

Microbiological criterion and value of sampling

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Microbiological Criteria

A microbiological criterion defines the limit above which a food is considered to be contaminated at an unacceptable level with a micro-organism, its toxin or metabolite and is therefore considered to be unsafe for consumption.

A microbiological criterion also contains the following components:

- the sampling plan (the number of samples of a food that should be taken)
- the laboratory method (the method which should be used to test the food)
- the stage in the food chain where the criterion applies
- the corrective action to be taken when the criterion is not met (the action to be taken when there are unsatisfactory results).

Types of microbiological criteria

- Process hygiene criteria: These criteria indicate if the production process is operating in a hygienic manner. They are applicable to foodstuffs at various stages throughout their production processes.
- Food safety criteria: These criteria define the acceptability of a food in terms of its microbiological safety. They are applicable to food placed on the market and throughout the shelf-life of the food.

Microbiological criterion under Indian regulations

Canned meat & meat products (2002)

Total Plate Count –	1000cfu/g
<i>E. coli</i>	0/25g
<i>Salmonella</i>	0/25g
<i>Staph aureus</i>	0/25g
<i>Clostridium botulinum</i>	0/25g
<i>Clostridium perfringens</i>	0/25g

Frozen mutton, goat, beef & buffalo meat (2002)

Total Plate Count	1,00,000cfu/g
<i>Salmonella</i>	0/25g
<i>Listeria</i>	0/25g
<i>E. coli</i>	100cfu/g
<i>Staph aureus</i>	100cfu/g
<i>Clostridium botulinum</i>	30cfu/g
<i>Clostridium perfringens</i>	30cfu/g

Microbiological criterion under Indian regulations

Spices(2006)

Salmonella

0cfu/25g

Frozen prawns, Raw (2005)

Total Plate count Not more than 5,00,000 cfu/g

E. coli Not more than 20 cfu/g

Staph aureus Not more than 100 cfu/g

Salmonella 0 cfu/25g

Shigella 0 cfu/25g

Vibro cholerae 0 cfu/25g

Vibro parahaemolyticus 0 cfu/25g

Frozen prawns, Cooked (2005)

Total Plate count	Not more than 1,00,000 cfu/g
<i>E. coli</i>	0 cfu/25g
<i>Staph aureus</i>	0 cfu/25g
<i>Salmonella</i>	0 cfu/25g
<i>Shigella</i>	0 cfu/25g
<i>Vibro cholerae</i>	0 cfu/25g
<i>Vibro parahaemolyticus</i>	0 cfu/25g

Carbonated beverages, ready to serve beverages Fruit beverages (2005)

Total plate Count	Not more than	50cfu/ml
Yeast and Mould count	Not more than	2cfu/ml
Coliform		0/100ml

Yoghurt/Dahi(2006)

Total Plate Count	Not more than	10,00,000cfu/g
<i>Coliform</i>	<i>Not more than</i>	<i>10cfu/g</i>
<i>E. coli</i>		<i>0cfu/g</i>
<i>Salmonella</i>		<i>0cfu/25g</i>
<i>Shigella</i>		<i>0cfu/25g</i>
<i>Staph aureus</i>	<i>Not more than</i>	<i>100cfu/g</i>
<i>Yeast & mould</i>	<i>Not more than</i>	<i>100cfu/g</i>
<i>Anaerobic Spore count</i>		<i>0cfu/g</i>
<i>Listeria monocytogens</i>		<i>0cfu/g</i>

Components of Microbiological Criteria as per Codex

1. A statement of the organisms of concern and /or their toxins
2. The analytical methods for their detection and quantitation
3. A sampling plan, when and where sampling to be taken
4. Microbial limits considered appropriate to the food
5. The number of sample units that should conform to these limits

What is sampling plan?

It is a statement of the criteria applied to a lot based on appropriate examination of a required number of sample units by specified methods. It should have a sampling procedure and decision criteria.

USFDA refusals on account of presence of *Salmonella*

Month	% consignments
August	7
July	26
June	24
May	9
April	17
March	15

False negative at the time of shipping and positive on arrival at US port

Could it be due to

- error in sampling ?
- Improper laboratory methods used ?

