

DISCLAIMER

The opinion expressed in this presentation and on the following slides are solely those of the presenter based on applicable food regulations and not necessarily those of Herbalife Nutrition.

Retrospection of Nutra Regulatory Framework

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AGENDA

- ❖ Background
- ❖ Journey to-date
- ❖ Overview- FSSAI (Nutra) Regulations, 2022
- ❖ Evolution of overall Regulatory Framework: Gaps Identified / Addressed : 2016-22
- ❖ Impact on Industry
- ❖ Overall Outcome
- ❖ Global References
- ❖ Observation

BACKGROUND

Section 22 of FSS Act 2006 for the first time, provided definition and regulatory conditions for specialized foods like HS, Nutraceuticals, FSDUs, FSMPs, Functional Foods etc.

Dosage based foods like Tablets and Capsules secured entry in the law

FSS Regulation on Nutraceuticals, 2016 notified (with a progressive thought process) for implementation from 2018 January 1st

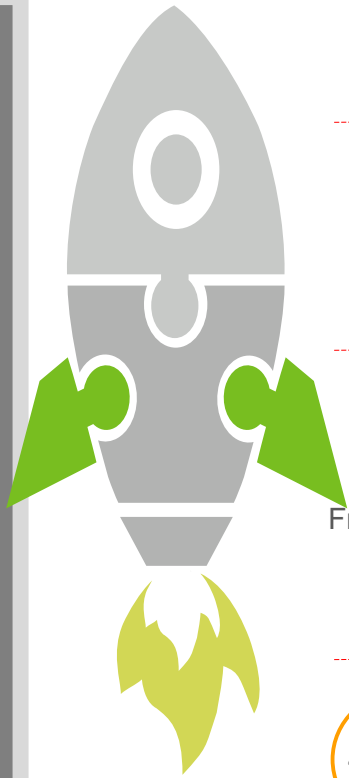


Term “Nutraceuticals” – introduced and now a dominant category

Drafting of Framework started in 2012 by trade chambers in coordination with FSSAI

Several amendments / advisories followed – making the regulation too complicated

JOURNEY TO-DATE



2018
Compliance
From 1st Jan 2018



Dec 2016
Nutraceutical
Regulation Notified



2020
FSS Act Amendment
Initiated



2018-2021

Major revisions/amendments/FAQs
like

- Mere combination of vitamins and Minerals were out of the purview
- Allowance of more than 1RDA for FSDUs
- Restricted use of several ingredients
- History of Safe Use – condition deviated
- Restriction on Advertisement of FSDU products
- Use of ingredients / additives broad based on NIN



2022

- ▲ Regulation Overhaul Operationalized
- ▲ Draft Nutraceutical Regulations issued for stakeholder consultation



Harmonization of Additives
with Codex

2017

Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022. [FSSAI (Nutra) Regulations, 2022]

