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Development of Microbiological Criteria : Indonesia's Experience

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Outlines

- Introduction
- Food (Microbiological) Risk Management in Indonesia
- Indonesia Standard of Microbiological Limit for Foods *Perka* 2009
- Initiatives for the Development of New Microbiological Standards in Foods
- Steps in Developing Microbiological Criteria in Indonesia
- Microbiological Criteria *Perka* 16 2016
- Challenges
- Conclusions

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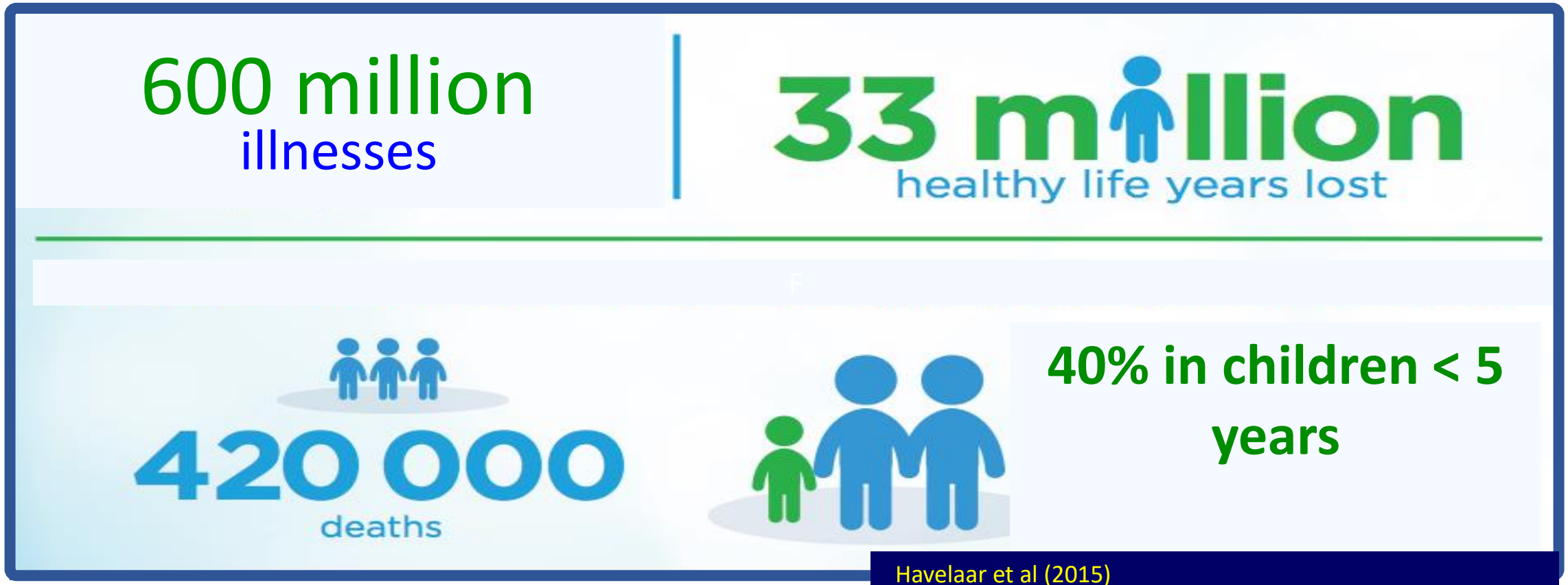
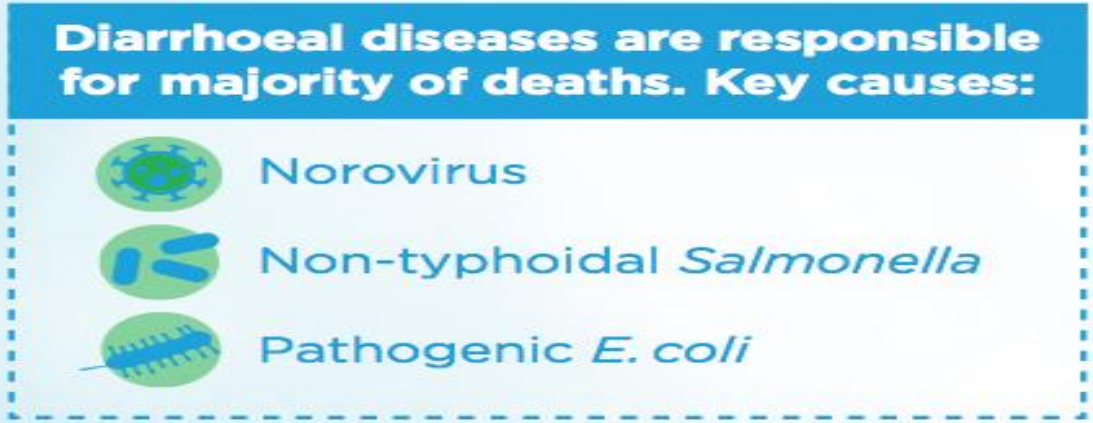
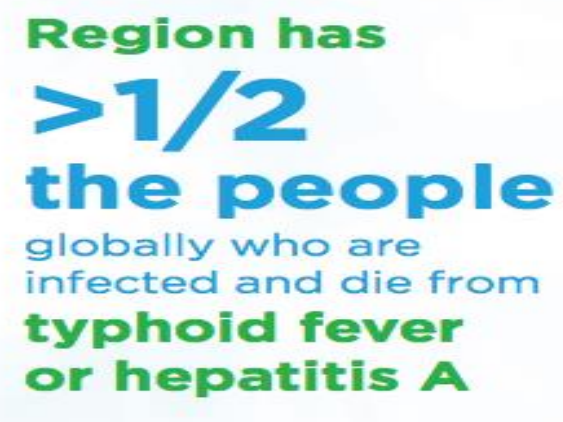
Introduction



