidly. The US-FDA has already embarked on sequencing the microbial community (otherwise known as the microbiome) in food related products. As whole genome sequencing costs are dropping dramatically, routine sequencing is more common. In one example, the FDA has sequenced the microbiome of tomatoes from different states and found California tomatoes to have a different community compared with east coast states (Virginia, Maryland, and North Carolina).[16] In another case, the FDA explored the impact of routine sanitation on the microbiome in a produce processing facility. Here, they sampled various areas on the production floor before and after daily sanitation and assessed for viable members of the microbiome.[17] The microbiomes of foods from plant and animal sources have also been analyzed by the FDA.[18] These are preliminary studies by the FDA but they could establish a baseline for future regulatory approaches. Indeed, as the cost of DNA sequencing is dropping, the cost of acquiring microbiome data will be trivial and will likely be used in future regulatory approaches.

Recent work at the UCD Centre for Food safety, led by Professor Seamus Fanning, in collaboration with Creme Global has demonstrated the use of data science and machine learning to build meaningful insights from factory environmental swab data in combination with available site metadata. The research partnership[19], funded by Enterprise Ireland and industry, sought to sequence the microbial community in these environments for use in data modelling to reduce contamination in the food supply chain. Downstream data modelling and predictive analysis was conducted by Creme Global, a scientific modelling, data analytics and computing company. Creme Global is now offering this as a complete service, from data collection to predictive results, for manufacturing facilities in the US and Europe.

7

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