ISSN 1726-5274



Food and Agriculture Organization of the United Nations



Statistical Aspects of Microbiological Criteria Related to Foods

A RISK MANAGERS GUIDE



MICROBIOLOGICAL RISK ASSESSMENT SERIES For further information on the joint FAO/WHO activities on microbiological risk assessment and related areas, please contact

Office of Food Safety Agriculture and Consumer Protection Department Food and Agriculture Organization of the United Nations Viale delle Terme di Caracalla 00153 Rome, Italy

Email: jemra@fao.org Website: www.fao.org/food/food-safety-quality

Or

Department of Food Safety and Zoonoses World Health Organization 20 Avenue Appia 1211 Geneva 27, Switzerland

Email: jemra@who.int Website: www.who.int/foodsafety

Cover design Food and Agriculture Organization of the United Nations and World Health Organization

Cover picture © Dennis Kunkel Microscopy, Inc



Statistical Aspects of Microbiological Criteria Related to Foods

A RISK MANAGERS GUIDE

Food and Agriculture Organization of the United Nations World Health Organization

Rome, 2016

The designations employed and the presentation of material in this information product do not imply the expression of any opinion whatsoever on the part of the Food and Agriculture Organization of the United Nations (FAO) or of the World Health Organization (WHO) concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. The mention of specific companies or products of manufacturers, whether or not these have been patented, does not imply that these are or have been endorsed or recommended by FAO or WHO in preference to others of a similar nature that are not mentioned. All reasonable precautions have been taken by FAO and WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall FAO and WHO be liable for damages arising from its use.

The views expressed herein are those of the authors and do not necessarily represent those of FAO or WHO.

FAO and WHO declines all responsibility for errors or deficiencies in the software associated with this document, for program maintenance and upgrading as well as for any damage that may arise from them. FAO and WHO also declines any responsibility for updating the software and assumes no responsibility for errors and omissions in the data provided. Users are, however, kindly asked to report any errors or deficiencies in this product to FAO (jemra@who.int) and WHO (foodsafety@who.int).

WHO Library Cataloguing-in-Publication Data: Statistical aspects of microbiological criteria related to foods: a risk manager's guide.

(Microbiological risk assessment series, 24)

1.Food Microbiology - statistics and numerical data. 2.Models, Statistical. 3.Risk Management. 4.Food Contamination. I.World Health Organization. II.Food and Agriculture Organization of the United Nations.

ISBN 978 92 4 156531 8 (WHO) ISBN 978-92-5-108516-5 (FAO) ISSN 1726-5274 (NLM classification: QW 85)

Recommended citation:

FAO/WHO [Food and Agriculture Organization of the United Nations/World Health Organization]. 2016. Statistical Aspects of Microbiological Criteria Related to Foods. A Risk Managers Guide. *Microbiological Risk Assessment Series*, no 24. Rome. 120pp

FAO and WHO encourage the use, reproduction and dissemination of material in this information product. Except where otherwise indicated, material may be copied, downloaded and printed for private study, research and teaching purposes, or for use in non-commercial products or services, provided that appropriate acknowledgement of FAO and WHO as the source and copyright holder is given and that their endorsement of users' views, products or services is not implied in any way. All requests for translation and adaptation rights, and for resale and other commercial use rights should be made via

www.fao.org/contact-us/licencerequest or addressed to copyright@fao.org.

FAO information products are available on the FAO website (www.fao.org/publications) and can be purchased through publications-sales@fao.org.

© FAO/WHO 2016

Contents

	Preface	ix
	Acknowledgements	xi
	Contributors	xii
	Key terms and definitions	xiv
	List of abbreviations and mathematical symbols	xvii
	Executive Summary	xix
	Introduction	1
	About this document	3
1	Basic concepts related to microorganisms in food and	
1	sampling	5
	1.1 Why do we undertake sampling and microbiological testing of	on food? 5
	1.2 What do we need to remember about the characteristics of microbiological populations in food?	6
	1.3 What are the key types of sampling plans?	22
2	Making decisions about an individual lot	30
	2.1 What is a lot?	30
	2.2 Can we redefine the lot after detecting a problem?	31
	2.3 Can microbiological testing be used to define a lot	20
	(e.g. for continuous production)?	32
	2.4 What makes lots independent?	32
	2.5 Can we define a lot geographically?	33
	2.6 What is meant by between-lot testing and lot-by-lot testing	? 33
	2.7 What is the purpose of lot-by-lot testing and who does this?	34
	2.8 What are the important types of sampling plans?	35

