



Introduction to Probiotics and Codex; - IPA Initiative and Future Perspectives



George Paraskevacos, MBA
Executive Director
International Probiotics Association
10th Probiotics, Prebiotics, & New Foods
Rome, September 8 -10 2019

OVERVIEW

- History (FAO/WHO)
- IPA & IPA Europe
- Codex Alimentarius and proposed new work for probiotics
- Future perspectives

History 2001 - 2002

Argentina and Canada

- Expert consultation evaluating latest scientific evidence
 - ✓ focus on functional and safety aspects
- Scope: Probiotics and prebiotics in food
 - ✓ exclude any reference to the term biotherapeutic agents
- Recommendations of the expert panel:
 - ✓ Identification of the strain(s),
 - ✓ good manufacturing practices,
 - ✓ market surveillance,
 - ✓ proper storage conditions, ...



The opinions expressed in the report do not imply any opinion of the part of FAO and WHO

History 2001 - 2002

Argentina and Canada

Figure 1. Guidelines for the Evaluation of Probiotics for Food Use

Strain identification by phenotypic and genotypic methods (Detailed in Section 3.1)

- Genus, species, strain
- Deposit strain in international culture collection

Probiotics in food
Health and nutritional properties
and guidelines for evaluation

FAO
FOOD AND
NUTRITION
PAPER
85

“Live microorganisms which when administered in adequate amounts confer a health benefit on the host”

Labeling (Detailed in Section 3.5)

- Contents – genus, species, strain designation
- Minimum numbers of viable bacteria at end of shelf-life
- Proper storage conditions
- Corporate contact details for consumer information

WORLD HEALTH ORGANIZATION
PROBIOTICS AND PREBIOTICS
2001

Probiotic Games

Globally Regulatory Divergence Reigns



- **The Regulatory Category:**
 - ❑ *foods vs. supplements vs. drugs*
- **The Type and Level of the intended Claim:**
 - ❑ *generic vs. specific vs. therapeutic*
- **The Regulatory System:**
 - ❑ *notification vs. licensing vs. self-determination*

