Food Additives and FCS Regulations

PFNDAI

A step towards modernised science based Indian food regulations

Shreya Pandey

Agenda

- History - Codex Standard on Food Additives
- India journey
- Current operationalisation
- Reading the document
- Future work –Next steps-Challenges

History

- Codex standard for Food additives

Why additives are used ?

Additive is used for technological functions :

- To preserve the nutritional quality of the food;
- To enhance the keeping quality or stability of a food;
- To improve its organoleptic properties;
- To provide aids in the manufacture, processing, preparation, treatment, packing, transport or storage of food.

Additive should not

- change the nature, substance or quality of the food so as to deceive or mislead the consumer;
- disguise the effects of the use of faulty raw materials or of undesirable (including unhygienic) practices

Types and classes

- Food additives classes are 27 -
  - Acidity Regulator
  - Anticaking Agent
  - Antifoaming Agent
  - Antioxidant
  - Bleaching Agent
  - Bulking Agent
  - Carbonating Agent
  - Colour
  - Colour Retention Agent
  - Emulsifier
  - Emulsifying Salt
  - Firming Agent
  - Flavour Enhancer
  - Flour Treatment Agent
  - Foaming Agent
  - Gelling Agent
  - Glazing Agent
  - Humectant
  - Preservative
  - Propellant
  - Raising Agent
  - Sequestrant
  - Stabilizer
  - Sweetener
  - Thickener
- INS numbering for all additives…

Additive Regulations

3.1.2 - Colouring matter

- **Natural** - Example: Carotenes, Chlorophyll, Annatto, Curcumin - all foods @GMP unless otherwise prohibited in regulations
- **Inorganic /Synthetic** - Example : Ponceau 4R, Tartrazine, Erythorsine, Brilliant Blue - only in certain foods as given in regulations

3.1.3 - Artificial Sweeteners

- Sodium saccharin, Aspartame, Acesulfame K, Sucralose, Neotame - In various foods at different levels approved
- Combination rule: If both used in combination then proportions should not exceed the max limit

3.1.3(4) – Use of Polyols

- Examples: Isomalt, Erythritol, Maltitol. In few foods @GMP with Labeling

3.1.3 (5) – Use of Polydextrose

- In few foods with GMP with Labeling

Regulations

3.1.4 - Preservatives

- Class I – Sugar, Salt, Oil, vinegar, Spices, Honey - all foods @GMP
- Class II – Benzoic Acid, Sulphites, Sorbates, Nitrates, Nisin – various foods @ Levels specified

3.1.5 – Antioxidants

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- Others - various foods @ Levels specified

3.1.6 - Emulsifying and Stabilising agents

- Various allowances for various foods

3.1.7 – Anticaking agents

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3.1.9 - Releasing agents

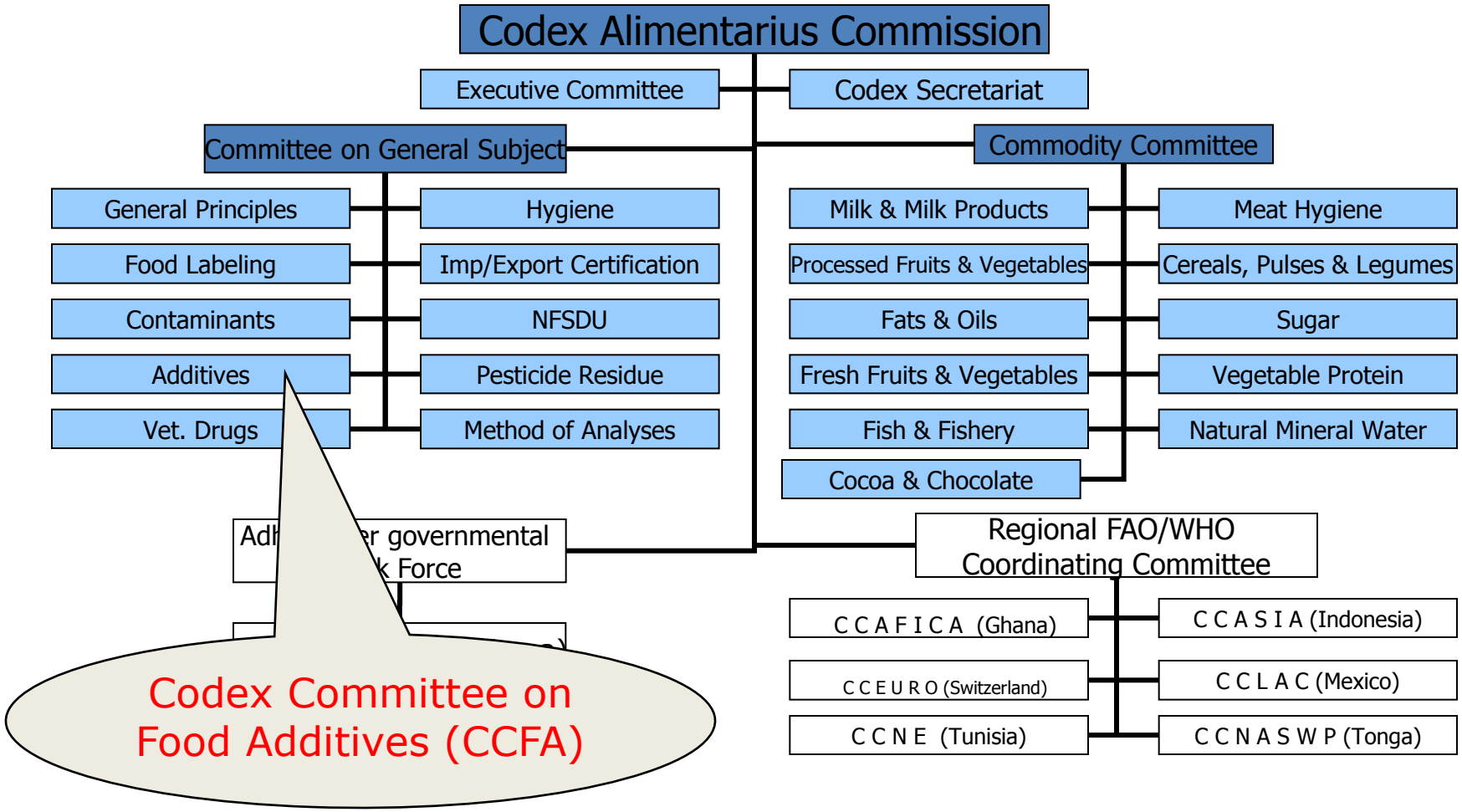
3.1.10 - Flavoring agents and related substances

