Food Control 58 (2015) 12–16

Contents lists available at ScienceDirect

Food Control

journal homepage: www.elsevier.com/locate/foodcont

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

Virginia N. Scott [a, *], Mark Powell [b], Josefina Cabrera [c], Maria E. Carullo [d], Inés Martinez [e], Virachnee Lohachoompol [f]

[a] U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, HFS-300, College Park, MD 20740, USA
[b] U.S. Department of Agriculture, Office of Risk Assessment and Cost Benefit Analysis, 1400 Independence Avenue (MS 3811), SW, Washington, DC 20250, USA
[c] National Food Institute, INAL – ANMAT, Ministry of Health, Estados Unidos 25, Piso 1, Microbiologia, C1101AAA Buenos Aires, Argentina
[d] National Service for Health and Quality, Agri-Food (SENASA), Av. Paseo Colon 439, 1063 CABA, Argentina
[e] Technological Laboratory of Uruguay – Latu, Avda. Italia 6201, C.P. 11500 Montevideo, Uruguay
[f] National Bureau of Agricultural Commodity and Food Standards, Ministry of Agriculture and Cooperatives, 50 Phaholyothin Rd., Ladyao, Chatuchak, Bangkok, 10900, Thailand

ARTICLE INFO

Article history:
Received 19 December 2013
Received in revised form
12 September 2014
Accepted 19 September 2014
Available online 30 September 2014

Keywords:
Microbiological criterion
Sampling plans
Lot acceptability
Verification
Milk powder

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.

* Corresponding author. Tel.: +1 240 402 2166.
E-mail addresses: jennyscott@verizon.net, jenny.scott@fda.hhs.gov (V.N. Scott).

http://dx.doi.org/10.1016/j.foodcont.2014.09.026
0956-7135/

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.).

levels of these microorganisms would be low in milk powder; they serve as an indicator of general contamination and the adequacy of GHPs.

Enterobacteriaceae are tested as indicators of the history of the hygiene of the food production process (ICMSF, 2011a, chap. 23). Significant numbers of Enterobacteriaceae frequently indicate inadequacy of GHPs. As with mesophilic aerobic microorganisms, because milk powder is made from pasteurized milk and has a low water activity that does not support growth of Enterobacteriaceae, expected levels would be low and represent contamination from the environment (ICMSF, 2011a, chap. 23). Although *Salmonella* is a member of the family Enterobacteriaceae, there is no well-defined direct relationship between the presence of Enterobacteriaceae and *Salmonella*; testing for Enterobacteriaceae alone is not suitable, as low levels cannot guarantee the absence of *Salmonella* in the product (ICMSF, 2011a, chap. 23).

5. Sampling plans

A sampling plan defining the number of sample units to be taken (n), the size of the analytical unit, the acceptance number (c) and the microbial limits are components of an MC. Suggested sampling plans based on the degree of concern relative to utility and health hazard and whether conditions of handling increase or reduce the degree of concern can be found in the literature (ICMSF, 2002, chap. 8). For this example, it is recommended that the size of the sample from which the analytical unit will be obtained should be approximately 100 g (which may be a composite from multiple locations) to ensure sufficient sample for all tests and to obtain a more representative sample from the lot (which is defined by the manufacturer). In order to maintain the integrity of the sample until arrival at the laboratory and minimize the potential for organism die-off, milk powder should be transported at room temperature with a maximum of 30 °C.

It should be noted that although the lot is defined by the manufacturer, the product represented by a microbiological test may be more than the defined lot. For example, a manufacturer may define a lot based on a production time period, such as an 8-h shift. However, if a product tests positive for a pathogen such as *Salmonella* because of a contaminated ingredient and there was no kill step in producing products made with the contaminated ingredient, other lots than the one tested would be implicated by the test.

Table 1 provides the criteria determined appropriate by a Codex Committee on Food Hygiene working group (established to develop examples for types of microbiological criteria described in the *Principles and Guidelines for the Establishment and Application of Microbiological Criteria*, CAC, 2013) for milk powder to be consumed without further treatment to inactivate microorganisms. Table 1 was derived from recommendations by the International Commission on Microbiological Specifications for Foods (ICMSF, 2011a, chap. 23) and/or working group members based on their experience. As noted in Section 4, other criteria may be appropriate for different circumstances.

5.1. Performance characteristics of the sampling plans

The performance characteristics of sampling plans can be calculated using a downloadable spreadsheet provided by ICMSF at http://www.icmsf.org/main/software_downloads.html.) Readers are referred to Appendix A in Microorganisms in Foods 8: Use of data for Assessing Process Control and Product Acceptance (ICMSF, 2011b) and Appendix 1 in the paper by Van Schothorst et al. (2009) for a more detailed summary of the statistical basis and operation of sampling plans, including helpful figures.