Whatever the oversight or regulation a mosaic of different requirements persists

Probiotic Games Exempt or safe lists

NHP Probiotics monograph

Customs Union micro-organisms

Probiotic Korea

QPS

可用于食品的菌种名单

Probiotic Species for Food - China

Malaysia permitted and prohibited list

Mexico list

Brazil list in

South Africa list

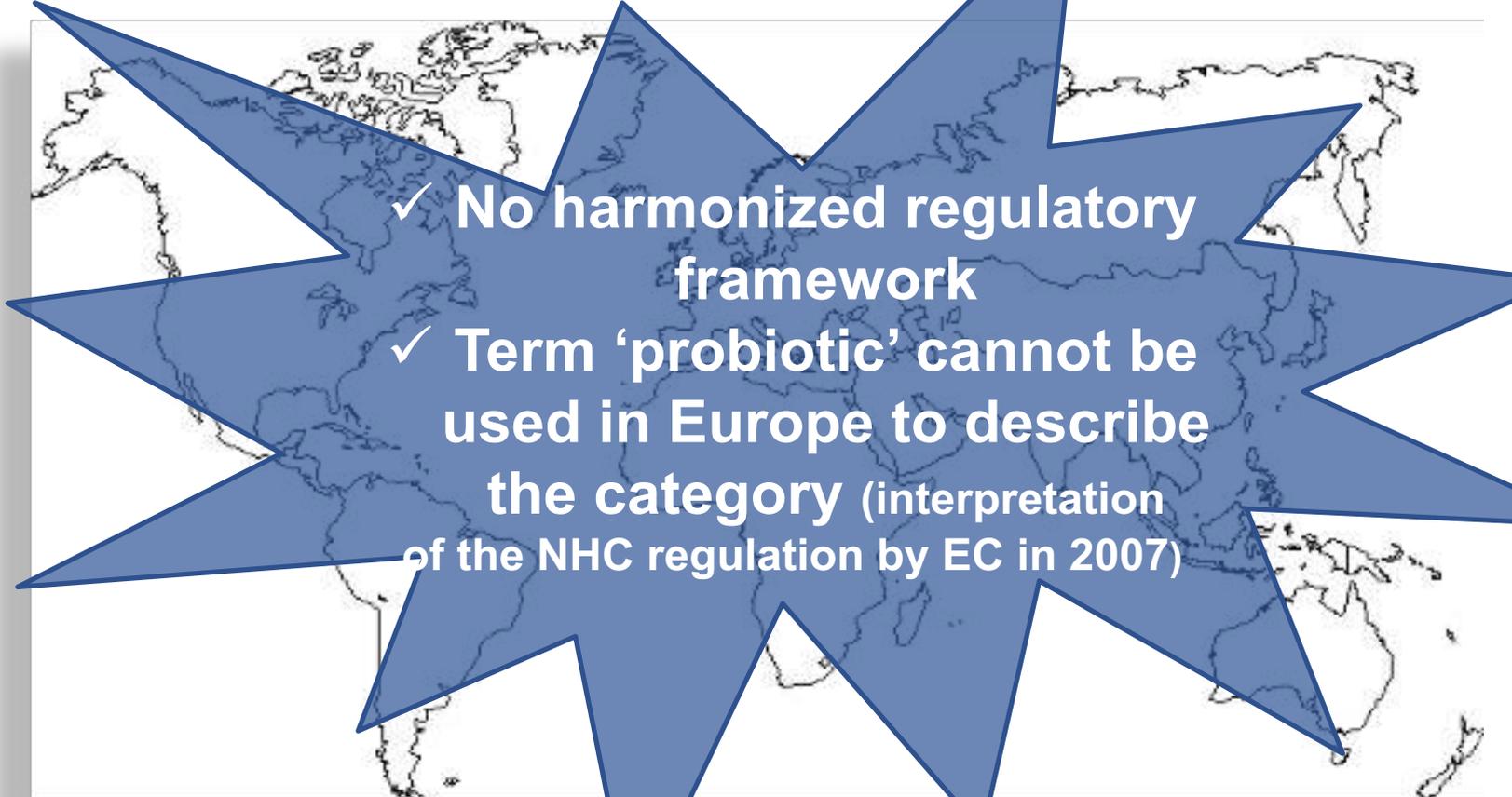
IFAC List (FCC)

haila list

Complementary medicines list

Probiotic Games

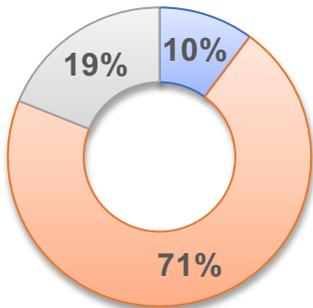
Regulatory Confusion Globally

- 
- ✓ No harmonized regulatory framework
 - ✓ Term 'probiotic' cannot be used in Europe to describe the category (interpretation of the NHC regulation by EC in 2007)

Defining an Approach

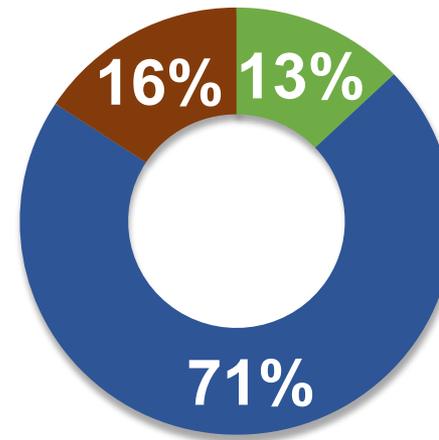
Why is it Important?