- Natural, Nature identical, Artificial – can be used @GMP but need to be labeled

3.1.11 – Sequestering and Buffering agents

- Acids Bases and Salts –different foods different levels

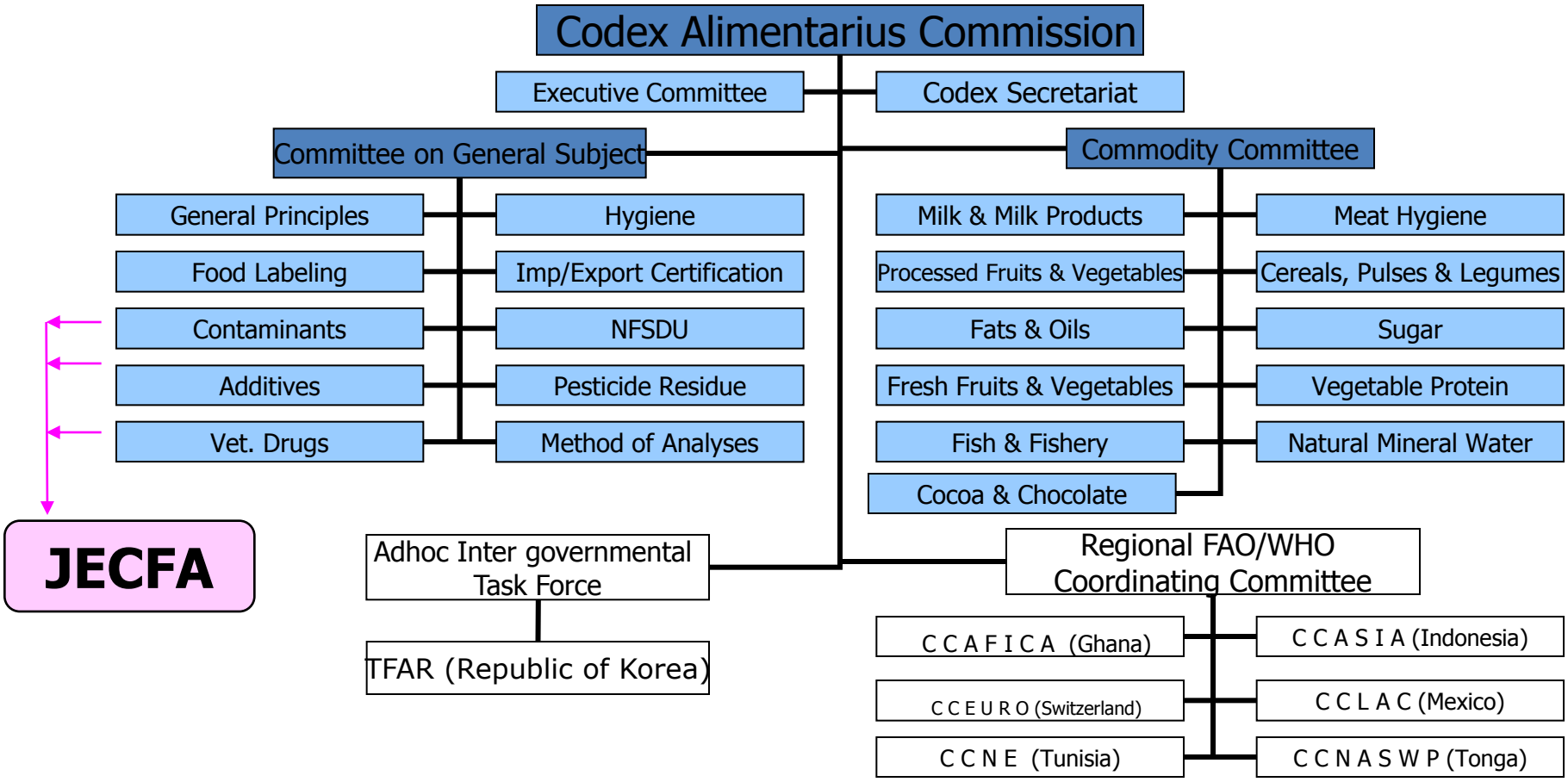
Codex Alimentarius - Organization

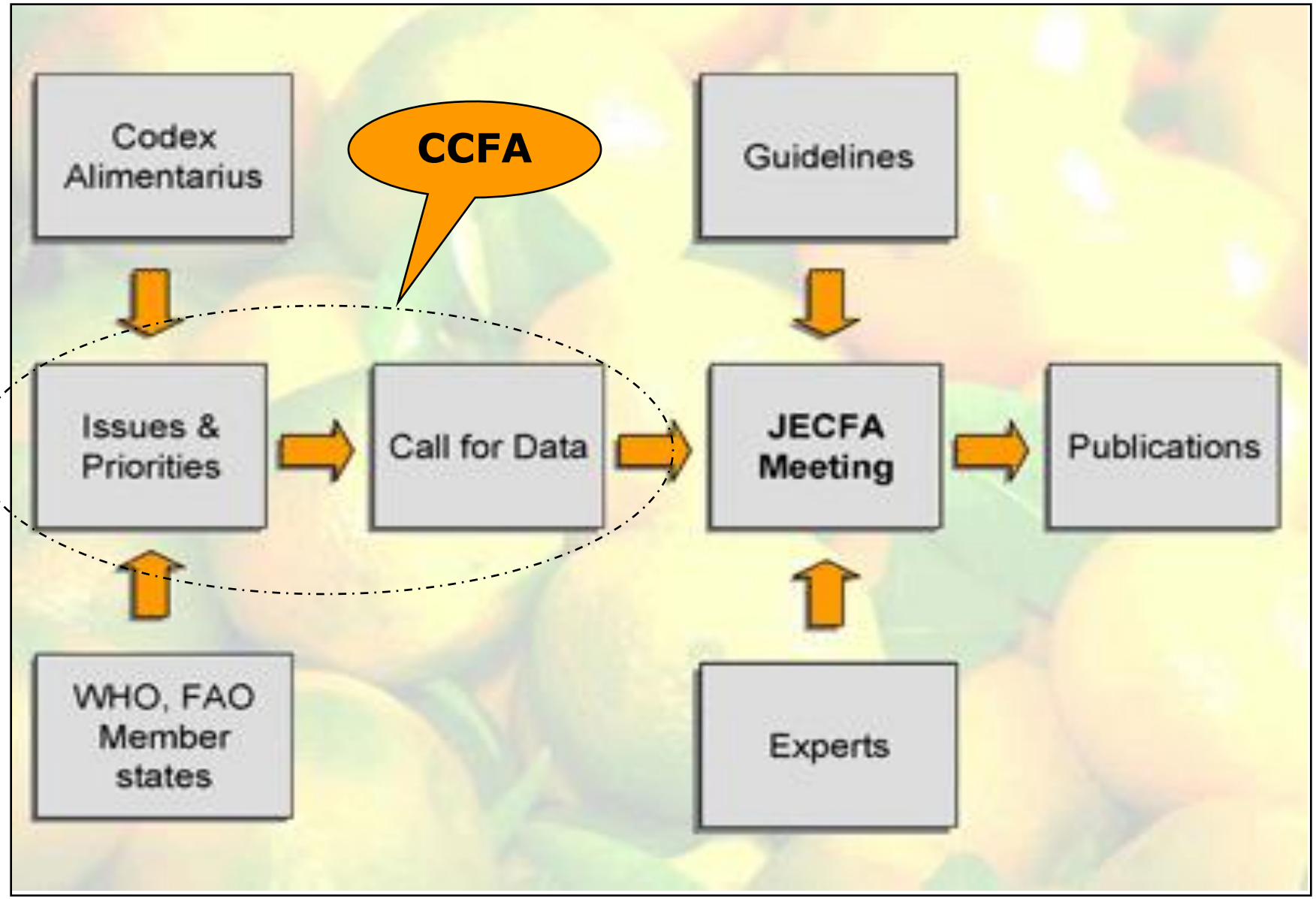


Joint FAO/WHO Expert Committee on Food Additive (JECFA)

- **Independent, international expert scientific committee** which evaluates safety of Food Additives, Contaminants, NOTS and RVDs.
- Subject matter experts who are a part of JECFA evaluations, come in **individual capacity**
- Advises FAO, WHO and member countries on Food additives.
- Main principles of developing scientific advice in JECFA - *Excellence, Independence, Transparency & Universality*

