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Application of the moving window approach in the verification of the performance of food safety management systems

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ABSTRACT

In a food business, microbiological testing is one of several methods of verifying the performance and acceptability of the entire food safety management system. Demonstrating compliance with microbiological criteria applicable for end products through the *moving window* approach is a practical and cost-effective approach for well-managed food safety management systems based on Hazard Analysis and Critical Control Points (HACCP).

This article discusses the *moving windows* approach and provides an example of how the approach can be used by a food business operator to verify compliance over time with a microbiological criterion applicable to end products manufactured within a HACCP-based food safety management system.

The approach consists of sampling a defined number of analytical units at a specified frequency over a defined time period. Compliance with the microbiological criteria is demonstrated when (i) the specified absolute maximum level of acceptability (M) is not exceeded in any sample and (ii) any specified maximum frequency (c) of all samples taken during the specified period (*window*) do not exceed a marginally acceptable level (m). Corrective action is triggered by exceeding either c or M, which, depending on the type of organism, includes action on the operation or design of the food safety management system and may include actions on affected lots such as withdrawal/recall.

1. Introduction

In a food processing facility, an effective Hazard Analysis and Critical Control Point (HACCP) system depends on (i) correct validation of control measures selected to control correctly identified hazards, (ii) effective monitoring of Critical Control Points (CCPs) and (iii) application of corrective actions. It is built on well implemented and managed Prerequisite Programs (PRPs), on management awareness and on the commitment of the food business operator. Consequently, the implementation, application and performance of the HACCP plan depend on the effectiveness of the chosen PRPs. A microbiological criterion (MC) applied for the verification of the performance of a food safety management system can assist in verifying whether both the HACCP plan and the PRPs are implemented as intended.

In a food business, several other methods of verification are applied in addition (e.g. review of records, environmental monitoring, on-site inspection, audit). However, microbiological testing is not always the most appropriate method. Where microbiological testing is used, the specific MC are applied at various locations covered by the scope of the food safety management system, e.g. the raw materials, the ingredients, at specified steps along the process, and/or for food at the point of sale.

However, the sampling location along the food processing line reflects which elements of the system are subjected to verification. For instance, sampling of end products can be used as one of several means to verify the performance of the entire food safety management system, whereas samples earlier in the process flow can only be used to verify the performance of specific control measure(s) or steps up to the point of sampling.

For example:

- An MC for *Bacillus cereus* spores in purchased dried spice can be applied to verify that the supplier meets communicated or expected specifications.

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- An MC for *Enterobacteriaceae* on a 100 cm^2 surface can be applied to verify that the cleaning procedure of floor surfaces in processing areas where food is exposed to the processing environment is effective.
- An MC for *Staphylococcus aureus* in cheese can be applied at the process step where concentrations may peak (e.g. the step prior to ripening, after which the organism will die out) to verify that *S. aureus* is kept below concentrations that may trigger the production of staphylococcal enterotoxins.
- An MC for thermoduric bacteria in packaged processed cheese can be applied to the final product to verify that the entire food safety management system is kept under control.

The *moving window* approach is a routine testing approach that is based on taking a single sample unit (defined amount of product) at each sampling occasion, which is different to traditional lot-by-lot testing. In a *moving window* approach, as described by CAC (2013), a specified number of sample units (n) are collected over a defined period of time (the *window*). The results of the latest n sample units are compared with the microbiological limit(s) (m, M) using the acceptance number c. Each time a new result from the sampling period is available, it is added to the window while the oldest result is removed, creating the *moving window*. The window, always consisting of n results, moves one result or set of results forward in time. In other words, the number of samples (n) of an MC defined for lot-by-lot testing is spread over the defined *window* and the set of results obtained in that window is then interpreted based on the limits c, m and M.

Notwithstanding other applications of MC, the objective of this article is to illustrate how the *moving window* approach can be used by a food business operator to verify compliance over time with an MC. A hypothetical cheese production scenario is presented as an example.

