

# **DISCLAIMER**

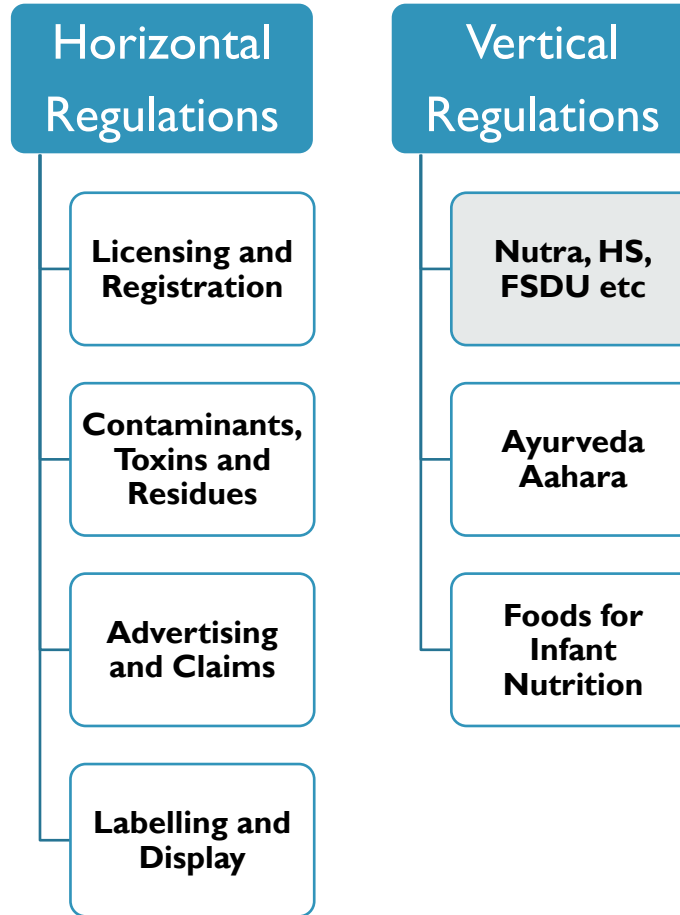
**The opinion expressed in this presentation and on the following slides are solely those of the presenter based on applicable food regulations and not necessarily those of Herbalife.**



# The Food Safety and Standards Authority of India (FSSAI)

Established under Food Safety and Standards, 2006

Created for laying down science-based standards for articles of food and to regulate their manufacture, storage, distribution, sale and import to ensure availability of safe and wholesome food for human consumption.





**Food Safety and Standards  
(Health Supplements,  
Nutraceuticals, Food for Special  
Dietary Use, Food for Special  
Medical Purpose, and Prebiotic  
and Probiotic Food)  
Regulations, 2022**

# 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.

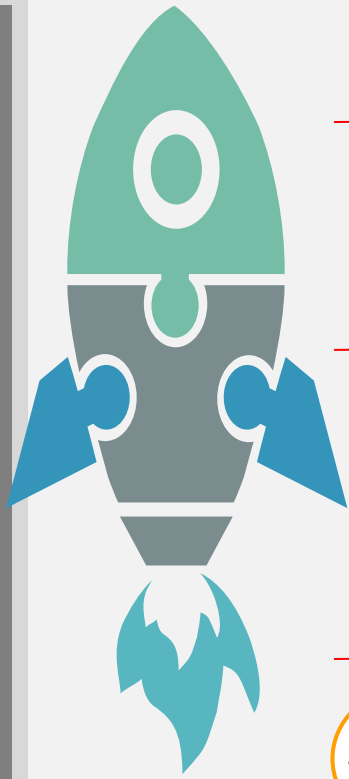
Dosage based foods like Tablets and Capsules mentioned



Drafting of Framework started in 2012  
in coordination with FSSAI

FSS Regulation on Nutraceuticals, 2016  
notified for implementation from January 2018

