Development of Microbiological Criteria for Processed Foods: Indonesia's Experience

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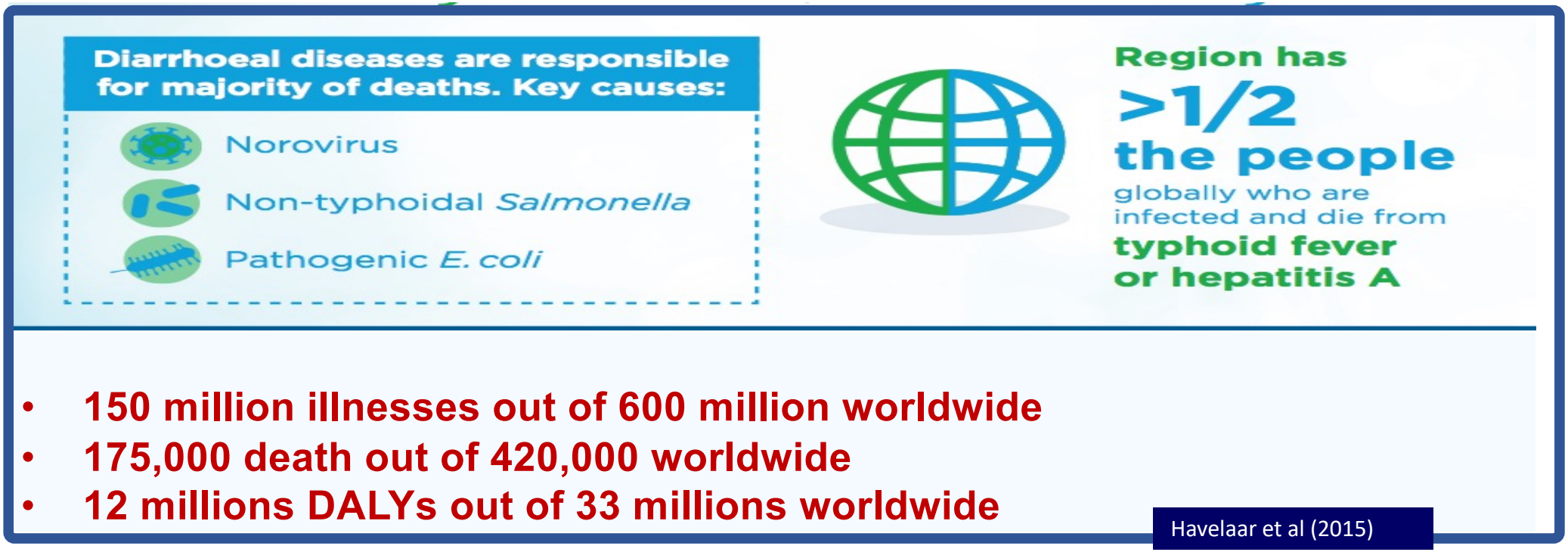
International Commission on Microbiological Specification for Foods (ICMSF)

Outlines

- Introduction
- Microbiological Risk Management of Processed Foods by NADFC
- Standard for Microbiological Contaminants in Foods 2009
- Development Microbiological Criteria in Foods
    - Microbiological Criteria NADFC 16/2016,
    - Evaluation of the implementation of NADFC/16 2016
    - Revised Microbiological Criteria (NADFC 13/2019)
    - Technical Guide to the application of NADFC/13 2019
- Conclusions

