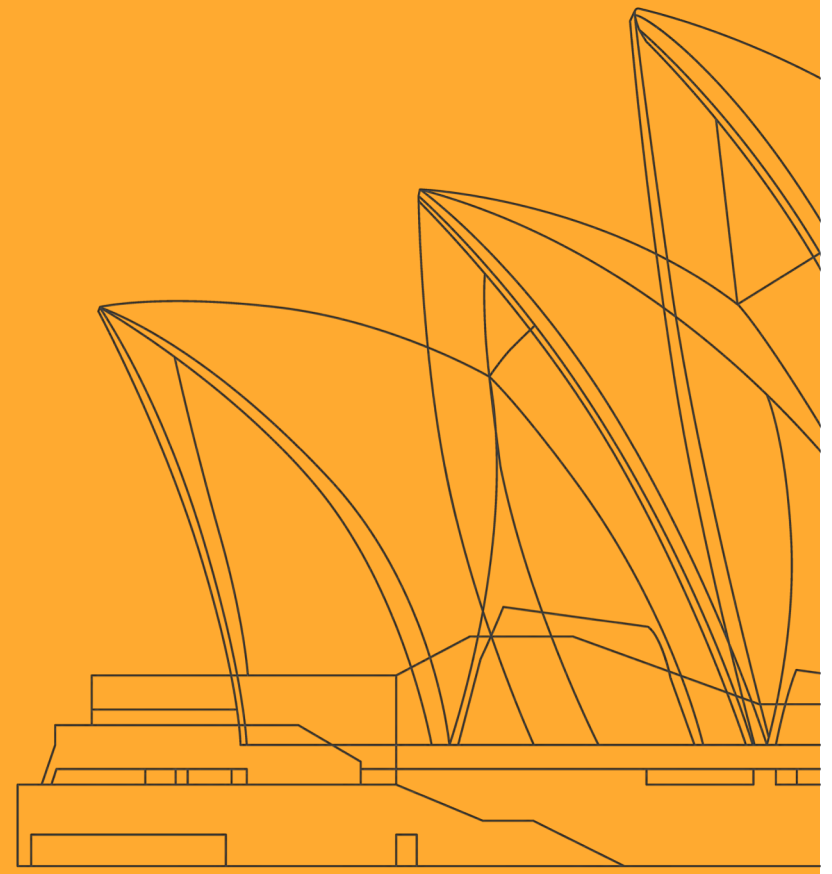
IADSA

International Alliance of Dietary/
Food Supplement Associations

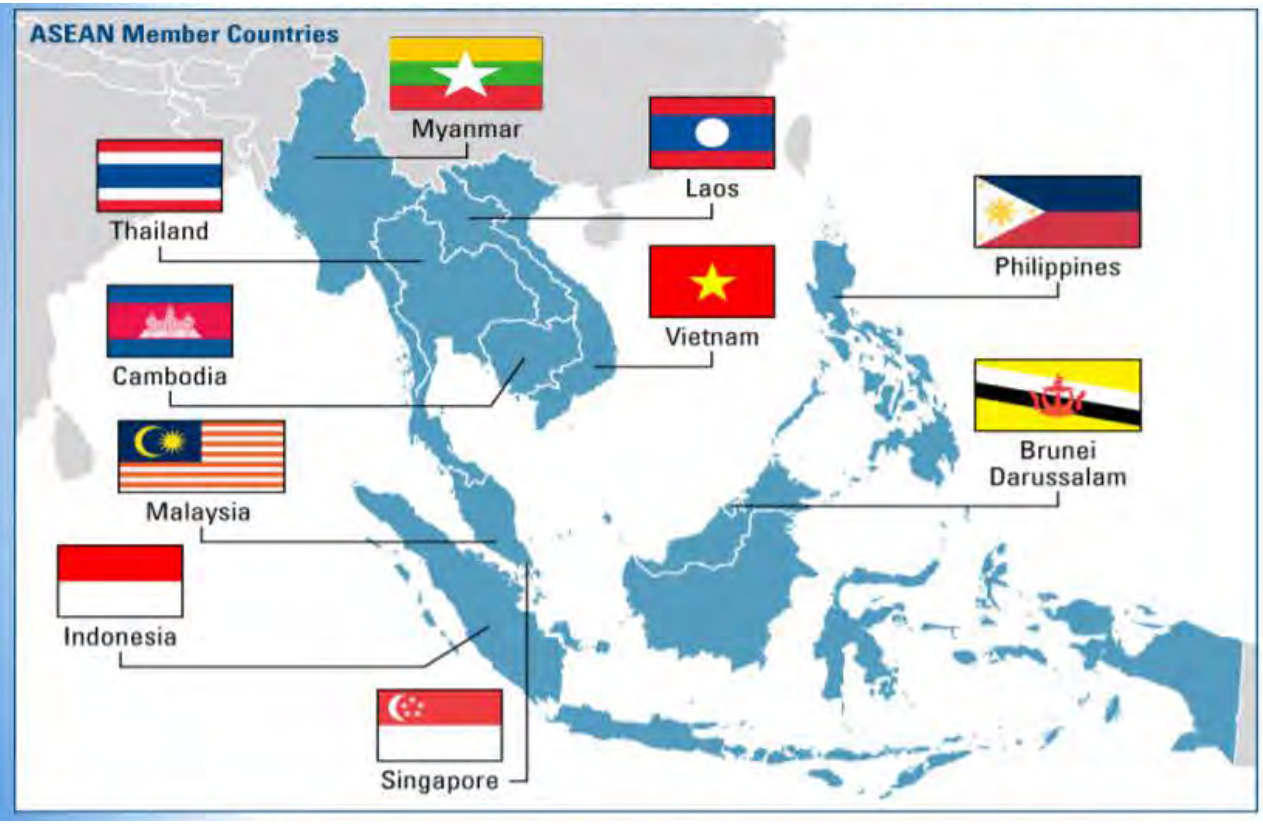


UP TO SPEED

2019

ASEAN + THAILAND

ASSOCIATION OF SOUTHEAST ASIAN NATIONS



ASEAN Harmonisation Health Supplements Sector Update

AAHSA
ASEAN Alliance of Health Supplement Associations

Daniel Quek
Chairman
ASEAN Alliance of Health Supplement Associations
Sydney 10 April 2019

Outline

- ASEAN HS Harmonisation Overview
- Current stage of TMHS PWG progress
- Implementation Challenges Crucial Action 2019-2020 & Beyond

3 PILLARS Targeted for 2020

ASEAN SECURITY COMMUNITY

ASEAN SOCIAL COMMUNITY

ASEAN ECONOMIC COMMUNITY

ACCSQ
ASEAN Consultative Committee for Standards and Quality

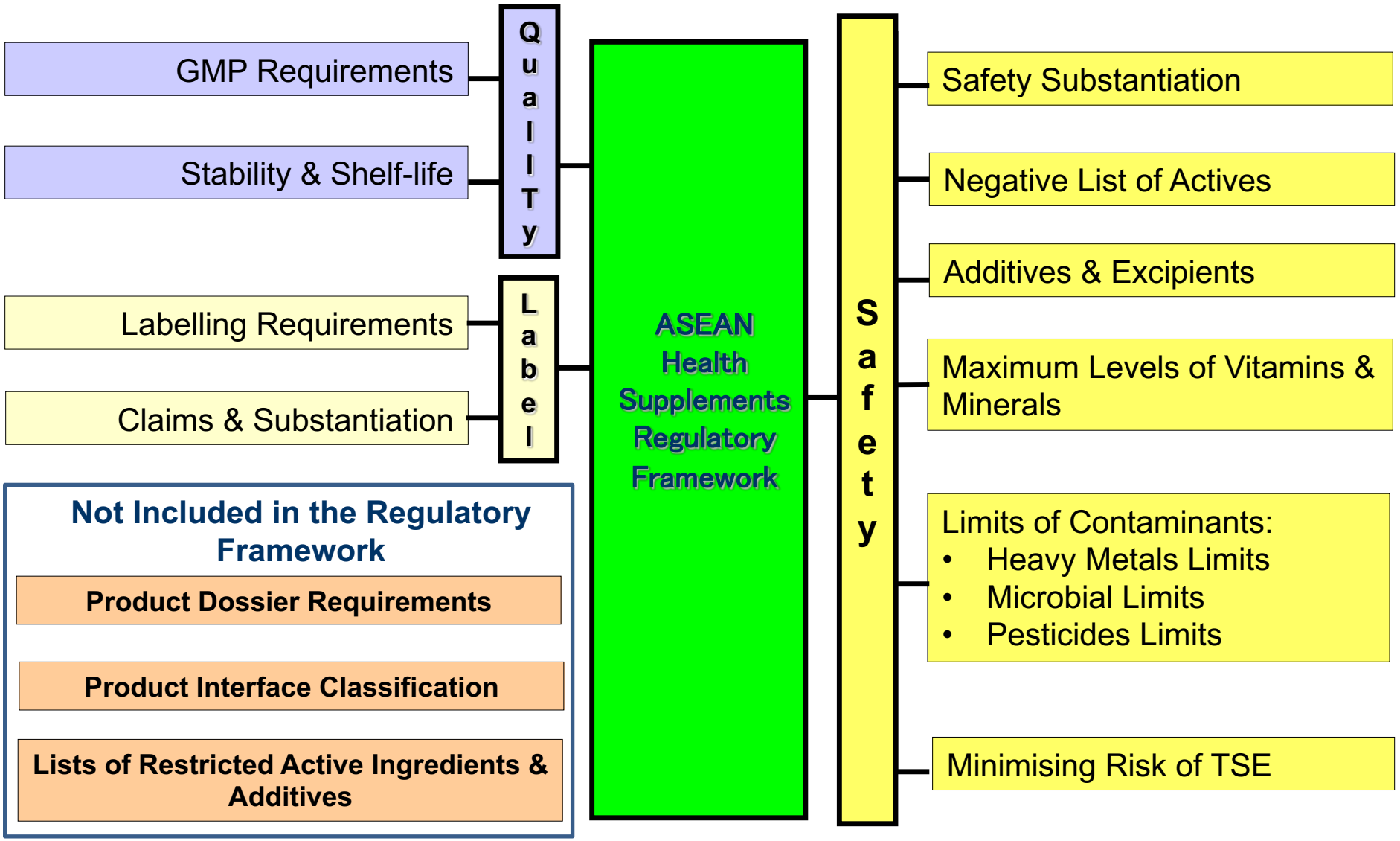
ASEAN HS industry representation

Traditional Medicines / Health Supplements Product Working Group

AEC : Accelerate to 2015

AEC: 11 priority sectors including health supplements

What are the standards and technical requirements for health supplements that will be harmonised in ASEAN?



Key Phases of Harmonisation

Phase 1	• Finalisation of Agreement & Guidelines
Phase 2	• Final Endorsement by TMHS PWG
Phase 3	• Signing By AEM
Phase 4	• Ratification & Implementation

Close to Competing Phase 2

i. The TMHSPWG has agreed on the instruments: "***ASEAN Agreement on Regulatory Framework for Traditional Medicines***" and "***ASEAN Agreement on Regulatory Framework for Health Supplements***".

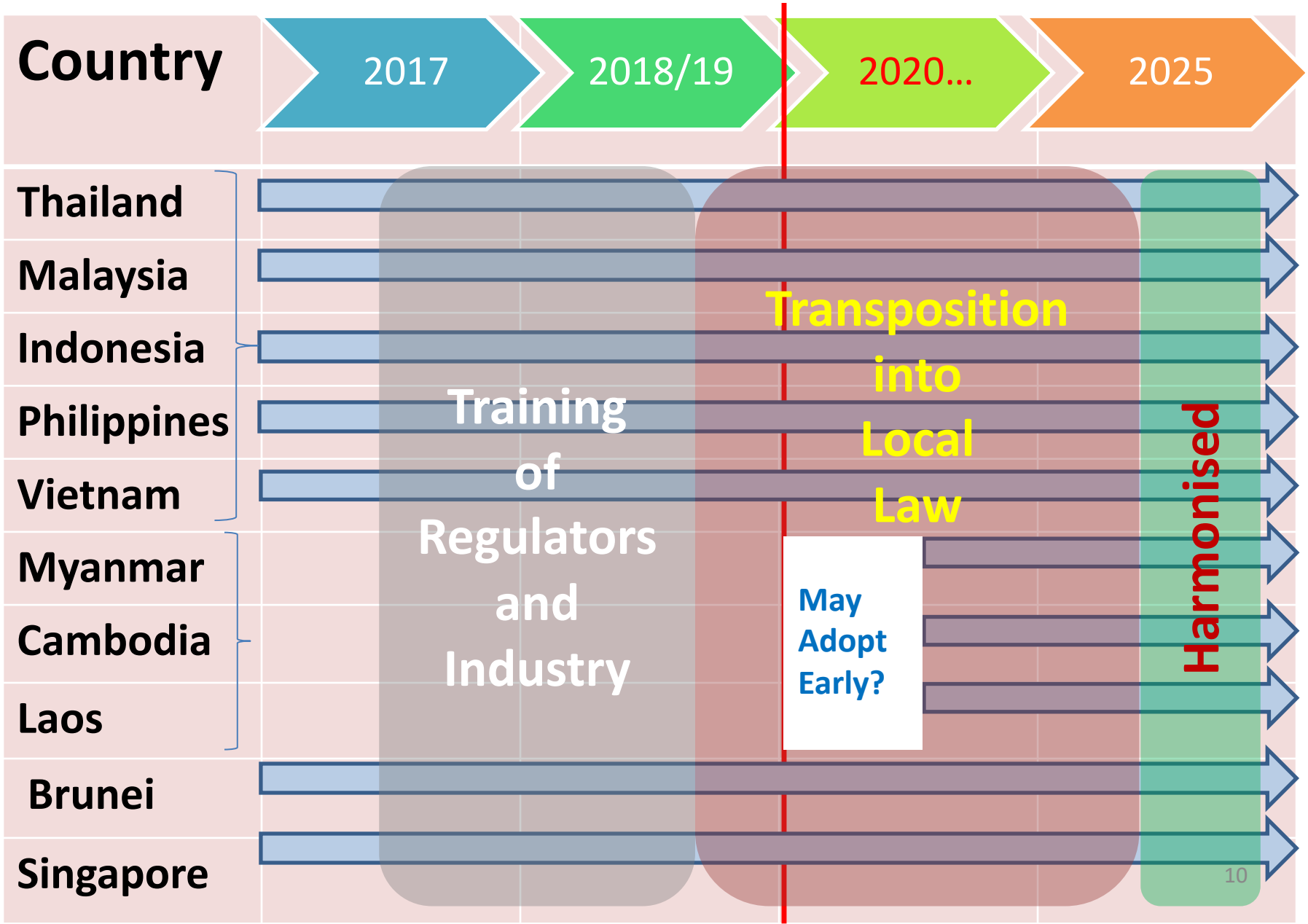
ii. In order to clarify the term "Regulatory Framework" as used in the titles that the Agreements ***do not include the harmonisation of the regulatory regimes*** of TM and HS, a "**Question and Answer (Q&A)**" has been developed by TMHSPWG.

HS Harmonisation Schedule

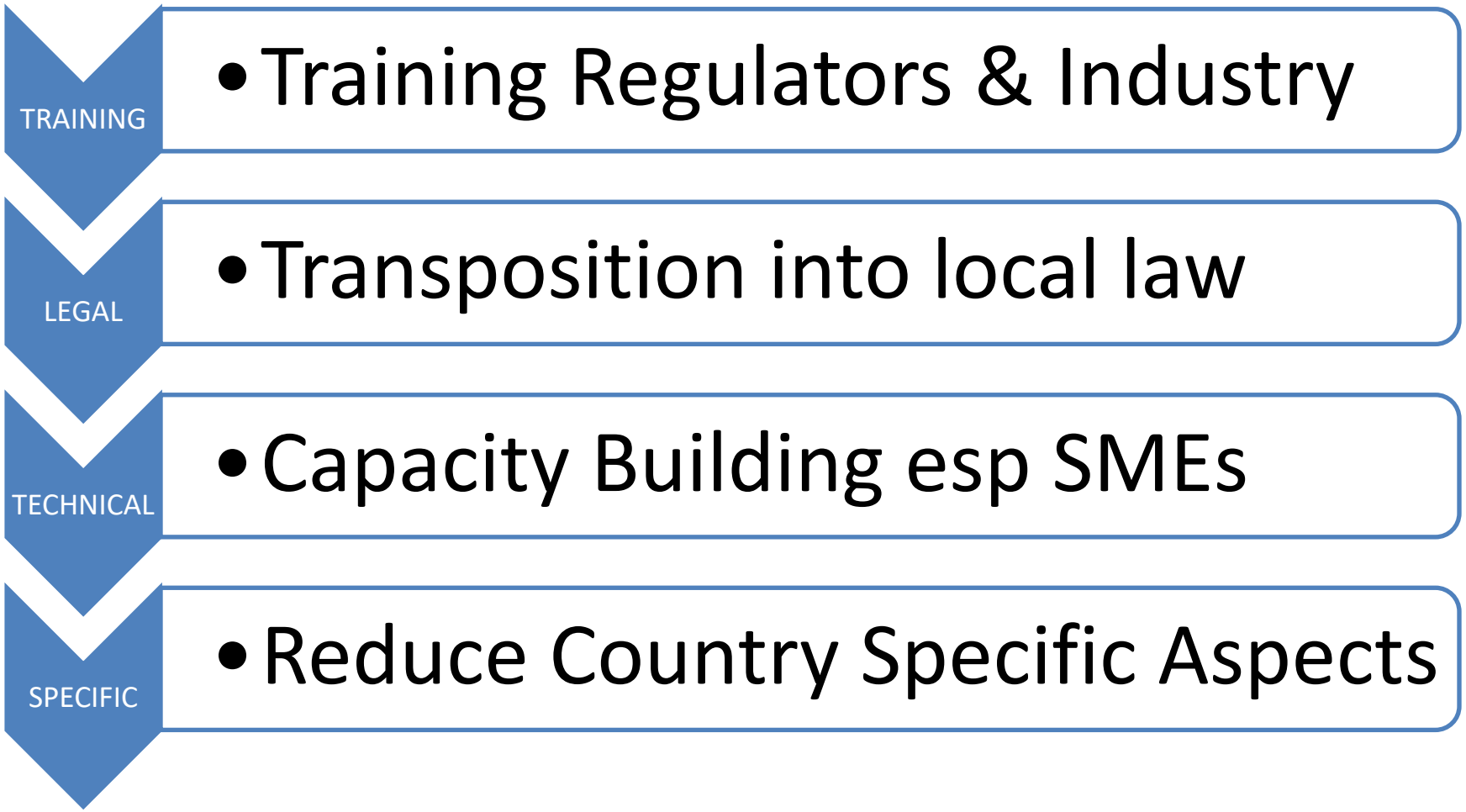
- **April/May 2019** = 31st TMHS PWG (Lao PDR)
- **June 2019** = Finalisation/Endorsement of the Agreement by TMHS PWG
- **July 2019 – Jan 2020** = National approval procedures
- **February 2020** = Endorsement by ACCSQ
- **April 2020** = Signing of the Agreement by AEMs
- **June 2020 – June 2025** = Ratification & Notification to ASEAN Secretariat
- **June 2025** = Full Implementation by all ASEAN

Crucial Action to address Implementation Challenges

Framework Transposed in Respective Country By?



