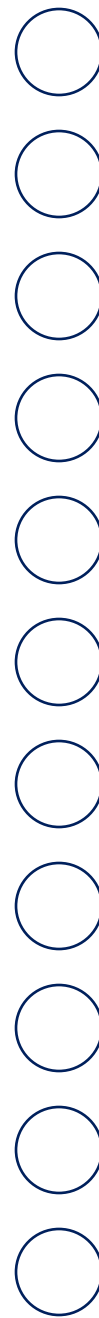




Global Congress on Implementation of  
the Code of Marketing of Breast-milk Substitutes  
June 2023



# The program will begin at 13:45

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Global Congress on Implementation of  
the Code of Marketing of Breast-milk Substitutes  
June 2023



# Welcome!

**Please take your seats.**

**The program will begin shortly.**



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June 2023

# Katherine Shats

Legal specialist, nutrition  
UNICEF

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# Carlos Santos-Burgoa

Director, Public Health Policy Program

George Washington University School of Public Health in  
Washington DC



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June 2023

# Strengthening coordination and governance mechanisms in national laws

**Carlos Santos-Burgoa**, Professor, Global Health  
Policy, The George Washington University

**Katherine Shats**, Legal Specialist,  
Nutrition, UNICEF



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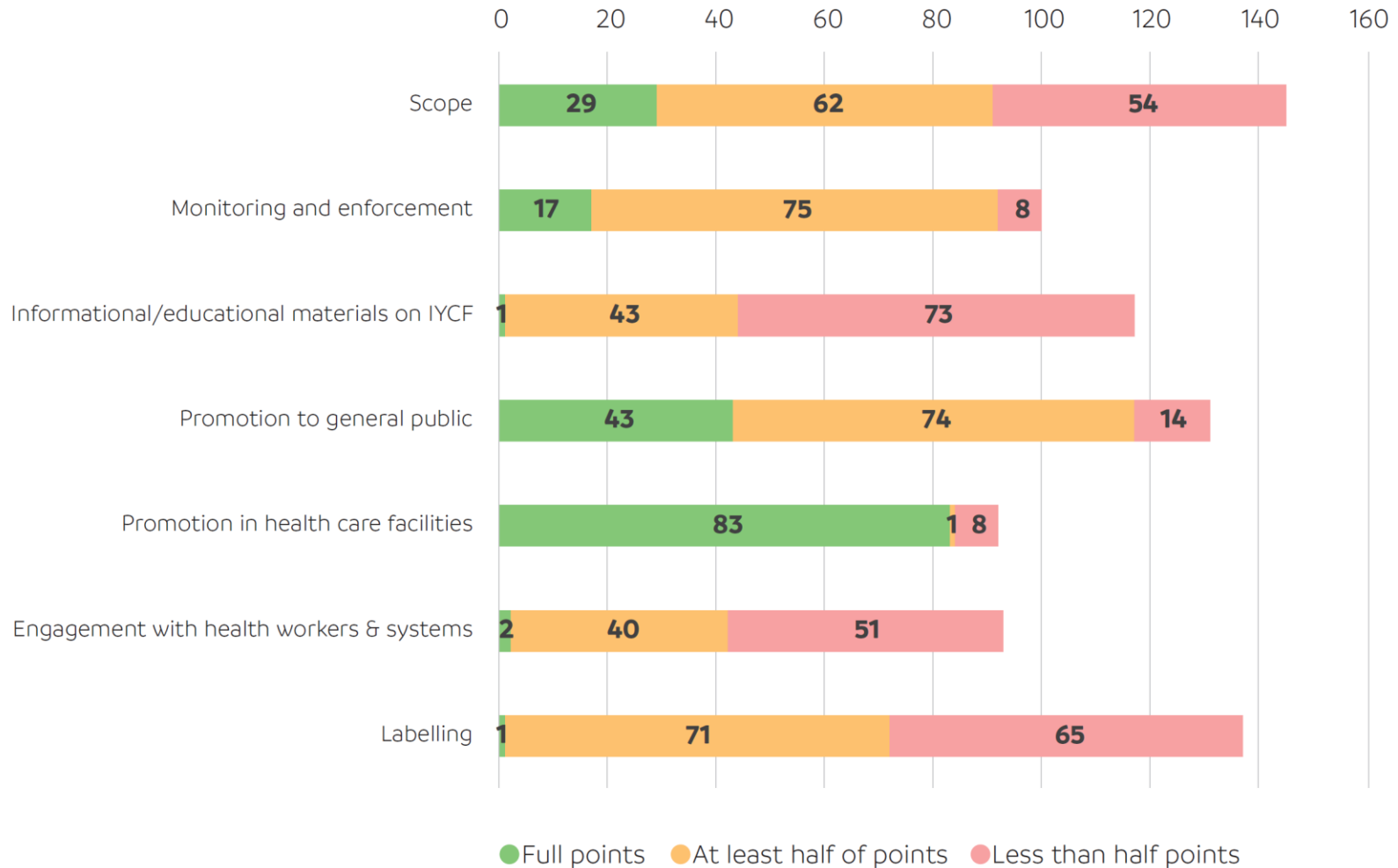
# Observations from implementing laws and policies in the health sector