Havelaar et al (2015)

Introduction





- 150 million illnesses
- 175 000 death
- 12 millions DALYs

Havelaar et al (2015)

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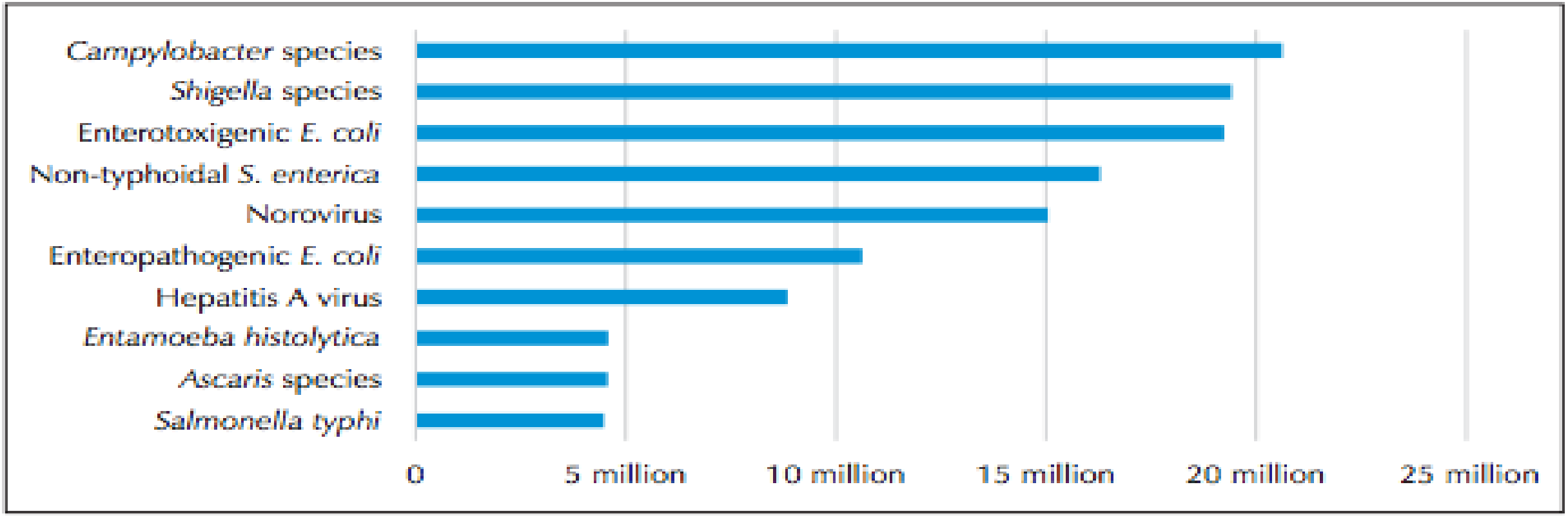
10 Most Common Foodborne Pathogens in SEA