The distribution of microorganisms throughout a food or food lot influences the performance of a sampling plan, and therefore, we provide data for four different values for the standard deviation (s.d.) 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. It is not feasible under normal business situations to determine what standard deviation is likely for production lots being tested. The impact of this is illustrated below for the mesophilic aerobic colony count.

5.1.1. Performance characteristics for the criterion for mesophilic aerobic colony count

Table 2 shows the performance characteristics for the criterion for mesophilic aerobic colony count. The shaded cell in Table 2 can be interpreted as follows: Assuming a lognormal distribution of the target microorganisms in the food, this sampling plan should ensure that food lots with a geometric mean contamination level of 4.22 log cfu/g (16,600 cfu/g) and a standard deviation of the log counts of 0.25 will be rejected 95% of the time. The log of the arithmetic mean concentration of such a lot is 4.29 log cfu/g (19,500 cfu/g). As the standard deviation of the contamination increases, the mean contamination level will be higher before rejection of the lot. For example, the geometric mean concentration increases from 4.22 log cfu/g (16,600 cfu/g) at a standard deviation of the log counts of 0.25 to 4.59 log cfu/g (38,900 cfu/g) at a standard deviation of the log counts of 1.2.

5.1.2. Performance characteristics for the criterion for Enterobacteriaceae

Table 3 shows the performance characteristics for the criterion for Enterobacteriaceae. The shaded cell can be interpreted as follows: Assuming a log normal distribution, this sampling plan will provide 95% probability that a lot of food containing a geometric mean concentration of 4.8 cfu/g (0.68 log cfu/g) and a standard deviation of 0.25 log cfu/g will be rejected. The arithmetic mean concentration of such a lot is 5.7 cfu/g.

5.1.3. Performance characteristics for the criterion for Salmonella spp.

Table 4 shows the performance characteristics for the criterion for *Salmonella* spp. For two-class sampling plans based on a presence-absence detection method, the probability of lot rejection can be calculated based on an assumed statistical distribution of the microbial concentration in a lot. Assuming that the average concentration is lognormally distributed and that the number of cfu in

Table 2
Performance characteristics for the criterion for mesophilic aerobic colony count.

n	*c*	*m*	*M*	Probability of lot rejection	Geometric mean concentration (log_{10} cfu/g)			
					s.d.[a] = 0.25	s.d. = 0.50	s.d. = 0.80	s.d. = 1.2
5	2	10^4 cfu/g (4 log_{10} cfu/g)	10^5 cfu/g (5 log_{10} cfu/g)	0.95	4.22	4.40	4.52	4.59

[a] s.d., standard deviation, log_{10} cfu/g.

Table 3
Performance characteristics for the criterion for Enterobacteriaceae.

n	*c*	*m*	*M*	Probability of lot rejection	Geometric mean concentration (log_{10} cfu/g)			
					s.d.[a] = 0.25	s.d. = 0.50	s.d. = 0.80	s.d. = 1.2
5	2	<3MPN/g (<0.48 log_{10} cfu/g)	9.4 MPN/g (0.97 log_{10} cfu/g)	0.95	0.68	0.76	0.78	0.77

[a] s.d., standard deviation, log_{10} cfu/g.

Table 4
Performance characteristics for the criterion for *Salmonella* spp.

n	*c*	*m*	Probability of lot rejection	Geometric mean concentration (log_{10} cfu/g)			
				s.d.[a] = 0.25	s.d. = 0.50	s.d. = 0.80	s.d. = 1.2
10	0	absence in 25 g	0.95	−1.97	−2.08	−2.25	−2.49

[a] s.d., standard deviation, log_{10} cfu/g.

an analytical unit varies randomly according to the Poisson distribution, the result is a Poisson-log normal distribution (Van Schothorst et al., 2009). The shaded cell can be interpreted as follows: Assuming a Poisson-log normal distribution, this sampling plan will provide 95% probability that a lot of product characterized by a geometric mean concentration of 0.011 cfu/g (−1.97 log cfu/g, or 11 cfu/kg) and a standard deviation of 0.25 log cfu/g will be detected and rejected if any one of the 10 analytical units of 25 g tests positive for *Salmonella*. The arithmetic mean concentration of such a lot is 0.013 cfu/g (13 cfu/kg). Note that such a lot may consist of 74% of the 25 g analytical units being negative and up to 26% of the analytical units being positive for *Salmonella*; 0.38% of this lot could contain concentrations above 0.05 cfu/g. (The performance characteristics of the *Salmonella* sampling plan can be calculated using the "2 class enrichment" worksheet provided by ICMSF at http://www.icmsf.org/main/software_downloads.html.)

Generally contamination of milk powders is a post process occurrence during spray drying. Jongenburger, Reij, Boer, Gorris, and Zwietering (2011) estimated the standard deviation of the distribution of *Cronobacter* in a recalled batch of infant formula powder to be approximately 1.0. Therefore standard deviations of 0.25 or 0.5 are unlikely to be true reflections of reality in such situations (Jongenburger et al., 2011).