World Retail Value
US\$38 billion in 2013



In 5 years ~ \$6Bn
USD market
growth

World Retail Value
US\$43.8 billion in 2018

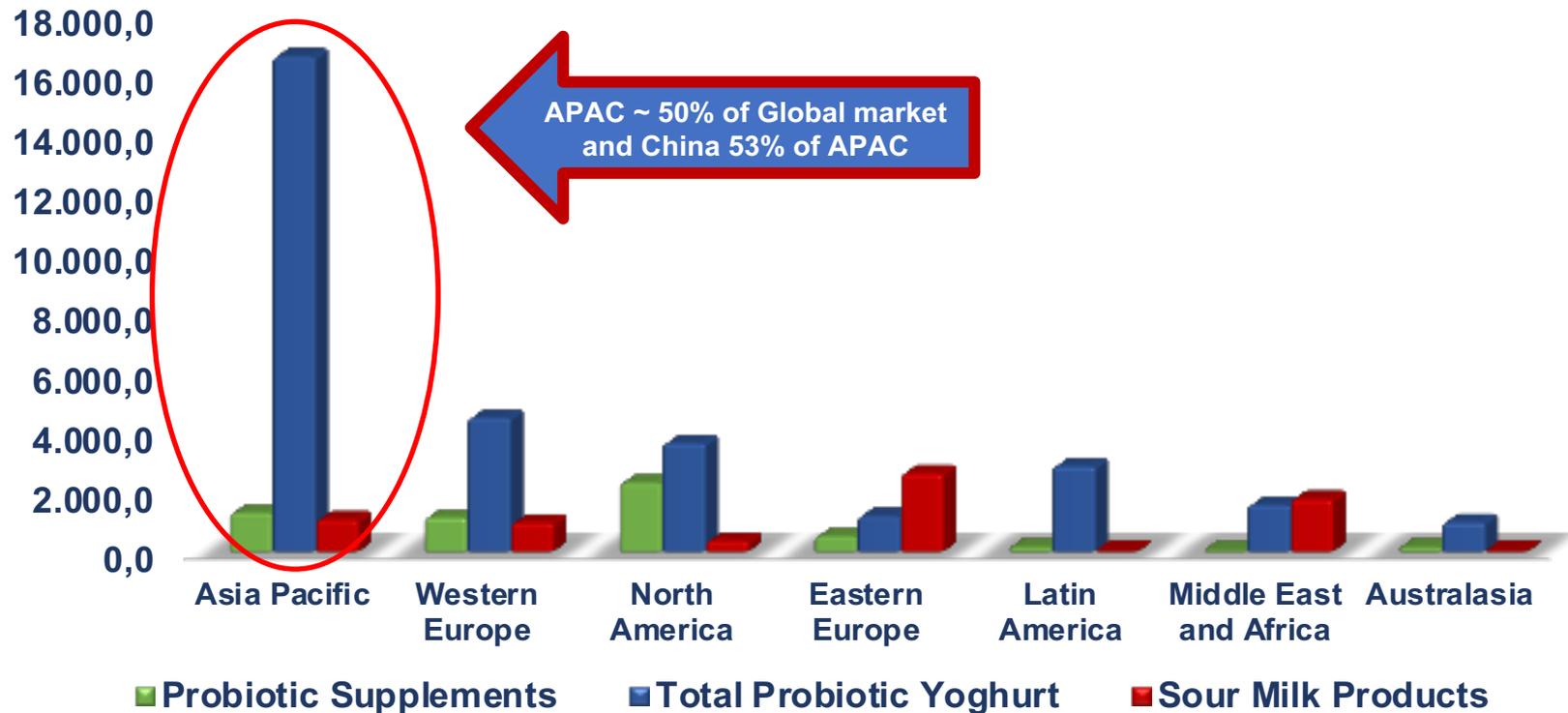


- Probiotic Supplements
- Probiotic Dairy-based yoghurt
- Sour Milk Products

Defining an Approach

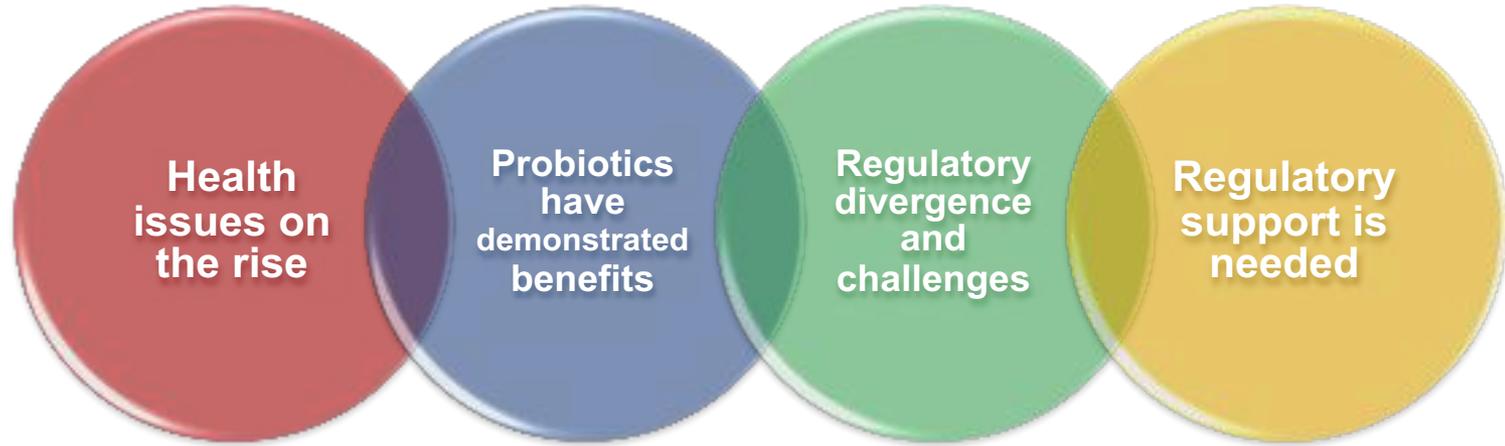
Why is it Important?

Retail Value of Probiotics by Region 2018



Defining an Approach

Why is it Important?



IPA & IPA EU

Who We Are & What We Do?

- IPA is **Global non for profit** & The ‘Global Voice of Probiotics®’
- IPA EU is a **European non profit** & the ‘European Voice of Probiotics®’
- IPA has **110 member companies** spanning 29 countries
 - ✓ over 1,900 scientists, researchers, academics,
 - ✓ majority of the world’s industrial producers
- IPA EU **8 members**
- IPA holds **NGO status** before *Codex Alimentarius*
- IPA Europe has been recognized as formal stakeholder of **EFSA**
- **IPA & IPA Europe** developed guidelines to qualify a microorganism to be termed as ‘probiotic’:
 - ✓ Taxonomy determined at Genus and species level
 - ✓ Probiotics identifiable at the strain level
 - ✓ Probiotic strains should be characterized
 - ✓ Documented history of safe use
 - ✓ Storage

IPA & IPA EU Codex Task Force

A Codex taskforce was established existing of:



- George Paraskevakos
- Rosanna Pecere
- Amy Smith (chair)
- Svend Laulund
- Jennifer Boyd
- Aileen Green
- Bart Degeest
- Pierre-Hubert Cuypers
- Huub Scheeres
- Solange Henoud
- Audrey Bru
- David Keller
- Marjon Wolters

Codex Alimentarius



- Consensus based
- 189 Member states + EU, 229 Observers
- Standards at highest technical and scientific levels
- Revised as technology evolves
- Underpinned by WHO, FAO and RASB
- Standards & Guidelines Voluntary
- Food regulation Harmonization globally
 - ✓ One of the key objectives