Source: FERG Report (2015)

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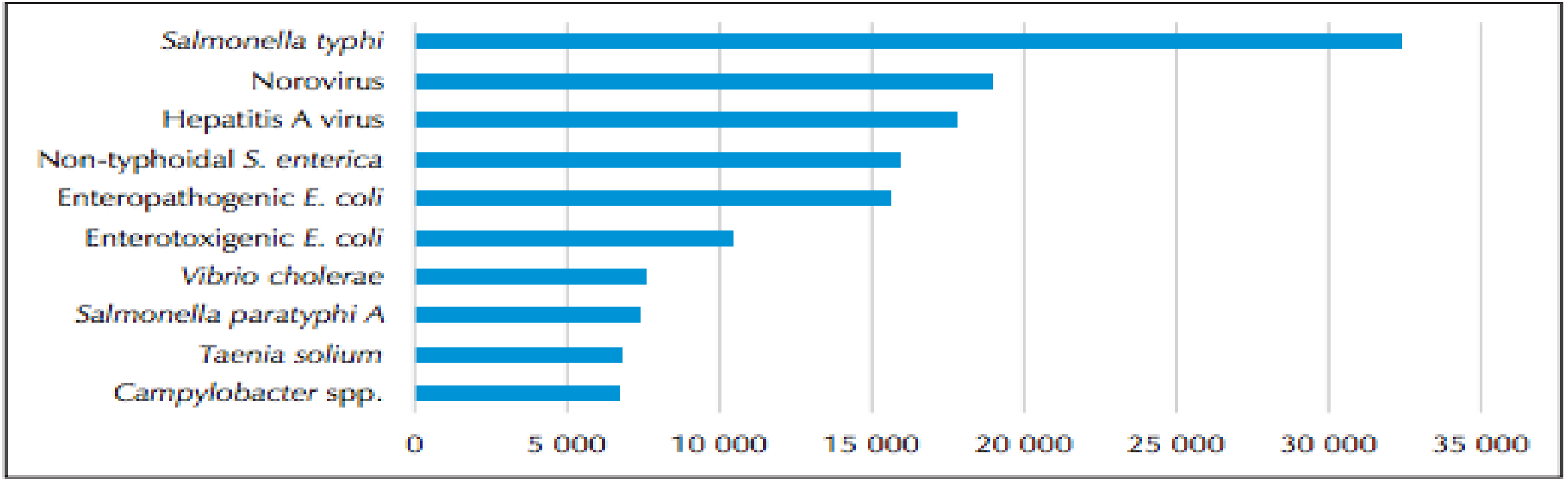
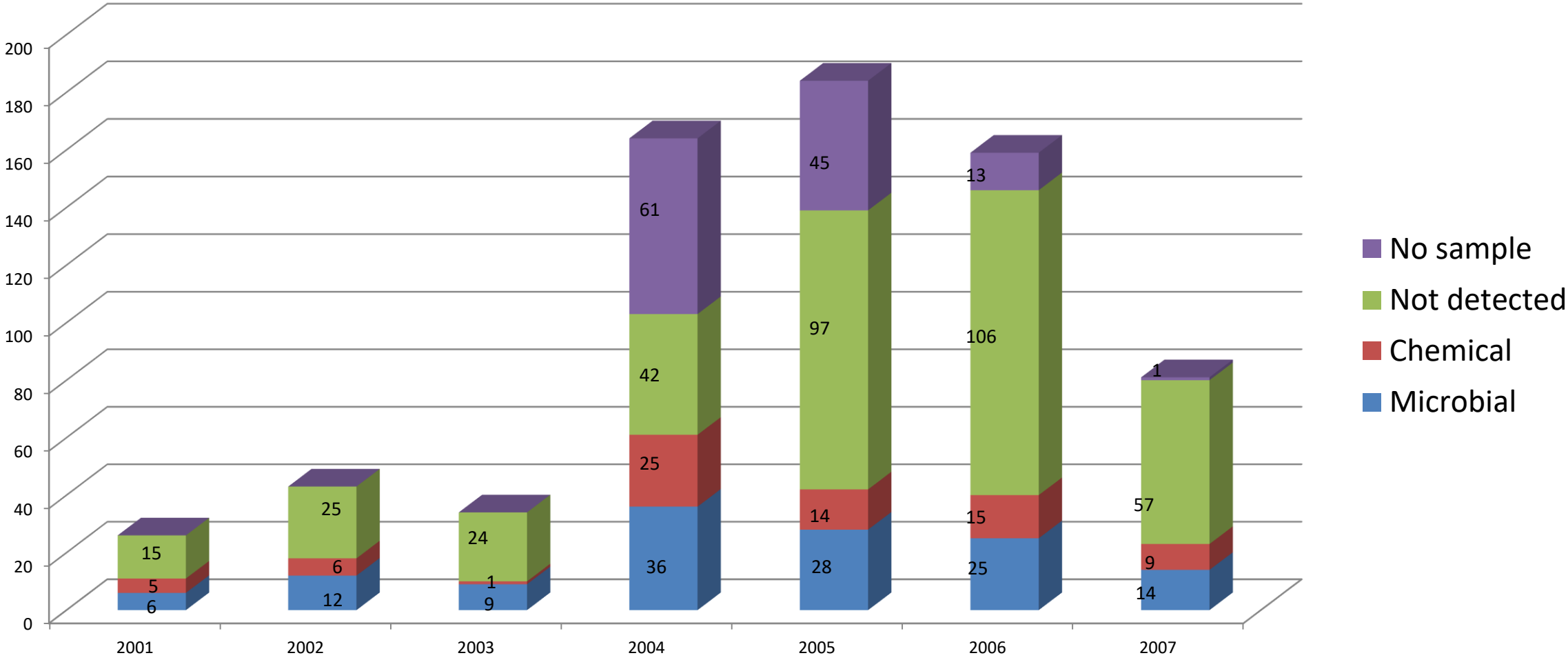
10 Most Common Foodborne Pathogens Causing Fatal Foodborne Disease Outbreaks in SEA