*“If men were angels, no Government would be necessary” –James Madison, Federalist papers, no. 51, 1788*

*“That is, if all men were angels. But in a world in which all resources are limited, a single nonangel in the commons spoils the context for all.” – Garret Harding, 1974*

- The appropriate use of health authority is crucial and must be respected; it can be a valuable tool for advancing common agendas.
- Building a common agenda requires a deep understanding of the concerns held by “others”, which serves as the foundation for collaboration and governance within institutions.
- To ensure effective governance, it is essential to invest time and attention in intersectoral dialogues, seeking agreement, identifying synergies, and following up on the implementation of shared goals.
- However, the success of all these efforts relies on a dynamic institutional architecture that provides a solid framework for effective action.
- Furthermore, the execution of agreed rules depends on the organizational capabilities and the availability of human, technical, legal, and financial resources necessary for their enforcement.

# NOW... WE ARE CONFRONTED WITH THIS



**Figure 3.** Number of countries receiving full, at least half, or at least some points on each section of the scoring algorithm

# What is the limited progress telling us? What is impeding implementation of Code laws?

- Most (83/137) comfortable to act “within” the medical health care facilities, on “promotion”
- But the *exercise of authority* on labeling (1/137) or enforcement (17/137) are the least implemented
- Although within health care, promotion is managed, there is less progress to limit the actions of health care providers, shown by the scarce prohibition of information by industry (27/137), gifts to healthcare workers (33/137), or sponsorships of professional activities (21/137)
- The *impact* is that after 40 years of The Code, while progress has been made, much work remains to increase the global breastfeeding rates above 50%