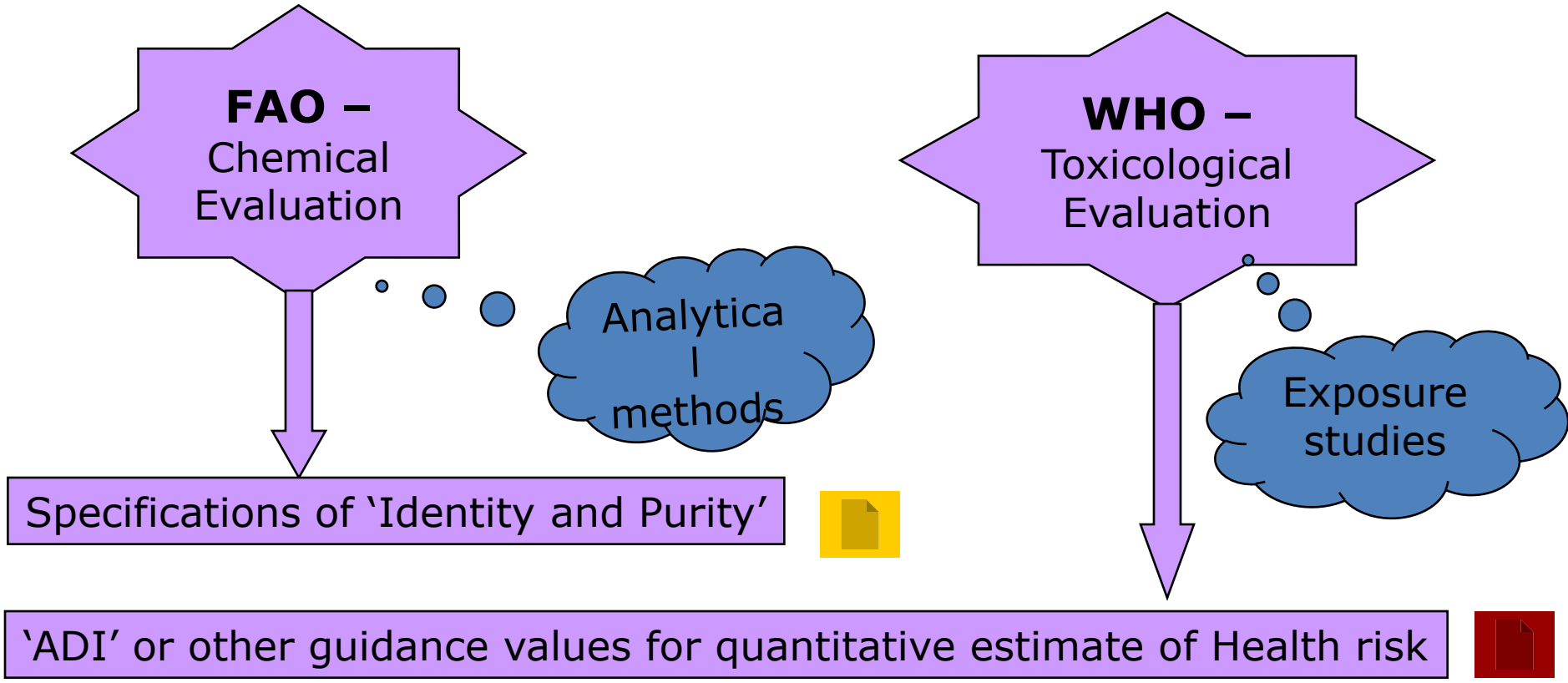
JECFA and Codex





JECFA's reliable and independent scientific opinion plays a vital role in setting standards for additives …