Source: FERG Report (2015)

Reported Foodborne Disease Outbreaks in Indonesia 2001-2007



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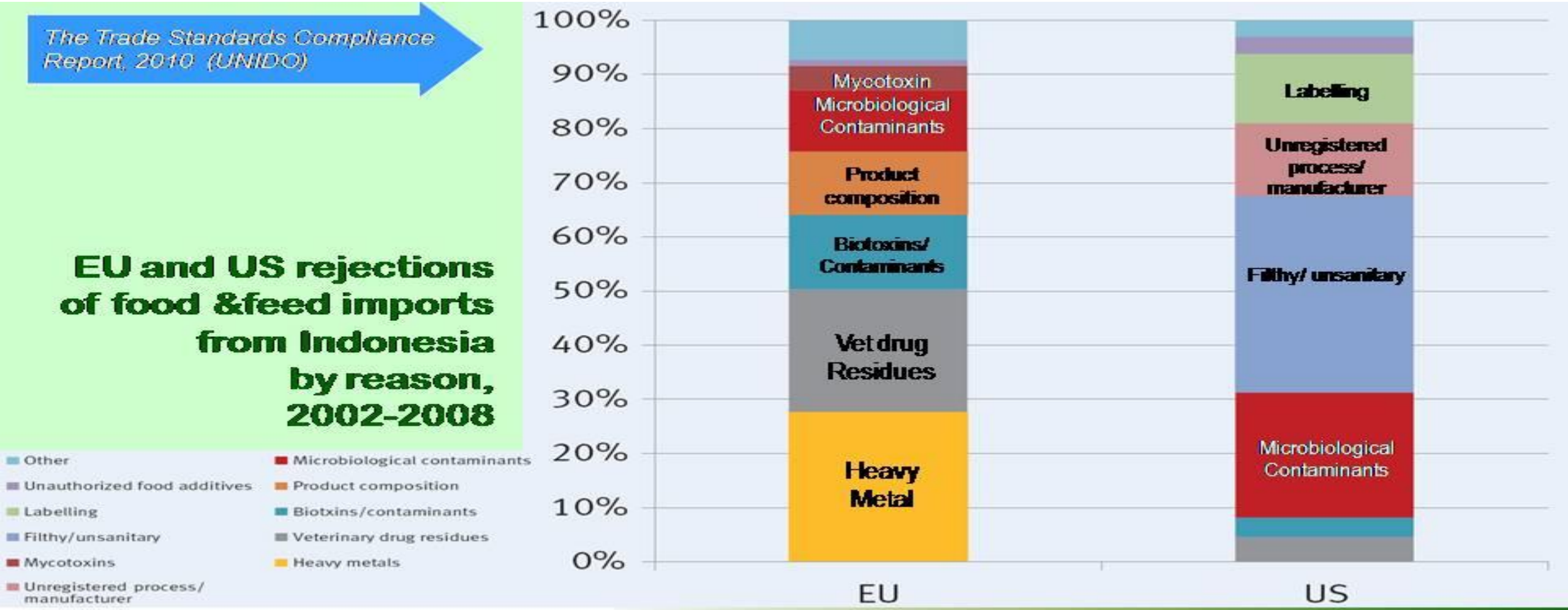
Food Safety and International Trade

