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Development of microbiological criteria to assess the acceptability of a food lot – An example for milk powder☆

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ABSTRACT

Milk powder to be consumed without further treatment to inactivate microorganisms was selected to illustrate the process for establishing and applying a microbiological criterion to assess the acceptability of a food lot. Example criteria (size of analytical unit, sampling plan and limits) were specified for mesophilic aerobic colony count and Enterobacteriaceae as indicators of the adequacy of Good Hygienic Practices and for *Salmonella* as a food safety criterion. Performance characteristics were determined for each criterion using four values for standard deviation of the microbial counts to illustrate how sampling plan performance depends on the within-lot standard deviation, which is uncertain for any given lot and varies among lots. Methods of analysis were specified. A description of how to interpret the results and examples of actions that could be taken by food business operators and competent authorities are provided.

1. Introduction

Microbiological criteria have been used internationally for many years as a means of assessing the safety and suitability of foods. Principles for the establishment and application of microbiological criteria for foods were established by Codex Alimentarius in 1997 and revised in 2013 (CAC, 2013). Microbiological criteria have commonly used as a means for accepting or rejecting a lot of food. However, preventive approaches such as Hazard Analysis and Critical Control Points (HACCP) systems are more effective in ensuring control of microbial hazards in foods. Moreover, advances in microbial risk assessment and risk management frameworks have allowed a more direct relationship between microbiological criteria and public health outcomes and changed some of the ways in which microbiological criteria are being used (CAC, 2007; EFSA, 2007). In revising the principles for the establishment and application of microbiological criteria for foods, the Codex Committee on Food Hygiene established a working group to develop examples for types of microbiological criteria described in the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods*, CAC, 2013). One of the examples is described below.

The primary objective of this example is to illustrate for governments and industry the process for establishing and applying a microbiological criterion (MC) to evaluate a specific lot of food to determine its acceptance or rejection. In addition, the criterion can be used to verify the lot is acceptable for its intended purpose (e.g., verification of control measures such as Good Hygienic Practices (GHPs) and HACCP). For this example, we have selected milk powder intended for direct consumption (i.e., milk powder that will

☆ This example is only intended to help provide an understanding of the development and use of such a microbiological criterion consistent with the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods*; it is not intended that the criteria or actions described in this document be considered universally applicable, nor should these criteria be considered to be the positions of any of the countries that participated in the development of this document.

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be consumed without further treatment to inactivate microorganisms). These criteria would apply to milk powder to be reconstituted with water and consumed, as well as milk powder used to manufacture another product for which there is no microbial inactivation step in the production of that product (e.g., a whipped topping, a seasoning blend).

Competent authorities might use such criteria for testing milk powder for import/export or as part of domestic food control procedures. The criteria might be applied by a food business operator as a verification procedure for milk powder manufactured by that food business (a use that goes beyond the acceptance or rejection of a single lot of food in that this testing becomes part of assessing a process/food safety control system). Food business operators might also use the criteria for accepting from a supplier milk powder that will be used for manufacturing other products that will not receive a treatment that would inactivate pathogens prior to consumption. When food business operators are purchasing milk powder from a supplier, the testing could be performed for acceptance of each lot or as periodic verification of the supplier's controls, depending on the confidence in the supplier's control procedures (e.g., GHPs, HACCP).

A manufacturer may conduct periodic verification testing in accordance with the criteria below, but if such testing indicates a problem, the manufacturer may determine that other (e.g., more stringent) criteria may be appropriate (such as $n = 20$ for *Salmonella* compared to the $n = 10$ proposed in Table 1). Other criteria may also be appropriate when there is an unusual event such as construction or the need for wet cleaning in a dry milk facility. Similarly, use of milk powder in the production of infant formula may indicate the need for additional MC (e.g., MC for *Cronobacter* spp.) or more stringent criteria (e.g., $n = 60$ for *Salmonella*).

2. Purpose

The purpose of these MC is to assess the acceptability of a milk powder lot intended for direct consumption, i.e., the milk powder will be consumed directly or as an ingredient without further treatment to inactivate microorganisms. The MC can also be used for verification of process control.