***WHAT IS STOPPING US FROM  
ACTUALLY DELIVERING WHAT WE ALL  
KNOW IS NEEDED AND CAN BE DONE?***



# It's time to fully deliver. What do we need now?

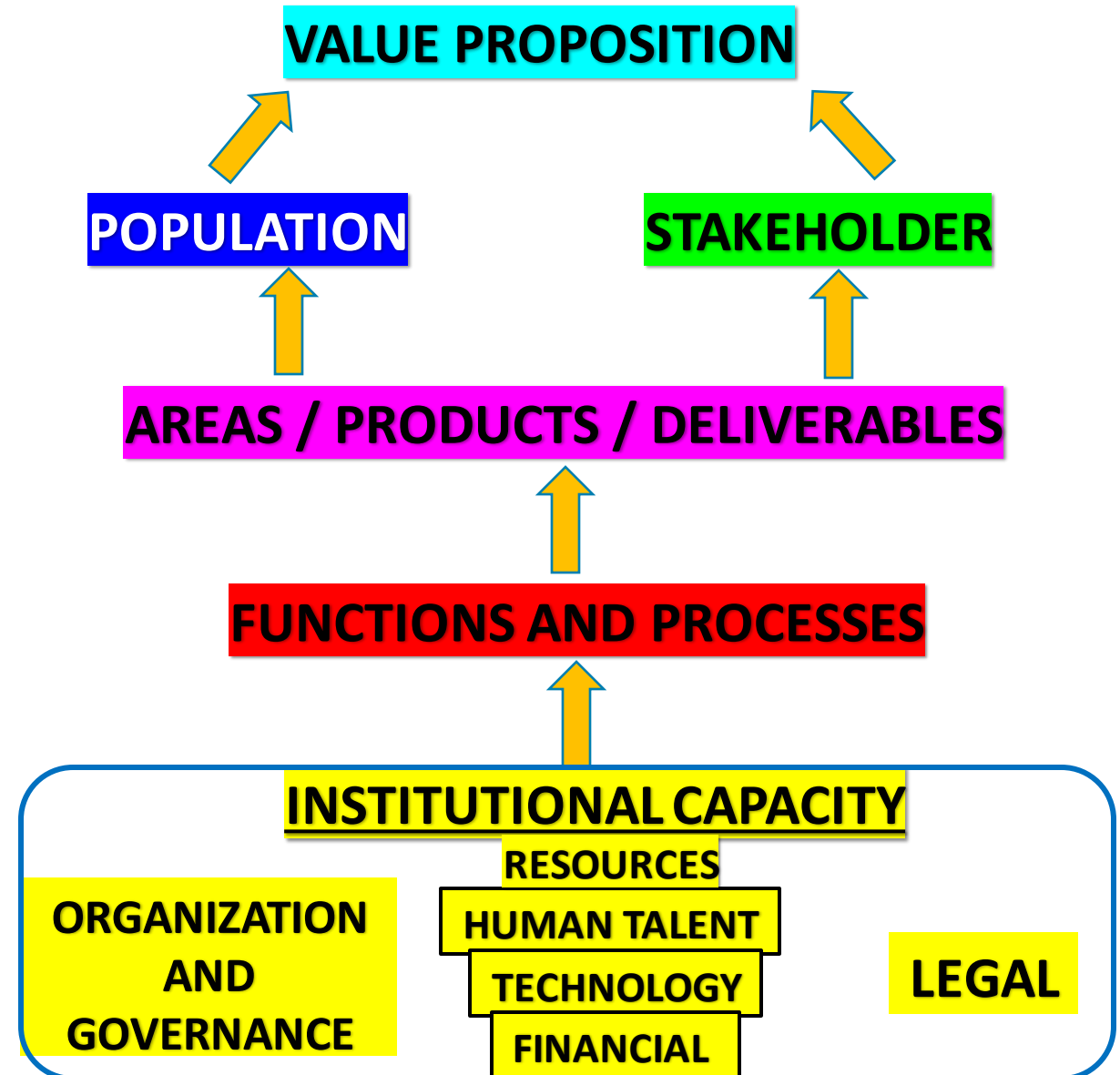
- To tackle the lack of clarity
- To clearly define the exercise of health authority
  - Who is responsible?
  - How are efforts distributed?
  - What is the institutional capacity (who, where, when, how, with what resources...)?

# Regulating to Protect Population Health

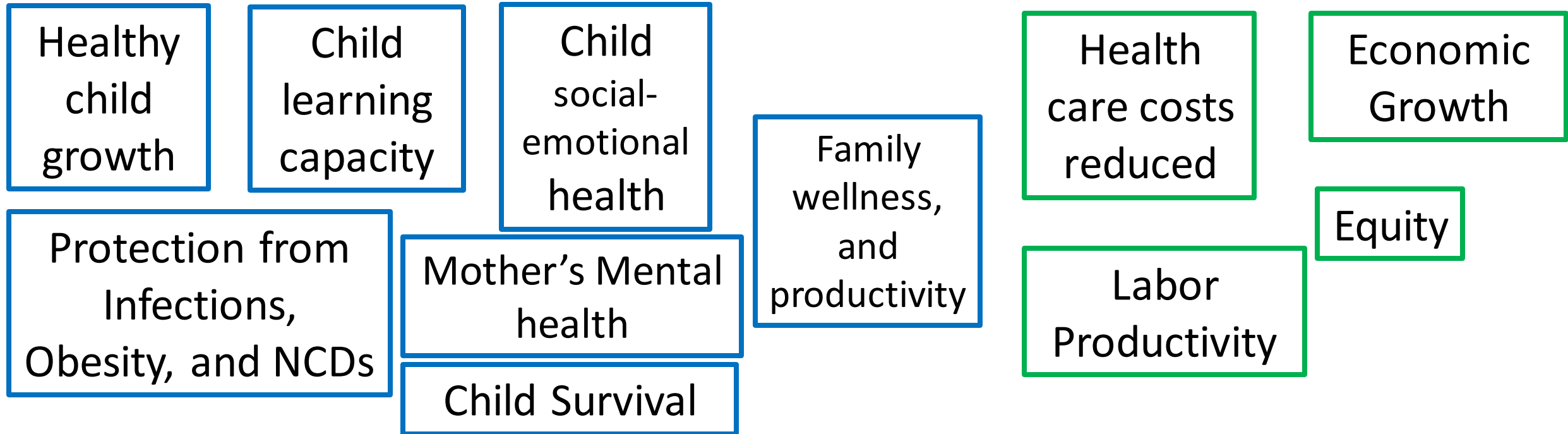
- What is the social value?
- Who benefits?
- What is delivered, what is done?
- What functions are needed to deliver the service, to get the value?
- What is the institutional capacity? With what resources? With what financial resources?
- Who exercises the authority to obtain such products? Who is responsible? How is such authority distributed?