The Trade Standards Compliance Report, 2010 (UNIDO)

EU and US rejections of food &feed imports from Indonesia by reason, 2002-2008



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Food (Microbiological) Risk Management in Indonesia

- Pre-market Evaluation :

  registration of products : information on facility, evaluation of GMP (and HACCP, when applicable), product testing to meet the standard

- Post-market Evaluation

  assessment of GMP (and HACCP, when applicable) in the facility by food inspectors and product testing at retail (sampling priority, risk-based)

Indonesia Standard of Microbiological Limits for Foods *Perka* 2009

- Standard for food product testing was issued by BPOM or NADFC (The National Agency for Drug and Food Control) : HK.00.06.1.52.4011, 28 October 2009
- Mandatory
- Are also adopted by the National Standardization Agency for standards of commodity etc

Indonesia Standard of Microbiological Limits for Foods *Perka* 2009

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LAMPIRAN
PERATURAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN
REPUBLIK INDONESIA
NOMOR HK.00.06.1.52.4011
TANGGAL 28 OKTOBER 2009

A. JENIS DAN BATAS MAKSIMUM CEMARAN MIKROBA DALAM MAKANAN

	14 food categories	Types of M.o.	Limit
1	Susu pasteurisasi (*plain* atau berperisa)	ALT (30°C, 72 jam)	$5x10^4$ koloni/ml
		APM Koliform	10/ml *
		APM *Escherichia coli*	<3/ml
		Salmonella sp.	negatif/25 ml

Indonesia Standard of Microbiological Limits for Foods *Perka* 2009

Examples

No	Food	Microorganisms	Limit
6	Non-dairy creamer	APC (30°C, 72 h)	2x 10^2 CFU/g
		MPN Coliform	10/g
		Salmonella sp	negative/25 g
		S aureus	1 x 10^2 CFU/g
7	Pasteurized cream	APC (30°C, 72h)	5x10^4 CFU/g
		MPN Coliform	10/g
		Salmonella sp	negative/25 g
		S aureus	1 x 10^2 CFU/g
		L. monocytogenes	negative/25 g

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Indonesia Standard of Microbiological Limits for Foods *Perka* 2009

Problems

- The standard does not have a sampling plan, does not call for sample number : in practice producers may test only one sample in a lot which does not say much about the quality and safety of the whole lot, some do “retesting” when a pathogen is present
- The standard does not specify methods : cause confusion regarding methods to be used
- A “go” lot (tested in the country) sometimes is rejected in the importing countries (microbiological distribution)

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Initiatives for the Development of New Microbiological Standards in Foods

In 2013 The NADFC initiated an effort to revise its standards using Microbiological criteria (Codex 1997, revised in 2013) as a reference, acknowledging :

- the distribution of microorganisms in foods
- testing only one sample in a lot can not depict the microbiological distribution in a lot
- the more samples tested, the better microbiological distribution in a lot can be estimated
- testing only will not assure food safety

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Microbiological Criteria

- A microbiological criterion is a risk management metric which indicates the acceptability of a food, or the performance of either a process or a food safety control system following the outcome of sampling and testing for microorganisms, their toxins/metabolites or markers associated with pathogenicity or other traits at a specified point of the food chain.