Introduction

FERG-WHO : Estimated Foodborne Disease Burden in SEA

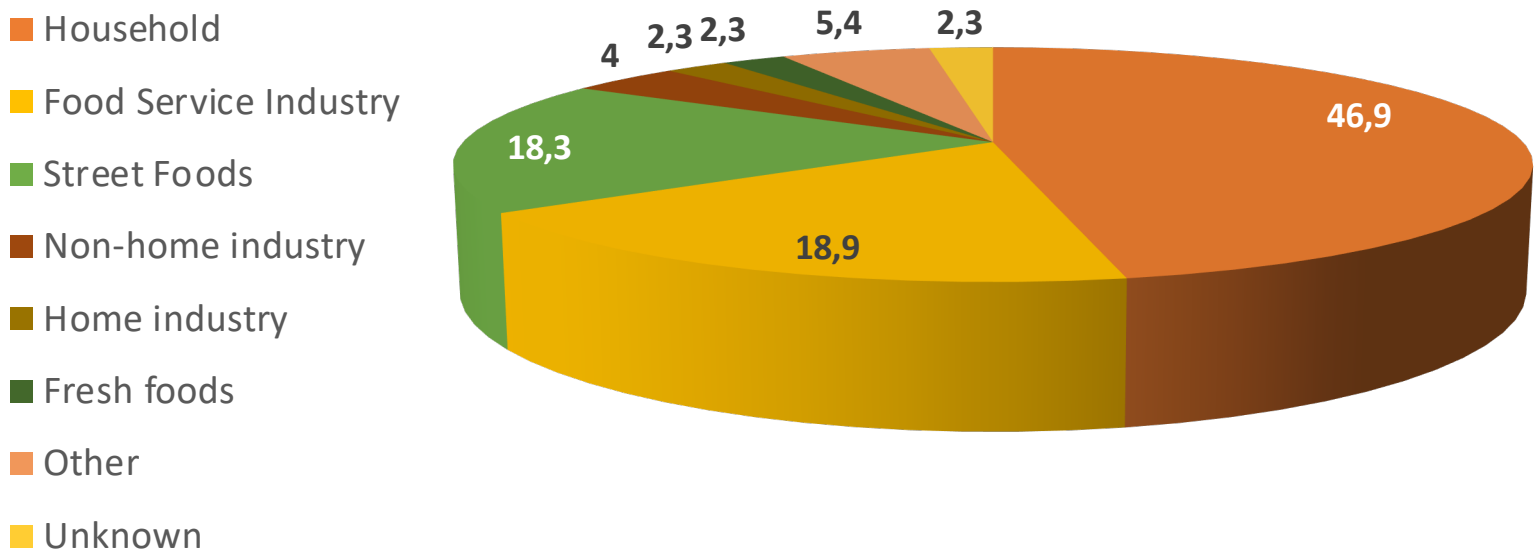


- **150 million illnesses out of 600 million worldwide**
- **175,000 death out of 420,000 worldwide**
- **12 millions DALYs out of 33 millions worldwide**

Havelaar et al (2015)

Foodborne Diseases in Indonesia

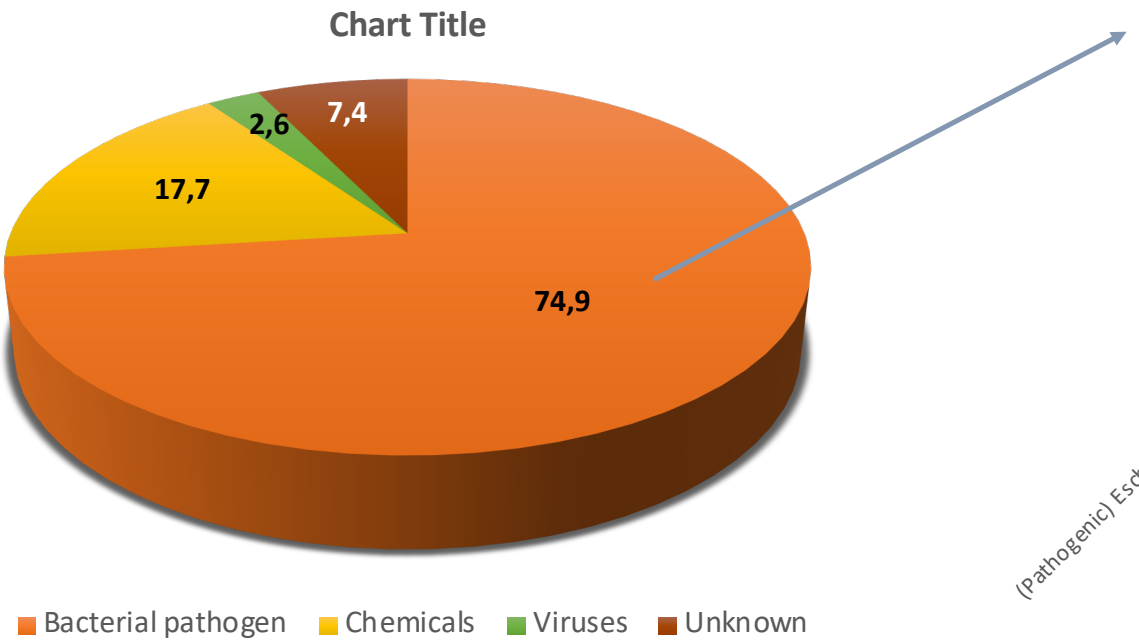
Foods Epidemiologically Linked to the Outbreaks[1]