# JOURNEY TO-DATE



**2018**  
Compliance  
From 1<sup>st</sup> Jan 2018



**Dec 2016**  
Nutraceutical  
Regulation Notified

**2018-2021**  
Major revisions/amendments/FAQs like

- Mere combination of vitamins and Minerals were out of the purview
- Allowance of more than IRDA 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
- FAQs



**2022**

Regulation Overhaul  
Operationalized

Harmonization of Additives  
with Codex

**2017**

# FSSAI (Nutra) Regulations, 2022

Concept behind is to make it simple, unambiguous and clear



FSS(Nutra) Regulations 2022 superseded FSS (Nutra) Regulations 2016

These foods are intended for population above the age of 2 years

Operationalized  
w.e.f  
1st April 2022

# Definitions under FSSAI

**Health supplement** is a category of foods, which consists of a **concentrated source of nutrients** (like proteins, minerals, vitamins, amino acids) and/or other ingredients with nutritional or physiological effects, singly or in combination, whose purpose is to supplement the normal diet.

**Nutraceutical** is a category of foods which consists of extracts, isolates and purified chemical compounds having a physiological benefit and help to maintain health



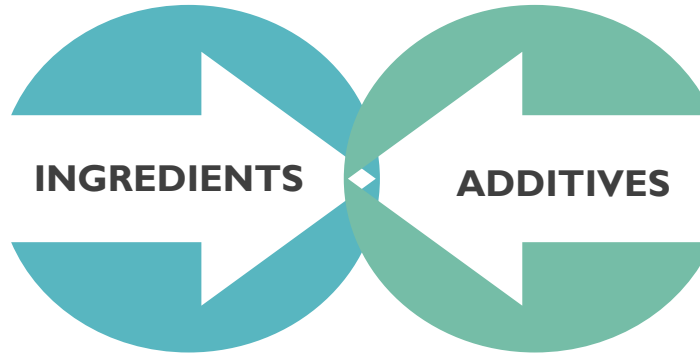
**Schedule I:** Nutrients (vitamins, minerals, amino acids and other nutrients)

**Schedule II:** Plant or botanicals

**Schedule III:**

Molecules/isolates/extracts other than Schedule II

**Schedule IV:** Prebiotics and Probiotics and



- Food for Special Medical Purpose including dietetic formulae for slimming purposes and weight reduction
- Food for special Dietary Use
- **Health supplements, Nutraceuticals, Prebiotics and Probiotics**
- Formats such as tablets, capsules and syrups

Standardized or permitted ingredients for use in preparation of the other standardized foods as specified in the FSS (Food Products Standards and Food Additives) Regulations, 2011.

In addition to the general labelling requirements supplements needs to carry the other information on the label (**Front or Back of the Pack or Accompanied Leaflet** )



Applicable category name



Target consumer group and/or age group



Specific Statements like

- Not for medicinal use
- Recommended usage level
- Not to exceed the recommended daily usage
- Product is required to be stored out of reach of children
- Where a danger may exist with excess consumption;
- Warning on any other precautions to be taken while consuming, known side effects



Health supplements term on the label may be interchangeably use by the terms, namely, Dietary supplements or Food supplements.

# CLAIMS



Shall not claim to **treat, cure, mitigate or prevent any specific disease, disorder or condition** or refer to such properties, unless specifically permitted by Food Authority