Impact

- Food safety objective is defeated
- Economic loss to the country
- Effect on the image of the country

A well designed sampling plan

can define the probability of detecting
microorganism in lot

but no sampling plan ensure the absence of a
particular organism

Choice of plan to should take into account

1.Risks to public health associated with hazard

2.Susceptibility of the target group of consumers

3.Heterogeneity of distribution of micro
organisms when variable plans are employed

Decision Tree for Sampling plan

Organism of Concern

Presence or absence tests

No

Yes

Measured by count

2- class attributes plan

3- class attributes plan

Accept the presence of this organism?

No

Yes

$C = 0$

$C > 0$

Essential elements of sampling plan

1. The microbe or group of microbes of concern or interest
2. Number of samples tested (n)
3. Testing methods (s)
4. Microbiological limit (s),
 - . Acceptable ($< m$)
 - . Marginally acceptable ($> m$ and $< M$)
 - . Unacceptable ($> M$)
5. Number of samples which fall into each category of microbiological limits(ie acceptable /marginal/unacceptable)

Operating characteristic curve should accompany the sampling plan

Types of Sampling

Two class attributes plan

One limit

Two attributes Less than or equivalent
More than the limit

Three class attributes plan

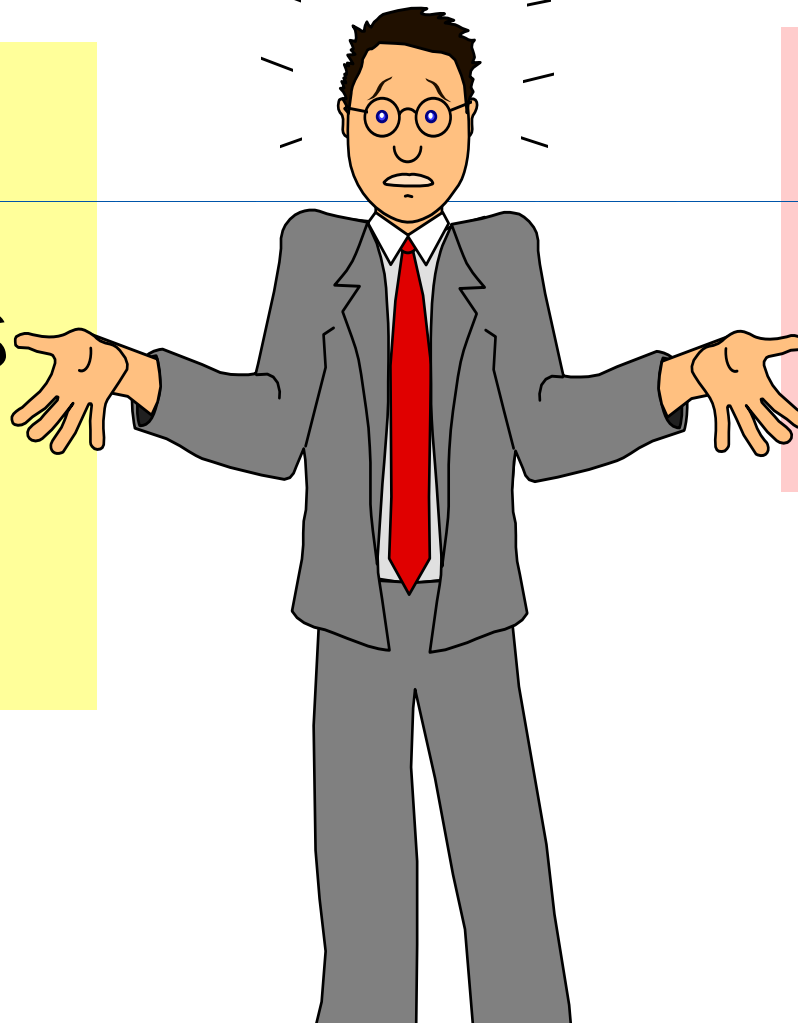
Two limits

Three attributes Less than or equivalent GMP limit
More than GMP but less than hazardous limit
More than hazardous limits