Crucial Actions in Preparation for Implementation = AAHSA must push in TMHS PWG & separately



Support For Implementation 2019-20

- **Training for Regulators and Industry - major training programme is ongoing**
  - Stability study requirements training 4-6 October 2016
  - Safety Substantiation training 25-28 April 2017
  - GMP training 3-4 May 2017
- **2019 Key Activities**
  - **Claims Substantiation training for regulators & industry (IADSA / AAHSA)**
  - SMEs training and capacity building (AAHSA / ASEAN Regulators)
- **2020 & Beyond : Continued support for ASEAN harmonisation**
  - IADSA/AAHSA strategic and scientific guidance/support for ASEAN TMHS Committee (ATMHSC) ie after the Agreement has been signed
  - IADSA/AAHSA to drive Increased participation from National HS Associations and member companies
    - Target on minimising country specific requirements
    - Focus on consistency in guidelines applications
    - Tracking transposition to local law
    - Initiate training as required
  - AAHSA/IADSA advocacy with respective Min of Trade and Min of Health to advocate for quick adoption & transposition into local law

Next 3 Key TMHS PWG Meetings

- 31st TMHS PWG Meeting is scheduled to be held in the Lao PDR on 29 April - 3 May 2019.

- 32nd TMHS PWG Meeting, tentatively scheduled in the October of 2019 in Kuala Lumpur/Penang.

- 33rd TMHS PWG meeting, tentatively scheduled in the 1st half of 2020 in Myanmar. * Signing of the Agreement by AEMs.

Action & Timeline

- TMHS PWG = Need to maintain current office bearers until 2020 / signing
  - No changes ie no rocking the boat
  - National HS Associations to push for national implementation preparation

- ASEAN Secretariat = IADSA/AAHSA visibility and push for HS Agreement signing
  - Clearly understand ASEC processes /procedures
  - Enlist ASEAN Secretary General & Team to push for implementation preparation in member countries
  - Continued involvement in ATMHSC especially on implementation challenges

ASEAN
THAILAND 2019
ADVANCING PARTNERSHIP
FOR SUSTAINABILITY

Thank You for Your Attention

AAHSA
ASEAN Alliance of
Health Supplement Associations

Daniel Quek
Chairman
ASEAN Alliance of Health Supplement Associations
Sydney 10 April 2019

Thai FDA and ASEAN Harmonization

Janjira Intra
Health Food Supplement Association
(HFSA)

Thai FDA Stance

Background

From the 30th meeting of ASEAN TMHS:

I. **Thailand reported their response on the comments of the proposed modified text on the Annexes V (Stability and Shelf-life) and VIII (GMP) received from the AMS.**
II. **Thailand conducted internal consultation on Annex V and Annex VIII**
   - **Ministry of Public Health (Thai FDA, Department of Thai Traditional Medicines and Alternative Medicines)**
   - **Ministry of Foreign Affairs (Department of Treaty and Legal Affairs, Department of ASEAN Affairs),**
   - **Ministry of Commerce (Department of Trade Negotiation)**
   - **Ministry of Industry (Bureau of the Industry Standards).**

The consultation meeting concluded that Annexes V and VIII are "grave" constraints for both TM and HS industries in Thailand.

A). Legal issues to enforce different GMP standards (PIC/S GMP vs ASEAN GMP) for TM manufacturers (TM is a pharmaceutical in Thailand)

b) Impractical enforcement of ASEAN GMP in HS manufacturers co-producing other types of food products under Thai GMP

c) Technical capacities and unbearable economic burdens for both TM and HS industries

d) The proposal to modify the texts in the Annexes V and VIII in order to accommodate the "grave" concerns are not the right approach in that there is high risk to various interpretations that may potentially cause trade disputes among AMS in the future upon implementation, and it does not solve the problems but a temporary measure to address the problems that will most likely re-surface in the future.

Thailand Proposal:

Thailand withdraw the proposed modified texts in Annexes V and VIII from future consideration and requested the omission of Annexes V and VIII from the draft ASEAN Agreements for both TM and HS.

AMS Point of View (9 AMS except Thailand)

- Annexes V and VIII are important Guidelines and agreed to be retained in the Agreements.
- The guidelines provide flexibility to accommodate the differences in AMS.
- The proposed additional texts on Annexes V and VIII could be further discussed to accommodate Thailand ‘s situation, without excluding Annexes V and VIII from the Agreements.

AAHSA and AATMI Points of View

- AAHSA shared that the HS industry is supportive of the flexibility on the implementation of the Guidelines, and for the AMS and industry to have common interpretations and understanding on the implementation of the Guidelines.
- AATMI, coming from a legal view, shared that when making a rule, not define in detail so it will not limit the future. The existing flexibility provided in the existing Guidelines is sufficient for AATMI.

HOD:

HOD Meeting:

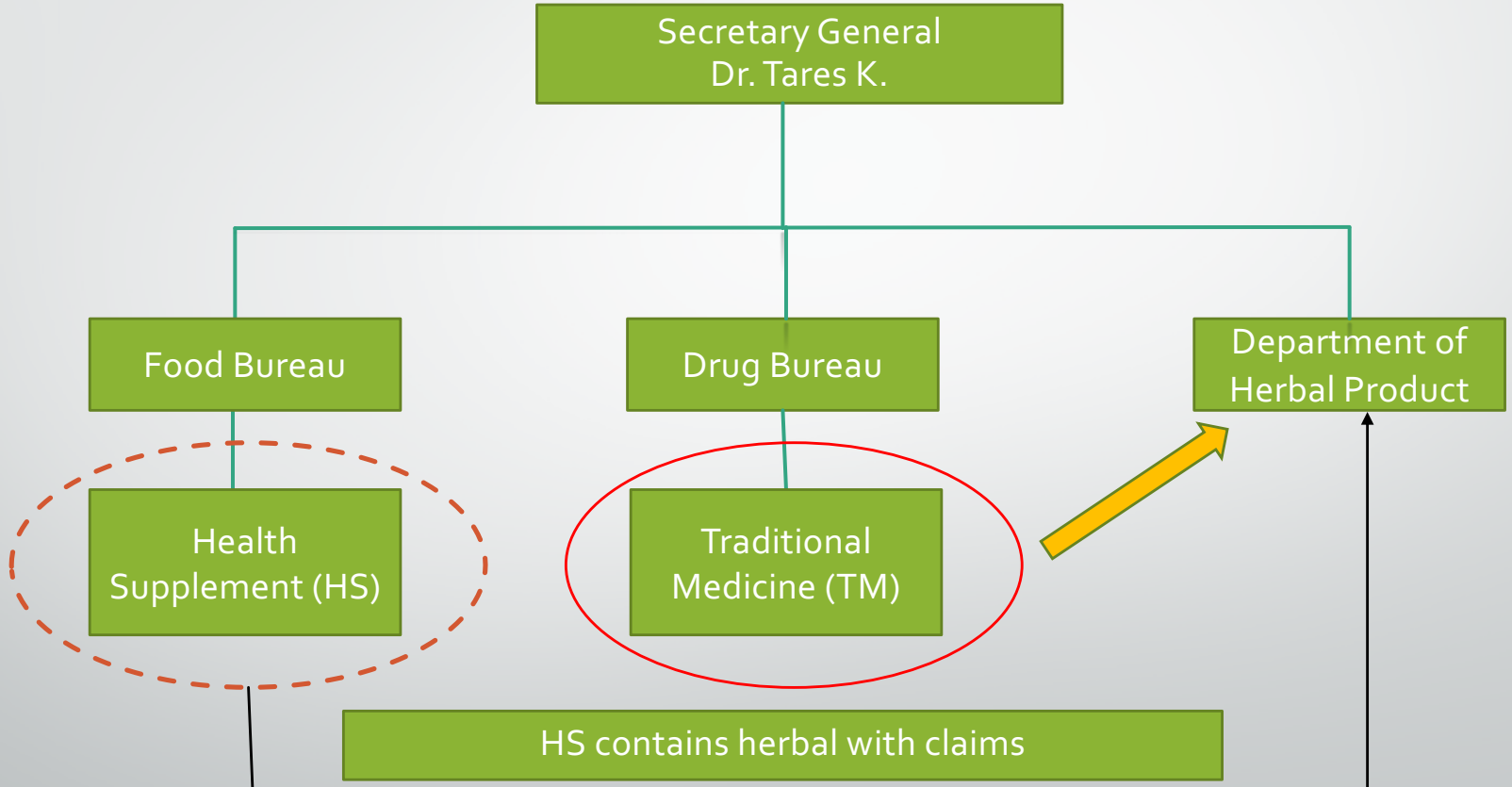
Option 1: Annexes V and VIII to be removed form the Agreements on TM and HS.

Option 2: To insert a language in Article 4 of the Agreements on TM and HS.

Option 3: To insert a language in Annexes V and VIII of the Agreements on TM and HS.

Meeting agreed to exclude Option 3 and focused on Thailand's proposal to remove Annexes V and VIII from the Agreements on TM and HS, and the 9 AMS to keep Annexes V and VIII, taking into consideration the proposed language from the ASEAN Secretariat to be inserted in Article 4 of the Agreements on TM and HS.

Thai FDA Organization



HFSA action plans to support HS Agreement to be signed and implementation

SUBMIT LETTER TO THAI FDA ON THE POSITIONING OF HFSA AND INDUSTRY TO SEE THE HARMONIZATION OF ASEAN. HFSA REQUESTED THAI FDA TO AGREE ON BOTH ANNEXES.

MET WITH DIRECTOR OF HERBAL PRODUCT (NEW DEPARTMENT OF THAI FDA WHICH TM WILL MOVE INTO THIS DEPARTMENT).

FROM MEETING WITH DIRECTOR OF HERBAL PRODUCT, THE DIRECTOR AGREED THAT THAILAND SHOULD ADOPT ON BOTH ANNEXES.

What next?

HS: Thailand will agree with both Annexes.

TM: For the next meeting, TM might not be able to finalize the agreement.
If TM moves to new department, high chance for Thailand to agree on both annexes for TM.

AUSTRALIA

Australian Government
Department of Health
Therapeutic Goods Administration

Australia: Leaders in Progressive Legislation

Adjunct Prof John Skerritt

Deputy Secretary, Australian Department of Health

International Alliance of Dietary /Food Supplement Associations

Sydney 10 April 2019

TGA Health Safety Regulation

In Australia, dietary supplements are regulated either as medicines or foods in Australia

Medicines (therapeutic good) if

- they are "represented …..or in the way in which the goods are presented…..**likely to be taken to be for therapeutic use"**

Foods if

- there is an **Australian NZ Food Standard relating to the product** (e.g. standard 2.9.4 for Sports supplements), or
- they have a **tradition of use as foods** for humans in the form in which they are presented

HOWEVER:

If a food standard applies, making therapeutic claims or presenting the product as a medicine does not make it a medicine in law

Why does it matter ?

Whether a product is regulated as a food or medicine will determine:

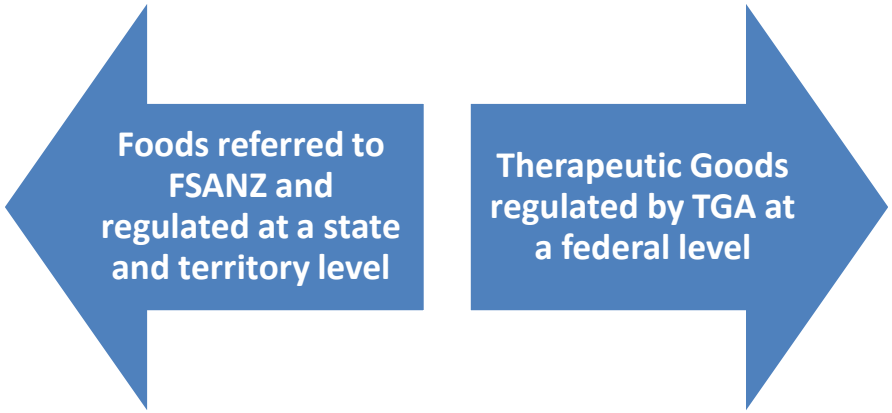
- **Who regulates it**
  - The national medicines regulator (TGA), or
  - State and Territory food regulators (agencies and/or parts of health departments)
- **What information** the company sponsor is required to hold
- **What product claims** can be made, including in advertising

An online Food-Medicine Interface tool helps in classifying dietary supplements

Food Medicine Interface: just because something is in a capsule or tablet form does not make it a medicine!

- Honey products
- Vitamin gummies
- Herbal teas
- Androgen modulators
- Pre-workout stimulants
- Weight loss products
- Adulteration of ‘food’ products

- Need to know who regulates if there are adverse reactions, packaging, tampering or illegal ingredients, or advertising issues
- Has become more complex over recent years as health claims are made in for a wider range of products



But the rest of my presentation will consider complementary medicines

Dietary supplements that are therapeutic goods usually are categorised as "listed" complementary medicines

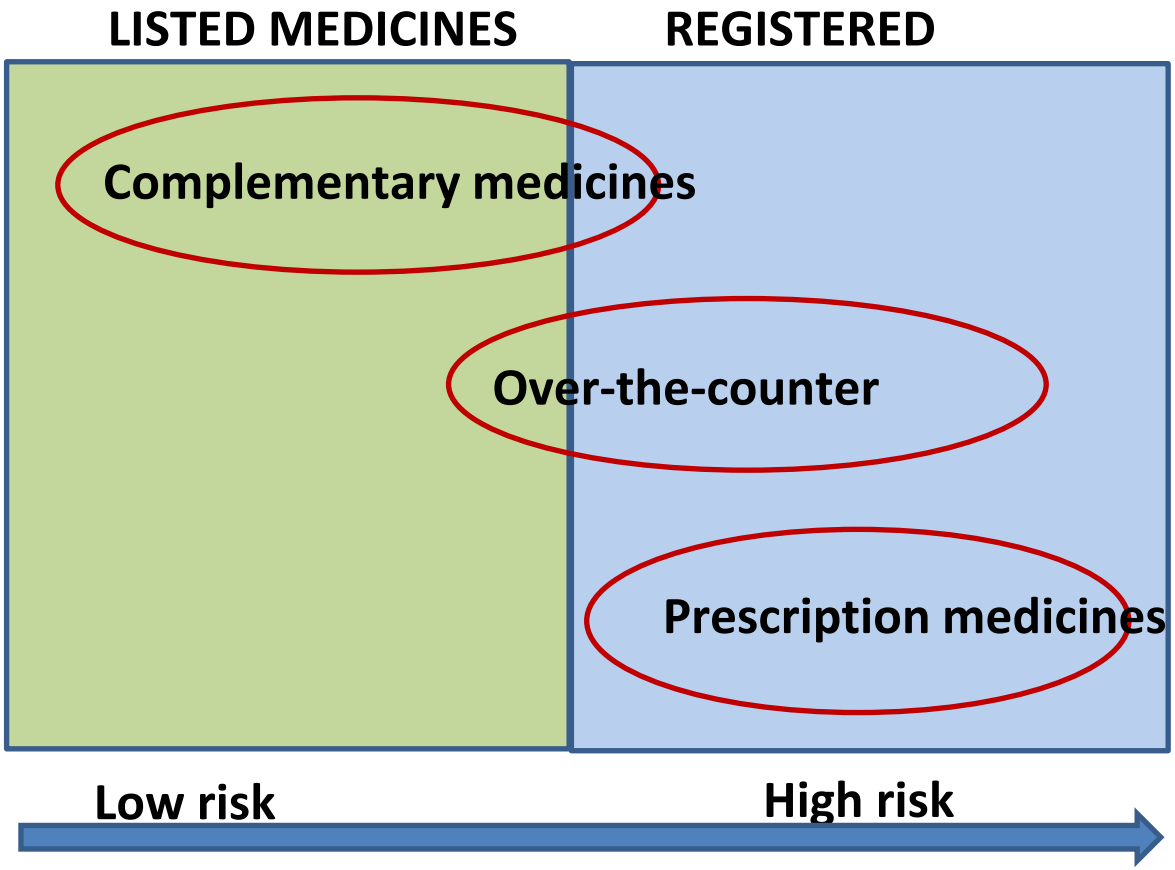
The over 11,000 Complementary medicine products on the ARTG contain one or more designated active ingredients, each of which has an established identity:

- Plant or herbal materials
- Vitamins and minerals, Amino acids, Essential oils
- Homoeopathic preparations
- Other substances such as: carbohydrates. Lipids, animal substances (e.g. cartilage), microorganisms (e.g. *Acidophilus sp*)

A major review of Australia's regulatory system including complementary medicines was carried out between 2014 and 2016

Reforms are being implemented between 2017 and 2020

A tiered system: Unless exempt, complementary medicines supplied in Australia must be in the Australian Register of Therapeutic Goods (ARTG)



Complementary medicines are classified on their ingredients and indications (health benefits) they claim

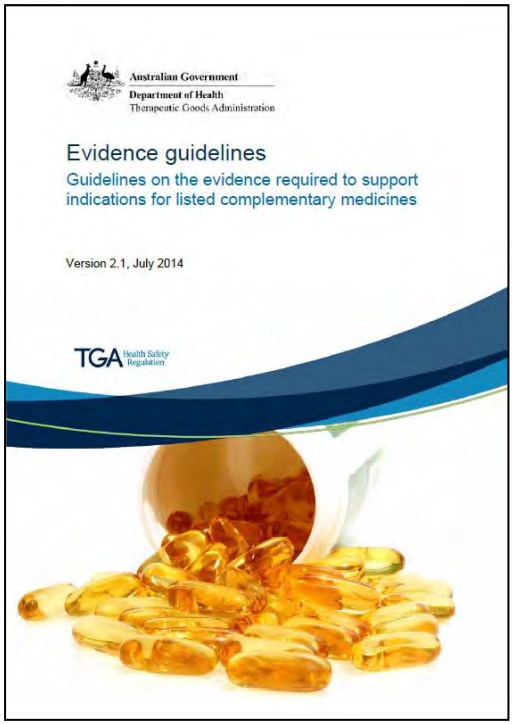
AUST L	AUST L(A)	AUST R
Listed medicines	Assessed Listed medicines	Registered complementary medicines
No premarket evaluation • GMP • Permitted ingredients • Permitted indications	**Premarket evaluation for Efficacy only** (Intermediate level & permitted indications) • GMP • Permitted ingredients Can use a claimer	**Full premarket evaluation for**: • Quality • Safety • Efficacy Can use a claimer
Lower risk		**Higher risk**