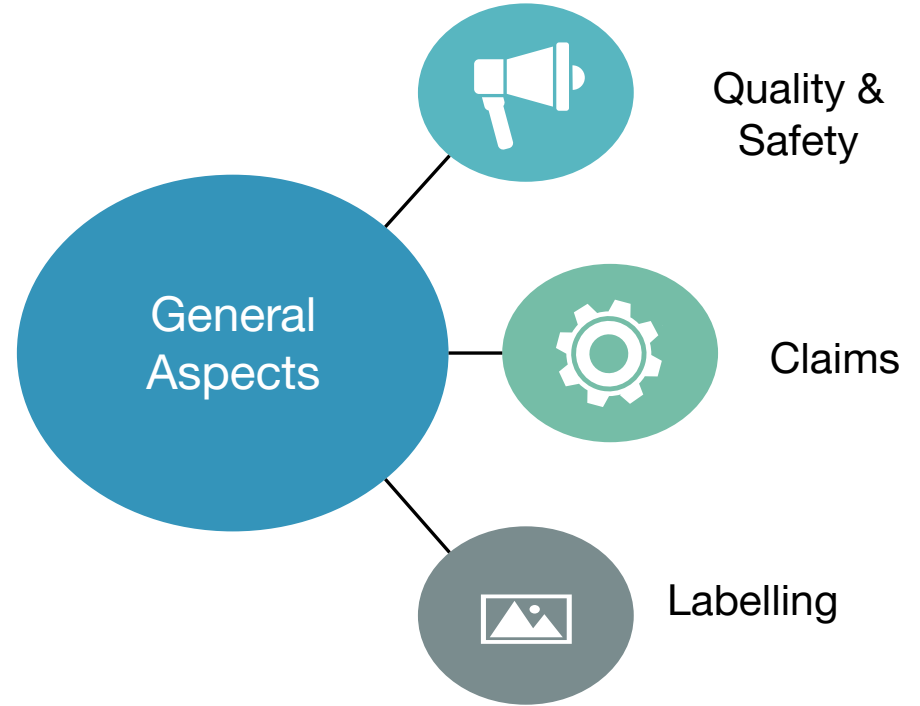


Nutritional or health claims or reduction of disease risk claims (DRR) that are listed under FSS (Claims and Advertisements) Regulations, 2018.

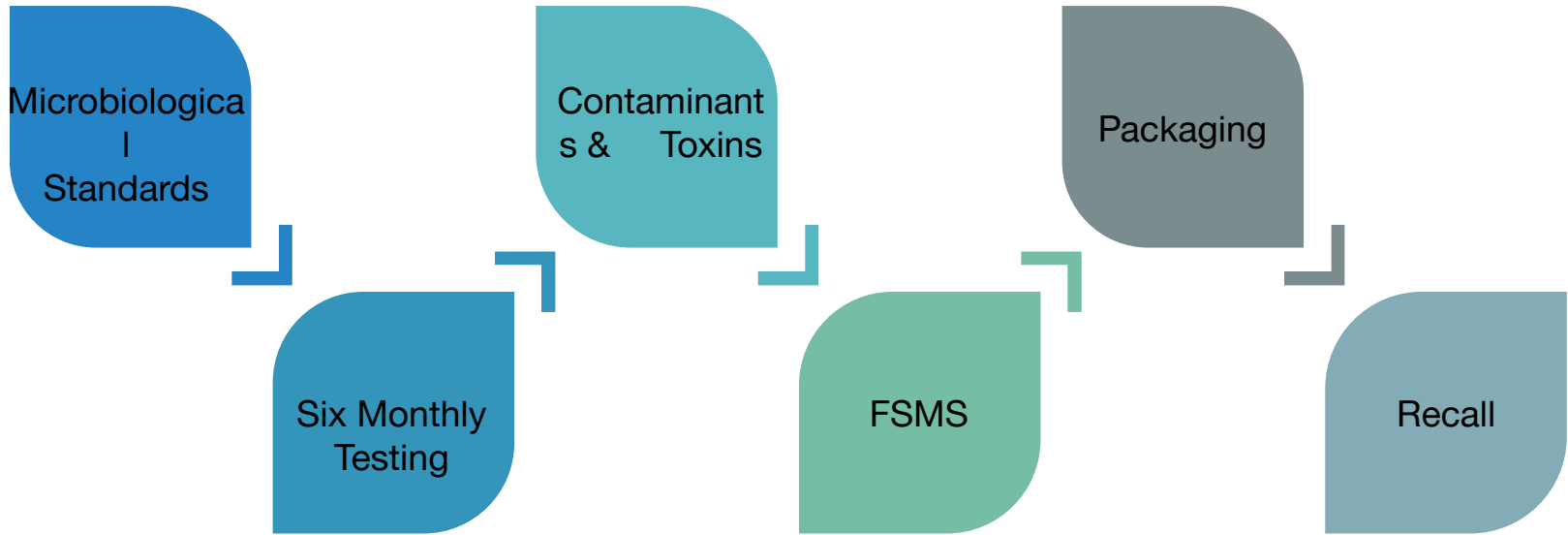


Structure, function or general well-being of the body may be allowed by the Food Authority if the statement is supported by the generally accepted scientific data.

