Finished product testing and limitations to identification of low prevalence contamination

In its 1986 article on management of *Salmonella* spp. in powdered milk products, Habraken et al. stated in the introduction: “The lack of reliability of the mere examination of finished products when evaluating the microbiological wholesomeness of food products has been known to microbiologists for a long time”, quoting six references, among them one dated from 1931. Following an outbreak of *Salmonella* Agona in 2005 in France, the investigation team stated in their article report (Brouard et al., 2007): “Routine microbiological controls are insufficient to detect a low-grade contamination”.

Recent reported outbreaks for *Listeria monocytogenes* and *Salmonella* spp., and more rarely *Cronobacter* spp., have shown the implications of a lack of control of the microbiological burden in the processing environment, and the consequent contamination of food products. For the aforementioned reasons, it is now standard practice in the food industry that dedicated monitoring of the microbial burden of the processing environment is to be undertaken, with a risk-based approach for implementing the sampling program. In its guidelines for establishing microbiological criteria related to foods, the Codex Committee on Food Hygiene of the Codex Alimentarius states: “Criteria for monitoring of the food-processing environment are often considered important parts of the food safety control system”(Codex, 2013).

Processing environment monitoring to ensure efficacy of the food safety management system

The ICMSF equation (ICMSF, 2002, 2018) has been used for almost 20 years to conceptualize the microbial risks and subsequent control measures in place to meet the expected food safety objective (FSO):

\[
H_0: \text{Prevalence and levels of microorganisms from the initial contamination} \\
\Sigma R: \text{Reduction} \\
\Sigma I: \text{Increase; growth (G) and re-contamination (C)}
\]

\[
H_0 - \Sigma R + \Sigma I (G + C) \leq FSO
\]
Recontamination of dairy products throughout the dairy chain must be anticipated with a proactive approach. In recent years, following foodborne outbreaks in various food types which have been linked to processing environment contamination, regulations have been enforced to ensure that food business operators include this proactive approach in their food safety management systems (Canada, 2004; European Union, 2005; New Zealand Ministry for Primary Industries, 2006 & 2020; United States, 2011).

Samples from surfaces of the dairy processing environment are generally used for verification of effective hygienic practices and cleaning and sanitizing procedures, not to define the safety or quality of dairy products. Two classifications are considered by the different Codex Alimentarius documents: food contact and non-food contact surfaces. Some regulations, publications and guidelines (e.g. US-FDA, Zone1 to Zone4) use a four-level compartmentation approach based on proximity to the food product: one for food contact surfaces, and three for non-food contact surfaces.

ISO has recently updated its technical specification for providing horizontal methods for sampling techniques using contact plates, stick swabs, sponges and cloths on surfaces in the food chain environment in order to detect and enumerate culturable microorganisms such as pathogenic or non-pathogenic bacteria or yeasts and moulds (ISO, 2018).

As highlighted in the ISO standard, swabbing surfaces in the processing environment during the production shift is not meant to validate or verify cleaning and sanitation procedures. The number of times that swabbing is carried out is important from both the aspect of relevance of results (e.g. samples taken directly after application of a sanitizer are not useful, except for verifying the effectiveness of the sanitizer), and interpretation of results (e.g. samples taken directly after sanitizer application could be misinterpreted as a “clean environment”).

The scope of processing environment monitoring is to confirm that the food handlers are working in a hygienic and safe (foodwise) environment. Processing environment monitoring will help to focus priorities on either zoning, training of the food handlers, frequency and efficacy of cleaning procedures, as well as eradication of harbourage niches.
Gate keepers and scouts: routine and investigation sampling

The number of swabs taken, and the frequency of sampling cannot be standardised globally, as there is too much variation in processes and in the design of facilities. Each dairy processing plant must implement a processing environment monitoring program that has been defined for that facility. However, the risk-based rationale that underpins the sampling plan can be generalized.

Sampling of the dairy processing environment should be neither random nor completely fixed: it is a subtle mixture of both. One should first consider the fixed points of sampling, which are precisely defined locations. These may be referred to as “gate keepers” with the objective that no microorganisms of concern are detected.

The sampling plan should be flexible for adaptation to the “real life” of the processing plant. In addition to taking routine samples, the sample taker should be properly trained to identify points of concern that may require further consideration, or “investigation” sample points. In contrast to “gate keeper” sample points, “investigation” samples are meant to identify potential harbourage niches of the microorganisms of concern. It is therefore expected that “investigation” samples will detect the microorganism under investigation.

Classically, “gate keeper” samples are food contact surfaces, and non-food contact surfaces with high proximity to food contact surfaces, while “investigation” samples are usually located further away with a lower potential of food product contamination (with the possible exception of those sampled during a foodborne outbreak). Results of routine results should be treated with trend analysis, separately from investigation results. Analytical results in a routine context should be treated with trend analysis, separately from investigation results.

Corrective actions and vector samples

As for any monitoring, the dairy business operator is expected to have a plan for corrective actions / preventive actions to deal with positive processing environment samples (detection testing or enumeration of the microorganism of concern above a certain threshold). Following a positive result, thorough cleaning and sanitation followed by swabbing for verification of the cleaning process is a mandatory corrective action. Each positive surface tested should initiate a root cause analysis, that would be more efficient with an extensive sampling approach around the positive point BEFORE cleaning (starburst sampling or vector samples), and AFTER cleaning, to better characterize the deviation, and to identify which corrections, corrective and preventive actions are most relevant to implement.

The corrective action swabbing plan before cleaning should be done on surfaces with varying proximity classification to initial positive processing environment samples, in order to identify the source(s) of the contamination, to understand how extended the contamination is, and whether there is a significant risk of product contamination. Strain typing of the isolates in case of numerous positive swabbing would be needed to define how many harbourage niches should be investigated. This type of approach helps to define which corrective actions could be implemented over and above specific cleaning operations, like increased frequency of testing for the finished product.
What is the dairy sector doing?

For every processing facility, processing environment monitoring is recommended to evaluate the efficacy of zoning, application of good hygienic practices, correct cleaning and sanitation procedures and correct implementation of other prerequisite programmes. Currently, next to the application of good hygienic practices and the implementation of a robust HACCP plan, this remains one of the best pro-active approaches to ensuring the safety of dairy processes and preventing recontamination events from foodborne pathogens. It will help to identify at an early stage, deviations in the application of good hygienic practices.

Modern and traditional microbiological techniques, from standard plating to the whole genome sequencing, are being used by the dairy sector to give meaningful information from processing environment monitoring samples. For example, strain typing for *Listeria monocytogenes*, *Salmonella* spp. or *Cronobacter* spp. is being undertaken. The information generated allows for the identification and discrimination of resident and transient microflora, which in turn allows the processing plant to control the contamination in a timely manner, thus avoiding food contamination and public health issues.

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