JECFA Evaluations - Risk Assessment



JECFA Evaluations - Risk Assessment

2 aspects of JECFA Evaluations are -

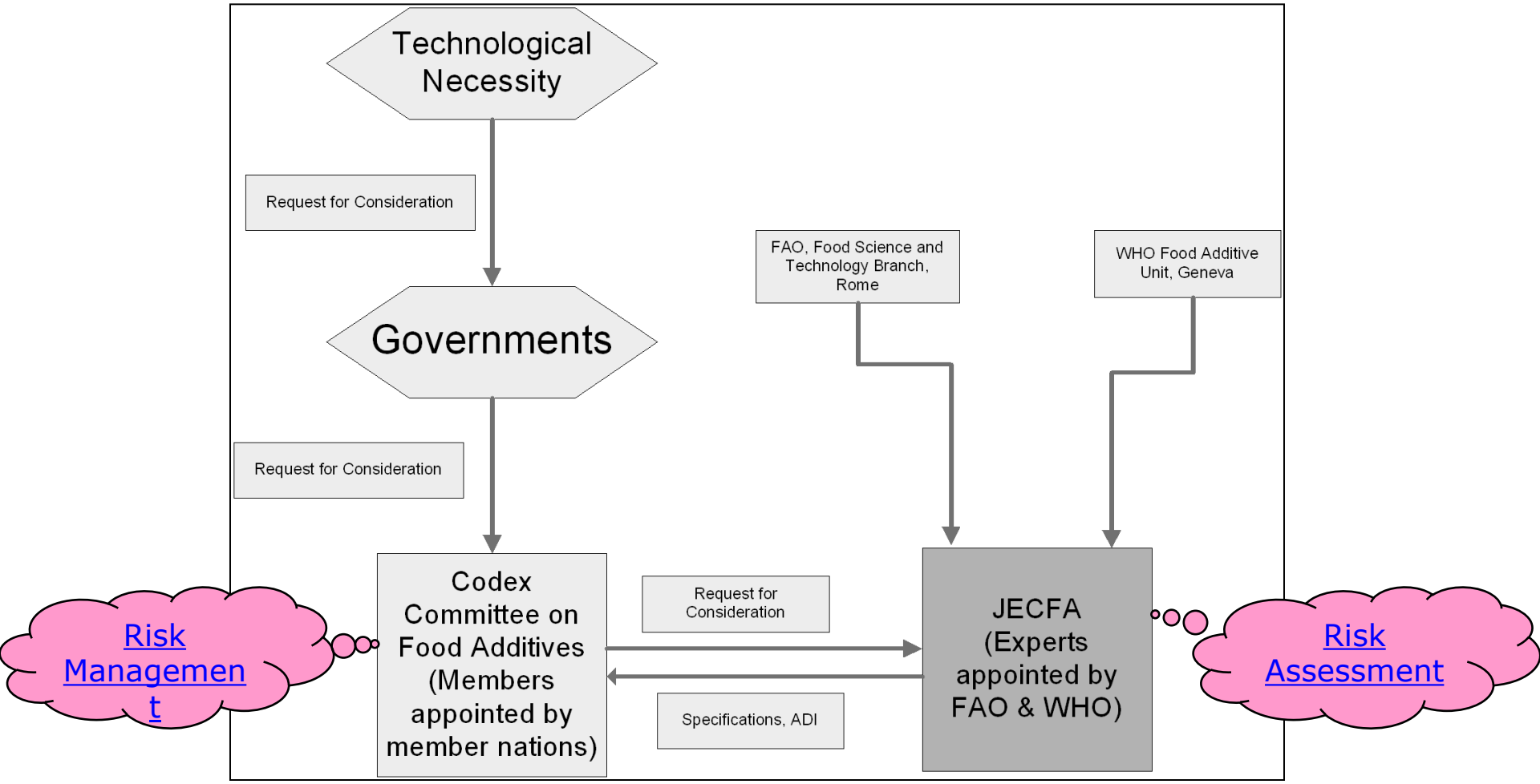
1. Specifications
   - Identity and Purity
   - Analytical methods

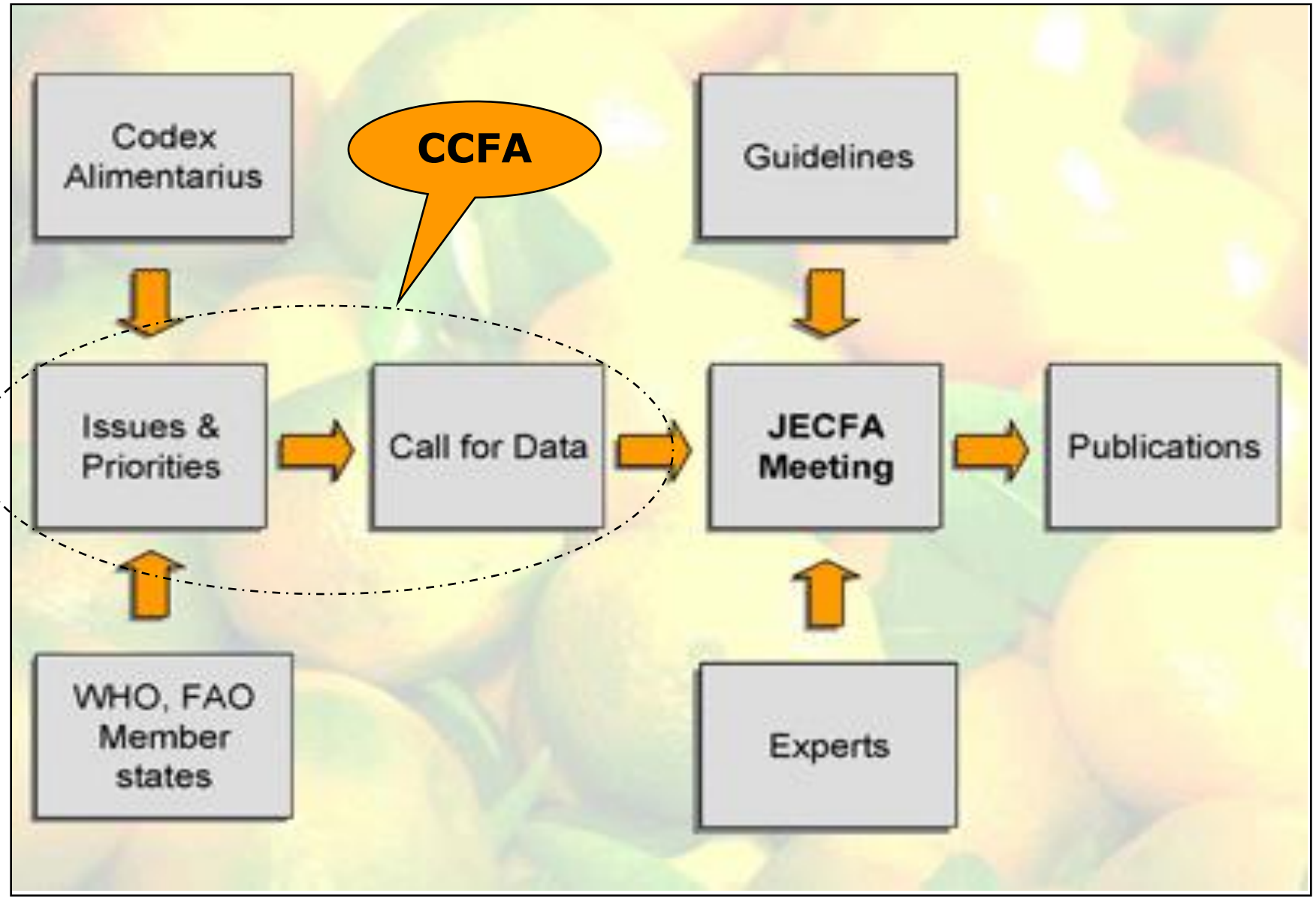
2. Reports and Toxicological Monographs
   - Acceptable Daily Intake (ADI)
   - Acceptable Daily Intake "Not Specified“ [ADI- NS]