# MAPPING THE DEVELOPMENT OF REGULATORY CAPACITY FOR THE CODE

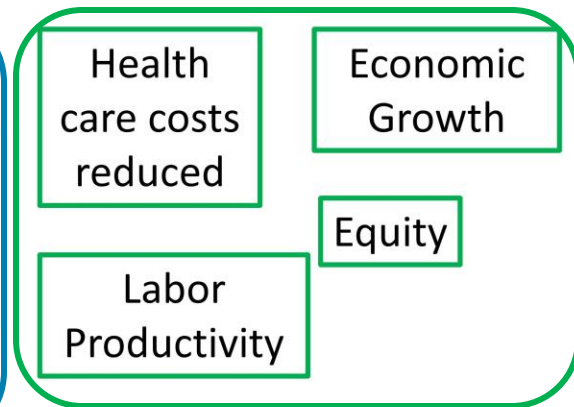
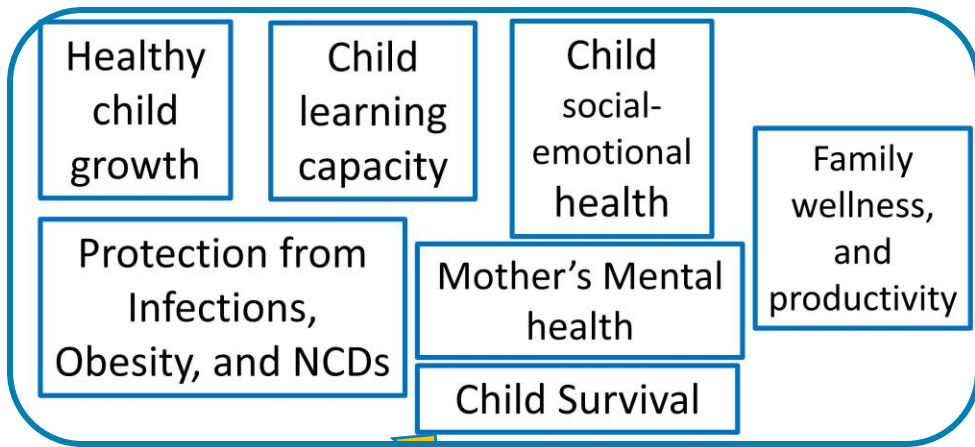
- What is the social value?
- Who benefits?
- What is delivered?
- Which functions?
- What is the institutional capacity?
- Who exercises the authority?