6. Method(s) of analysis

Microbiological criteria should also specify the analytical method that applies to the criteria. For the purpose of this example, the following methods (which can be found at http://www.iso.org/iso/home/standards.htm) are provided:

- Mesophilic aerobic colony count: ISO 4833
- Enterobacteriaceae: ISO 21528-1 (MPN technique)
- *Salmonella* spp.: ISO 6785 (Milk and milk products – Detection of *Salmonella* spp.) or ISO 6579 (Horizontal method for the detection of *Salmonella* spp.)

The most recent edition of the ISO standards should be used. Other methods that provide equivalent sensitivity, reproducibility and reliability can be employed if they have been appropriately validated.

7. Interpretation of results

The results of testing for mesophilic aerobic colony count and/or Enterobacteriaceae would be considered as follows:

- satisfactory, if all the values observed are $\leq m$
- acceptable, if a maximum of c units have values that are between m and M and the rest of the values observed are $\leq m$
- unsatisfactory if one or more of the values observed is $> M$ or more than c units are between m and M

The results of testing for *Salmonella* spp. would be considered as follows:

- satisfactory if all values observed indicate the absence of the bacterium
- unsatisfactory if the presence of the bacterium is detected in any of the analytical units

8. Actions in case of non-conformance

Actions to be taken in case of non-conformance should be determined in advance of testing. These actions are often part of business agreements.

8.1. Examples of actions that could be taken by food business operators

Non-conformance with the criteria for mesophilic aerobic microorganisms and/or Enterobacteriaceae:

- Food business operators purchasing from a supplier: (1) Notify the supplier; (2) determine appropriate disposition of the non-conforming lot (e.g., refuse lot or accept marginal quality lot, depending on business contractual arrangements)
- Food business operators manufacturing the milk powder: (1) Check on the efficacy of heat treatment and procedures for prevention of recontamination (2) determine and correct the root cause of the failure: (3) consider the need for pathogen testing; (4) as appropriate, review and revise monitoring procedures, environmental surveillance and prerequisite programs; and (5) determine appropriate disposition of lot (which may include an alternative use for the milk powder).

Non-conformance with the criterion for *Salmonella* spp.:

- Food business operators purchasing from a supplier: (1) Notify the supplier; (2) do not use the milk powder, or if the milk powder has been used do not ship the product; (3) if product has been shipped, recall the product; and (4) determine appropriate steps with respect to the supplier.

- Food business operators manufacturing the milk powder: (1) prevent the affected lot from being released for human consumption; (2) recall the product if it has been released for human consumption; and (3) determine and correct the root cause of the failure.

8.2. Examples of actions that could be taken by competent authorities

Non-conformance with mesophilic aerobic microorganisms and/or Enterobacteriaceae.

(1) notify the manufacturing facility (or, for imports, the competent authority in the country of origin) so the manufacturing facility can (a) take corrective actions with respect to hygienic practices and (b) verify the efficacy of heat treatment and procedures to prevent recontamination
(2) determine disposition of the affected lot, e.g., whether to allow reconditioning of lot, allow use of lot for other purposes, or request destruction (or, for imports, return to country of origin)

Non-conformance with criterion for *Salmonella* spp.:

(1) notify the manufacturer
(2) prevent the affected lot from being released for human consumption;
(3) ensure the food business operator removes product from the market place if it has been released for human consumption;
(4) reject lot at port of entry

9. Summary

This exercise was to develop an example to illustrate the process for establishing and applying a microbiological criterion (MC) to evaluate a specific lot of food to determine its acceptance or rejection. The working group decided that this would be most meaningful if applied to a specific food product in order to identify appropriate microorganisms and applicable criteria; the working group selected milk powder intended for direct consumption (i.e., milk powder that will be consumed without further treatment to inactivate microorganisms) for the exercise. Developing agreed upon criteria was challenging, since a variety of criteria have been used for this and similar products in different countries for a number of years. Ultimately, MC for mesophilic aerobic colony count and Enterobacteriaceae (as hygiene indictors) and *Salmonella* spp (as a food safety criterion) were selected as appropriate for this product, although it was recognized that under certain circumstances criteria for other microorganisms might be appropriate. The working group concluded that the specific MC in Table 1 were appropriate based on recommendations by ICMSF (ICMSF, 2011a, chap. 23) and/or based on the experience of working group members. However, it was recognized that there may be circumstances where different criteria might be appropriate, e.g., if testing indicates a problem may have occurred. The performance of the recommended sampling plans is dependent on the standard deviation of the microbial counts in a lot, which is generally unknown and varies among lots. Thus the performance characteristics of the sampling plans were shown for four different standard deviations to illustrate this. Methods of analysis, interpretation of results and actions to be taken in case of non-conformance, often neglected in the establishment of a microbiological criterion, were also established, although it should be recognized that the actions taken may need to be adjusted based on the specific circumstances of a situation. This example also illustrates that the same MC can be applied not only for accepting/rejecting a single lot, but can be useful for a variety of purposes that are relevant to the production and acceptability of a food lot for its intended use.