# OTHER KEY REGULATORY REQUIREMENTS



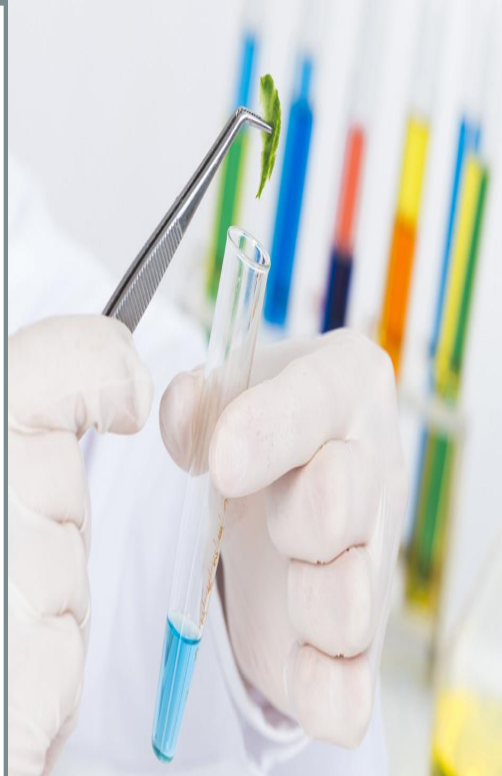
# Quality & Safety





## Microbiological Standards

- Process Hygiene Criteria
  - Aerobic Plate Count
  - Yeast and Mold Count
  - Enterobacteriaceae count
- Food Safety Criteria
  - Salmonella
  - Listeria monocytogenes



## Six monthly testing

- Testing of relevant chemical and/or microbiological contaminants at least once in six months

# FSMS REQUIREMENTS

As per the condition of license under FSS (Licensing & Registration of Food Businesses) Regulations 2011, every food business operator (FBO) applying for licensing must comply with schedule 4.

Schedule 4 introduces the concept of FSMS based on implementation of Good Manufacturing Practices (GMP) and Good Hygiene Practices (GHP) by food businesses and is divided into five parts

Schedule 4	General Requirements
Part 1	General hygienic and sanitary practices to be followed by food business operators applying for registration - Petty food operators and Street food vendors
Part 2	General hygienic and sanitary practices to be followed by food business operators applying for license- Manufacturing/ processing/ packaging/storage/distribution
Part 3	General hygienic and sanitary practices to be followed by food business operators applying for license- Milk and milk products
Part 4	General hygienic and sanitary practices to be followed by food business operators applying for license- Slaughter house and meat processing
Part 5	General hygienic and sanitary practices to be followed by food business operators applying for license- Catering