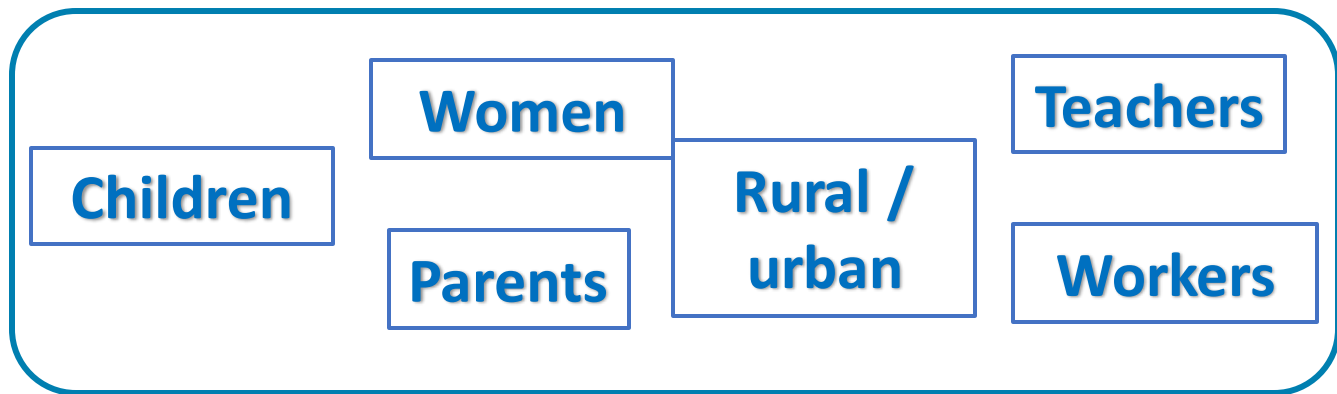
# VALUE PROPOSITION FOR PUBLIC HEALTH, WELFARE, AND DEVELOPMENT



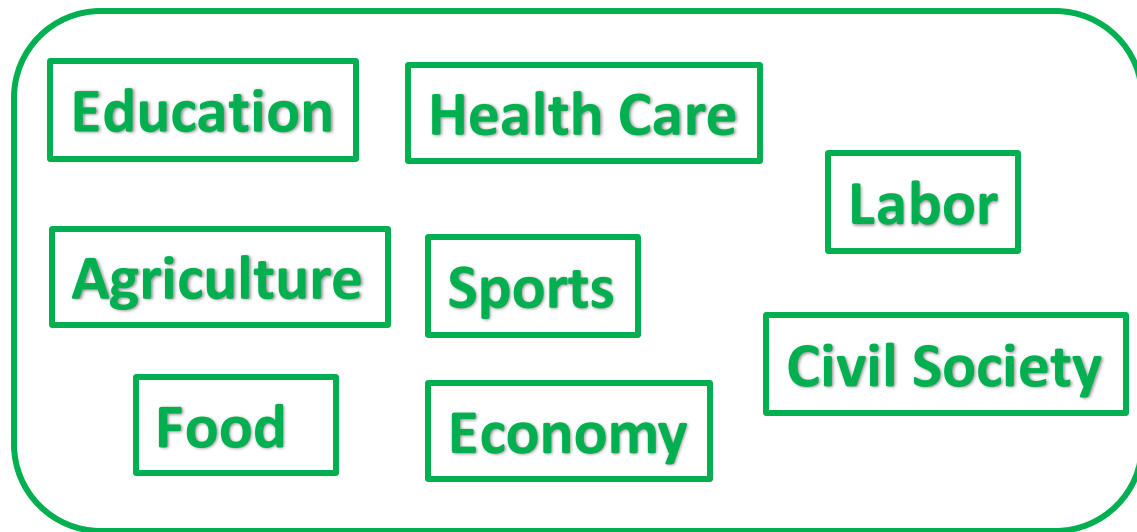
## VALUE PROPOSITION



## POPULATION



## STAKEHOLDER



# CAPABILITIES FOR PRODUCTS / DELIVERABLES

## PROHIBITIONS

Education from industry  
Promotion @ health care  
Point of sale  
Nutrition / health claims

Advertising  
Gifts/Grants to healthcare  
Sponsorship  
Pictures idealize

## MONITOR & ENFORCE

Reliable responsible  
Violation sanctions



**Monitoring**

**Enforcement**

**Educational materials  
on IYCF**

**Informational**

**Promotion to general  
public and mothers**

**Manufacturers and  
distributors employees**

**Labelling**

**Promotion in health-care  
facilities**

**Engagement with health  
workers and systems**



# FUNCTIONS AND PROCESSES

Surveillance and Risk  
Characterization

Licensing and  
authorizations

Implementation  
supervision

Post-marketing  
follow-up

Rule development and regulatory instruments

Inter-sector collaboration and delegations

Health  
Promotion

Media and Platforms  
Analytics

# **INSTITUTIONAL CAPACITY**

## **GOVERNANCE**

Leadership

Organization

- Central structure
- Subnational
- Local
- Quality improvement

- Intersectoral Coordination
- Authority distribution
- Sub-national Delegation
- Civil Society and Academia
- Management Industry Interest