Image courtesy of DPE International Consulting

IPA & IPA EU

Define the Category

Definition of Probiotics

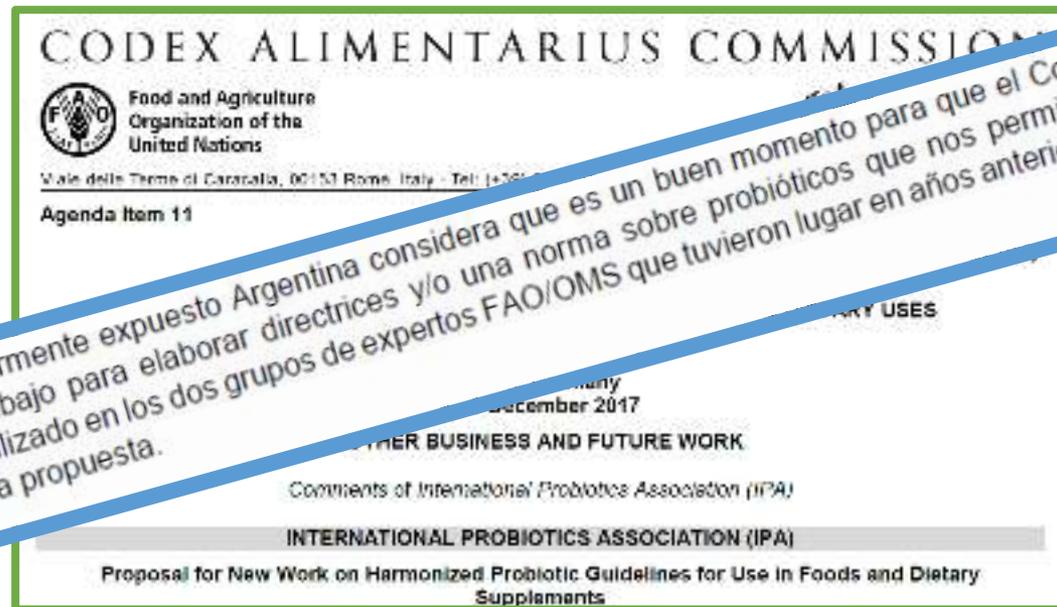
“Live microorganisms, that when administered in adequate amounts, confer a health benefit on the host”

Translational



Codex Alimentarius

Some history – Dec 2017



- CCNFSDU39 IPA presented a proposal
 - ✓ develop a harmonized framework for the use of probiotics
- Argentina supported the proposal
 - ✓ Agrees to lead and prepare a discussion paper for CCNFSDU40

Codex Alimentarius

Some history - Dec 2018

Draft
document
prepared and
submitted by
Argentina for
CCNFSDU40

CODEX ALIMENTARIUS COMMISSION

 Food and Agriculture
Organization of the
United Nations

 World Health
Organization

Viale della Terme di Caracalla, 00152 Roma - Italy - Tel: +39 06 57001 - E-mail: codex@fas.org - www.codexalimentarius.org

Agenda Item 11 CCNFSDU 18/40/12

JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

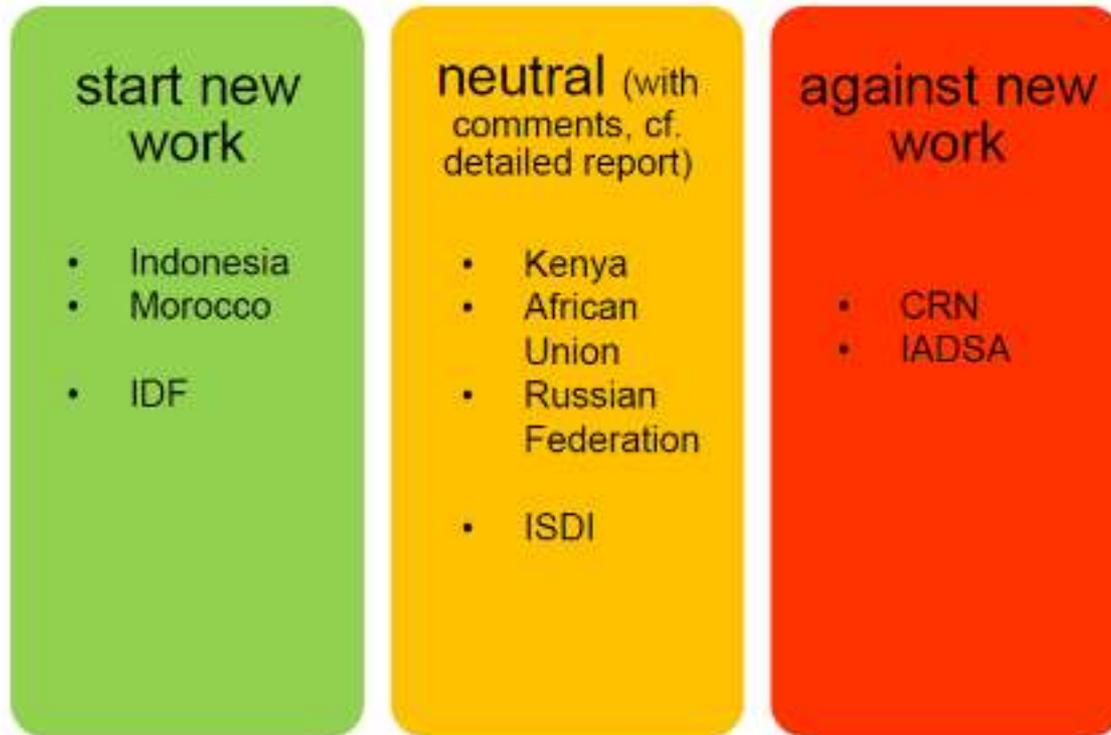
Forbach Session
Berlin, Germany
26 - 30 November 2018