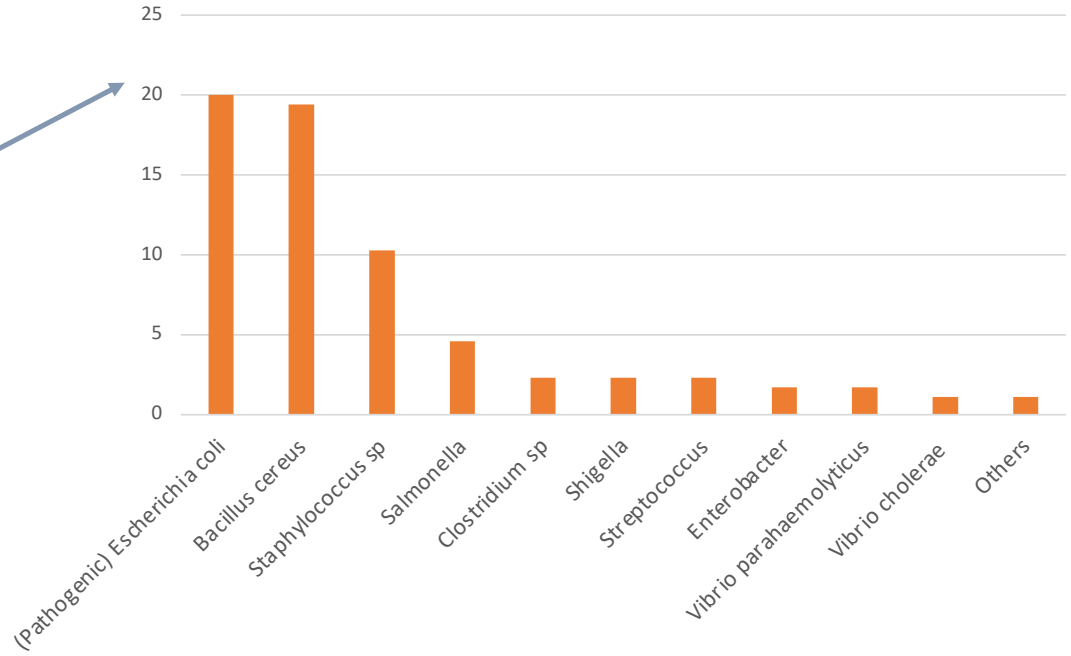


[1]Arisanti, Indriani, Wilopo.2018. *BKM Journal of Community Medicine and Public Health 34(3) :96-106*