## **RESOURCES**

**HUMAN TALENT**

**TECHNOLOGY**

**FINANCIAL**

## **LEGAL**

Laws

Rulings

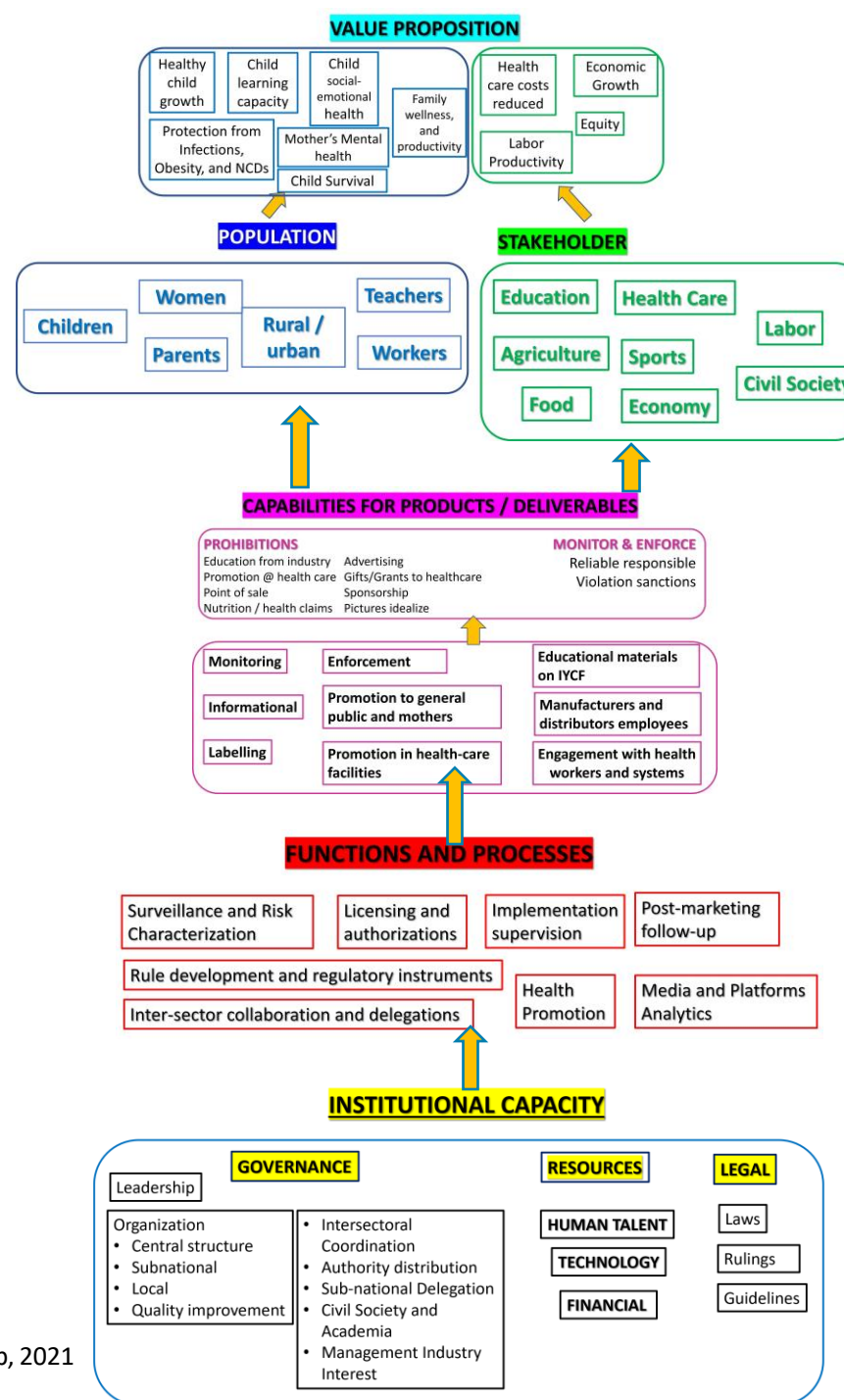
Guidelines

# A NOTE ON FINANCING... MAKING THE PIE BIGGER

**TABLE 7.** Potential sources and typical uses of revenue for entities that regulate NCD risks

General taxpayer revenue	Regulated entity fees and fines
<ul style="list-style-type: none"><li>• Establishment and organization</li><li>• Basic science for risk assessment</li><li>• Development of norms and standards</li><li>• Laboratory development</li><li>• Evaluation of regulation</li><li>• All other activities</li></ul>	<ul style="list-style-type: none"><li>• Registration</li><li>• Registration renewal</li><li>• Licenses</li><li>• License renewal</li><li>• Authorizations and certificates</li><li>• Laboratory analyses and verifications</li><li>• Inspection and monitoring</li><li>• Sanctions</li></ul>

# MAPPING THE DEVELOPMENT OF REGULATION CAPACITY FOR THE BMS CODE



PERFORMANCE  
EVALUATION &  
IMPROVEMENT

INSTITUTIONAL  
DEVELOPMENT

# Steps to strengthening governance during policy development

# Overview

1. Establishing the public health problem and setting objectives
2. Reviewing existing laws and policies
3. Accounting for implementation and enforcement
4. Determining when to use legislation or regulations
5. Safeguarding against conflicts of interest
6. Preparing to draft the law
7. Drafting the law