Codex 1997, rev. 2013

Microbiological Criteria

A microbiological criterion consists of the following components:

- The purpose of the microbiological criterion;
- The food, process or food safety control system to which the microbiological criterion applies;
- The specified point in the food chain where the microbiological criterion applies;
- The microorganism(s) and the reason for its selection;
- The microbiological limits (m, M) or other limits (e.g. a level of risk);
- A sampling plan defining the number of sample units to be taken (n), the size of the analytical unit and where appropriate, the acceptance number (c);
- Depending on its purpose, an indication of the statistical performance of the sampling plan; and
- Analytical methods and their performance parameters.

Codex 1997, rev. 2013

Steps in the Development of Microbiological Criteria in Indonesia

- Establish a core team consisted of officials at the Directorate of Standardization of NADFC and Center Laboratory for Food Analysis as well as expert panel from academia and laboratories related to food microbiology and food processing
- Establish communication with internal stakeholders (Directorates within NADFC and district offices/laboratories) and external stakeholders (food industry associations and other ministries) through : (a) seminar, (b) call for data, (c) public consultations, (d) meetings, (e) e-mail etc (2013-2015)

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Steps in the Development of Microbiological Criteria in Indonesia

The Core Team Assigments:

1. Define the objectives
2. Determine the food categories
3. Determine the point of testing
4. Define microorganisms associated with the food
5. Establish the cases (n, c)
6. Determine m and M
7. Propose the analytical methods

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Steps in the Development of Microbiological Criteria in Indonesia

1 Determine the Objectives

The main use of the standard (MC) developed is as the guideline for producers in releasing food products to achieve the expected quality and safety

Steps in the Development of Microbiological Criteria in Indonesia

2 Determine the Foods

- The food types to be regulated are all (processed) foods to be registered and distributed in Indonesia, including imported foods
- The NADFC had a Document of Food Category (based on Codex Food Category) which was undergoing revision at the time of the MC development

Steps in the Development of Microbiological Criteria in Indonesia

3 Determine the Point of Testing :

The main application of the new MC is for NADFC task/authority in evaluating processed food (end products) through pre and post market evaluation

- To be applied in product registration
- To be applied at retail level during shelf life
- Could be applied by other institution at point of entry, i.e. for imported foods

Steps in the Development of Microbiological Criteria in Indonesia

4 Define the microorganisms

- Utility microorganisms to represent good manufacturing practices : aerobic plate count, total yeast, total mold
- Indicator microorganisms to represent hygiene/ sanitation practices : coliform, *Escherichia coli, Enterobacteriaceae*
- Pathogens with epidemiological associations with the foods; mainly *Salmonella*, *Listeria monocytogenes*, *Staphylococcus aureus* etc

Steps in the Development of Microbiological Criteria in Indonesia

4 Define the microorganisms

- Ranking of pathogen follows ICMSF (2002)
- Types of pathogen are chosen based on (1) the track record of the pathogen in foodborne outbreaks (food-pathogen pair), (2) food processing and their effect on microorganisms and (3) microbial pathogen potentially present in raw materials

- Team uses Codex, other countries' MC as references as well as data on outbreaks and/or food safety issues in Indonesia

Microbiological Criteria Used as Comparison

- EU Commission Regulation for Foodstuff (2005)
- China GB 29921-2013
- The Phillippines (2013)
- Australia New Zealand Food Standard on Microbial Limit (2000)
- *Perka* 2009

And

- ICMSF documents and spreadsheets

Steps in the Development of Microbiological Criteria in Indonesia

5 Establish Cases

- Table of Cases (ICMSF 2002) was initially used as a reference
- A case defines the number of sample to be tested (n) and the number of sample allowed to exceed microbial limit (m) or have a marginal quality (between m and M)
- Several guidelines in Codex is also used
- There was reluctance (by stakeholders) for larger n, except for PIF

Cases (Stringency of Sampling Plan)