Foodborne Diseases in Indonesia

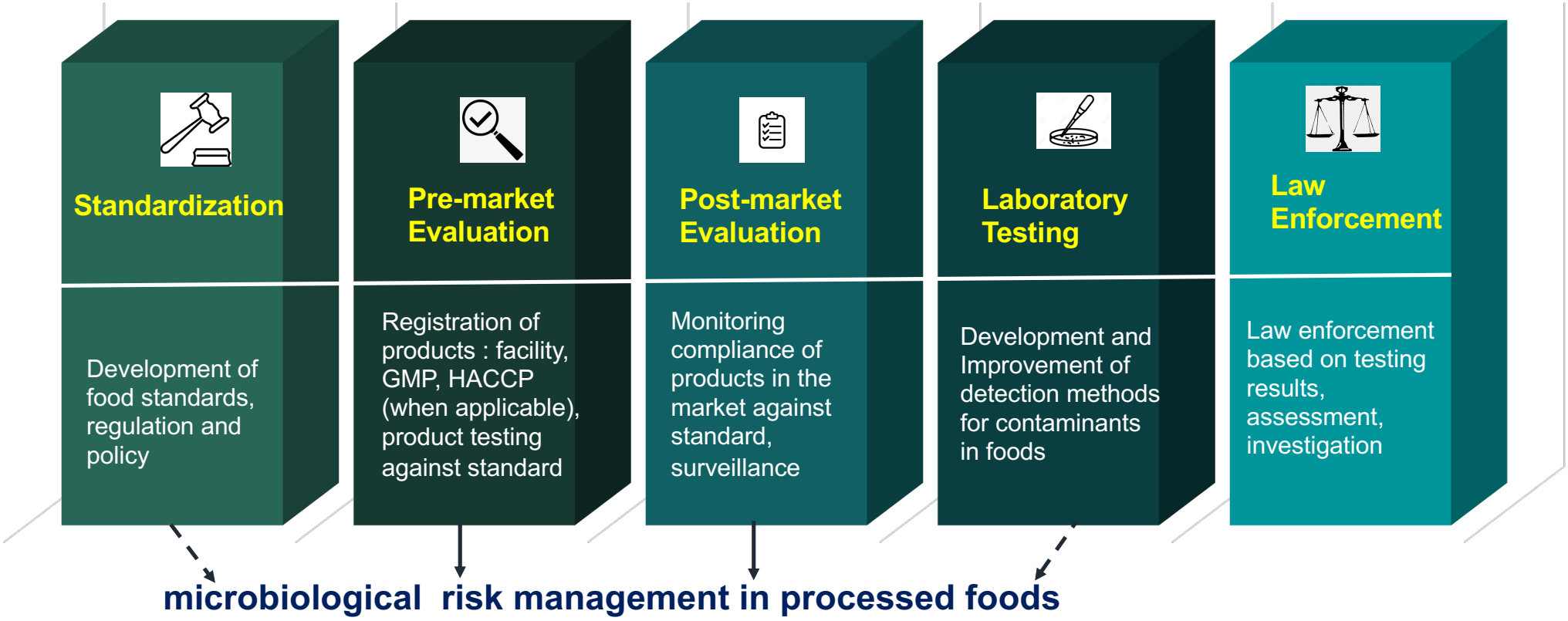
Etiological Agents[1]





[1]Arisanti, Indriani, Wilopo.2018. *BKM Journal of Community Medicine and Public Health 34(3) :96-106*

Microbiological Risk Management of Processed Foods in NADFC[1] Food Safety Management System[2]



[1]NADFC : National Agency for Drug and Food Control, [1]Etikasari 2021)

Standard for Microbiological Contaminants in Foods

- The Government Regulation no 86 2019 (previously GR 28 2004) mandates the NADFC (National Agency for Drug and Food Control) to set limits for microbial contamination for processed foods
- The requirement is also to be adopted by the National Standardization Agency (NSA) for commodity standards
- Perka BPOM HK.00.06.1.52.4011 year 2009 (NADFC Regulation no : HK.00.06.1.52.4011 year 2009) set the limits for contaminant in processed foods which were mandatory

Standard for Microbiological Contaminants in Foods

- **NADFC HK.00.06.1.52.4011 2009 set the microbiological limits (bacteria, yeast, mold) for various food categories, with a single limit**
- **Legal standard for industry to comply**

BADAN PENGAWAS OBAT DAN MAKANAN
REPUBLIK INDONESIA

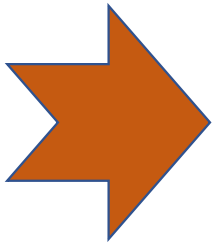
LAMPIRAN
PERATURAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN
REPUBLIK INDONESIA
NOMOR HK.00.06.1.52.4011
TANGGAL 28 OKTOBER 2009

An example

Foods	Microorganisms	Maximum limit
Pasteurized milk	TPC (72 h, 30^0C)	5 x 10^4
	MPN coliform	10/mL
	MPN E. coli	<3/mL
	Salmonella	Negative/25 mL
	Staphylococcus aureus	1 X 10^2 CFU/ML

Standard for Microbiological Contaminants in Foods : NADFC HK.00.06.1.52.4011/2009

- The standard is used as reference by food manufacturers for accepting the lots
- Was developed based on standards from other countries
- Since it does not state the sampling plan :



  - producers may test only one sample in a lot
  - producers "retest" when a pathogen is present
  - a "go" lot (tested in the country) sometimes is rejected in the importing countries

Standard for Microbiological Contaminants in Foods : NADFC HK.00.06.1.52.4011/2009

- The standard does not fulfil CAC/GL 21/1997 (rev 2013) on Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods[1] :
  - Objective is not stated
  - Sampling plan is not included : sample number (n), number exceeding limit (c)
  - Microbiological limit (m and/or M) : only m is included
  - Step in which a standard apply : not stated
  - Reference methods : not available
- Some of the requirements are too stringent or irrelevant[1]

Martoyo, Dewanti-Hariyadi, Rahayu.2014. Jurnal Standardisasi 16(2): 113-124

Microbiological Criteria

Definition

- A microbiological criterion (MC) 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.