# 1. Establish the public health problem and policy objectives

- Establish baseline measures: breastfeeding rates, current marketing practices, companies operating in the country etc
- Consider whether other legal or non-legal attempts have been made to address Code violations, and whether they have been successful. If not, document why not
- Identify any vulnerable groups or sub-populations that may be disproportionately affected and ensure the law will not leave them behind
- Clearly articulate layered policy objectives against which the success of the measure can be assessed. Objectives should reflect short-term, measurable outcomes



**These will help ensure the legal measures will be able to withstand industry threats and challenges**

## 2. Review existing laws

- Most public health issues have been addressed in some way before
- Your country may already have laws that address aspects of the Code and/or laws about similar issues can provide useful insights
- Understanding how effectively existing laws are working helps to:
  - Avoid repeating mistakes
  - Take advantage of existing systems that work well
  - Discover new advocacy opportunities



# Which laws?



- Look broadly – all existing laws and secondary instruments (such as regulations) that might be relevant
  - E.g., existing laws implementing the Code, food marketing laws, tobacco control laws, broad public health laws, advertising and communications laws, food labelling laws, child protection laws, pharmaceutical regulations, consumer laws, administrative codes etc.
- Check national policies or plans – such as nutrition strategies, public health commitments or government documents setting out policy priorities.

# Are the laws effective?

## **Is it hard to tell?**

- Why? Is it because there are no monitoring requirements built into the law?

What is working well?

## **If they are not effective, why?**

- Are the laws themselves drafted poorly? Do they contain loopholes?
- Have enforcement agencies or courts interpreted the existing laws unfavorably?

# Are the existing laws being enforced? If not:

- Do they lack appropriate enforcement mechanisms?
  - Are the right agencies given legal authority to enforce the law?
  - Is there a range of appropriate enforcement mechanisms?
  - Are the responsibilities to comply placed on the appropriate entities?
- Do they contain appropriate enforcement mechanisms that are not being used? Is this due to:
  - Resource constraints?
  - The appropriate agencies not having the right equipment/manpower?
  - Lack of inter-agency cooperation?



### 3. Account for implementation and enforcement



- Many public health laws are successfully passed but never implemented because the details of how they will work in practice are not addressed at the beginning of the process.
- Although implementation and enforcement are often seen as issues to be considered after a law is passed, the vast majority of issues can and should be addressed in the law itself.



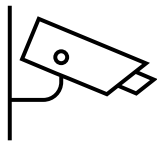
# Which government bodies are going to implement, enforce and monitor the law?

Do the appropriate bodies exist or will new ones need to be created?

Does a lead agency need to be established?

What are the remits of existing inspection/enforcement bodies?

If the appropriate bodies exist, how will this proposed law connect with the law that governs them?



# Which government agencies are going to implement, enforce and monitor the law?



Are there a number of agencies that will be required to coordinate or share information through an inter-agency coordination mechanism? Does the law need to provide for this?

Does the body already enforce other legislation or impose similar sanctions?

Will the body require additional resources or expertise to enforce the law?



## **Do the agencies identified to implement the law have the political will to do so? Have they been consulted?**

- Will they be vulnerable to industry interference and conflicts of interest? If so, how will this risk be managed?

## **How will compliance be monitored?**

- Are there inspectors? Or other mechanisms to monitor?
- Are there existing regimes (such as health and safety inspections) that can be adapted and used to monitor this law?
- Can civil society organizations and/or the public submit complaints to the monitoring mechanism?
- Is there sufficient funding for the compliance mechanism?

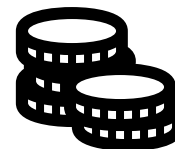
## **What are the most appropriate sanctions?**

## 4. Consider financing mechanisms



Once the appropriate agencies are identified, consider how they will be **financed**.

- What is covered under the agency's current budget? Will it need to be increased to include Code violations? Is it tied to the scope of their duties as defined in another law? Should the law expand their duties so that extra budget can be allocated?
- What about manpower/human resources to issue warnings, adjudicate complaints, refer for prosecution?



- Are there mechanisms to use collected fines for enforcement budgets?
- At which point in the policy or implementation cycle are budgetary allocations and decisions for each agency made?
- Can the law or regulations help secure financing mechanisms for all components of the law?
- Can civil society help by engaging in budget advocacy for Code enforcement?