Acknowledgments

The authors wish to acknowledge the contributions of those in the country working groups, including from Argentina: Gabriella Alejandra Catalani, Soledad Sarniguet, Daniela Rocchi, Nancy Passalacqua, Estella Maris Reffi, Verónica Trevisan, Margarita Henriquez, Ricardo A. Sobol, Sergio Epsztein, Gerado Leotta, Roberto Urrere; from FAO: Marisa Caipo; from Thailand: Cheunjit Prakitchaiwattana and Pisan Pongsapitch; from the U.S.: John Bowers, Philip Bronstein, Kerry Dearfield, Emily Mathusa Shoaf and Errol Strain; from Uruguay: Pedro Friedrich, Dora Martha Gonzalez, Adriana Da Silva, Graciela Oficialdegui, Ana Ma. Maquieira, Norman Bennett, Graciela Mazzeo, Oscar Gonzalez, Marianela Cremona, Raquel Troche, Gustavo Lancibidad and Mónica Bertacchi.

References

CAC (Codex Alimentarius Commission). (2007). *Principles and guidelines for the conduct of microbiological risk management (MRM) (CAC/GL 63-2007)*.

CAC (Codex Alimentarius Commission). (2008). *Code of hygienic practice for powdered formulae for infants and young children (CAC/RCP 66 – 2008)*.

CAC (Codex Alimentarius Commission). (2013). *Principles and guidelines for the establishment and application of microbiological criteria related to foods (CAC/GL 21-1997)*. Available at http://www.codexalimentarius.org/standards/list-of-standards/ Accessed 28.08.14.

EFSA (European Food Safety Authority). (2007). Opinion of the scientific panel on biological hazards (BIOHAZ) on microbiological criteria and targets based on risk analysis. *EFSA Journal, 462*, 1–29. http://dx.doi.org/10.2903/j.efsa.2007.462. Available at http://www.efsa.europa.eu/en/efsajournal/pub/462.htm Accessed 28.08.14.

ICMSF (International Commission on Microbiological Specifications for Foods). (2002). Microorganisms in foods 7: Microbiological testing in food safety management. In *Selection of cases and attributes plans* (pp. 145–165). New York: Kluwer Academic/Plenum Publishers.

ICMSF (International Commission on Microbiological Specifications for Foods). (2005). Microorganisms in foods 6. Microbial ecology of food commodities (2nd ed.). In *Milk and dairy products* (pp. 643–715). New York: Kluwer Academic/Plenum Publishers.

ICMSF (International Commission on Microbiological Specifications for Foods). (2011a). Microorganisms in Foods 8: Use of data for assessing process control and product acceptance. In *Milk and dairy products* (pp. 305–327). New York: Springer.

ICMSF (International Commission on Microbiological Specifications for Foods). (2011b). Microorganisms in foods 8: Use of data for assessing process control and product acceptance. In *Appendix A. Sampling considerations and statistical aspects of sampling plans* (pp. 355–364). New York: Springer.

Jongenburger, I., Reij, M. W., Boer, E. P. J., Gorris, L. G. M., & Zwietering, M. H. (2011). Actual distribution of *Cronobacter* spp. in industrial batches of powdered infant formula and consequences for performance of sampling strategies. *International Journal of Food Microbiology, 151*, 62–69.

Rowe, B., Hutchinson, D. N., Gilbert, R. J., Hales, B. H., Begg, N. T., Dawkins, H. C., et al. (1987). *Salmonella* Ealing infections associated with consumption of infant dried milk. *Lancet, 330*, 900–903.

Van Schothorst, M., Zwietering, M. H., Ross, T., Buchanan, R. L., Cole, M. B., & International Commission on Microbiological Specifications for Foods (ICMSF). (2009). Relating microbiological criteria to food safety objectives and performance objectives. *Food Control, 20*, 967–979. Also available at http://www.icmsf.org/pdf/JFCO1631.pdf.

Weissman, J. B., Deen, R. M. A. D., Williams, M., Swanton, N., & Ali, S. (1977). An island-wide epidemic of salmonellosis in Trinidad traced to contaminated powdered milk. *West Indian Medical Journal, 26*, 135–143. As cited in D'Aoust, J.-Y., & Maurer J. (2007). *Salmonella* species, pp. 187–236. In Doyle M. P. & L. R. Beuchat (Eds.). Food Microbiology: Fundamentals and Frontiers. (3rd ed.) Washington, D.C: ASM Press.