Operationalized w.e.f
1st April 2022



FSS(Nutra) Regulations
2022 will supersede FSS
(Nutra) Regulations 2016

Concept behind is to make it
simple, unambiguous and
clear

Draft notification issued for
stakeholder consultation in
June 2022

EVOLUTION OF THE REGULATORY FRAMEWORK: GAPS IDENTIFIED / ADDRESSED : 2016-22

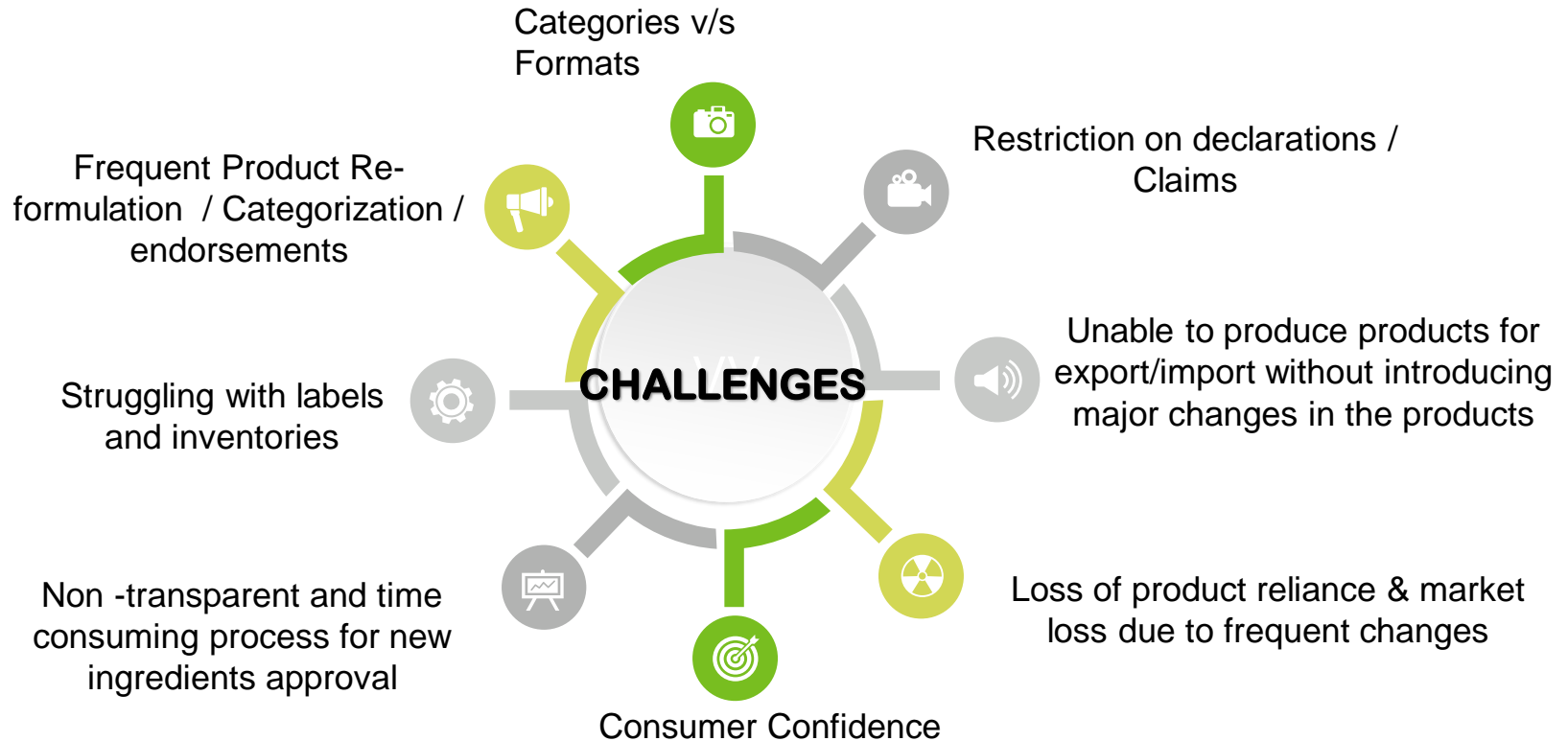
ADMINISTRATIVE

- Frequent amendments / extensions hurdles for implementation
- Non- alignment with the global regulations/practice
- Absence of robust framework for testing of food supplements / specialized products
- Implementation of Risk based approach
- Transparency
- Conflicting requirements / Interpretations
- Over complexity due to too many notifications/ advisories/orders
- Ambiguity around implementation of these regulations
- Status Quo : Recommended Dietary Allowance (RDA) for nutrients

TECHNICAL

- Restrictive 1 RDA requirement/TUL not recognised
- Many ingredients/additives left out
- Deletion of Disease risk reduction claims
- Acceptance for mere combination of vitamins & minerals
- Restriction on delivery formats
- Acceptance of documented history of safe usage of ingredients
- Broaden up Formats and categories
- Exemption of NI table for Tablet / Capsule format
- Restriction on use of Solvents
- Ambiguity over use of Additives and ingredients
- Unfeasible tolerance limits for nutrients
- Additional & rigid label declaratory requirements
- New categories with ambiguity like products for sportsperson
- Overlapping with ingredients from Ayurveda origin and their limits