Components

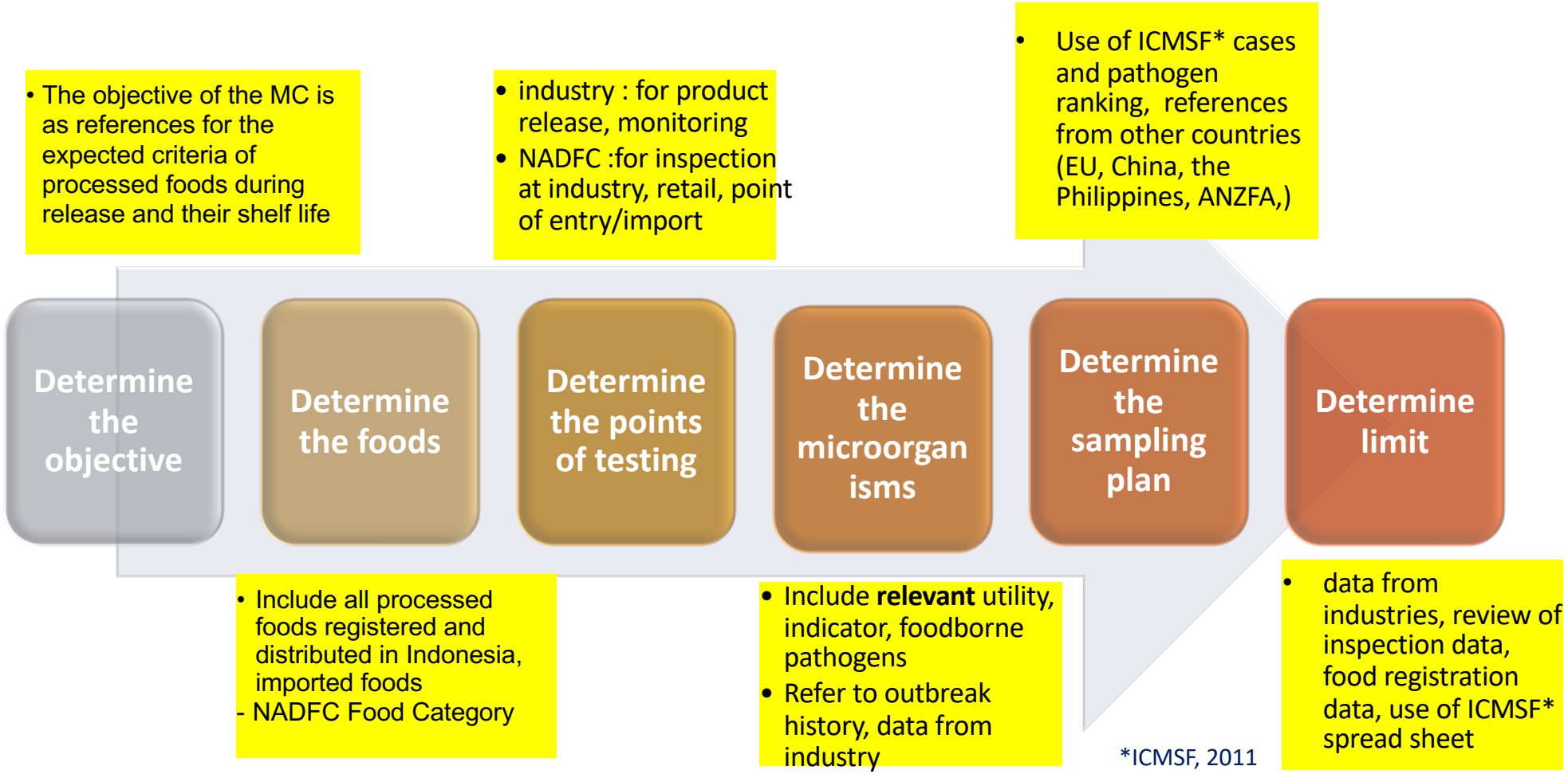
- The purpose of the microbiological criterion;
- The food, process or food safety control system to which the MC applies;
- The specified point in the food chain where the MC applies;
- The microorganism(s) and the reason for its selection;
- The microbiological limits (m, M) or other limits
- A sampling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