Indications (health claims or benefits) and product classification

AUST L listed medicines	AUST L(A) assessed listed medicines	AUST R registered comp medicines
A low level indication may refer to: • **health enhancement** • health maintenance • prevention of dietary deficiency • a disease, ailment, defect or injury other than a serious form of those diseases	**Intermediate indications** that are not appropriate for the list of permitted indications Intermediate level indications may refer to: • the **prevention, alleviation, or cure** of a non-serious disease/ailment • restricted representations (i.e. a serious form of a disease)	**High-level indications** that refer to the prevention, alleviation or cure of a more **serious form of a disease, ailment or injury**
Lower risk		**Higher risk**

Evidence for AUST L listed medicines

- **Sponsor must hold evidence** for **all** indications and claims **at the time of listing**
- **Guidelines on the evidence required** provide information on:
  - types of evidence and evidence sources
  - quality and credibility of evidence
  - how to present evidence
- For a low-level **scientific specific indication**
  - need an RCT OR an observational study plus a review/ reference text/ monograph
- For a low-level **scientific non-specific indication**
  - two observational studies OR Two reviews, reference text, monograph/regulatory review



Indications can be based on a traditional or a scientific paradigm

Traditional indications

- present factual statements of a health benefit relating to a historical record of use **within a traditional paradigm**
- cannot make a **scientific claim of efficacy** e.g. lowers HB1Ac in diabetes
- must be **based on evidence of a history of medicinal use** of the ingredients or medicine
  - that exceeds three generations (75 years) **and**
  - is extensively recorded in recognised evidence sources for traditional medicine

AUST L listed medicines

Only Permitted ingredients

Good manufacturing practice (GMP)

Only Permitted indications

No premarket evaluation

Medicine listed in the ARTG with AUSTL number

Post-market compliance

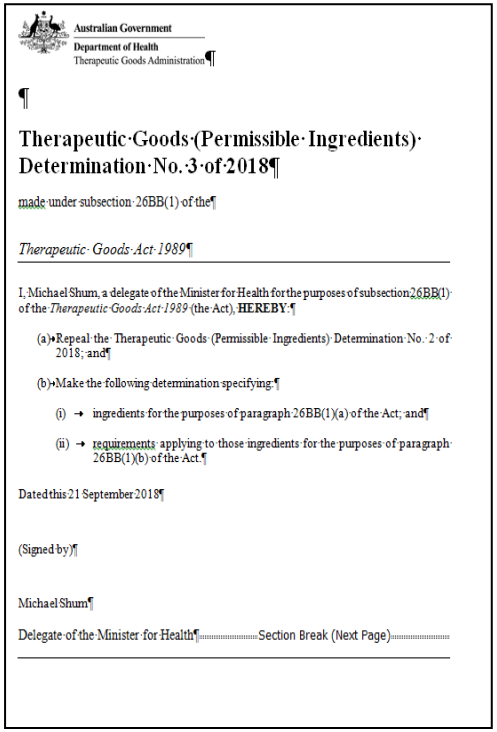
Listed medicines - permitted ingredients

Permitted ingredients

Good manufacturing practice (GMP)

Permitted indications

- Low risk ingredients that have been specifically approved by the TGA, and present in a searchable database
- Must not contain a scheduled substance
- Some ingredients may have restrictions, such as:
  - concentration limits
  - route of administration
  - plant parts
  - type of preparation
  - container type
  - warning statements



Australian Government
Department of Health
Therapeutic Goods Administration

Therapeutic Goods (Permissible Ingredients) Determination No. 3 of 2018

made under subsection 26BB(1) of the

Therapeutic Goods Act 1989

I, Michael Shum, a delegate of the Minister for Health for the purposes of subsection 26BB(1) of the *Therapeutic Goods Act 1989* (the Act), **HEREBY**:

(a) Repeal the Therapeutic Goods (Permissible Ingredients) Determination No. 2 of 2018; and

(b) Make the following determination specifying:

(i) ingredients for the purposes of paragraph 26BB(1)(a) of the Act; and

(ii) requirements applying to those ingredients for the purposes of paragraph 26BB(1)(b) of the Act.

Dated this 21 September 2018

(Signed by)

Michael Shum

Delegate of the Minister for Health Section Break (Next Page)

Included in a legislative instrument

Market exclusivity for new ingredients

- A successful applicant for a new permitted ingredient may '**opt in' to have 2 years exclusive use** of that ingredient
- The applicant can assign rights of use of that ingredient to others
- **At the end of the exclusivity period**, any company can include the ingredient in their listed medicine product

Good manufacturing practice

Permitted ingredients

Good manufacturing practice (GMP)

Permitted indications

- **Good manufacturing practice (GMP)**
  - all listed medicines MUST be manufactured under the principles of GMP
  - ensures the products are of high quality
- **Medicines standard (PIC/S) GMP** but recognising the lower risks of non-prescription oral and topical products
- **Australian manufacturers** must hold a GMP licence
- **Overseas manufacturers** must hold GMP clearance certificate

Permitted indications - AUST L

Included in a legislative instrument

Must Relate to:

- **health maintenance** - normal physiological consequences for good health associated with a product, or provision of nutritional support
- **health enhancement** - for normal healthy people, such as improving, promoting, enhancing or optimising body organs or systems.
- **prevention of a dietary deficiency**;
- or for **certain non-serious, self-limiting diseases, ailments, defects or injuries** - claim can relate to the temporary relief of a particular symptom

Permitted indications

- **Transparency for industry** on what indications are accepted for listed complementary medicines
- May also require a warning statement / specify population for which the indication is not suitable
- **Avoids consumers from being misled** by inappropriate indications to increase consumer confidence in listed medicines
- From **6 March 2018**, all new listed medicines must select permitted indications …. and existing listed medicines must transition by **6 March 2021**
- **Can alter wording on the product label** (pack) if the intent and meaning does not change

Using permitted indications

1. Select tradition of use
(mandatory for traditional indications)

2. Select core permitted indication
(Mandatory)

3. Select linked indication
(Optional)

4. Select specifying qualifiers
(Optional)

Healthy target population

Time of use

Tradition of use

'Traditionally used in Western herbal medicine to'….

Core permitted indication

'Relieve symptoms of indigestion'

Linked indications

'Relieve abdominal bloating'
'Relieve cramping'

Indication qualifiers

Time of use: 'after eating'

Target population: 'in adults'

Final permitted indication on product label

'Traditionally used in Western herbal medicine to relieve symptoms of indigestion (such as abdominal bloating and cramping) after eating in adults'

AUST L(A) assessed listed medicines

- **Ingredient** must meet
  - safety (permitted ingredients) list
  - quality (pre-approved GMP) of their medicine
- **TGA pre-market assessment of scientific evidence** supporting efficacy of the indications in finished product
- Must have at least one **intermediate** indication that is not included on the permitted indications list
  - prevents cold sores
  - reduces symptoms of tinnitus
  - relieves rheumatoid arthritis symptoms
- Can also include low level permitted indications
- Have the **option to use an efficacy 'claimer'**

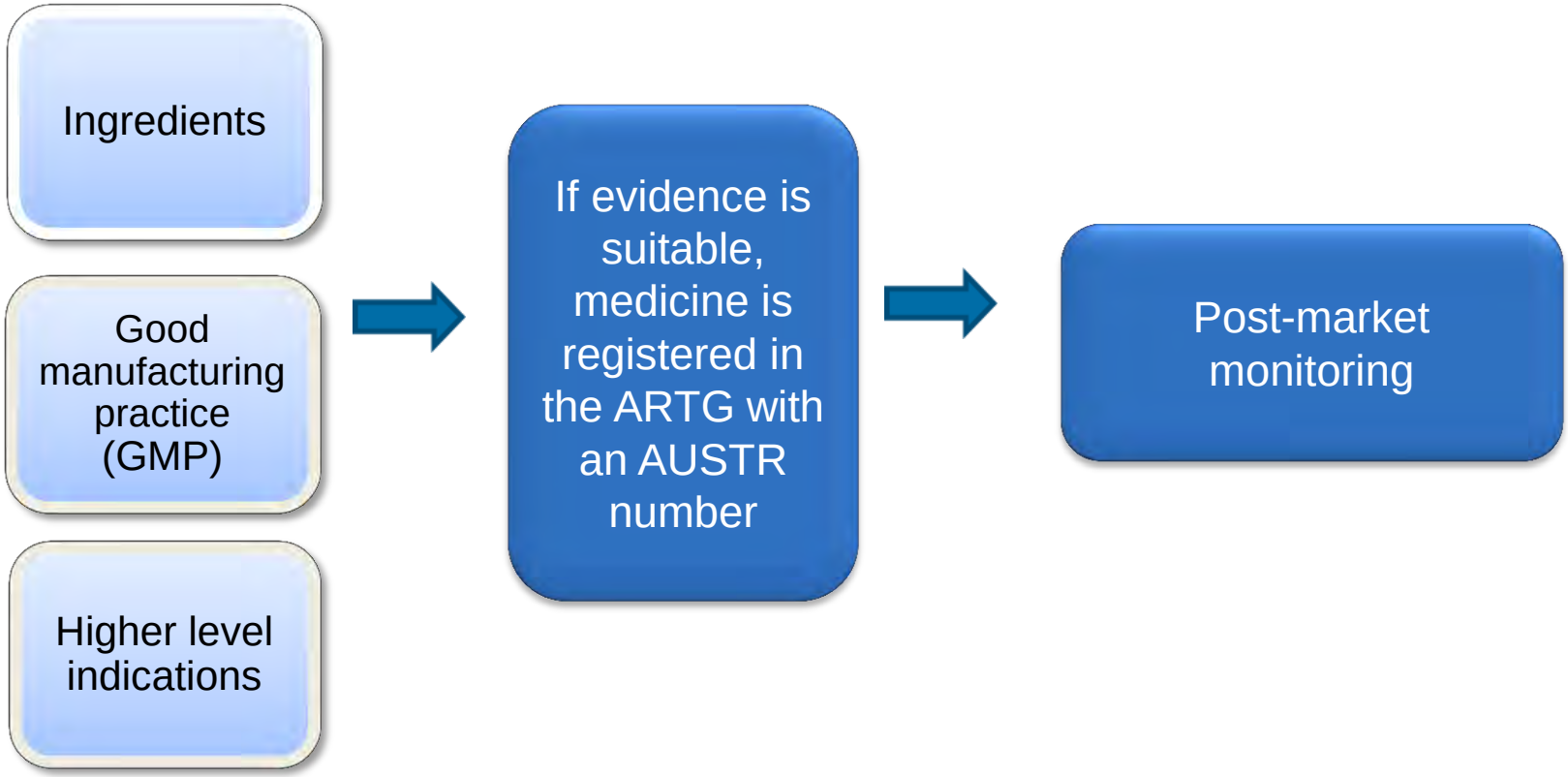
Claimer of efficacy

- Sponsors of assessed listed medicines and registered complementary medicines have **the option** to indicate that the efficacy of the product has been assessed by the TGA
- The claimer can be used on all promotional materials and on the medicine label
- The claimer can be the approved symbol **and/or** the approved label statement

Evidence for the approved indications has been assessed by the TGA

Registered complementary medicines

- Full pre-market evaluation of quality, safety, efficacy of the product
- Can refer to prevention or alleviation of a serious form of a disease
- But must not refer to a prohibited representation



Use of comparable international regulators evaluations for complementary medicines

- Where possible, the TGA makes use of evaluations from certain other regulators
  - for evaluation of a substance or a full product
  - for use in listed or registered complementary medicines
- Complicated by the lack of alignment of different regulatory systems internationally
- Can use part or all of an evaluation e.g. just safety or efficacy assessment
- Will require applicant to submit the information to us

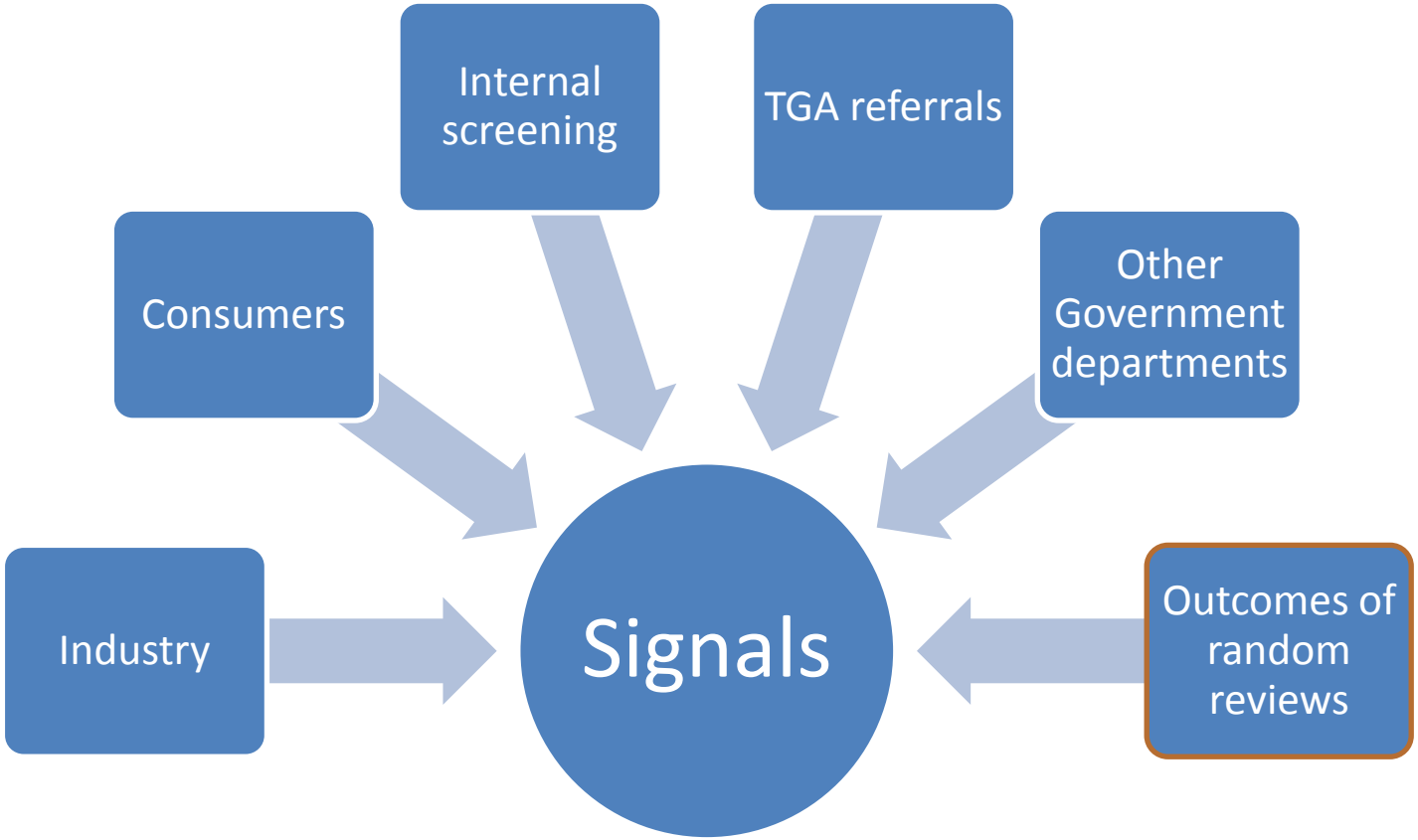
Post market (on - market) compliance for listed complementary medicines

Products may be randomly selected or targeted for review

Risk based regulatory approach includes:

- desk-based audits of listed medicines – ‘compliance reviews’
- laboratory testing of products and ingredients
- monitoring of adverse reactions
- recalls
- audit of manufacturing sites
- controls over advertising

Where do our signals come from to monitor for compliance and safety?