SAMPLE SIZE

Too Big:

- Requires too many resources



Too small:

- Won't do the job

Binomial probability of detecting defective units with increasing sample units from a lot having 3% true defectives

Probability of detecting defective units

No of samples tested	0	1	2
5	0.86	0.133	0.008
10	0.74	0.228	0.032
20	0.54	0.336	0.099
50	0.22	0.337	0.256

Calculation of sample number based on expected levels of contamination

Binomial distribution: CI 95%, RP=20%

10%	864
15%	544
20%	384
25%	288
30%	224
35%	178
40%	144
45%	117
50%	96

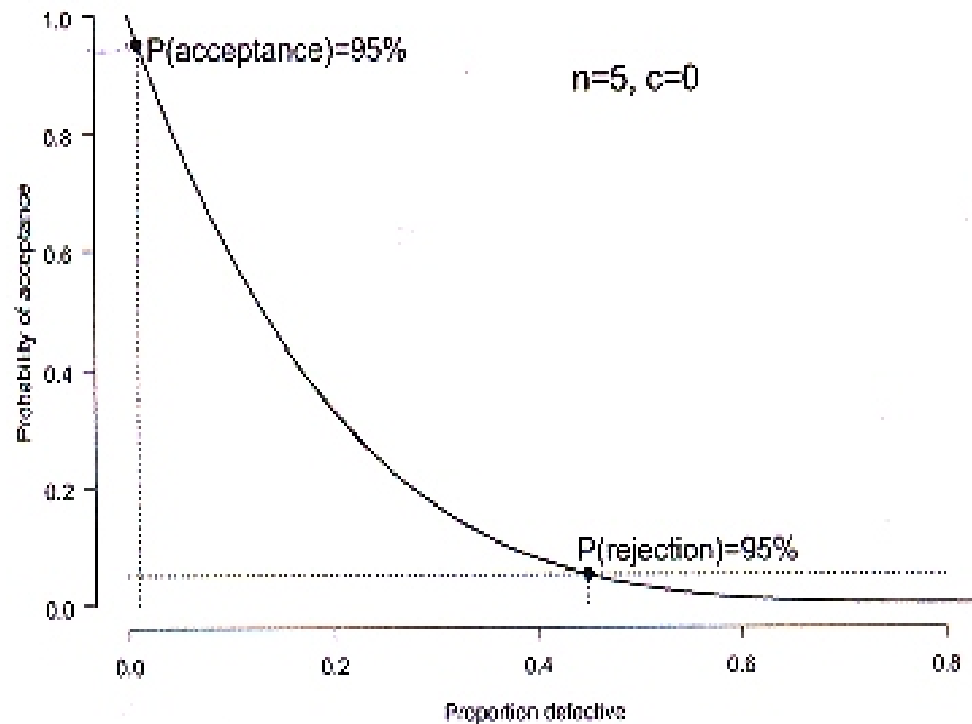


Figure 1 OC-curve for a two-class sampling plan in relation to proportion defective

Ref: Dahms S, Mitt.Lebensm, Hyg, 95, 32-44 (2004)