CAC/GL 21 1997, rev. 2013

Development of New Microbiological Standards for Processed Foods in INdonesia

- In 2013 the NADFC initiated an effort to revise its standards, using a more scientific approaches and national contaminant data as well as reference of CAC GL 1997 (rev 2013) to improve food safety and quality
  - Establish a team (NADFC Directorate of Standardization, NADFC Central Laboratory for Food Testing and expert panel)
  - Assign the team to draft Microbiological Standard according to CAC/GL 21 1997 (rev 2013)
  - Establish communication with **internal stakeholders** (Directorates within the 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)

Development of New Microbiological Standards for Processed Foods in Indonesia



Challenges during the Development of Microbiological Criteria

- National data of outbreak is limited, hence also refer to international outbreaks
- For establishing m and M, data from registration were less useful because those are data from products that comply the existing standards, limited data from inspection and surveillance as well as from industry (voluntary) were available
- 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 would be done step by step, thus with the current *regulation;* in some cases the lower performance were acknowledged

Microbiological Criteria for Foods : NADFC Reg. 16/2016

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

PERATURAN KEPALA BADAN PENGAWAS OBAT DAN MAKANAN
REPUBLIK INDONESIA
NOMOR 16 TAHUN 2016
TENTANG
KRITERIA MIKROBIOLOGI DALAM PANGAN OLAHAN

DENGAN RAHMAT TUHAN YANG MAHA ESA

KEPALA BADAN PENGAWAS OBAT DAN MAKANAN

Microbiological Criteria in Indonesia NADFC 16/2016

Article I
General Requirement
(Clause 1)

Article II
Microbiological Criteria
(Clauses 2-3)

Article III
Controls
(Clause 4)

Article IV
Sanctions
(Clause 5)

Article V
Transition Period
(Clause 6)

Article VI
Closing Statement
(Clauses 7-8)

Attachment
Microbiolgical Criteria for Processed Foods

Microbiological Criteria in Indonesia NADFC 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 Implementation

A qualitative study surveying informants from industry and government for evaluation of the implementation of the NADFC 16/12016 was carried out

- Industry : several criteria especially pertaining SPC and yeast/molds for certain products (coffee, cacao, herbs) were still considered too stringent
- Government (inspectors): there is still confusion on the concept of sampling plan, especially at the district laboratories

2018

A qualitative study on the implementation of NADFC 16/2016*

1. Revision of NADFC 16/2016
2. Development of the technical guide for the implementation of the new regulation

July 9 2019

NADFC no.13 year 2019 on Revised Microbiological Criteria for Processed Foods is issued

Revision:

1. Addition of definition
2. New clausul on the definition of microbiological criteria, microbial limit, and sampling plan
3. Revision on microbiological limit for some foods

*Informants from industry (15) and NADFC (45) : Interview and focus group discussion