Compliance review outcomes

Where we identify a compliance problem TGA can:

- Issue a **proposal to cancel notice**
  - sponsor has opportunity to correct the issue, and product can continue to be marketed, OR
  - product can be cancelled if the concerns are not addressed
- **Cancel** product immediately – major safety issue
- **Suspend** the product from the ARTG
- **Recall** the product from the marketplace

Cancelled/suspended medicines cannot be supplied

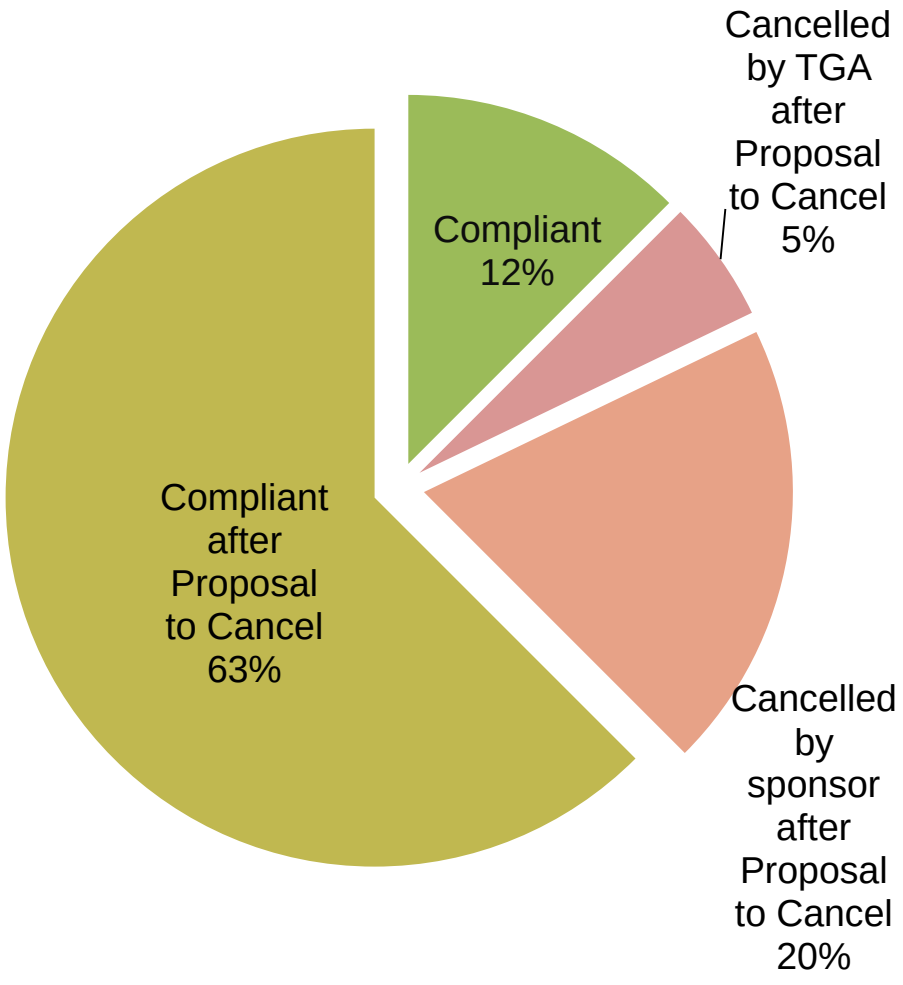
Overall, compliance is not very good

Random plus targeted compliance reviews	2016-17	2017-18
	July to June	
Actions following a Request for Information		
Medicines found to be compliant	87	42
Proposal to cancel notice/ warning sent by TGA	330	129
Total	417	171
Actions following Proposal to Cancel notice		
Medicines cancelled by the TGA	17	10
Medicines cancelled by sponsors	84	45
Compliance breaches addressed	229	74
Total	330	129

Compliance problems

- Indications and/or ingredients don't comply with listing requirements
- Manufacturing, quality, formulation
- Labelling
- Advertising
- Unacceptable presentation
- Evidence provided does not support claims made
- Safety

TGA reviews do bring many products back into compliance



TGA is implementing enhancements to the compliance monitoring program

As consulted upon with stakeholders, these include:

- **More information on** review outcomes through publication on our website
- **Greater targeting** of sponsors found to have non-compliant products
- New **online training** modules for sponsors

Advertising of complementary medicines to the general public

- **Regulated by TGA through a legally binding Code, to support appropriate use of products** and advertising does not mislead or deceive
- **Mandatory pre-approvals of certain types of advertising will be abolished by 1 July 2020**
- TGA now the **single body** responsible for handling **advertising complaints**
- **Investigation and enforcement powers** have been broadened
- **Sponsor education programs** to assist in compliance also enhanced

Aspects of the Advertising Code

- Requirements for **'prominently displayed or communicated'** in adverts
- New mandatory statements apply for internet sales (where purchaser cant see physical product)
- **Comparisons** in adverts cannot claim others are harmful or ineffective
- Adverts cannot **offer free samples** (except sunscreens and condoms)
- **Scientific representations** (cited research and scientific claims), **endorsements and testimonials** carry particular disclosure requirements
- Requirements for advertising **directed primarily to children**
- Requirements to have **"health warnings"** such as allergens

Some complementary medicine products have specific requirements

- If **based on traditional use**, the paradigm must be prominently displayed or communicated
- **Vitamins and mineral supplements** must not claim they are a substitute for good nutrition or a balanced diet
- **Weight management** product advertisements
  - Must balance claims with need for healthy energy controlled diet
  - cannot claim that supplement will reverse effects of over-eating
  - individuals featured in advertisements must represent average / expected results

Classification of advertising complaints

Despite the most stringent regulatory schemes globally, some consumer groups are not happy

Some groups have proposed:

- Premarket **evaluation** of all products
- **Limitation** of scientific claims
- **Abolition** of traditional use claims
- Sales of homoeopathic products **not permitted**
- **Larger number** of complementary medicine on-market reviews
- **More immediate cancellations** of products
- **More consumer education** on products and their regulation

And even the average consumer says they are unsure…despite widespread use of complementary medicines

Agreed complementary medicines are:	Panel (n=1045)	Opt-in (n=684)
Appropriately regulated	32.2%	14.5%
Trusted	37.6%	23.9%
Safe	38.5%	25.8%

Responses from a July 2018 survey of random consumers (panel) commissioned by TGA

TGA also continues to receive over 100 new advertising complaints each month, many relating to the advertising of complementary medicines

BREXIT

CRN UK
Council for Responsible Nutrition

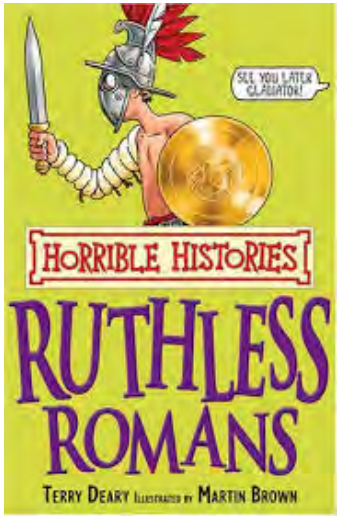
Leading the Food Supplement Industry

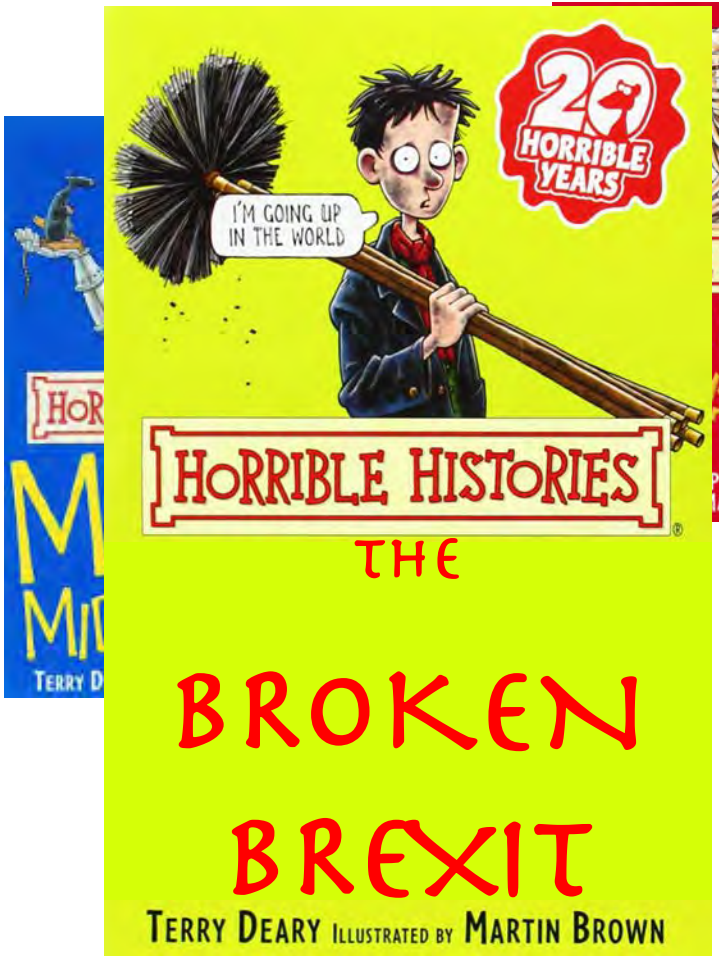
Implications of Brexit

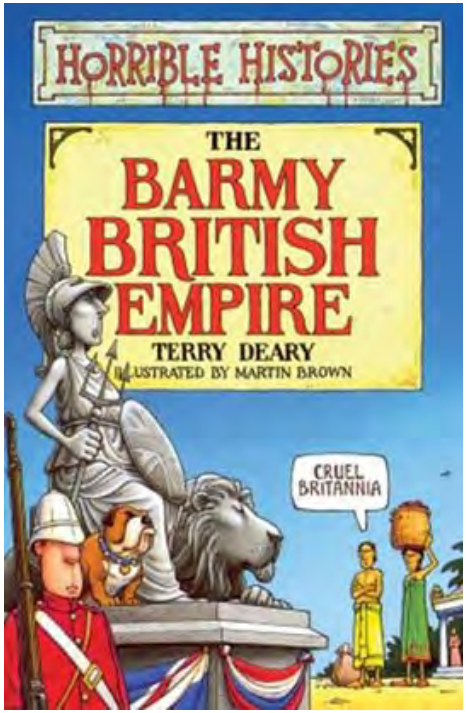
Sam Jennings, Technical Adviser to CRN UK

"Future generations will not forgive us if they have to study this in history lessons."

CRNUK
Council for Responsible Nutrition

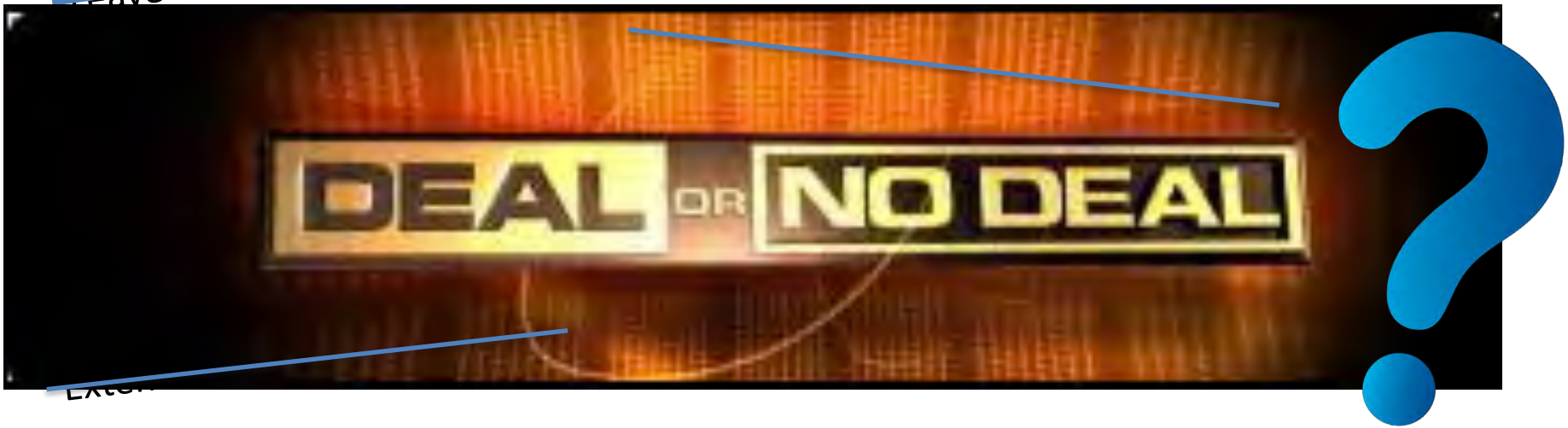






CRNUK
Council for Responsible Nutrition

~~Leave on 29th March 2019~~



~~Exte~~

Agreed with EU last night: 'Flexible extension' to 31st October 2019

Implications?

Product labelling

Distribution

Health ID marks

Labour

Tariffs

Import system

Intellectual property

Free Trade Agreements

Export system

Where will future UK regulation go?

"Little or no change for 2 years"

Health claims

Novel foods

'Safety' legislation

Devolved Administrations

What are we doing?

EU Exit Roundtable
- Various government agencies
- Monthly physical meetings
- Weekly conference calls

Maintaining formal and informal contact with different government agencies

Supporting our members!

Maintaining inter-industry communication

Meanwhile…

The Week, 29/3/19

…and normal life carries on!

Thank you for listening!

spj@berryottaway.co.uk

www.crnuk.org

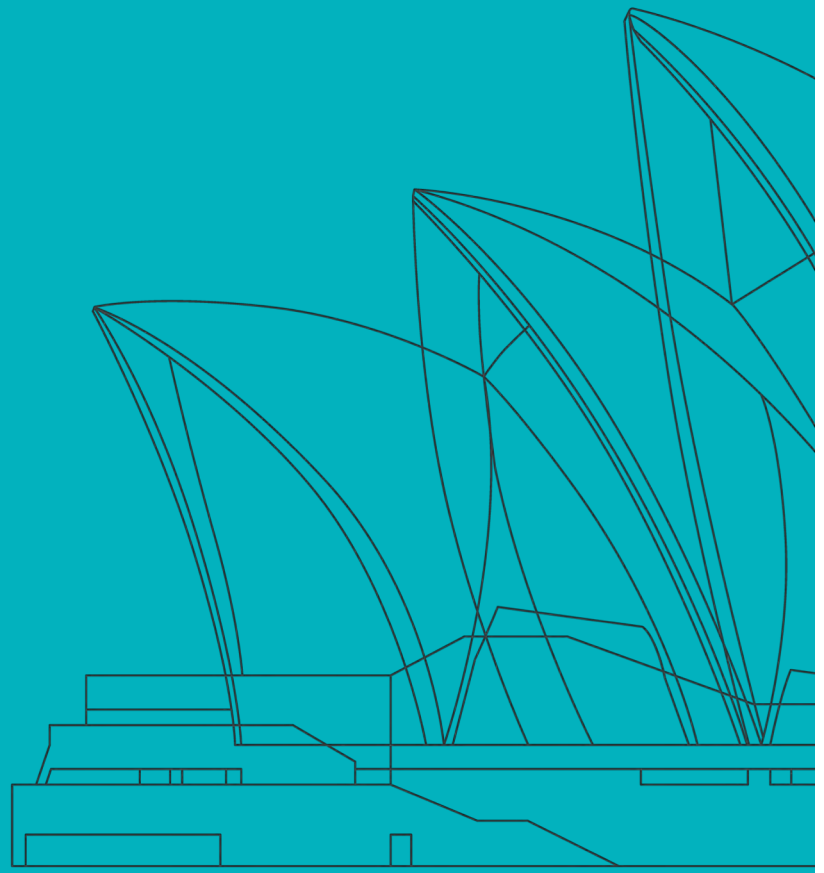
CHINA

IADSA

International Alliance of Dietary/
Food Supplement Associations

UP TO SPEED
…CHINA BRIEF

IADSA ∘ SYDNEY ∘ APRIL 2019

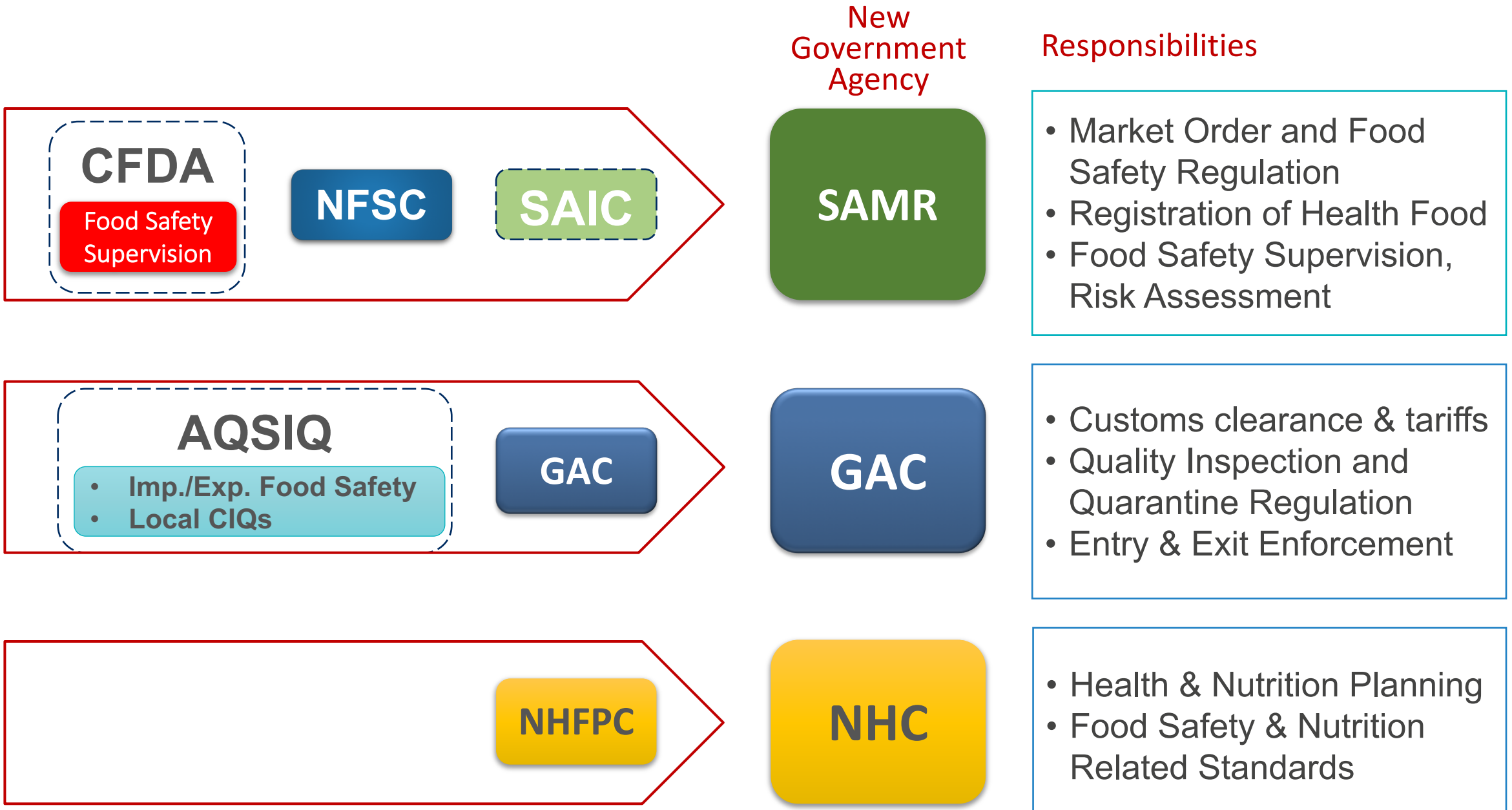



Social stability

TIMELINE …. 2018

Government Announced Reorganization

IADSA
International Alliance of Dietary/ Food Supplement Associations



State Administration for Market Regulation (SAMR)

Food Safety

- CFDA
- National Food Safety Committee of the State Council
- CNCA
- SAC

Market Order and Competition

- SAIC: Direct selling, anti-unfair competition, Consumer Protection; Advertising;
- MOFCOM: M&A Approval
- State Council's Anti-Monopoly Committee
- NDRC: Anti-price monopoly

IPR Protection

- SIPO: Pattern
- SAIC: Trademark
- AQSIQ: Geographical Indications

Acronyms for Government Entities:

AQSIQ: the General Administration of Quality Supervision, Inspection and Quarantine
CDC: Centers for Disease Control
CFDA: China Food and Drug Administration
CIQs: China Entry-Exit Inspection and Quarantine Bureaus
CNCA: Certification and Accreditation Administration
GAC: General Administration of Customs
MOFCOM: Ministry of Commerce
NDRC: State Development and Reform Commission
NFSC: National Food Safety Committee of the State Council
NHC: National Health Commission
NHFPC: National Health & Family Planning Commission
SAC: Standardization Administration of China
SAIC: State Administration for Industry and Commerce
SAMR: State Administration for Market Regulation
SIPO: State Intellectual Property Office

TIMELINE …. MARCH-APRIL 2019

AGENDA

- SAMR structural changes
- Impact on functional food policy, landscape and operations

What happened?