DISCUSSION PAPER ON HARMONIZED PROBIOTIC GUIDELINES FOR USE IN FOODS AND DIETARY SUPPLEMENTS
(Proposed by Argentina)

Codex Alimentarius

Some history – Dec 2018

- Comments sent in writing prior to CCNFSDU40



Codex Alimentarius

Some history – Dec 2018

- Comments during the meeting post introduction by Argentina
- Many member states supported the new work
- Others did with a revision to the document



Codex Alimentarius

Some history – Dec 2018

Draft document prepared and submitted by Argentina for CCNFSDU40

Concluded that:
Argentina will revise the document particularly;

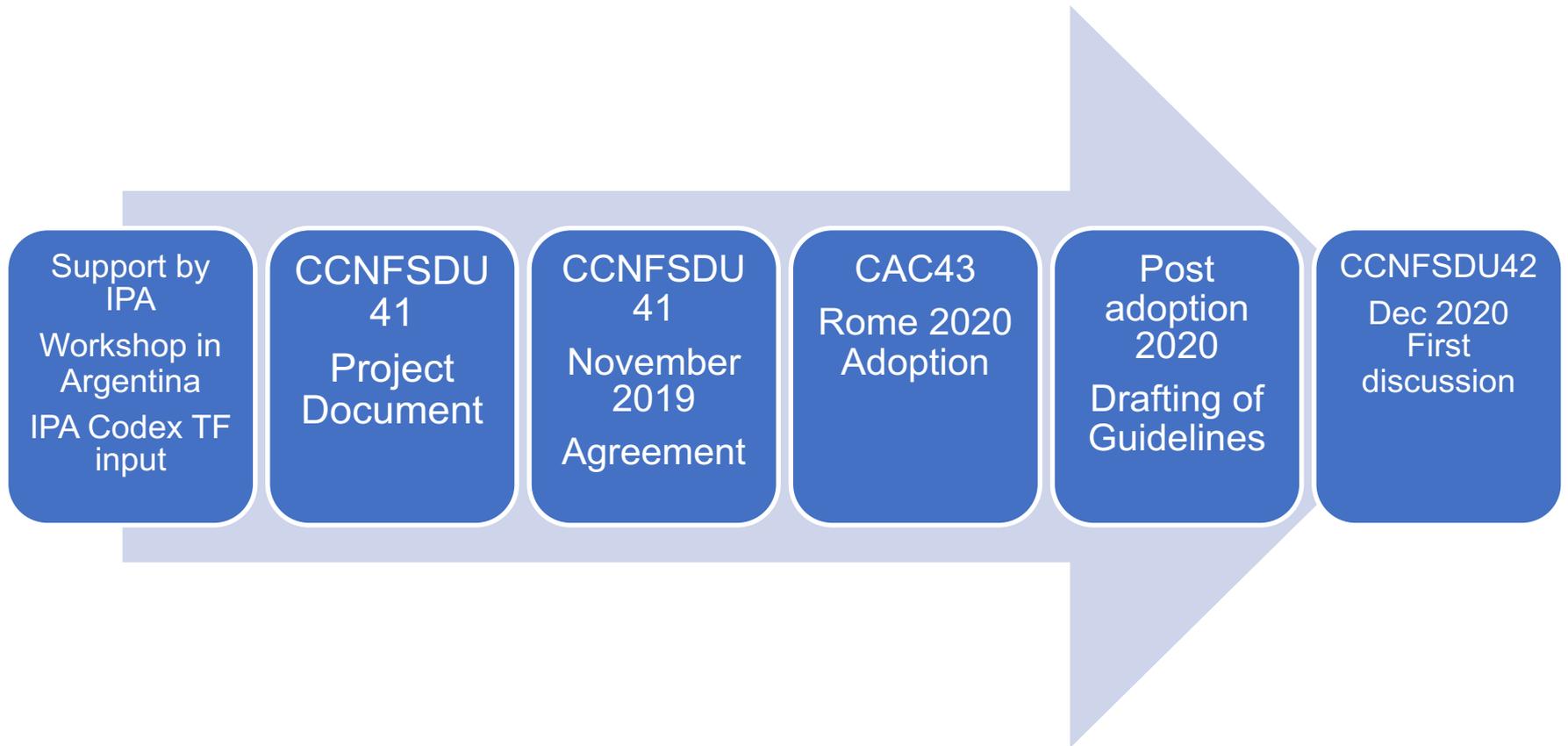
- The scope and definition
- Health & trade concerns