Codex Committee on Food Additives (CCFA)

- Establish maximum usage levels for individual food additives in various food categories
- Only Food Additives endorsed by JECFA that have “no appreciable health risks” are considered in CCFA.
- CCFA standards are called ‘General standards on Food Additives’ [GSFA]- which is a single authoritative reference point for Food additives usage.
- CODEX Commodity committees advise CCFA on the technological need of particular additive usage in foods.

Food Additive Regulations - Process





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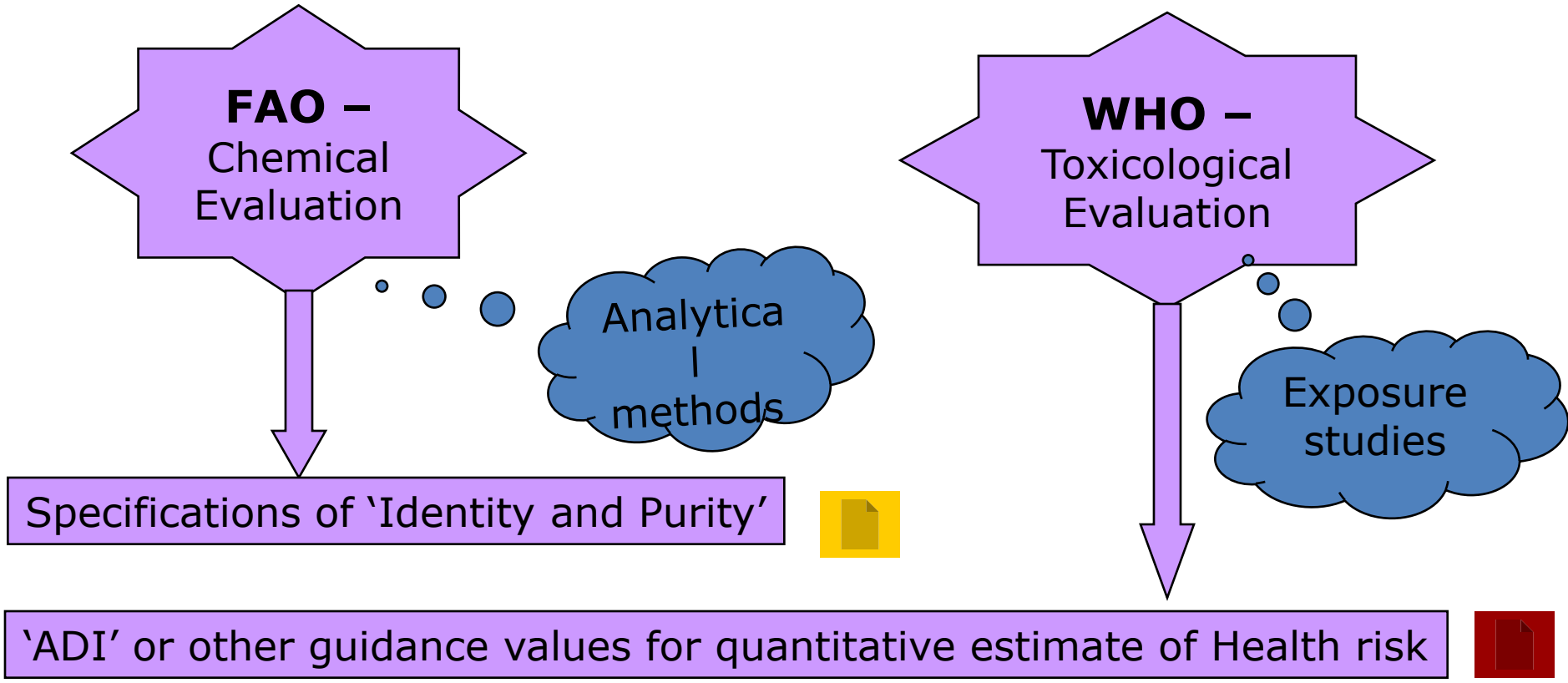