Type of Hazard	Conditions in which food is expected to be handled and consumed		
	Reduce degree of hazard	Cause no change in hazard	May increase hazard
		Increasing risk →	
No direct health hazard Utility (e.g. general contamination, reduced shelf life, and spoilage	Case 1 3 class, $n = 5, c = 3$	Case 2 3 class, $n = 5, c = 2$	Case 3 3 class, $n = 5, c = 1$
Health hazard			
Low, indirect (e.g indicator organism)	Case 4 3 class, $n = 5, c = 3$	Case 5 3 class, $n = 5, c = 2$	Case 6 3 class, $n = 5, c = 1$
Moderate, direct, limited spread	Case 7 3 class, $n = 5, c = 2$	Case 8 3 class, $n = 5, c = 1$	Case 9 3 class, $n = 10, c = 1$
Moderate, direct, potentially extensive spread	Case 10 2 class, $n = 5, c = 0$	Case 11 2 class, $n = 10, c = 0$	Case 12 2 class, $n = 20, c = 0$
Severe, direct	Case 13 2 class, $n = 15, c = 0$	Case 14 2 class, $n = 30, c = 0$	Case 15 2 class, $n = 60, c =$

↓ increasing severity

*ICMSF, 2002

Steps in the Development of Microbiological Criteria in Indonesia

6 Determine m and M

m = microbiological limit between good and bad product in 2-class sampling plan or between marginal and bad product in 3-class sampling

≤ m should be achieved by good manufacturing practices

M = microbiological limit between marginal and bad product in 3-class sampling plan

- m and M values were determined using data from industry (submitted upon call for data), data from registration using *Perka* 2009, inspection data, MC in other countries

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PO* ⟶ FSO* ⟷ ALOP*

- Mean concentration of lot based on industry data achievable under GMP
- Data from registration on product testing based on microbiological limit from *Perka* 2009
- Evaluation of the performance of MC's from other countries

*PO=Performance Objectives, FSO = Food Safety Objectives, ALOP =Apropriate Level of Protection (ICMSF 2002)

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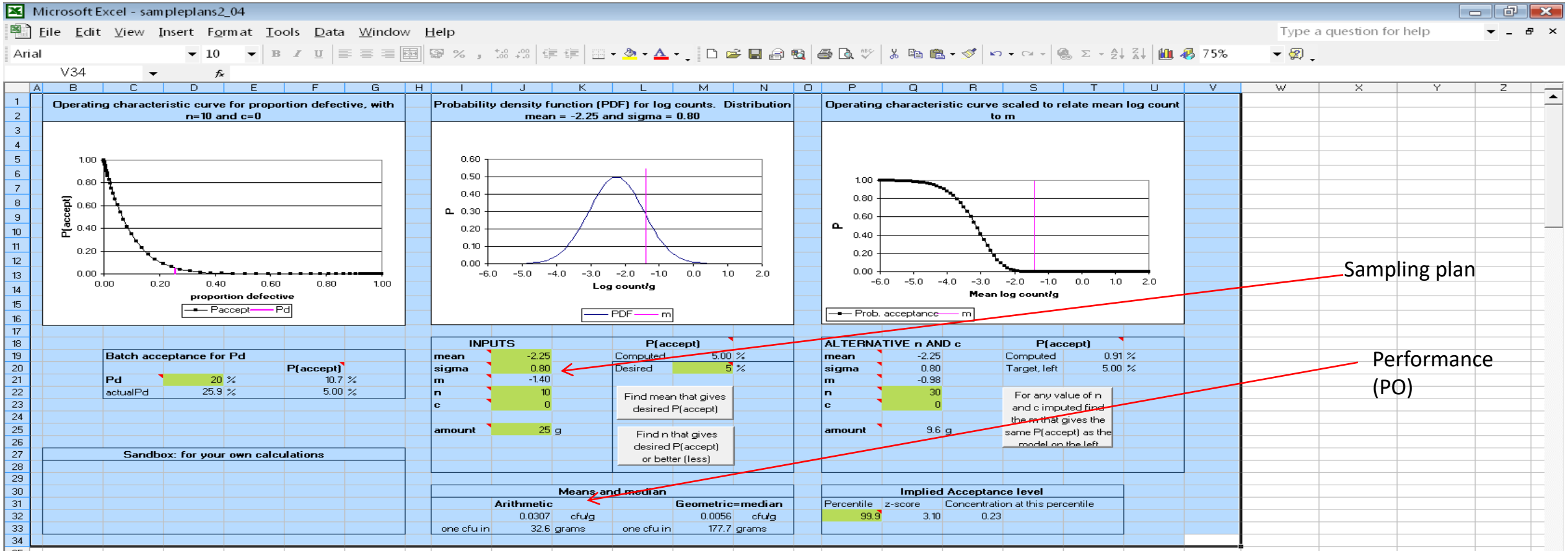
Spreadsheet for Sampling Plan