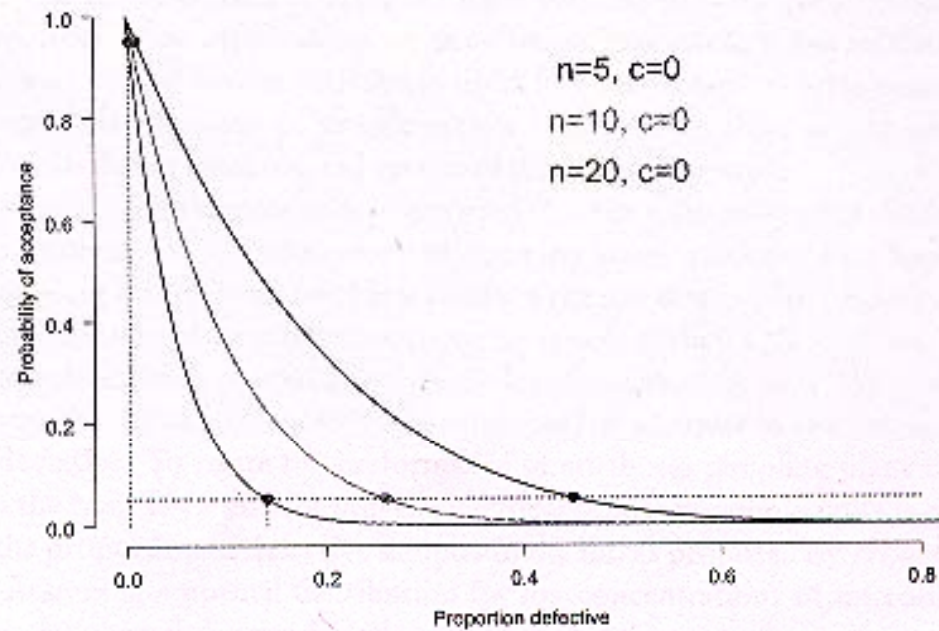


Figure 2 OC-curves for two-class sampling plans in relation to proportion defective with varying number of sample units

Ref: Dahms S, Mitt.Lebensm, Hyg, 95, 32-44 (2004)

Sampling Plan for *Salmonella* (USFDA)

Food Category I :- This includes the foods that would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption. they are intended for consumption by the aged, the infirm, and infants.

Food Category II :- This includes the foods that would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption

Food Category III :- Food that would normally be subjected to a process lethal to salmonella between the time of sampling and consumption

Sample size	Category I	60 units
	Category II	30 units
	Category III	15 units

Foods under different categories

Category I & II All High risk foods, nuts and nut products, oils, coffee-tea candies and prepared salads

Category III Processed grains , fresh vegetables, vegetable oils and food additives

Two class plan

Salmonella in beef

$$n=20$$

$$c=0$$

$$m=0$$

All the samples must be negative

If one sample is positive, entire lot is rejected

To make more effective sampling plan increase the number

Sampling Plans

Microbiological limit in foods

Poultry products

	n	c	m	M
<i>APC</i>	5	3	10^4	10^5
<i>S.aureus</i>	5	1	10^2	10^4
<i>E.coli</i>	5	2	10	10^2
<i>Salmonella</i>	10	0	0	0

Market samples of Poultry products in Hyderabad

Levels of *Staphylococcus aureus* contamination

Food	n	$\geq 10^6$	$\geq 10^4$	$\geq 10^2$
Chicken fried rice	94	8	2	7
Chicken noodles	94	12	3	5

Levels of *Salmonella* contamination

Food	n	$\geq 10^6$	$\geq 10^4$	$\geq 10^2$
Chicken fried rice	94	0	0	0
Chicken noodles	94	1	0	0

Plan stringency in relation to degree of health hazard and conditions of use

Type of Hazard	Conditions in Which Food Is Expected to Be Handled and Consumed after Sampling		
	Reduce Degree of Hazard	Cause No Change in Hazard	May Increase Hazard
<i>No direct health hazard</i>			
Utility (e.g., general contamination, reduced shelf-life, and spoilage)	Case 1	Case 2	Case 3
<i>Health hazard</i>			
Low, indirect (indicator)	Case 4	Case 5	Case 6
Moderate, direct, limited spread	Case 7	Case 8	Case 9
Moderate, direct, potentially extensive spread	Case 10	Case 11	Case 12
Severe, direct	Case 13	Case 14	Case 15

Source: ICMSF (16); copyright © 1986 by University of Toronto Press, used with permission.