The State Council

- **State Administration of Industry and Commerce (SAIC)** (No longer exists)
  - All responsibilities
- **State Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)** (No longer exists)
  - All responsibilities
- **China Food & Drug Administration (CFDA)** (No longer exists)
  - All responsibilities
- **National Development & Reform Commission (NDRC)**
  - Pricing supervision
  - Anti-monopoly of pricing sector
- **Ministry of Commerce (MOFCOM)**
  - Anti-monopoly for concentration of undertakings
- **The Office of Anti-Monopoly Committee of the State Council**
  - All responsibilities (originally based in MOFCOM)

March 2018
March 2019

State Administration for Market Regulation (SAMR)

** Local regulatory agencies have also been restructured accordingly*

China's unified market regulatory body

国家市场监督管理总局
State Administration for Market Regulation

28 + 2

- 28 internal departments
- Supervises 2 state bureaus: National Medical Products Administration (NMPA) and National Intellectual Property Administration (CNIPA)

800+

- Over 800 officials in total

18

- Lawful portfolios cover 18 areas, e.g. business registration, market supervision & law enforcement, anti-monopoly, IPR protection, domestic food safety, etc.

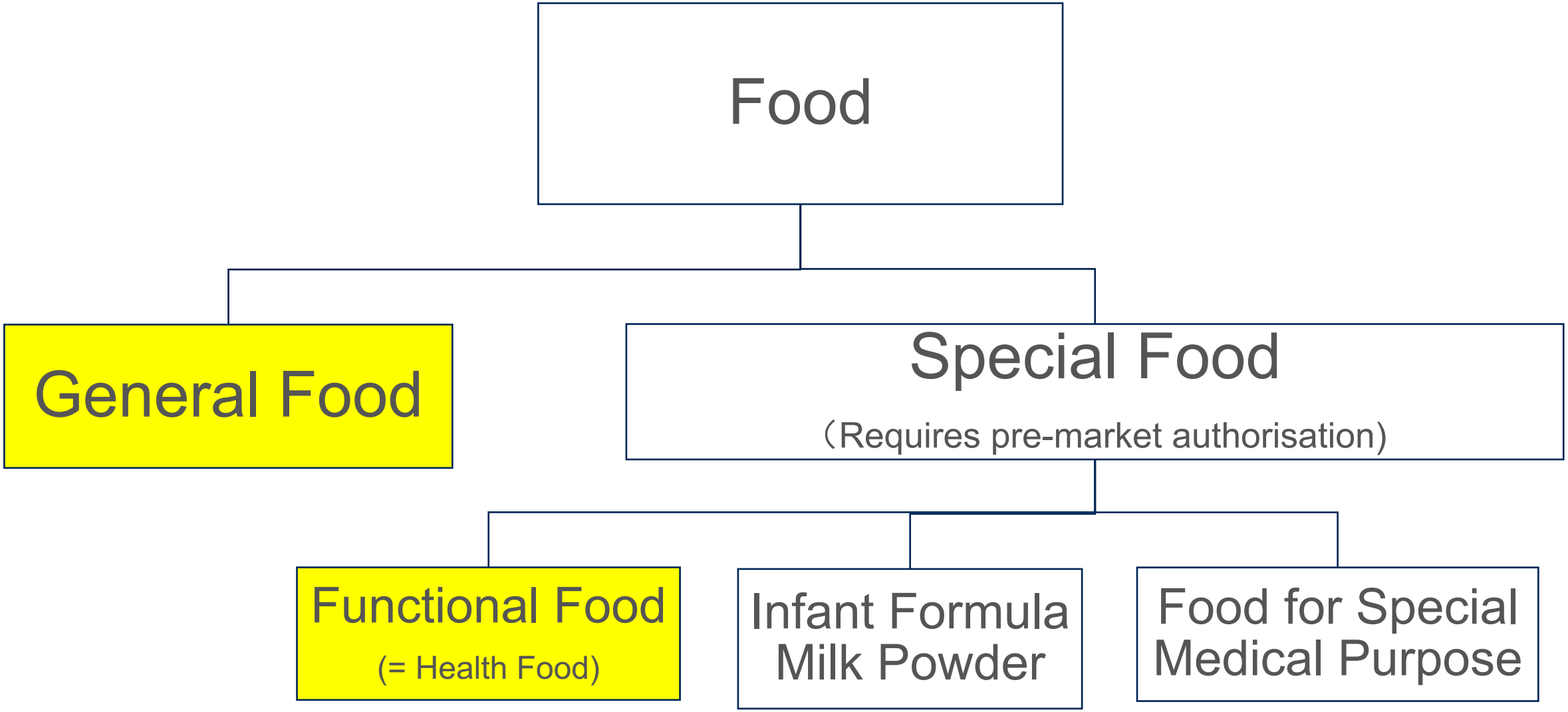
ZHANG, Mao

Minister, SAMR

Key oversight

- Function food (dietary supplements) registration/notification
- Food safety
- Consumer protection
- Advertising
- Licenses & permits (business registration, food operation permits, etc.)
- Direct Selling/anti-pyramid scheme

FOOD CLASSIFICATION IN CHINA



FUNCTIONAL (HEALTH) FOOD AUTHORISATION SYSTEM

27 FUNCTIONAL FOOD CLAIMS
FOR ‘BLUE HAT’ REGISTERED PRODUCTS

1	Enhance Immune
2	Assist Blood Lipids Reduction
3	Assist Blood Sugar Reduction
4	Anti-oxidant
5	Assist Memory Improvement
6	Alleviate Eye Fatigue
7	Alleviate Lead Excretion
8	Clear the Throat
9	Assist Blood Pressure Reduction
10	Sleep Improvement
11	Facilitate Milk Secretion
12	Alleviate Physical Fatigue
13	Enhance Anoxia Endurance
14	Assist Irradiation Hazard Protection

15	Weight Control
16	Improve Child Growth
17	Increase Bone Density
18	Improve Nutritional Anemia
19	Assist the Protection Against Chemical Injury of Liver
20	Eliminate Acne
21	Eliminate Skin Chlorasma
22	Improve Skin Water Content
23	Improving Skin Oil Content
24	Regulate Gastrointestinal Tract Flora
25	Facilitate Digestion
26	Facilitate Feces Excretion
27	Assist the Protection of Gastric Mucosa

SUPPLEMENT NUTRIENTS PERMITTED IN NOTIFIED FUNCTIONAL FOOD

22 Vitamin and Minerals

Calcium, Magnesium, Potassium, Manganese, Iron, Zinc, Selenium, Copper, Vitamins A, B1, B2, B6, B12, C, D, E, K, Nicotinic acid, Pantothenic acid, Folic acid, Biotin, Choline

27 Claims for registered functional foods

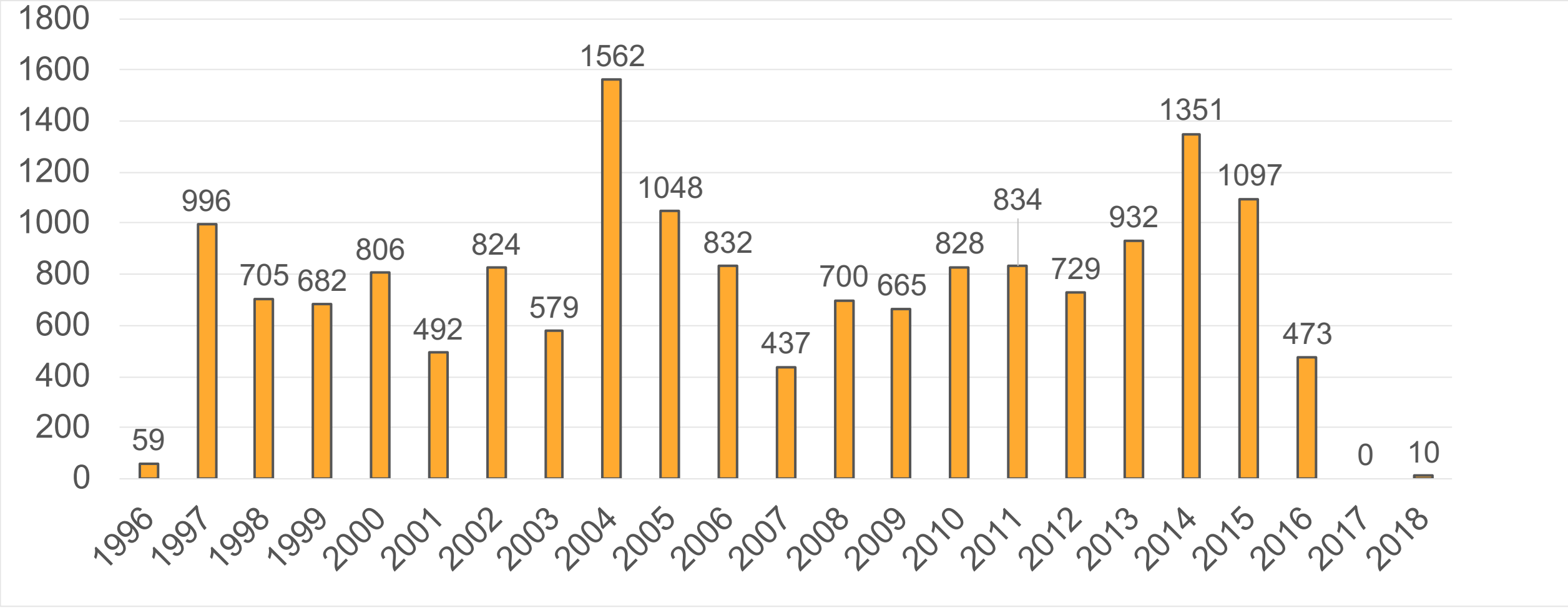
Vitamin/Mineral Supplements

by notification

Blue Hat

保健食品

Approved ‘Blue Hat’ Registered Functional Foods



Only **10** new Functional Food registrations approved since July 2016

Meanwhile, approved functional food notifications are booming, with domestic notifications exceeding 2000 from July 2017 to March 2019

RECENT REGULATORY POLICY CHANGES FROM SAMR

Registrations and Notifications

- strict control of functional food registrations with less new registrations likely to be approved
- more ingredients will be added into the functional food ingredient list to allow more notified functional food

Labeling

- an increase in functional food warning statements on product labels

Claims

- adjustments to the 27 functional food claims

PROPOSED FUNCTIONAL FOOD LABELING REGULATION

Current

Proposed

本品不能替代药物;保健食品不具有~~疾病预防，~~治疗功能.

This product cannot replace a drug; Functional Food has no ~~disease prevention~~ and disease treatment function.

1. SAMR agreed to delete sentence of “functional food has no disease prevention”
2. Finalized and effective wording TBD

PROPOSED CHANGES TO 27 FUNCTIONAL FOOD CLAIMS

On March 28, SAMR issued the drafting proposal for one month public comment to adjust nomenclature and control of functional food claims. Effective timing is still TBD.

1. Pre-2005 grandfathered functional food claims approved by the Ministry of Health
   - ❑ 18 functional claims will be canceled.

2. Current 27 functional food claims
   - ❑ 18 functional claims will be renamed (requiring labeling modification):
   - ❑ 3 functional claims will be canceled
   - ❑ 6 functional claims will be suspended for further study, e.g., assist blood lipids reduction
   - ❑ Most changes add “help XXX”;
     e.g. “weight control” will be renamed as “help adjust body fat”.

18 FUNCTIONAL CLAIMS TO BE RENAMED

	Current Function Claim	New Proposed Claim
1	Enhance Immune	Help Enhance Immune
2	Sleep Improvement	Help Sleep Improvement
3	Alleviate Physical Fatigue	Help to alleviate Physical Fatigue
4	Enhance Anoxia Endurance	Help to enhance Anoxia Endurance
5	Increase Bone Density	Help Increase Bone Density
6	Alleviate Eye Fatigue	Help to alleviate Eye Fatigue
7	Eliminate Acne	Help Eliminate Acne
8	Eliminating chlorasma	Help Eliminating chlorasma
9	Improve Skin Water Content	Help Improve Skin Water Content
10	Anti-oxidant	Help Anti-oxidant
11	Assist Memory Improvement	Help to assist Memory Improvement
12	Clear the Throat	Help to clear the Throat
13	Weight Control	Help Adjust Body Fat
14	Improve Nutritional Anemia	Help to improve Nutritional Anemia
15	Regulate Gastrointestinal Tract Flora	Help Regulate Gastrointestinal Tract Flora
16	Facilitate Digestion	Help Facilitate Digestion
17	Facilitate Feces Excretion	Help Facilitate Feces Excretion
18	Assist the Protection of Gastric Mucosa	Help to assist the Protection of Gastric Mucosa

6 FUNCTIONAL CLAIMS TBD AND 3 FUNCTIONAL CLAIMS TO BE CANCELED

19	Assist Blood Lipids Reduction	cancel or keep, TBD
20	Assist Blood Sugar Reduction	cancel or keep, TBD
21	Assist Blood Presure Reduction	cancel or keep, TBD
22	Alleviate Lead Excretion	cancel or keep, TBD
23	Assist the Protection Against Chemical Injury of Liver	cancel or keep, TBD
24	Assist Irradiation Hazard Protection	cancel or keep, TBD
25	Improving Skin Oil Content	cancel
26	Facilitate Milk Secretion	cancel
27	Improve Child Growth	cancel

A FEW CLOSING THOUGHTS ON FUNCTIONAL FOOD REGULATORY AND COMMERCIAL STRATEGIES

MAINTAIN EXISTING FUNCTIONAL FOOD REGISTRATIONS

CROSS BORDER E-COMMERCE 2017-2019 WILL LIKELY EXTEND

CONSIDER PRODUCT FORMULATIONS BASED ON PERMISSABLE NOTIFICATION NUTRIENTS

INTER-GOVERNMENT NEGOTIATED RELATIONSHIPS

Thank you

IADSA

International Alliance of Dietary/
Food Supplement Associations

RicHobby@Herbalife.com

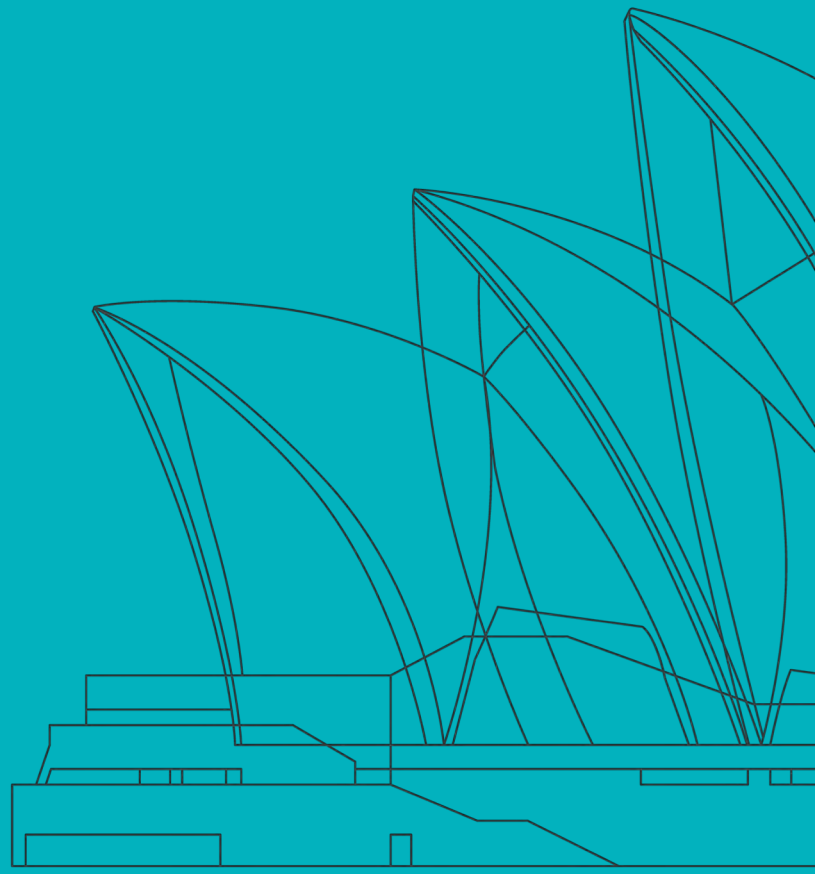
iadsa.org

INDIA

IADSA

International Alliance of Dietary/
Food Supplement Associations

INDIA



ReC HaN

Resource Centre for Health Supplements and Nutraceuticals

fssai

FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA

Inspiring Trust, Assuring Safe & Nutritious Food

Ministry of Health and Family Welfare, Government of India

CII

Confederation of Indian Industry

IADSA

International Alliance of Dietary/ Food Supplement Associations

COMPLIANCE DOCUMENT

GMP: INTEGRATION WITH FSSAI- FOSTAC INITIATIVE

Training Package prepared by ReCHaN included under FoSTaC training program

- ReCHaN in collaboration with FSSAI initiated a Consumer Awareness program at ***Eat Right Mela*** held on 14-16 December 2018, IGNCA, New Delhi.

- A ***Guidance Kit*** intended to create a sensitization on the myths and facts about Health Supplements & Nutraceuticals and their impact on overall health was developed and distributed

- To support this initiative, an ***Animated Video*** was developed, educating consumers on the basic aspects in both Hindi and English language.