3 Making decisions related to process verification	87
3.1 What is meant by food safety control system?	87
3.2 What is meant by verification?	89
3.3 What process control approaches are available?	92
3.4 Moving Windows	96
Concluding Remarks	105
References	107

ANNEXES

Annex 1	Mathematical Details	112
	A1.1 Converting the Mean and Standard Deviation from the \log_{10} scale to the arithmetic scale	112
	A1.2 Calculating the Analytical Unit Detection Probability given the Analytical Unit Amount	112
	A1.3 Two-class presence-absence sampling plans	113
	A1.4 Two-class concentration-based sampling plans	114
	A1.5 Three-class sampling plans	115
	A1.6 Variables sampling plans	115
Annex 2	Resources	117
Annex 3	Links to companion tools for this document	119

Figures

1.	Diagram of a 1 ml food sample containing 1 organism, from which a 10 μ l aliquot, represented by the small squares, is selected (sub-sampled) for testing, e.g. plating.	8
2.	Examples of the spatial distribution of 100 microorganisms over 25 portions of food.	10
3.	Plots of a \log_{10} -normal distribution (left) and normal distribution (right).	13
4.	Graphical representation of a lot of food units, from which a sample of $n = 5$ sample units is selected.	18
5.	Illustration of random, systematic and stratified random sampling for an 8-hour (480 minute) production process of milk powder.	22
6.	An example of a distribution of the \log_{10} concentration of a microorganism in a food lot with the microbiological limit m = 2 \log_{10} cfu/g.	25
7.	An example of a distribution of the \log_{10} concentration of a microorganism in a food lot with the microbiological limits m = 1.5 \log_{10} cfu/g and M = 3 \log_{10} cfu/g.	26
8.	Example OC curve for a two-class presence-absence sampling plan with $n = 15$ and $c = 0$.	37
9.	Two-class concentration-based sampling plan OC curves	39
10.	Idealized and actual OC curves for a food product that is assumed to be unacceptable when the prevalence of contamination is greater than 2%.	41
11.	OC curve showing the Producer's and Consumer's Risk Points.	42
12.	Effect of analytical unit amount (w) on the probability of detecting the organism (analytical unit detection probability)	46
13.	Effect of analytical unit amount on the probability of accepting lots	47
14.	Effect of sample size (n) on the probability of accepting lots, P(accept), when a zero acceptance number sampling plan ($c = 0$) is used.	49
15.	Effect of acceptance number (c) on the probability of accepting lots, P(accept), when the sample size is $n = 30$.	51
16.	Plot of a normal distribution with mean = $1 \log_{10} \text{ cfu/g}$, SD = 0.6 $\log_{10} \text{ cfu/g}$ and $m = 2 \log_{10} \text{ cfu/g}$.	54
17.	Plot of the probability that the concentration in the food exceeds $m = 2 \log_{10} \text{cfu/g}$ when SD = 0.6 $\log_{10} \text{cfu/g}$.	55
18.	Two-class concentration-based sampling plan OC curve using the mean \log_{10} concentration (\log_{10} geometric mean) on the X-axis for a sampling plan with $n = 5$, $c = 0$, $m = 2 \log_{10}$ cfu/g and SD = 0.6 \log_{10} cfu/g.	55
19.	Two-class concentration-based sampling plan OC curve using the arithmetic mean concentration on the X-axis for a sampling plan with $n = 5$, $c = 0$, $m = 2 \log_{10} \text{ cfu/g}$ and SD = 0.6 $\log_{10} \text{ cfu/g}$.	56
20.	Three normal distributions with different means and SDs.	58
21.	Two-class concentration-based sampling plan OC curves with $n = 5$, $c = 0$,	20
	$SD = 0.6 \log_{10} \text{ cfu/g for three different unacceptable limits (m).}$	59
22.	Two-class concentration-based sampling plan OC curves with $n = 5$, $c = 0$, $m = 2 \log_{10} \text{ cfu/g for three different SDs.}$	59