Table 21-3 ICMSF Sampling Plans and Recommended Microbiological Limits

Products	Tests	Case	Class Plan	N	c	m	M	Comments
Precooked breaded fish	APC	2	3	5	2	5×10^6	10^7	Products likely to be mishandled In-plant processing
	<i>E. coli</i>	5	3	5	2	11	500	
	<i>S. aureus</i>	8	3	5	1	10^3	10^4	
Raw chicken (fresh or frozen), during processing	APC	1	3	5	3	5×10^6	10^7	<i>m</i> value is an estimate
Frozen vegetables and fruit, pH 4.5	<i>E. coli</i>	5	3	5	2	10^2	10^3	
Comminuted raw meat (frozen) and chilled carcass meat	APC	1	3	5	3	10^6	10^7	In-plant control
Cereals	Molds	5	3	5	2	10^2-10^4	10^5	<i>m</i> values are estimates <i>m</i> value is estimated
Frozen entrées containing rice or corn flour as a main ingredient	<i>S. aureus</i>	8	3	5	1	10^3	10^4	
Noncarbonated natural mineral and bottled noncarbonated waters	Coliforms	5	2	5	0	0	—	Not for use in infant formula or use by highly susceptibles
Roast beef	<i>Salmonella</i>	12	2	20	0	0	—	
Frozen raw crustaceans	<i>S. aureus</i>	7	3	5	2	10^3	10^4	
	<i>V. parahaemolyticus</i>	8	3	5	1	10^2	10^3	
	<i>Salmonella</i> [*]	10	2	5	0	0	—	
	APC [†]	2	3	5	2	5×10^5	10^7	
	<i>E. coli</i> [†]	5	3	5	2	11	500	
	<i>S. aureus</i> [†]	8	2	5	0	10^3	—	

Note: Except where noted for in-plant use, they are intended primarily for foods in international trade and are cited here primarily to illustrate the assignment of products to case and limits on a variety of organisms. The ICMSF⁹ should be consulted for methods of analysis and more details in general.

^{*}Normal plans and limits.

[†]Additional tests where appropriate.

Example of effective use of Microbiological criteria and sampling design of ICMSF with HACCP

Rutgers Food Service Program

17 years experience

30 million meals

1600 food samples (1983-89)

1.24% contained pathogens

No foodborne illness

Ref : James Jay . Modern Food Microbiology 2005

KABP STUDY ON FOOD AND DRUG SAFETY IN INDIA - A REPORT

**World Bank Assisted Capacity Building Project on
Food Safety and Quality Control of Drugs**



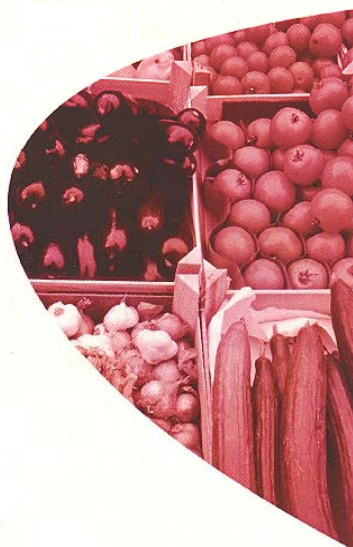
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Knowledge and practices of food safety regulators in Southern India

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Abstract

Purpose – To assess knowledge, perceptions and practices of grassroots-level food safety regulators.
Design/methodology/approach Knowledge, attitude and practices (KAP) study using quantitative and qualitative methods for data collection. Quantitative data was collected using a pre-tested knowledge assessment questionnaire. Qualitative data was collected by conducting a focus group discussion (FGD) and six in-depth interviews among food safety regulators from all 23 districts of the South Indian state of Andhra Pradesh. Quantitative data were analysed using SPSS package (version 14.5). The FGD and in-depth interviews' recordings were transcribed verbatim and translated into English before compiling them into individual reports. These reports were read independently by a group of researchers before inferences were drawn.

Findings – The respondents' knowledge on basic food microbiology was limited. They attributed their inability to monitor all cases of food poisoning/adulteration to delay in receiving information and lack of laboratory facilities. They had sound knowledge of conventional adulterations, but were not equipped to check newer adulterations. Their knowledge on health/nutrition claims on food labels is almost nil. Orientation towards food safety issues other than adulteration is the need of the hour.

Originality/value – The results of the study can serve as the basis for developing an in-service training module for food safety regulators.

Keywords Food safety, Regulation, India

Paper type Research paper

Thank you for your kind attention