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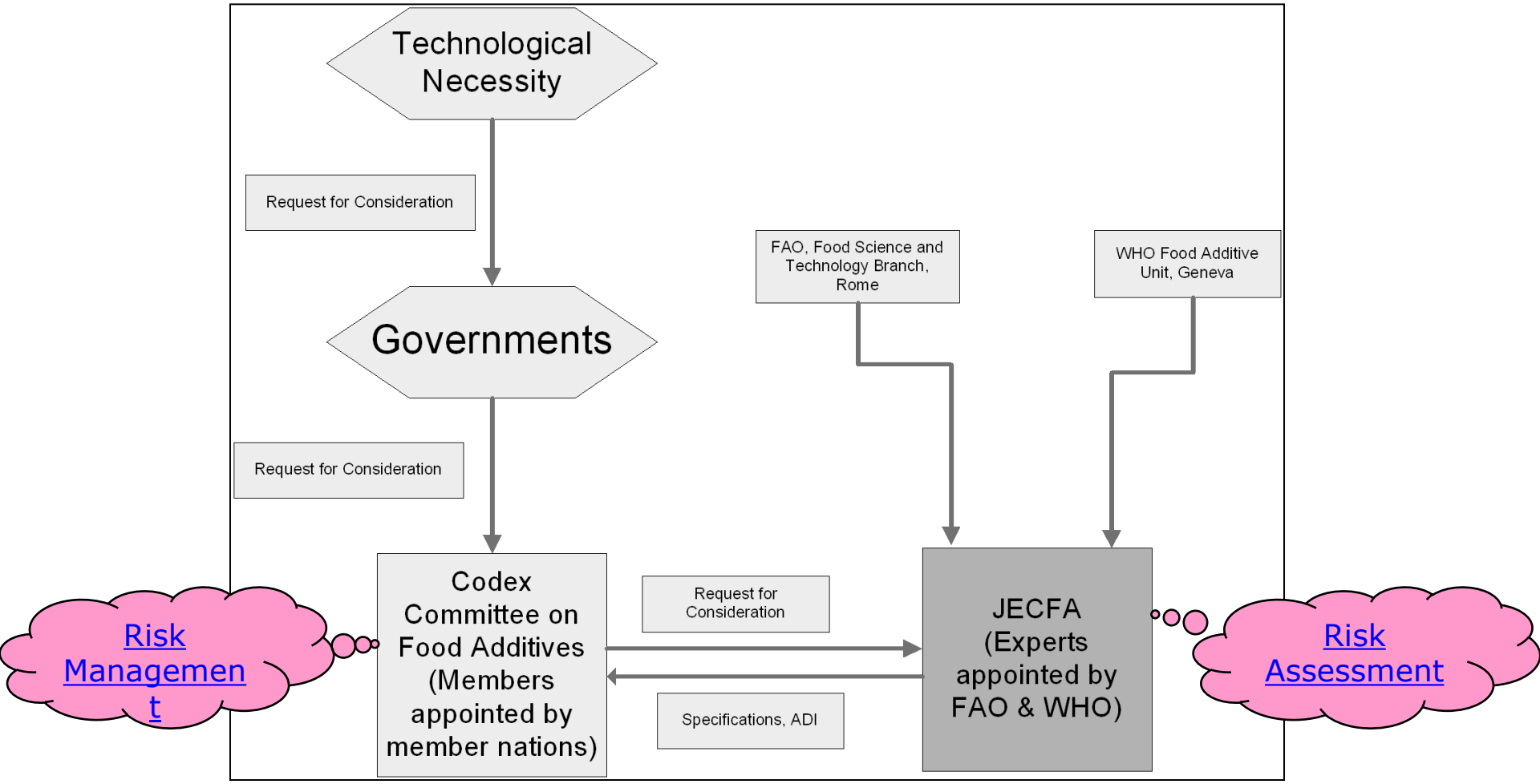