## Food Safety and Standards (Food Recall Procedure) Regulation, 2017

To prevent, reduce or eliminate a risk arising from a food

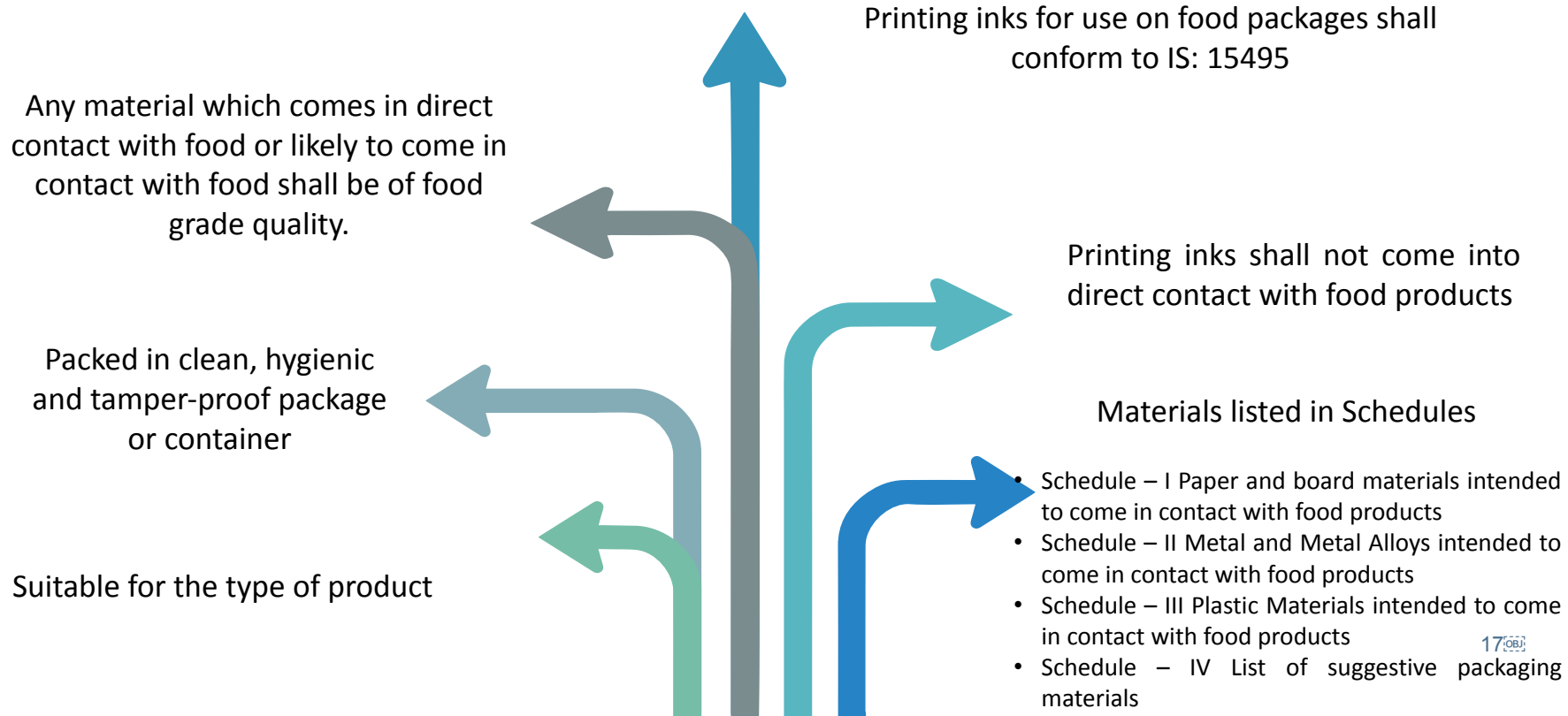
Food or food products that are determined or prima facie considered unsafe

## FSS(Contaminants, toxins and Residues) Regulations, 2011

Limits of metal contaminant, crop contaminants and naturally occurring toxic substances and antibiotics.