www.icmsf.org



Steps in the Development of Microbiological Criteria in Indonesia

7 Determine Analytical Methods

- The microbiological analysis methods were chosen based on the methods most commonly used by NADFC and all stakeholders' laboratories (ISO and BAM)

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Microbiological Criteria in Indonesia *Perka* 16 2016

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REPUBLIK INDONESIA
NOMOR 16 TAHUN 2016
TENTANG
KRITERIA MIKROBIOLOGI DALAM PANGAN OLAHAN

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Microbiological Criteria in Indonesia *Perka* 16 2016

Article I
General Requirement
(Clausul 1)

Article II
Microbiological Criteria
(Clausul 2-3)

Article III
Controls
(Clausul 4)

Article IV
Sanctions
(Clausul 5)

Article V
Transition Period
(Clausul 6)

Article VI
Closing Statement
(Clausul 7-8)

Attachment
Microbiolgical Croteria for Processed Foods

Microbiological Criteria in Indonesia *Perka* 16 2016

- Issued in August 2016, in effect August 2017
- Covers 14 food categories excluding thermally processed (sterile commercial) foods
- Attachment to *Perka* 16 2016 consists of :
  - food types
  - microorganisms to be tested
  - sampling plan and limits (n, c, m, M, unit analysis)
  - analytical methods

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Microbiological Criteria in Indonesia *Perka* 16 2016

Attachment

Food Category	Food Type	Microorganism tested	n	C	m	M	Analytical Method
01.0 Dairy and its analog, except those of category 02.0							
01.1.1.1. Milk (plain)	Pasteurized milk	APC	5	1	10^4 CFU/mL	10^5 CFU/mL	ISO4833-1 (2013); SNI2897 (2008)
		Enterobacteriaceae	5	2	< 1 MPN/mL	5 APM/mL	ISO 21528-1 (2012)
		Salmonella	5	0	Negative/25 mL	-	ISO 6579 (2002), SNI2897 (2008)
13.1 Foods for Special Purposes							
13.1.1 Powder Infant Formula		APC	5	2	$5x10^2$/g	$5x10^2$/g	IISO4833-1 (2013); SNI2897 (2008)
		Enterobacteriaceae	10	2	Negative/10 g	-	ISO 21528-1 (2012)
		Cronobacter sakazakii	30	0	Negative/10 g	-	ISO/TS 22964:2006
		Salmonella	30	0	Negative/25 g	-	ISO 6579 (2002), SNI2897 (2008)

Challenges during Development

- Determination of pathogens mostly referred to international cases since outbreak investigation report was limited
- For establishing m and M, data from registration were less useful because those are data from products that comply the existing standards, data from inspection and surveillance as well as from industry (voluntary) were limited
- The use of ICMSF Table to establish n and c is a challenge, it was decided that the changes toward a more stringent (and better performance) sampling plan will be done step by step and with the current *Perka* in some cases the lower performance was acknowledged

Challenges during Implementation

- During implementation (2017-2018) :
  - several criteria especially pertaining SPC and yeast/molds for certain products (coffee, cacao, herbs) were considered too stringent by industries
  - there is still a confusion on the concept of sampling plan, especially in the district testing labs
  - There are concerns regarding the definition of lots
  - A minor revision is underway, mainly to provide more information on the “unclear” definitions

Conclusions

- Indonesia had improved the food microbiological standards for processed foods
- It is acknowledged that while testing does provide better confidence for the producers, it does not guarantee safety
- Advisory and/or enforcement to ”built” safe food through prevention is of concern and is gradually being enforced, i.e. Risk Management Program for PIF; Separate Sterile Commercial Products Regulation
- Implementation of GMP and/or HACCP is also subject for premarket evaluation and inspection

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Thank You

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