Microbiological Criteria in Indonesia NADFC 13/2019

BADAN PENGAWAS OBAT DAN MAKANAN
REPUBLIK INDONESIA

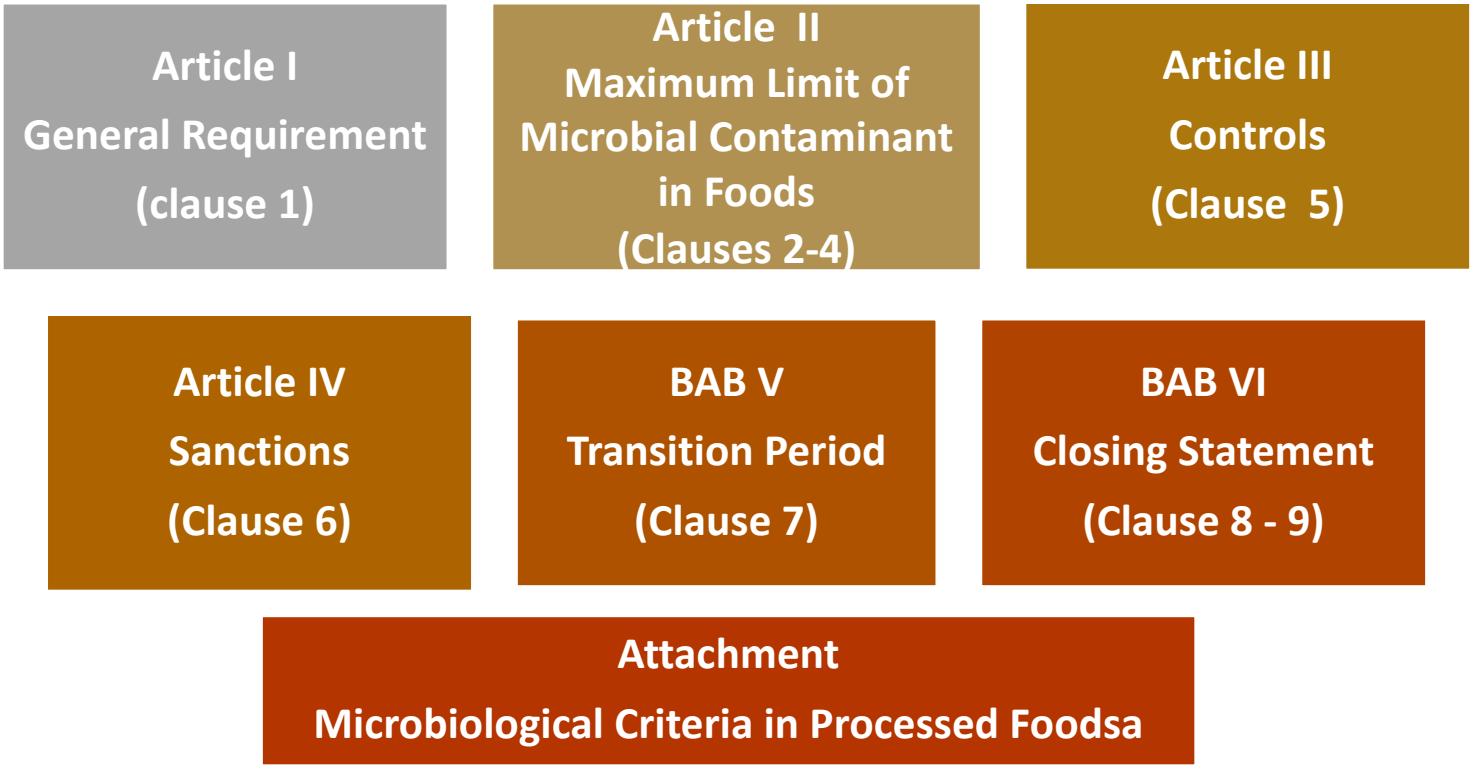
PERATURAN BADAN PENGAWAS OBAT DAN MAKANAN
NOMOR 13 TAHUN 2019
TENTANG
BATAS MAKSIMAL CEMARAN MIKROBA DALAM
PANGAN OLAHAN

DENGAN RAHMAT TUHAN YANG MAHA ESA

KEPALA BADAN PENGAWAS OBAT DAN MAKANAN,

- **Issued in July 9, 2019**
- **Covers 14 food categories excluding thermally processed (sterile commercial) foods – no changes**
- **Addition of 10 terms and definitions to the existing 6**
- **Addition of the definition on microbiological criteria**

Microbiological Criteria in Indonesia NADFC 13/2019



Technical Guide for the implementation of NADFC 13/2019

to help district inspectors for conducting

- Sampling
- Compositing, when necessary
- Testing
- Interpreting results
- Reduced sampling or tightened sampling
- etc

Conclusions

- Indonesia has integrated science to improve its microbiological standard for processed foods
- The new standard includes all components of microbiological criteria (CAC/GL 21 1997) and completed with the technical guidelines, thus it is expected to be able to reflect the microbiological quality and safety of the food product (lots)
- Microbiological Criteria is only one of the tools in improving food safety in Indonesia, advisory and/or enforcement to ”built” safe foods through **prevention** is paramount :
    - Implementation of GMP and/or HACCP
    - Risk Management Program for PIF (others to follow)
    - Separate Sterile Commercial Products Regulation

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Thank You

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