REP19/NFSDU	16
Discussion	
143.	Those delegations in support of the work noted that harmonized global guidelines would benefit the Codex community in light of the significant increase in global trade of probiotics for use in foods and dietary supplements in recent years and would assist national authorities in evaluating foods/supplements containing probiotics. One observer also supported new work on harmonized guidelines which would establish a definition with minimum characterization requirements as well as quality and labeling criteria for probiotics for use as an ingredient in foods and dietary supplements.
144.	Those delegations and an observer not in favour of starting new work at this point, expressed the following view or concerns: <ul style="list-style-type: none">• There was no perceived need for such work.• This work might not have the priority taking into account the current heavy workload of the Committee.• The paper needed to be revised to provide more clarity especially on the scope of the work.• Collection of information and data from Members should be first conducted to identify a globally applicable definition of probiotics.• Infant foods should be excluded since safety was of concern due to a limited number of studies.
Conclusion	
145.	The Committee agreed that Argentina should redraft the discussion paper for consideration at its next session elaborating further on the sections on scope, definition as well as health and trade concerns in particular.

Future Perspectives

Codex next steps



Future Perspectives

Why is the Codex work significant

- Obtain a recognized, harmonized definition for the probiotics category
- Provide correct information to consumers on the probiotics category
- Avoid misuse of the term probiotic



- Specific health claims are not within the scope of the Codex initiative

The 'Blue Sky' Vision for the Probiotics Sector

Harmonized Guidelines at the Global Level – living documents which will be updated to pace with technology and science

- **Industry Master Files with Specific Guidelines for Probiotics**
 - ✓ Thorough genomic sequencing, identification and characterization at raw material manufacturing
 - ✓ Genomic mining; for ABR, gene transferability, virulence factors, toxins, etc...
 - ✓ Labelling and Storage requirements (IPA labelling guidelines)
 - ✓ GMPs (IPA manufacturing guidelines)
- **Recognize probiotic general benefits**
 - ✓ Harmonize criteria for positive list of species + conditions at national level
- **And support science-based nutritional and conjunctive claims**

THANK YOU FOR YOUR ATTENTION

"The Global Voice of Probiotics"



10TH PROBIOTICS, PREBIOTICS
& NEW FOODS

ROME, SEPTEMBER 8-10 2019 UNIVERSITÀ URBANIANA



REFERENCES & CONTACT DETAILS

The **International Probiotics Association (IPA)** is a global non-profit organization bringing together through its membership, the probiotic sector's stakeholders including but not limited to academia, scientists, health care professionals, consumers, industry and regulators. The IPA's mission is to promote the safe and efficacious use of probiotics throughout the world. Holding NGO status before *Codex Alimentarius*, the IPA is also recognized as the unified "**Global Voice of Probiotics®**" around the world.

George Paraskevakos

Executive Director

International Probiotics Association

George@internationalprobiotics.org



The research from [Euromonitor International](#) is part of a global strategic intelligence that offers a complete picture of the commercial environment including but not limited to; market analysis, markets share, distribution channels, forecasting and much more.