23.	Two-class concentration-based sampling plan OC curves with $c = 0$, $m = 2 \log_{10} \text{cfu/g}$, SD = 0.6 $\log_{10} \text{cfu/g}$ for three different sample sizes.	60
24.	Two-class concentration-based sampling plan OC curves with $n=5$, $m=2 \log_{10} \text{ cfu/g}$, SD = 0.6 $\log_{10} \text{ cfu/g}$ for three different acceptance numbers.	61
25.	Two-class concentration-based sampling plan OC curves for three products with $SD = 0.3$, 0.6 and 0.9 \log_{10} cfu/g and a microbiological limit of $m = 2 \log_{10}$ cfu/g.	62
26.	Plot of a normal distribution with mean = $3.2 \log_{10} \text{ cfu/g}$, SD = $0.55 \log_{10} \text{ cfu/g}$ and microbiological limits $m = 2.7 \log_{10} \text{ cfu/g}$ and $M = 3.7 \log_{10} \text{ cfu/g}$.	65
27.	Probabilities that the concentration in the food is marginal, $P(m < Conc \le M)$, and unacceptable, $P(Conc > M)$, with $SD = 0.55 \log_{10} cfu/g$, $m = 2.7 \log_{10} cfu/g$ and $M = 3.7 \log_{10} cfu/g$.	66
28.	Three-class concentration-based sampling plan OC curve using the mean \log_{10} concentration (\log_{10} geometric mean) on the X-axis for a sampling plan with $n = 5$, $c = 2$, $m = 2.7 \log_{10}$ cfu/g, $M = 3.7 \log_{10}$ cfu/g and SD = 0.55 \log_{10} cfu/g.	66
29.	Three-class concentration-based sampling plan OC curve using the arithmetic mean concentration on the X-axis for a sampling plan with $n = 5$, $c = 2$, $m = 2.7 \log_{10} \text{cfu/g}$, $M = 3.7 \log_{10} \text{cfu/g}$ and SD = 0.55 $\log_{10} \text{cfu/g}$.	67
30.	Three-class concentration-based sampling plan OC curves with $n = 5$, $c = 2$, SD = 0.55 log ₁₀ cfu/g for three different, equally spaced combinations of m and M.	69
31.	Three-class concentration-based sampling plan OC curves with $n = 5$, $c = 2$, SD = 0.55 log ₁₀ cfu/g for three different, unequally spaced combinations of m and M .	70
32.	Three-class concentration-based sampling plan OC curves with $n = 5$, $c = 2$, $m = 2 \log_{10} \text{ cfu/g}$, and $M = 3 \log_{10} \text{ cfu/g}$, for three different SDs.	71
33.	Three-class concentration-based sampling plan OC curves with $c = 2$, $m = 2.7 \log_{10} \text{cfu/g}$, $M = 3.7 \log_{10} \text{cfu/g}$, SD = 0.55 $\log_{10} \text{cfu/g}$ for three different sample sizes.	72
34.	Three-class concentration-based sampling plan OC curves with $n = 5$, $m = 2.7$, $M = 3.7$, SD = 0.55 log ₁₀ cfu/g for three different number of marginally acceptable units (c).	72
35.	Plot of a normal distribution with mean = 0.5 \log_{10} cfu/g, SD = 0.6 \log_{10} cfu/g and microbiological limit m = 2 \log_{10} cfu/g.	76
36.	Plot of the probability that the concentration in the food exceeds $m = 2 \log_{10}$ cfu/g when SD = 0.6 cfu/g.	77
37.	OC curve using the mean concentration (geometric mean) on the X-axis for a variables sampling plan with $n = 5$, SD = 0.6 cfu/g, $m = 2$ cfu/g and	

预览已结束, 完整报告链接和二维码如下:



https://www.yunbaogao.cn/report/index/report?reportId=5_26872