KNOW YOUR SUPPLEMENTS


Know Your Supplements
https://twitter.com/IADSA_Global?lang=en
0:00 / 2:10
YouTube

CLAIMS TRAINING

Dr David Richardson

Dr Andrew Shao

TRAINING ON VITAMINS & MINERALS, MAX LEVELS

Mr. Basil Mathioudakis

Dr B.H. Lim

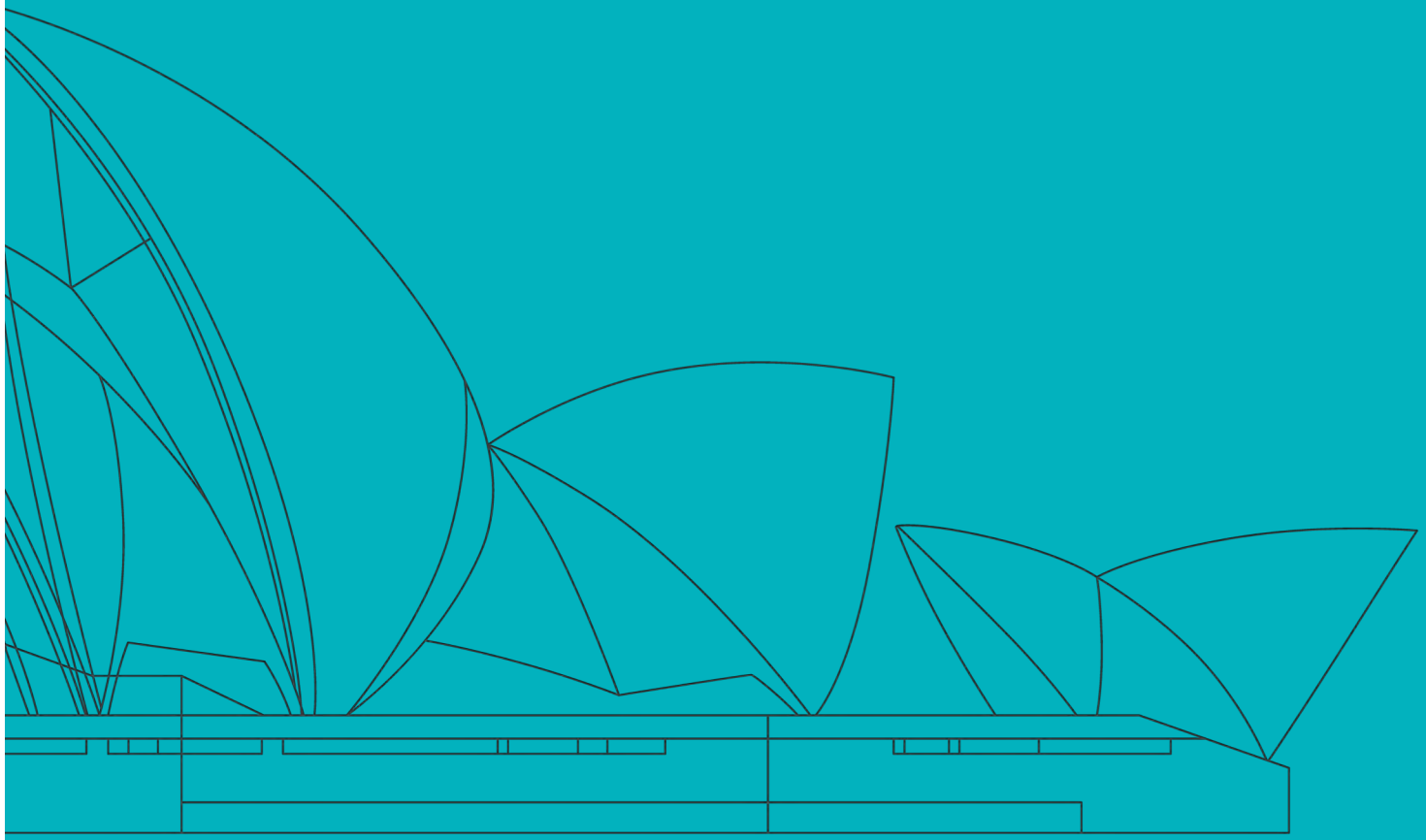
VALUE OF SUPPLEMENTATION

RESULTS

1. FSSAI confidence in the sector
2. Joint communication to consumers
3. Opportunity to talk directly to the scientific panel
4. Training the regulators
5. Open the door to review the 1X RDA limit for VMs
6. Institutionalize relationship with government

HOW SECURE IS THIS?

1. Keep delivering value
2. ReCHaN is not a trade association
3. Create bridges with other influencers



IADSA

International Alliance of Dietary/
Food Supplement Associations

iadsa.org

LATIN AMERICA

Up to speed:

What is going on in **Latin America?**

Juan Pablo Waimann- Executive Manager

Who are we?

The Latin American Alliance for Responsible Nutrition (ALANUR) is the main regional association of food supplements and ingredients in Latin America

Headquartered in São Paulo, Brazil

Founded in **November 2011** with the purpose of contributing to the development of a regulatory framework that **ensures the responsible access of food supplements and ingredients in Latin America**

Overview

- Latin America at a glance
- Opportunities for our sector
- Challenges for our sector
- Key takeaways

Latin America at a glance

- 20 sovereign states
- Population: +612 million
- Languages: Spanish, Portuguese, French
- GDP *(nominal)*: USD$ 5.2 T
- GDP per capita *(nominal)*: USD$ 9,274
- GDP growth 2019: 1.7%
- 2 countries with GDP over 1T: BR and MX

Latin America at a glance

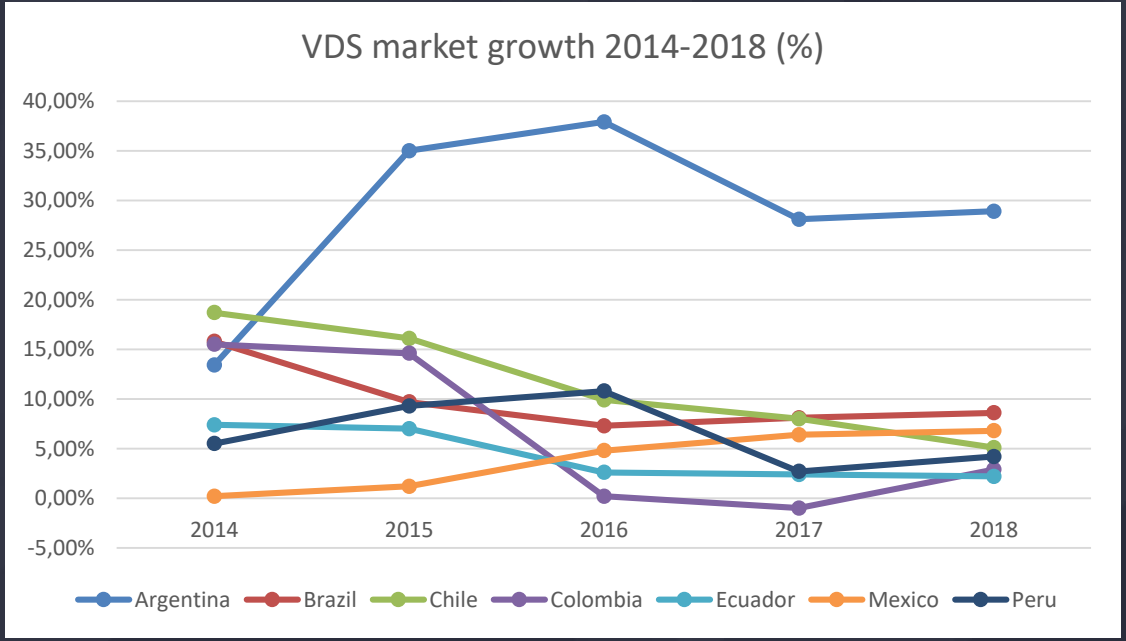
VDS largest markets in LATAM 2018

Brazil & Mexico represent 70% of the total

Source: Euromonitor International

Latin America at a glance

Argentina (28,4%)
Chile (11,4%)
Brazil (9,9%)
have been the fastest growing markets in the 2014-2018 period

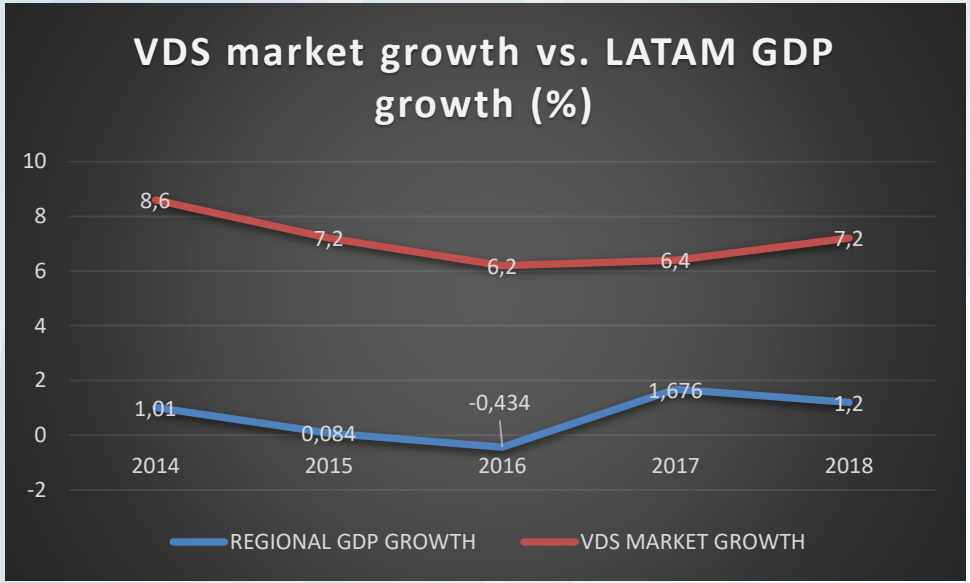


Source: Euromonitor International

Opportunities for our sector

Latin America

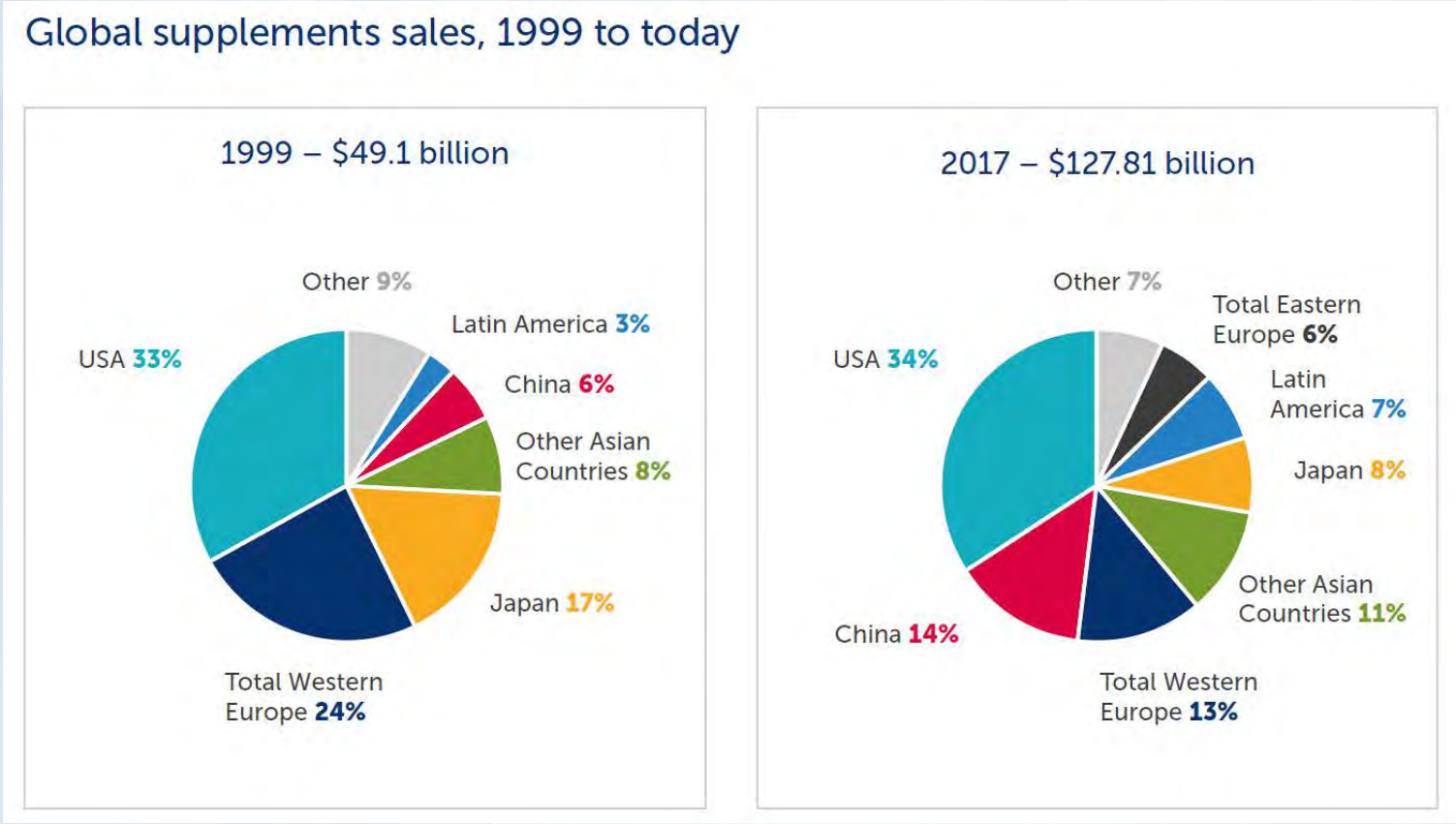
Steady growth continues



- Our market has performed with a healthy rate of growth even if the regional GDP has stagnated
- The regional sector experiences the second highest growth rate globally after APAC
- Interest on healthy lifestyles and nutrition are strong drivers

Source: Euromonitor International

Cementing a long-term trend



Source: IADSA, The Evolution of the Health Supplements Sector. From the 1990s to the current day

Formidable evolution of the regulatory landscape

✔ Regulatory frameworks improved drastically vs. a decade ago

✘ Normative divergence is vast, even between members of the same trade bloc

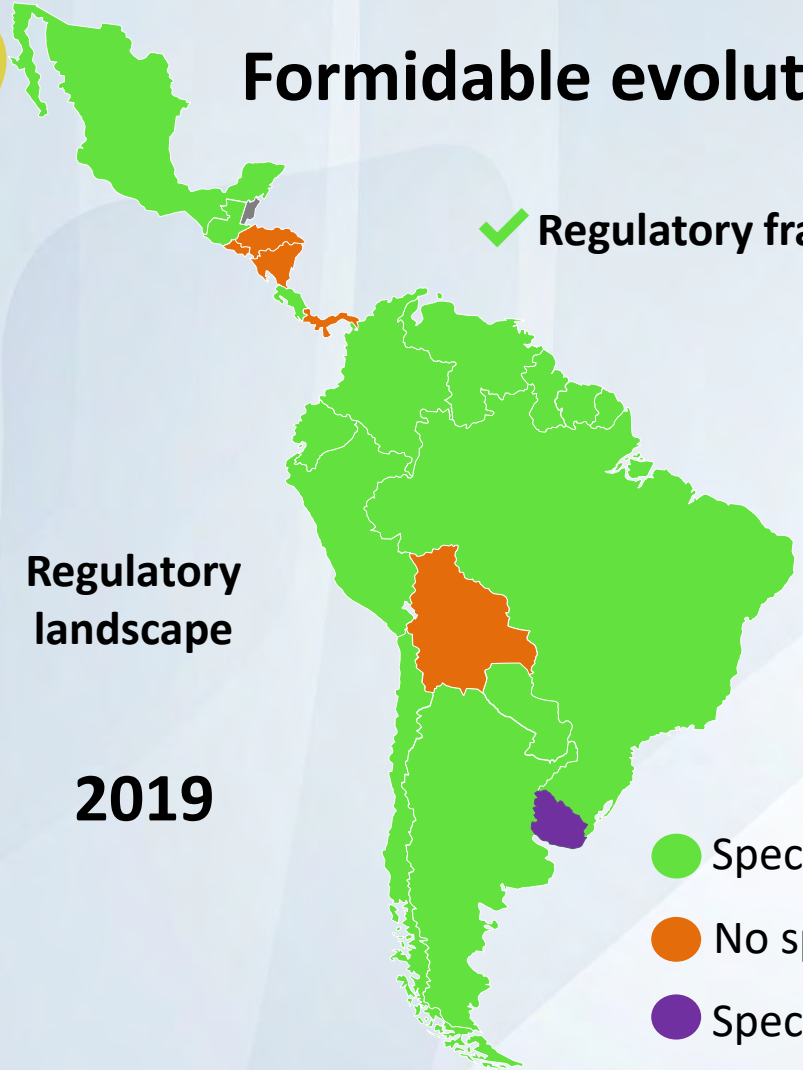
Formidable evolution of the regulatory landscape

✔ **Regulatory frameworks improved drastically vs. a decade ago**

✘ **Normative divergence is vast, even between members of the same trade bloc**

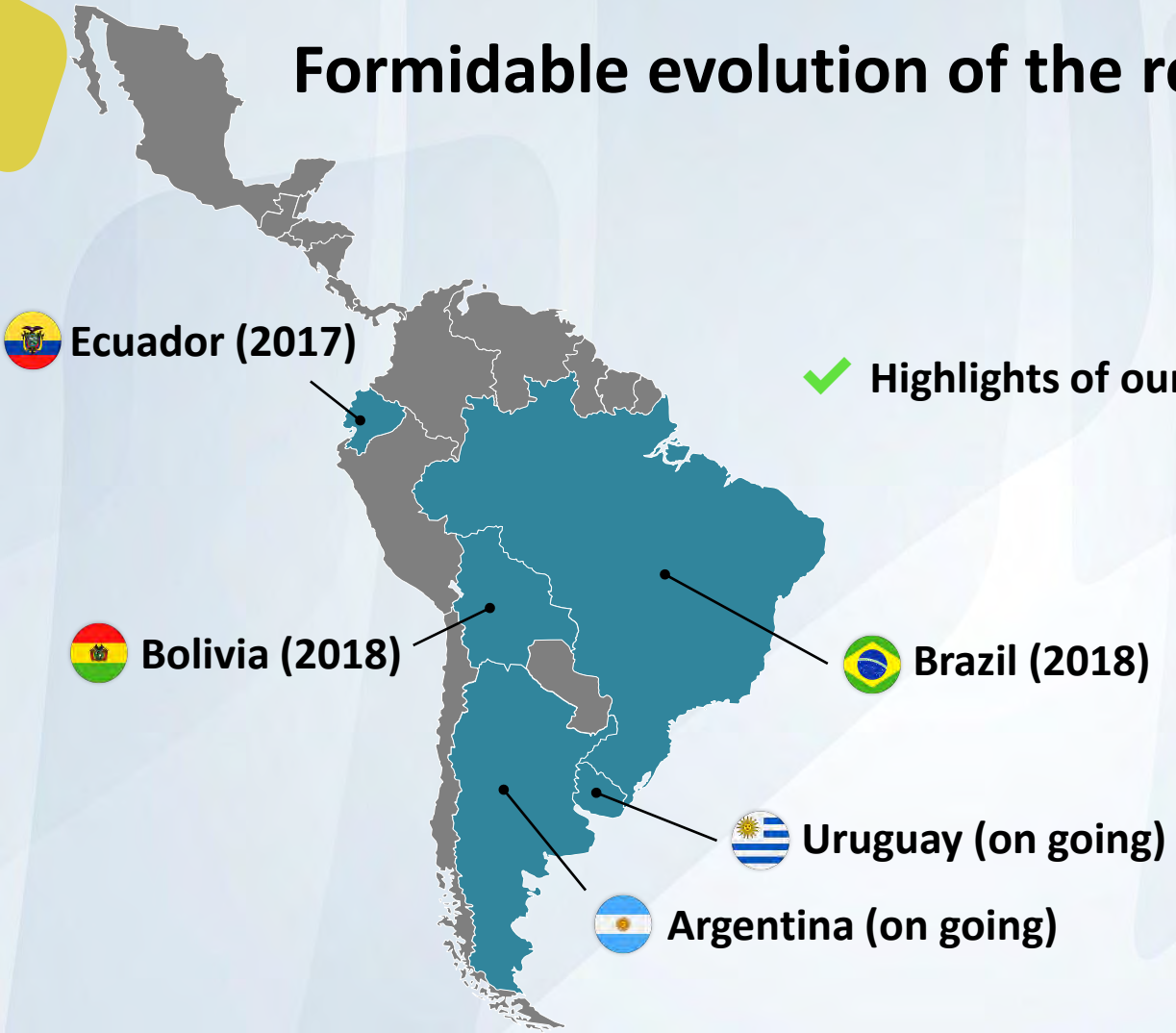
Regulatory landscape

2019



- Specific regulation for FS
- No specific regulation for FS
- Specific regulation for FS being developed