MANY REASONS LAWS ARE NOT EFFECTIVE COULD HAVE BEEN  
ADDRESSED FROM THE BEGINNING





# 5. Determining what to include in legislation vs regulations

\*Sometimes, this is a legal question based on the laws of the country. Often, other considerations play a role

## Legislation

- Typically made by a legislature or governing body
- Sets out definitions, key provisions and *should* provide clear authority for administrative agencies to implement, monitor and enforce the law
- Limits typically determined by the constitution (e.g., national vs subnational powers)

## Regulations

- Standards or rules adopted by administrative agencies that govern how laws will be implemented or enforced
- Will often require public consultation, but typically do not require legislative approval

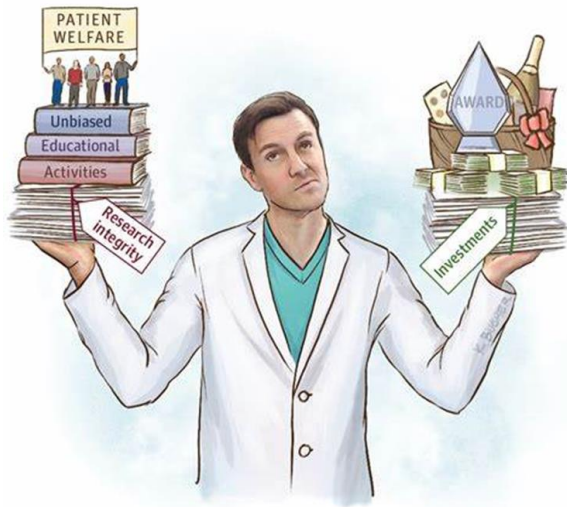


- Note: sometimes the authority to *implement* the law can be different to the authority to *enforce* the law

# What can be included in **legislation** help implementation?

- What is the scope of the authority for measures that are left for regulations?
- It is sufficiently broad/flexible?
  - Does it allow for additional measures to be added later?
- If progressive implementation is adopted, are there clear timelines?
- Can the law address what happens if implementing regulations are not passed within a certain timeframe?
- Is the law still capable of being implemented without the regulations?

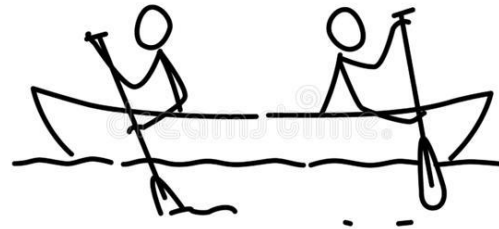
## 6. Safeguarding against conflicts of interest



- Many World Health Assembly resolutions (WHA49.15, WHA58.32, WHA61.20, WHA 65.60 and WHA69.9) specifically address conflicts of interest
- They call on states to establish adequate mechanisms to safeguard against potential conflicts of interest in nutrition action, and to develop processes and tools to safeguard against possible conflicts of interest in policy development and implementation of nutrition programmes

# Incorporating COI safeguards

- Are there existing COI safeguards in policy-making processes?
- How will COI be dealt with in the new legislation / regulation?
- Will it ensure that the baby formula and baby food industries cannot influence the policy-making process?
- Do the implementation provisions in the law specifically exclude industry participation?
- Are there transparency requirements that prohibit private meetings between government and industry?
- Are all government engagements with industry limited to public consultations?



# 7. Drafting the law

## Key components of a law

- Regulatory objective
- Definitions of key terms
- Scope
- The measures (covering promotion, samples, health care facilities, health care workers, supplies, information, labelling, quality)
- Duties of compliance
- Sanctions
- Powers and authorities
- Monitoring and evaluation
- Enforcement mechanisms

**We need to know exactly  
how the law will be  
implemented, monitored,  
enforced and funded before  
the drafting phase begins!**

Thank you!



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**Janneke Blomberg**

Nutrition Manager

UNICEF Laos



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Coordinator of maternal and child health  
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## **Rebone Ntsie**

Director of Nutrition  
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## **Shailendra Bir Karmacharya**

Senior consultant pediatrician  
Paropakar Maternity and Women's Hospital, Nepal

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## **Hannah Margaret Rabaja**

Food and Drug Regulation Officer  
Food and Drug Administration, Philippines



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**Scan the QR code to  
report the Code  
violations you  
encounter in the  
building.**

<https://ee.humanitarianresponse.info/x/q8YTbwrw>



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# Breakout Room Assignments Wednesday PM

Africa (English)	Room V
French	Auditorium left side / Z1
Arabic	D46025
Asia (English)	Room U
America & Caribbean (English)	Room T
Spanish	Cafeteria
Europe & Central Asia (English)	Auditorium right side / Z4



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# Coffee break

**15:15 – 15:45**

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# Group work

**15:45 – 17:15**

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# Social hour

**17:15**