# Food Safety and Standards (Packaging) Regulations, 2018



# Food Safety and Standards (Advertising and Claims) Regulations, 2018

## Nutrition Claims

Nutrient content claim

Nutrient comparative claim

## Non-addition claims

Non-addition of sugars

Non-addition of sodium salts

Non-addition of additives

## Health claims

Health Claims

Nutrient function claims

No reduction of disease risk claims

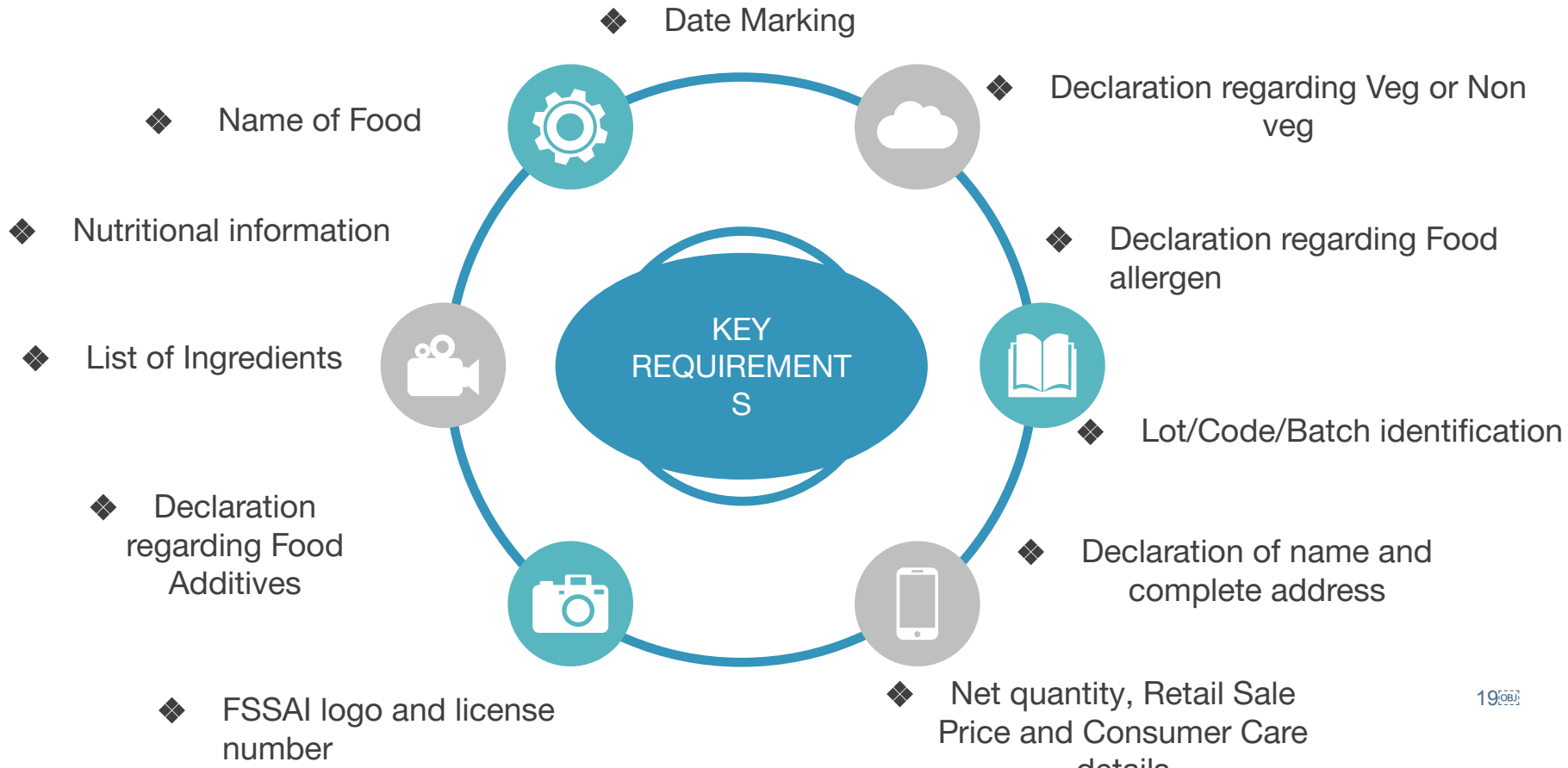
## Prohibited Claims

Prevention, alleviation, treatment or cure of a disease, disorder or particular physiological condition unless specifically permitted

Give rise to doubt or suspicion about the safety

Contain nutrients or constituents in quantity that increase the risk of disease or an adverse health-related condition.

# FOOD SAFETY AND STANDARDS (LABELLING AND DISPLAY) REGULATIONS, 2020



**Thank You**