3. Establishment and application of the criteria

These microbiological criteria may be established by competent authorities, food business operators, or industry associations. They may be applied by competent authorities or food business operators.

These microbiological criteria may be applied at multiple points in the food chain. They may be applied to milk powder

- at the manufacturing facility or in commerce for verification of lot acceptability by competent authorities as part of domestic food control procedures;
- received for import/export inspection by competent authorities;
- for lot acceptance by food business operators purchasing from a supplier;
- at point of manufacture as a verification of process control.

4. Organisms of concern

Different organisms may be of concern in milk powder and criteria established for more than one purpose. For example, hygiene criteria may be established for Mesophilic Aerobic Microorganisms and Enterobacteriaceae, while a food safety criterion may be established for *Salmonella* spp.

Outbreaks of salmonellosis have been caused by contaminated milk powder (ICMSF, 2005, chap. 16; Rowe et al., 1987; Weissman, Deen, Williams, Swanton, & Ali, 1977). Based on epidemiological data, *Salmonella* is considered to be a significant hazard to be controlled during manufacturing of dried products (ICMSF, 2011a, chap. 23). Other hazards that may be considered include *Staphylococcus aureus* and *Bacillus cereus*. However, these pathogens are generally only present sporadically at very low levels unless there is a major breakdown of GHPs. Such a breakdown could result in preformed staphylococcal enterotoxins or *B. cereus* emetic toxin due to growth of these organisms to high levels (ICMSF, 2011a, chap. 23). Low levels of these bacteria ($<10^2$ CFU/g) do not represent a risk to human health as long as the products are not mishandled after reconstitution and before consumption (ICMSF, 2011a, chap. 23). *Listeria monocytogenes* may also be a contaminant in dairy facilities and environmental contamination of product could occur, but there have been no outbreaks of listeriosis linked to dry dairy products and surveys of dry zones of dairy plants and of dry milk products have not indicated this organism would be an issue (ICMSF, 2005, chap. 16). When there is a lack of knowledge about the manufacturer and the controls employed for production, criteria for these organisms may be appropriate. For milk powder to be used for infant formula, an additional criterion would include *Cronobacter* spp. (CAC, 2008).

Mesophilic Aerobic Microorganisms are generally used as an index of utility, as indicators of general contamination, shelf life or spoilage, and are not usually related to a health hazard (ICMSF, 2002, chap. 8). In this example mesophilic aerobic microorganisms are not intended to be used for assessing the safety of a specific lot of product, but instead are intended to be used for verification of hygiene programs. Since milk powder is made from pasteurized milk and has a low water activity that does not support growth of mesophilic aerobic microorganisms, expected

Table 1
Microbiological criteria for mesophilic aerobic colony count, Enterobacteriaceae and *Salmonella* spp. in milk powder for direct consumption.

Organism	Size of analytical unit	Sampling plan		Limits		Class plan[e]
		n[a]	c[b]	m[c]	M[d]	
Mesophilic aerobic colony count	10 g	5	2	1×10^4 CFU/g	1×10^5 CFU/g	3
Enterobacteriaceae	10 g	5	2	<3 MPN/g (none detected)	9.4 MPN/g	3
Salmonella spp.	25 g	10	0	Not detected in 25 g	Not applicable	2

[a] n = Number of analytical units to be analyzed (i.e., analytical units).
[b] c = The maximum allowable number of non-conforming analytical units in a 2-class plan or marginally acceptable analytical units (i.e., between m and M) in a 3-class plan.
[c] m = A microbiological limit which, in a 2-class plan, separates conforming analytical units from non-conforming analytical units or, in a 3-class plan, separates conforming analytical units from marginally acceptable analytical units.
[d] M = A microbiological limit which, in a 3-class plan, separates marginally acceptable analytical units from non-conforming analytical units.
[e] In a 3-class plan a conforming analytical unit is $\leq m$ and marginally acceptable is $> m$ but $\leq M$. In the case of a 2-class plan based on counts (when $c = 0$), a lot will be accepted if all analytical units are less than m and rejected if any analytical unit is greater than or equal to m.).