IMPACT ON INDUSTRY



OVERALL OUTCOME ON BUSINESS

Reformulation

Cost & Time

Wiping out
established
products /
categories

Market Loss

Loss in Consumer
confidence

Impact on
export/import

Uncertainty &
challenge to Ease
of doing business

National Economy
Loss

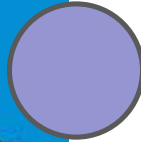
GLOBAL REFERENCES



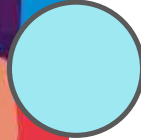
IGNORED



Single nomenclature like “Dietary Supplement” , “Food Supplement” etc.



Harmonized Claim framework



Scientific Risk management approach

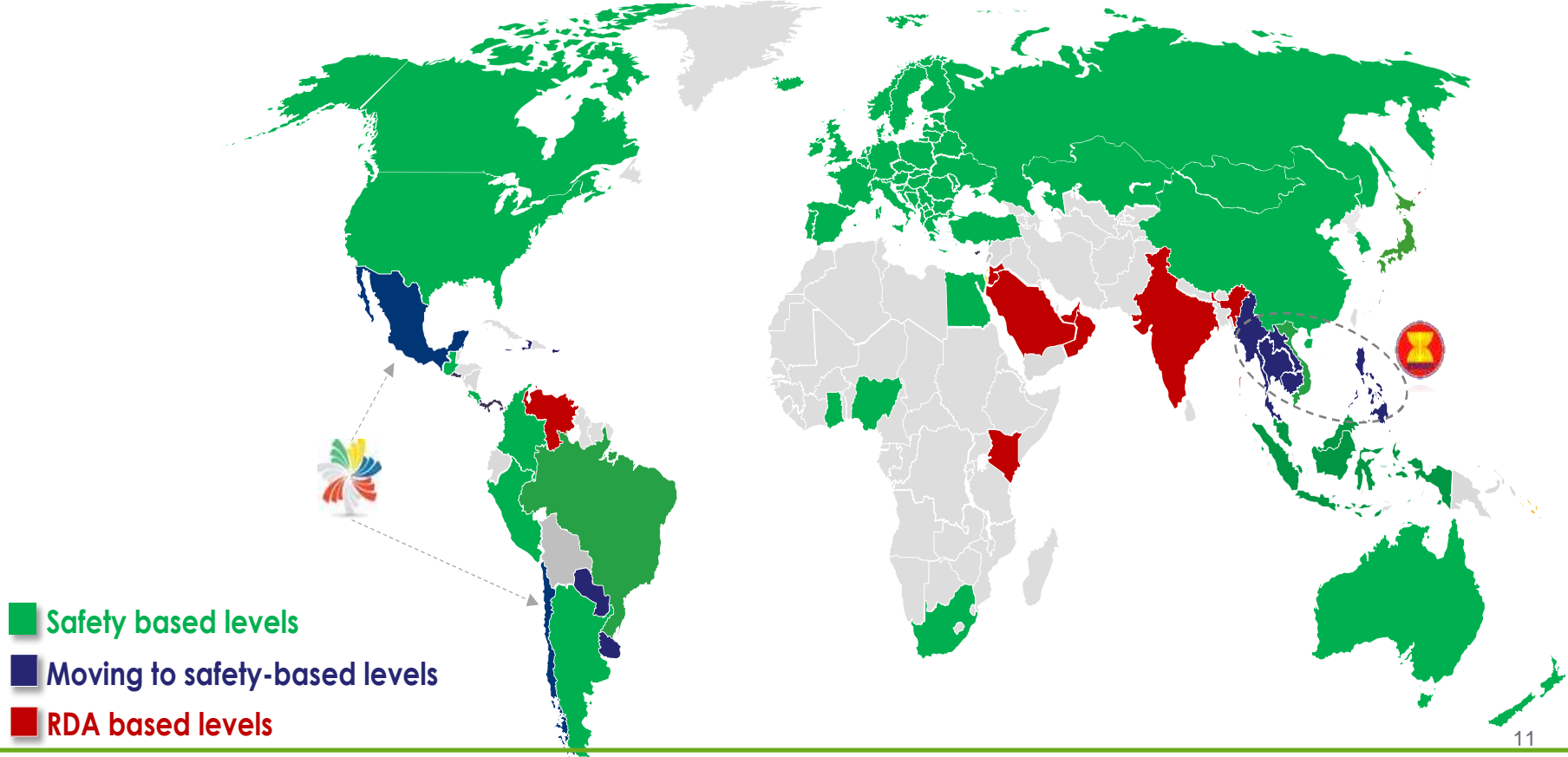


Safety based Limits for nutrients

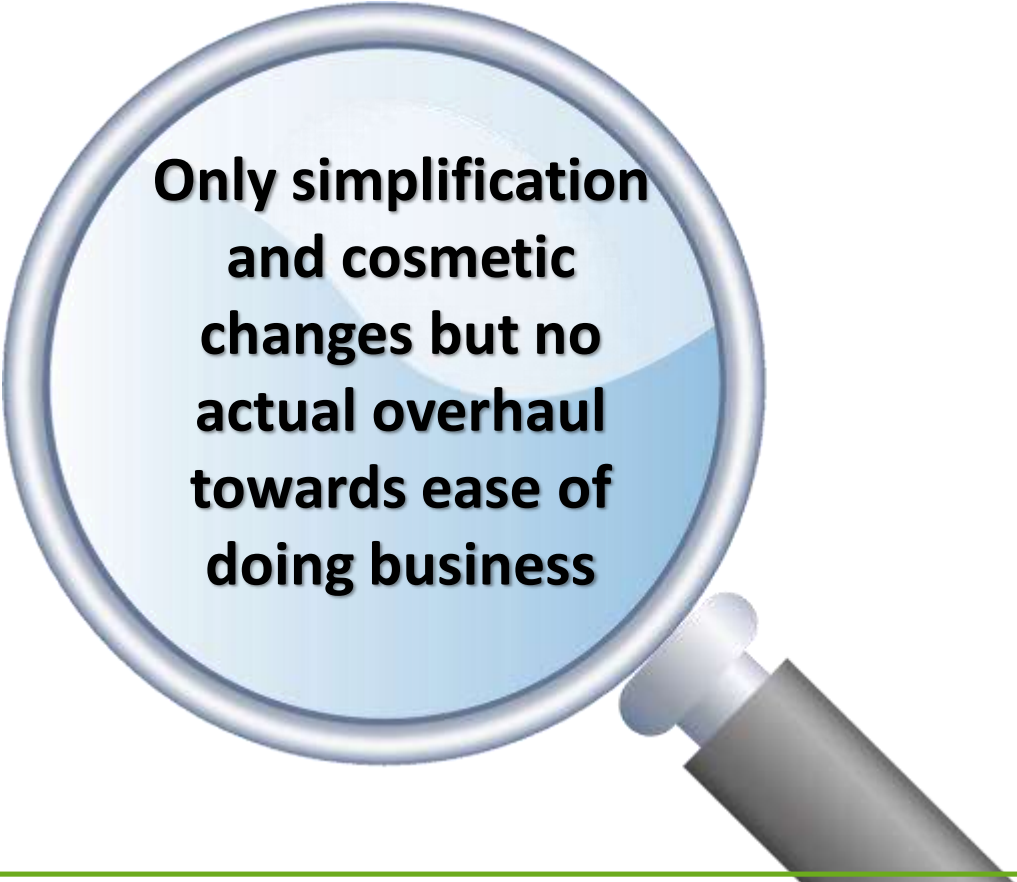


Use of nutrients as per intended use

GLOBAL MAP SHOWING SAFETY BASED MODELS



OBSERVATION



**Only simplification
and cosmetic
changes but no
actual overhaul
towards ease of
doing business**

Challenges for the sector continues...

OK,
SO WHAT'S
NEXT?

Thoughts
Welcome

THANK YOU