Formidable evolution of the regulatory landscape



Ecuador (2017)

Bolivia (2018)

Brazil (2018)

Uruguay (on going)

Argentina (on going)

✔ Highlights of our regulatory impact in recent years

Renewed levels of normative certainty for LATAM's largest market

Brazil

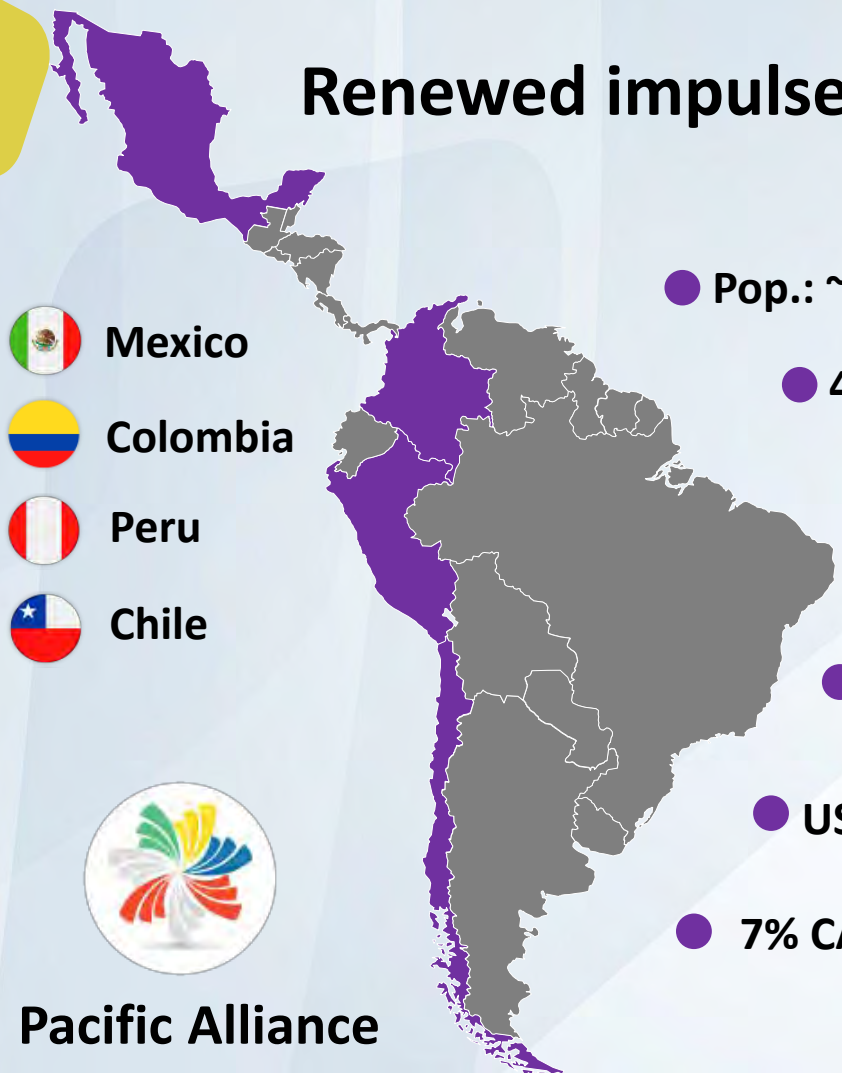
Pop.: 200 million
USD 1.8 B market
+40% of the LATAM market
9.9% CARG (2013-2018)

New Brazilian bloc of regulations for food supplements (2018)

- ✔ A sound definition for the category
- ✔ Notification procedure for most products
- ✔ Maximum levels for micronutrients not based on RDA
- ✔ 189 authorized claims in a positive list
- ✔ A positive list of +350 ingredients

- ✘ Probiotics
- ✘ Botanicals and other ingredients not included in the positive list
- ✘ Levels for specific micronutrients

Renewed impulse for regulatory harmonization

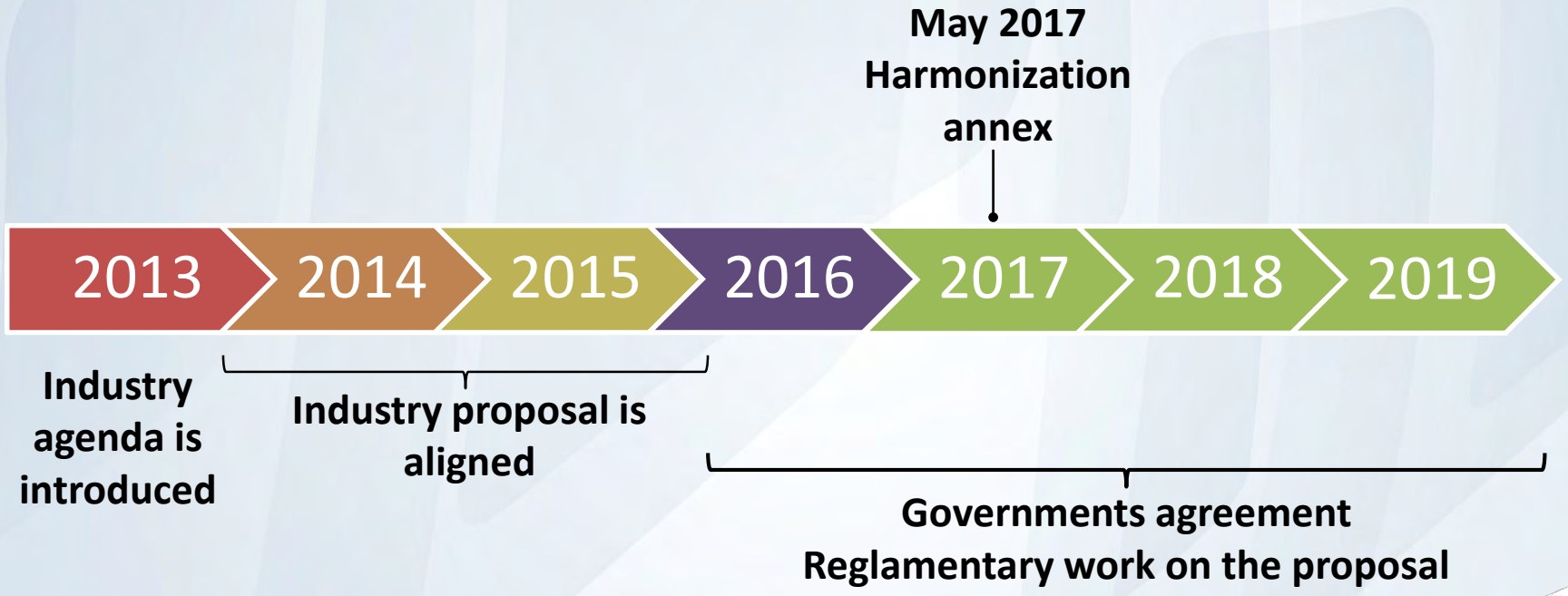


- Mexico
- Colombia
- Peru
- Chile

- Pop.: ~225 million
- 40% of regional GDP
- Growth will surpass regional average up to 2021
- 2nd, 3th, 4th and 6th largest FS markets in LATAM
- USD$ 1.9 B in 2018
- 7% CARG for the sector (2013-2018)

Pacific Alliance

Pacific Alliance harmonization initiative



Increased knowledge on our consumers

- ✔ Consumer surveys have been developed for LATAM largest FS markets
- ✔ Questionnaires are mutually comparable for most data
- ✔ Results to be used as a tool for raising governments awareness

Projects developed by ALANUR

Projects developed by ALANUR partners and third parties

Challenges for our sector

Latin America

Main regulatory challenges

Key stakeholders still hold misperceptions of the category

A vast diversity of regulatory definitions & categories

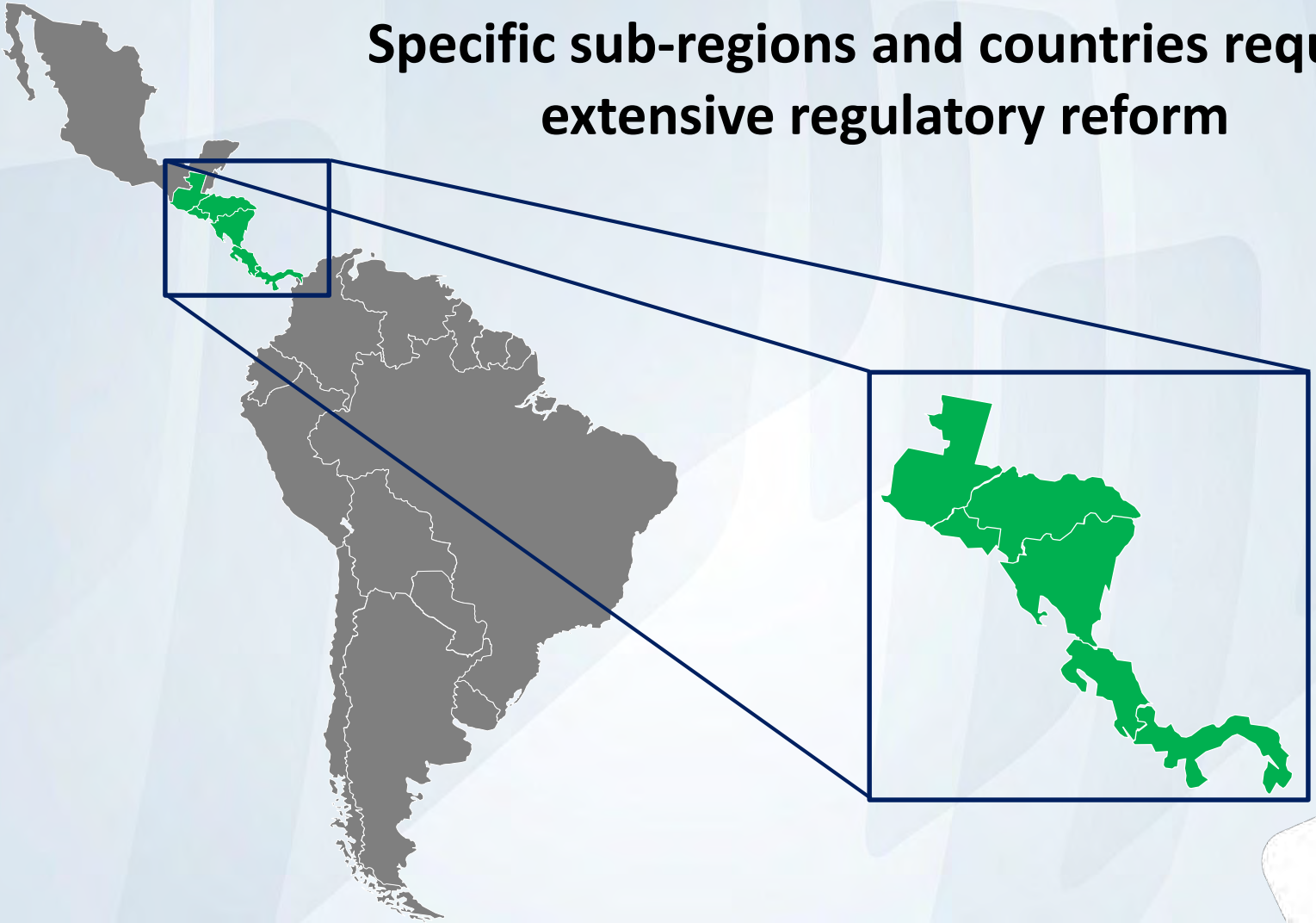
Prolonged registration processes

Restrictions in the use of health claims and in advertising

Restrictions in the use of some ingredients in specific countries

Probiotics
Enzymes
Botanicals
Bioactive compounds

Specific sub-regions and countries require extensive regulatory reform



Central America has the most underdeveloped regulatory frameworks in our region

- FS regulated as food
- FS regulated as drugs

- ✔ ~47 million people
- ✔ CAM is evidencing the highest rate of growth of LATAM
- ✔ PA & CR are projected to enjoy some of the highest GDP per capita rates in LATAM
- ✘ Regulatory reform is required for market growth to move along GDP growth
- ✘ Incentives for sub-regional harmonization are very low

Central America has the most underdeveloped regulatory frameworks in our region

How are we responding?

- ✔ From harmonization to convergence
- ✔ Focusing our effors on the national level
- ✔ Achieving national improvements to be spread to the rest of the countries

Harmonization is inherently complex & requires time

Mexico

Colombia

Peru

Chile

Pacific Alliance

Prominent pending proposals:

- Negative list of botanicals
- Harmonization of maximum levels for micronutrients
- Health claims

Increasing the expertise of public decision-makers is deemed vital

❌ Ideological collision with the sector in Chile
❌ The new administration in Mexico increased the levels of uncertainty

Harmonization is inherently complex & requires time

- Mexico
- Colombia
- Peru
- Chile

Pacific Alliance

How are we responding?

- ✔ Aligning the industry position
- ✔ Streghtening the technical resources of national associations
- ✔ Working along public authorities in their own countries

Key takeaways

- In the last 10 years the regional regulatory landscape has improved substantially, but not harmoniously: normative divergence is still an issue.
- We are better equipped to fight misperceptions thanks to the development and use of consumer surveys.
- Harmonization is still considered vital to make LATAM market more attractive and lower costs. However, the process is long and complex.
- Taking into account the experience from the EU and ASEAN can shed light on our own harmonization processes.
- General macroeconomic stability has made LATAM more attractive to FDI and the growth of the sector is showing resiliency

Thank you !

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www.alanurla.org

/ALANUR

alanur
ALIANZA LATINOAMERICANA DE NUTRICIÓN RESPONSABLE
ALIANÇA LATINO AMERICANA DE NUTRIÇÃO RESPONSÁVEL

NEW ZEALAND

Natural Health Products New Zealand Regulatory Update

IADSA

10 April 2019

Samantha Gray

NATURAL HEALTH PRODUCTS NZ™

WHO WE ARE

NEW ZEALAND INDUSTRY SECTOR

REGULATOR ENVIRONMENT AND PROGRESS

NATURAL HEALTH PRODUCTS NZ™

MISSION STATEMENT

The collective voice of the natural health products industry of New Zealand

VISION STATEMENT

*Natural Health Products New Zealand represents an **innovative** and **collaborative** industry that is **trusted** worldwide as a leading provider of natural health products*

Strategic Imperatives

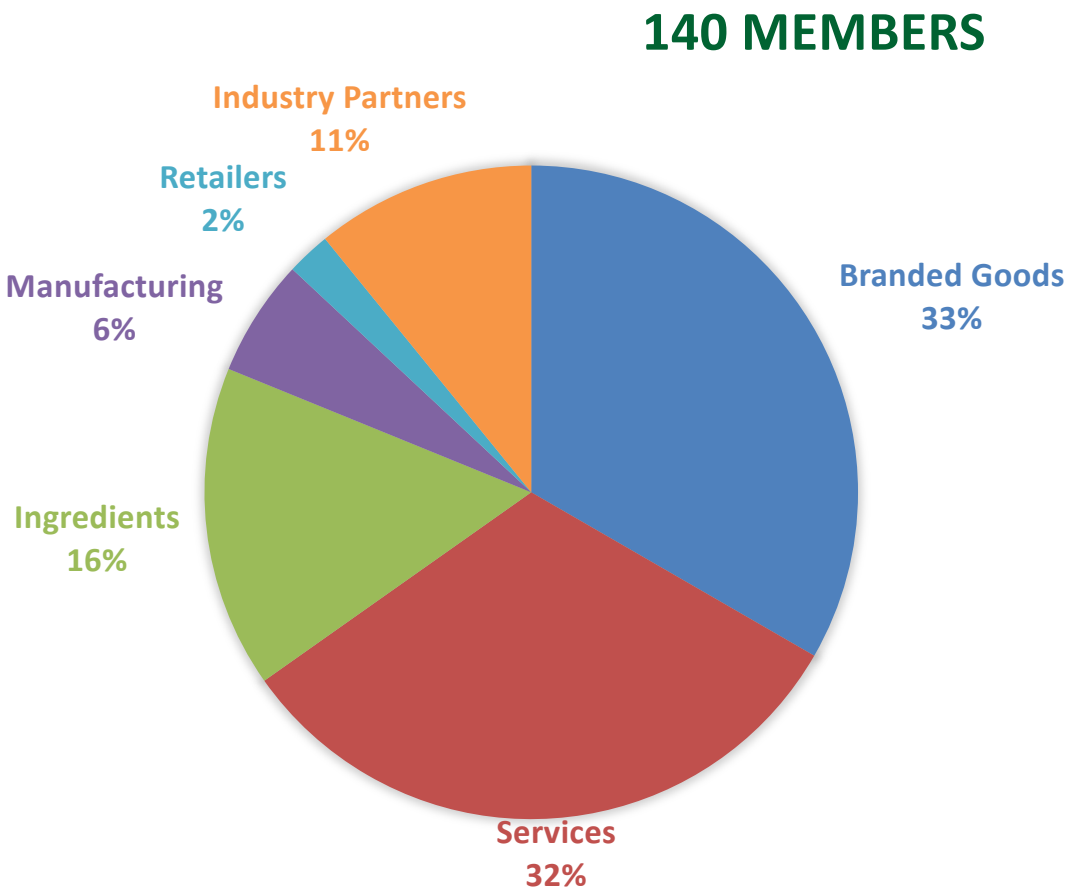
To be regarded as the authoritative and public voice of the industry in
NZ and internationally

To build trust in the industry -
collaboration and innovation

Support members through regulatory and legislative changes and improvements

Who is Natural Health Products NZ

- The industry association in New Zealand for natural products, including dietary supplements, plus more



NATURAL HEALTH PRODUCTS NZ™

Voice of the industry

- Representing over 85% of the industry

For a full list of members go to: www.naturalhealthproducts.nz/members

SECTOR AND SALES TRENDS

NZ'S NATURAL HEALTH PRODUCTS SECTOR

70% of NZ export earnings are from biologically based industries

Natural health products have made a significant and growing contribution to NZ's GDP over past decade.