2. Purpose of the *moving window*

The purpose of applying the *moving window* for an MC applicable to end products is, through product testing, to verify the control achieved through the correct functioning of the food safety management system. Such MC are used to indirectly verify the combined effect of all control measures applied up to the point of sampling. Compared to traditional lot-by-lot testing, which is focused on determining the acceptability of a food lot (or batch), the *moving window* approach focuses on determining the acceptability of the performance of a management system (or process).

A *moving window* complying with the MC does, together with the additional verification activities in place, verify that the system performance is effective.

In the context of the guidelines established by CAC (2013), the *moving window* approach complements but should not be confused with trend analysis. Trend analysis is a procedure to detect a change in the patterns of observations over longer time (usually over a relatively long period of time, often not predefined). Trend analysis can be applied to many types of information to detect a gradual, or sudden, loss of control or unacceptable patterns of results that might not be detected by a *moving window* approach (CAC, 2013). The moving window approach compares a limited number of analytical results (e.g. 5 or 10 results) against the sampling plan specified by the corresponding MC. Trend analyses of results for the same organism is not governed by an MC and is therefore independent of the sampling plan specified by the MC. Trend analysis is looking for long term trends or systematic patterns that typically will not be detected by the moving windows approach. For instance, trend analysis can be conducted on individual test results (e.g. counts) and/or on the occasions that the MC have been exceeded.

3. Application of the moving window

MCs used to verify the performance of a food safety management system are normally established by the food business operator, e.g. the HACCP team (CAC, 2003). The nature of the PRPs, the hazard analysis, the subsequent selection of specific control measures and design of the HACCP plan provide the rationale for selecting microbiological testing as a tool for verification.

MC established by regulatory (competent) authorities may have different purposes (e.g. for lot-by-lot testing at the port of entry, for specifying food safety targets, etc.). The *moving window* approach can be applied for regulatory MC, where permitted. However, when microbiological testing is chosen as the means of verification, the acceptable levels indirectly implied by the combination of limits and sampling plan of such regulatory MC should be used, where applicable.

The moving window approach is useful where routine or frequent sampling is chosen, where material can be obtained at each sampling occasion in which the between-lot variability is (much) less than the within-lot variability, and where PRPs and the HACCP plan are effectively implemented. Where this is the case, the *moving window* approach to demonstrate compliance with such MC provides added benefit through generating information on control over time.

The frequency of sampling, and hence the 'window' may be determined according to the production schedule, for example, once per day or week per production line; alternatively, the window may be defined by volume, for example, one sample per × number of units processed.

3.1. Typical application

The typical application of a *moving window* is based on specifying a maximum acceptable frequency of exceeding a marginally acceptable level of organisms during a specified period, and an absolute maximum level that shall not be exceeded (e.g. the number c samples out of n samples taken during the specified time period that may exceed the limit m, but not the limit M).

Fig. 1 illustrates a hypothetical 3-class sampling plan using the moving window approach. In this example, $n = 5$ and $c = 2$. Samples are taken on an ongoing basis, but only the five most recent results in the 'window' are used to assess the performance of the control measures up to the point of sampling. As a new sample is taken, the 'window' shifts to the right by one test result, and the oldest result on the left is removed. On the chart in Fig. 1, two 'windows' indicating non-compliance are highlighted as boxes. The first occasion of non-compliance with the MC had occurred in the spotted box to the left, samples 4 to 8, because m was exceeded on more than two occasions (i.e. $c > 2$), and corrective action would have been taken when the result of sample 8 was recorded. The most recent window of the chart is outlined in the spotted box to the right, and is out of compliance with the MC because M is exceeded in the most recent sample. It should be noted that the subsequent windows will also not be compliant with the MC as long as the result exceeding M appears in the window. However, once the cause of the non-compliance has been determined and effectively eliminated, it is normal to continue from scratch with a new window.

3.2. Application of "moving average" window

The application of a "*moving average" window* is focused on measuring over time the maximum average of results obtained