Natural health products exports are a significant and growing contributor

NZ's clean green image, ethics and high quality manufacturing standards mean that natural health products are trusted in export markets

Last Sector Survey

- NZ$1.4bn contribution to economy (+40%)
- 85% of respondents export, over $285 million per annum
- Strong growth projected
- Primary export markets are Australia, China – UK, USA and Europe

2014 Sector Survey

Sector Survey

- **Quality** rather than cost driven
- Strongly positive perceptions of NZ as a **manufacturing** provider
- Strongly positive perceptions for
  - **unique** and **innovative** products,
  - product **integrity, safety, quality, cost**
  - and **clean and green image**

NATURAL HEALTH PRODUCTS NZ™

STANDARDS AND REGULATION

NZ Manufacturers
- High Standards, safety assured

- NZ's natural health products industry is quality-driven rather than cost-driven, so has **high product quality, safety and efficacy** standards.

- NZ law requires products to be **true-to-label**.

- Most natural health products manufacturers **belong to Natural Health Products NZ**, which helps to ensure high quality standards are maintained.

- Many of NZ's natural health products manufacturers export their products and therefore **already** have to **comply with a range of internationally recognised requirements** (e.g. TGA (Australia), Organic (Biogro and AsureQuality), Halal, Kosher, NSF (USA), Medical Devices by Medsafe, ISO for Medical Devices (USA), meet PIC/S GMP standards, etc.)

Natural Health Products Bill

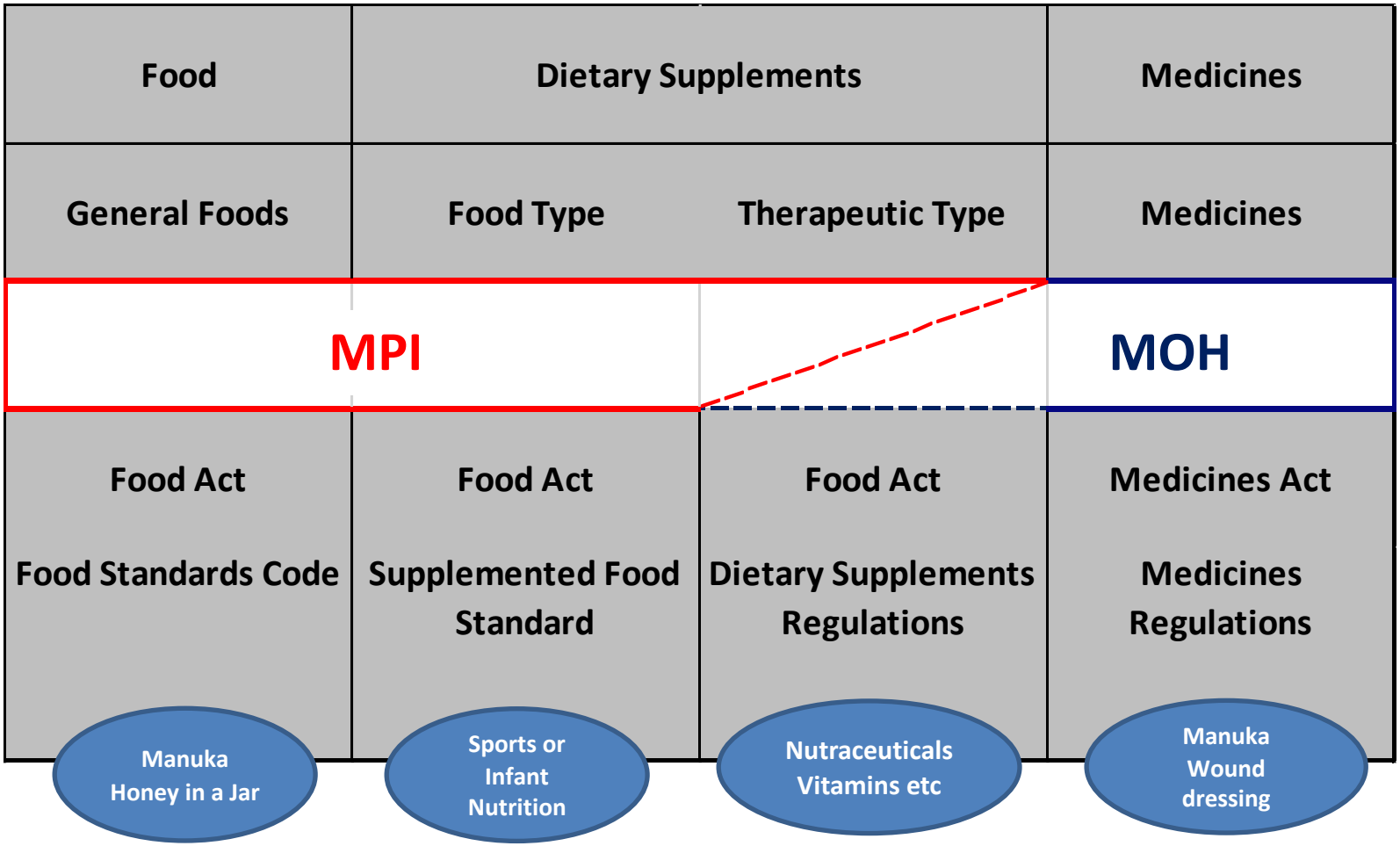
- NHPNZ has long been advocating for an update to our regulatory system, and continues to positively engage with the new coalition Government.
  - An appropriate regulatory system that reflects our unique culture, identity and place in the world
  - Safety and efficacy are paramount
  - Consumer information, to make informed comparative choices about efficacy and quality is fundamental
  - Our regulatory system must meet these needs and allow NZ to engage in to global market place to capitalise on opportunities for export growth
  - We are demographically a small country/industry so aligning all our industry is paramount to success – NHPNZ represents over 80% of ouyr sector
  - Our MMP political system both reflects these values and provides challenges to achieving these goals.

NATURAL HEALTH PRODUCTS NZ™

Natural Health Products Bill-19 years……

NATURAL HEALTH PRODUCTS NZ™

NZs Current Regulatory Structure



FAIR TRADING ACT

MPI = Ministry for Primary Industries **MoH** = Ministry of Health

We were nearly there – what happened ……

Condition of the coalition agreement at the time of the last election that the Bill was removed from the parliamentary order paper

Subsequently a private members bill introduced – not fit for purpose and was withdrawn

In mean time Dietary Supplements 1985 extended to March 2021

NHPNZ lobbying has resulted in a new plan now being worked on by the Ministry

- Ready late 2020
- May not meet next General Election deadline
- Group of dissenters active
- NHPNZ are hopeful

Ministries plan is:

- To provide advice to Ministers
- Starting with a survey of industry!

Thank you

USA

Four Issues for the U.S. Supplement Market

(and how the industry is responding)

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President & CEO

Council for Responsible Nutrition

Four Issues for Discussion:

- Legalization of CBD

- *Supplement Facts* Changes

- FDA Modernization of Regs

- Retailer, Third-Party Certification

1. A Legal Pathway to Market CBD in Food and Dietary Supplements

- Prior to December 2018, all *cannabis sativa,* including both hemp and marijuana, was considered a Schedule 1 controlled substance in the U.S.
- The 2018 Farm Bill, a comprehensive package of legislation affecting agriculture, removed hemp and its non-THC constituents from the Controlled Substances Act. Article must contain <.3% THC.
- Many falsely viewed that new law as removing ALL legal barriers to the sale of hemp and CBD. <u>It did not.</u>

CBD: Is it Legal in the US?

- FDA maintains CBD and “whole spectrum hemp extract” containing CBD, are prohibited from use in food or supplements for reasons unrelated to the CSA, its THC content, or its relationship to marijuana.
- FD&CA defines a “dietary ingredient” and expressly excludes any “article” that was first subject to substantial clinical investigations as a drug prior to being sold as a food or supplement. 21 USC §321(ff)(3)(B)
- But the provision also allows FDA to use its discretion through notice and comment rulemaking to alloinw use of the article a food or supplement—even if the drug was subject to substantial clinical investigations first.

So Is It Legal, Or Not?

- FDA has issued numerous warning letters (but no further enforcement) against CBD products making illegal drug (disease) claims.
- The agency continues to insist CBD is illegal in food and supplements, but asserts it is open to exploring “a legal pathway to market.”
- Then FDA proposes that a regulatory pathway could take 3-5 years; a legislative approach from Congress may be faster.
- Meanwhile, FDA concedes it is exercising enforcement discretion and only prosecuting those cases where the product is making unlawful disease claims.

How Does the Industry Respond?

- FDA Public Meeting scheduled for May 31.
- Most major retailers have resisted the temptation to sell food and supplements containing CBD; a couple are selling topical products without making claims.
- Small retailers and online platforms are selling CBD or whole hemp extract in all forms.
- CRN has announced it will consider CBD marketers for membership.
- Industry continues to pressure FDA and Congress to act, and to impose other supplement requirements on products marketed as supplements.

2. *Supplement Facts* Label Changes

- A 2017 FDA regulation mandates changes to the *Nutrition Facts* and *Supplement Facts* labels, effective January 2020.
  - The Percent Daily Values have changed for many nutrients to reflect updated science.
  - Added sugar must be disclosed prominently.
  - Fiber has been defined to eliminate some carbohydrates
  - International units (*iu*) have been replaced with milligrams (mg) or micrograms (mcg)
  - Folic acid listed as folate

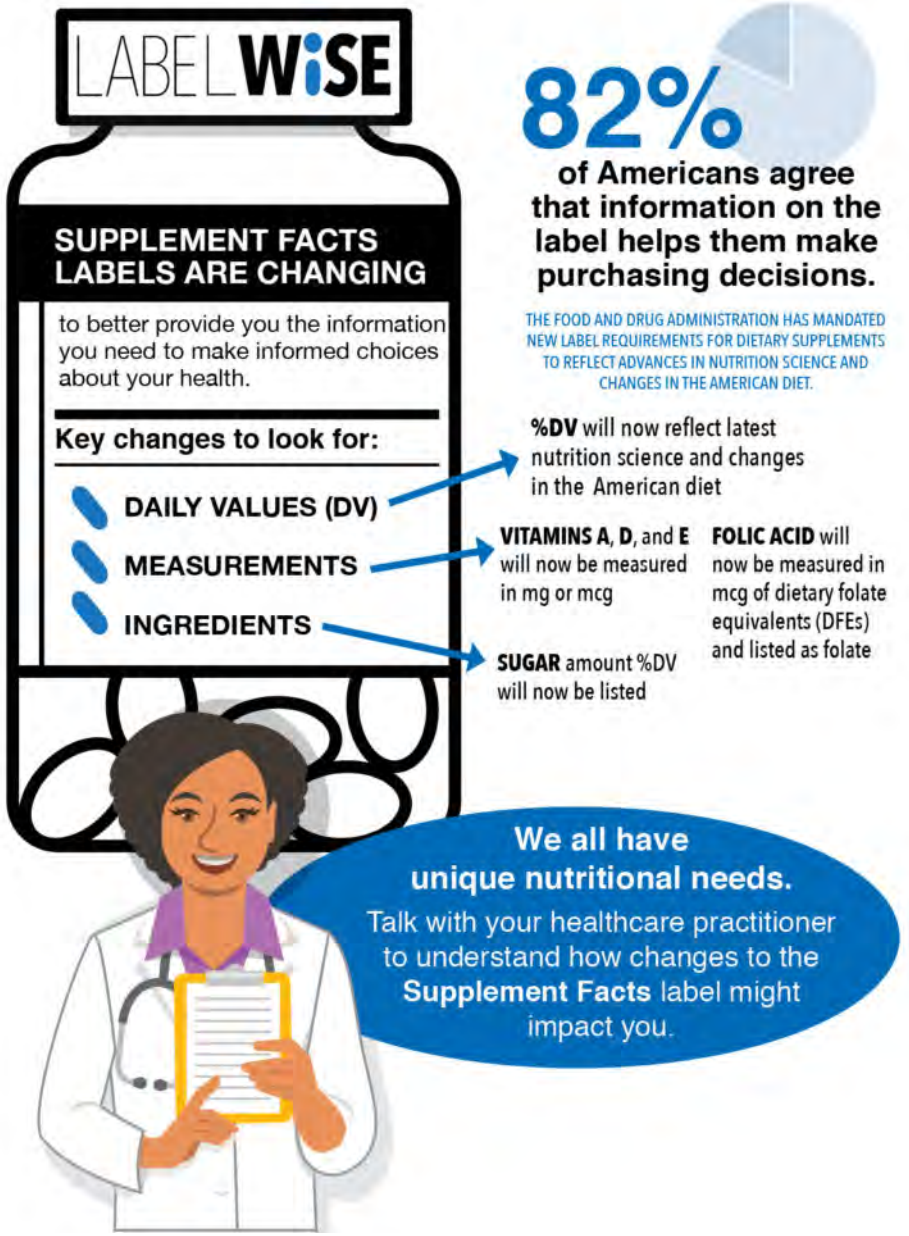
How Industry Responds

- CRN launches an education campaign to address consumer and retailer questions and concerns about the impending changes to the *Supplement Facts* Label.
- The campaign will fill the knowledge gap and assure the label changes are expected, viewed positively and perceived as helpful.
- Messaging underscore that the dietary supplement industry is regulated.
- The label has not been updated in over 20 years. In that time, science has developed and the American diet has changed.
- *Supplement Facts* labels are changing to better provide information consumers need to make informed choices.

LABEL WISE
A GUIDE TO UNDERSTANDING
Supplement Facts

Campaign Toolkit

- **www.BeLabelWise.org**
- **Fact Sheet**
  Produced by CRN to guide discussions
- **Infographic**
  Produced by CRN/optimized for social sharing
- **Microsite: BeLabelWise.org**
  Produced by CRN to curate materials
- **Explainer Video**
  Created with outside vendor
- **Social Media Content**
  Produced by CRN for sharing by members/partners
- **Bylines/Blog Posts**
  Produced by CRN for partners to share



3. FDA Recommendations to Modernize Dietary Supplement Regulation

FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's new efforts to strengthen regulation of dietary supplements by modernizing and reforming FDA's oversight

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For Immediate Release February 11, 2019

" a routine part of the American lifestyle"

"I've personally benefitted from the use of dietary supplements"

"as a physician, [I] recognize the benefits of certain supplements "

"It's clear to me that dietary supplements play an important role in our lives as we strive to stay healthy."

"DSHEA imposes a number of requirements around the manufacture and labeling of dietary supplements."

"we achieve the right balance between preserving consumer access…while…protect[ing] the public from unsafe and unlawful products."

FDA Recommendations

- Gottlieb's statement promised a public meeting this spring on "responsible innovation" to be held May 16th
- New rapid-response tool to alert consumers to unsafe products
- Updated compliance policy for NDIs
- Botanical Safety Consortium
- New enforcement strategies
- Additional steps "to modernize DSHEA":
  - Dietary supplement exclusivity
  - A product listing requirement

How Industry Responds

- Industry preparing to raise issues around definition of dietary ingredients (e.g., “nutritive value,” synthetic botanical constituents, items that increase daily intake)
- Clarity around New Dietary Ingredients
  - Grandfather date that separates “old” and “new” ingredients
  - Alternatives to NDIs: in the food supply, GRAS self-affirmation
  - When is an ingredient chemically altered?
- How can FDA incentivize innovation?
  - Master files for NDIs and piggy-backing on supplier safety data
  - Actual enforcement of IP from a “public safety” agency

FDA Proposes a Mandatory Registry

"A mandatory listing requirement could provide significant benefits by improving transparency in the marketplace and promoting risk-based regulation. It could also help facilitate efficient enforcement of the law and establish new mechanisms to identify bad actors who put the public at risk and undermine consumer confidence in the entire industry."

Statement of FDA Commissioner Scott Gottlieb, Feb. 11, 2019

"This proposal would require all products marketed as "dietary supplements" to be listed with FDA and give FDA authority to act against non-compliant products and the manufacturers and/or distributors of such products. This would allow FDA to know when new products are introduced, quickly identify and act against dangerous or otherwise illegal products, and improve transparency and promote risk-based regulation."

FDA Justification for Budget Estimates, Statement to Congress, March 18, 2019

FDA asks:

"[I]s it possible to design a product listing regime that helps us protect consumers and level the playing field for responsible industry participants by making it easier for us to take swift action against illegitimate and dangerous products, such as products that are tainted with drug ingredients? And is it possible to do this without disrupting the balance struck by DSHEA, and without imposing any significant new burdens on responsible firms? The answer to these questions may very well be yes."

Statement of FDA Commissioner Scott Gottlieb, Feb. 11, 2019

A Mandatory Product Listing: How Industry Responds

- The U.S. voluntary industry registry, the ***Supplement OWL***, launched in 2017, continues to grow.
- Industry evaluating the concept of an FDA-administered database and developing a position.
- Consideration given to “must-haves” from FDA and possible trade offs and concessions. Stay tuned….

4. Retailer Demands for Quality Assurance / Third-Party Certification

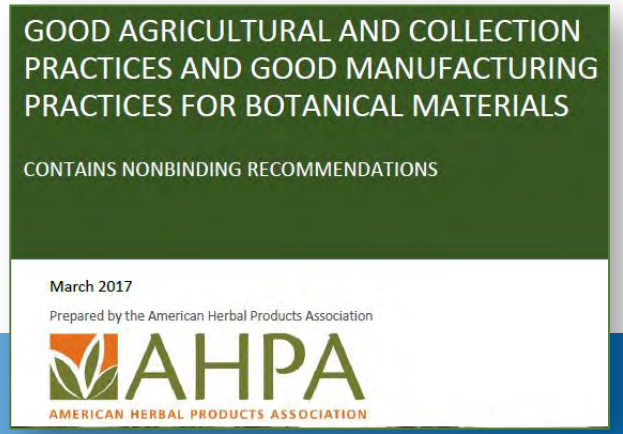
- Retailers increasing imposing their own requirements for quality and certification of GMPs, in addition to federal regulations.
- Increasing need for harmonized standards for third party audits for GMP certification and supply chains to create uniformity of audit standards and create efficiencies for both manufacturers and retailers.

How Industry Responds

- Industry-led initiatives to develop harmonized standards for both supply chain quality/integrity and for GMP inspections
- Benchmarking of third party standards and certification of the auditors.
- Encouraging major retailers to forestall their own requirements for widely agreed upon standards to promote efficiency as well.

GRMA
GLOBAL RETAILER AND MANUFACTURER ALLIANCE
Building quality standards together

SSCI



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Building quality standards together

- New ANSI-accredited standards to evaluate a dietary supplement firm's adherence to cGMPs.
- Coming soon: Auditing scheme using these standards and trained auditors accepted by retailers as satisfying their cGMP requirements.

Thanks for listening!

For more information, see our website at www.crnusa.org

or contact me at smister@crnusa.org