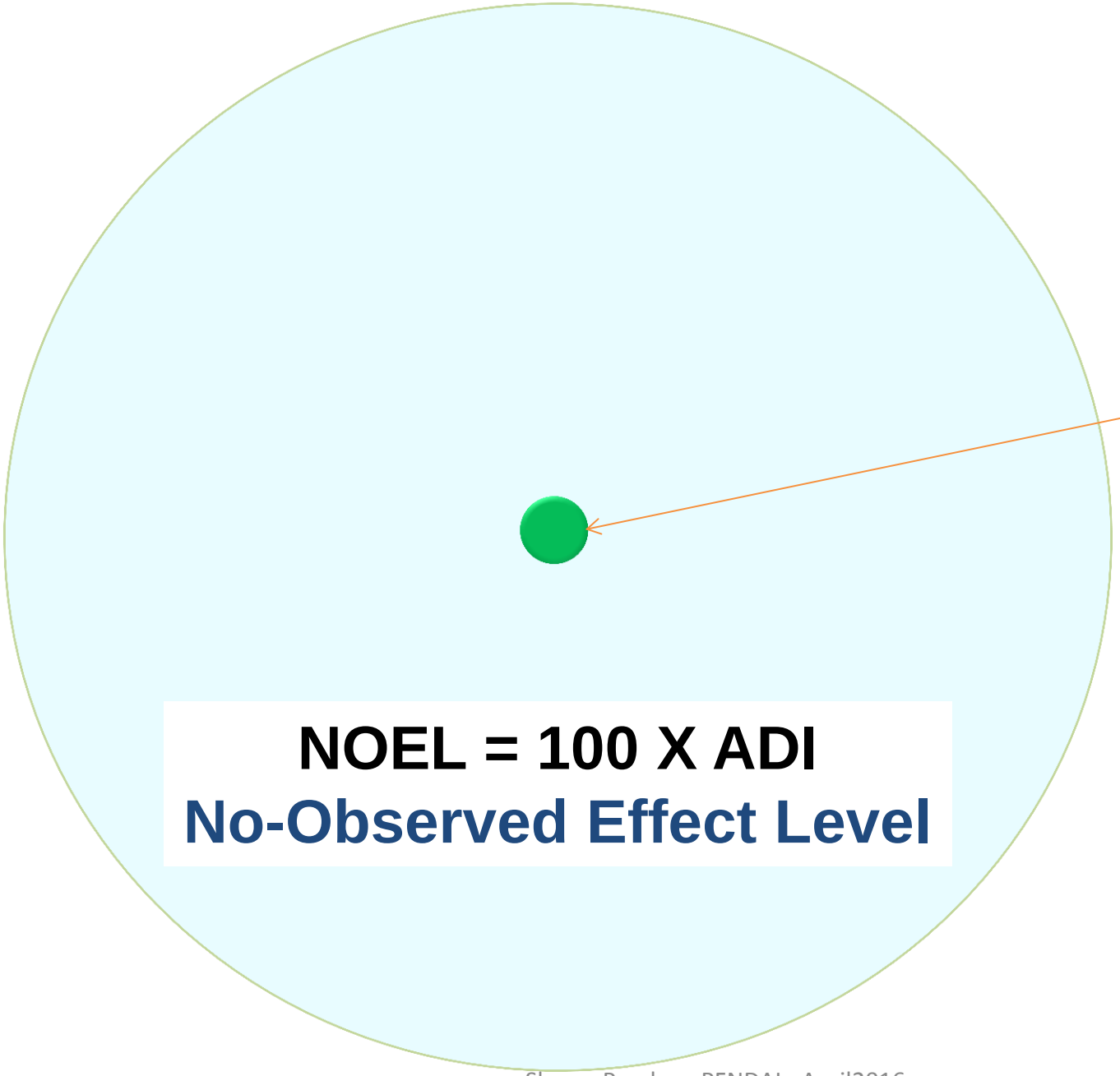
Principles in safety assessment of food additives

- Acceptable Daily Intake (ADI) = amount considered safe to consume every day over the life time without adverse effects

- ADI is set by food authorities
  - **No-Observed Effect Level (NOEL)** in chronic studies - The highest tested dose of a substance that has been reported to have no adverse health effects on people or animals

  - Apply "safety factors" to account for
    - differences between individuals (10 X)
    - differences between humans and animals (10 X)

- ADI (mg/kg/day) = NOEL/100
  - Hence even if consumption exceed ADI, it is unlikely to have any adverse effect because of conservative nature and "safety factor cushion"



An estimate by JECFA of the amount of a food additive, expressed on a body weight basis that can **be ingested daily over a lifetime without appreciable health risk.**

ADI

= NOEL/100

NOEL = 100 X ADI

No-Observed Effect Level

Principles in safety assessment of food additives

Acceptable Daily Intake "Not Specified" (NS) is a term applicable to a food substance of **very low toxicity** for which, on the basis of the available data (chemical, biochemical, toxicological, and other), the total dietary intake of the substance, arising from its use at the levels necessary to achieve the desired effect and from its acceptable background levels in food, does not, in the opinion of JECFA, represent a hazard to health.

For the above reason, and for reasons stated in individual JECFA evaluations, establishment of an **acceptable daily intake expressed in numerical form is not deemed necessary** by JECFA. An additive meeting the above criterion must be used within the bounds of **good manufacturing practice (GMP).**

Maximum Use Level of an additive is the **highest concentration of the additive determined to be functionally effective in a food or food category and agreed to be safe** by the Codex Alimentarius Commission. It is generally expressed as mg additive/kg of food. The maximum use level will not usually correspond to the optimum, recommended, or typical level of use.

Under GMP, the optimum, recommended, or typical use level will differ for each application of an additive and is dependent on the intended technical effect and the specific food in which the additive would be used, taking into account the type of raw material, food processing and post-manufacture storage, transport and handling by distributors, retailers, and consumers.

Codex – General Standard of Food Additive

- CCFA – Codex Committee on Food Additives
- JECFA –Risk Assessment Body
- GSFA – standards construct

Preamble

- Annex A (Guidelines for the estimation of appropriate levels of use of food additives)
- Annex B (Food categorization system for the GSFA)
- Annex C (Cross reference of Codex standards and FCS)

Table 1 - Alphabetically by Food Additives

Table 2 - By Food Categories

Table 3- Generally recognized as safe to be used under GMP

Annex to Table 3 (Food categories excluded from the general conditions of Table 3)

India Journey

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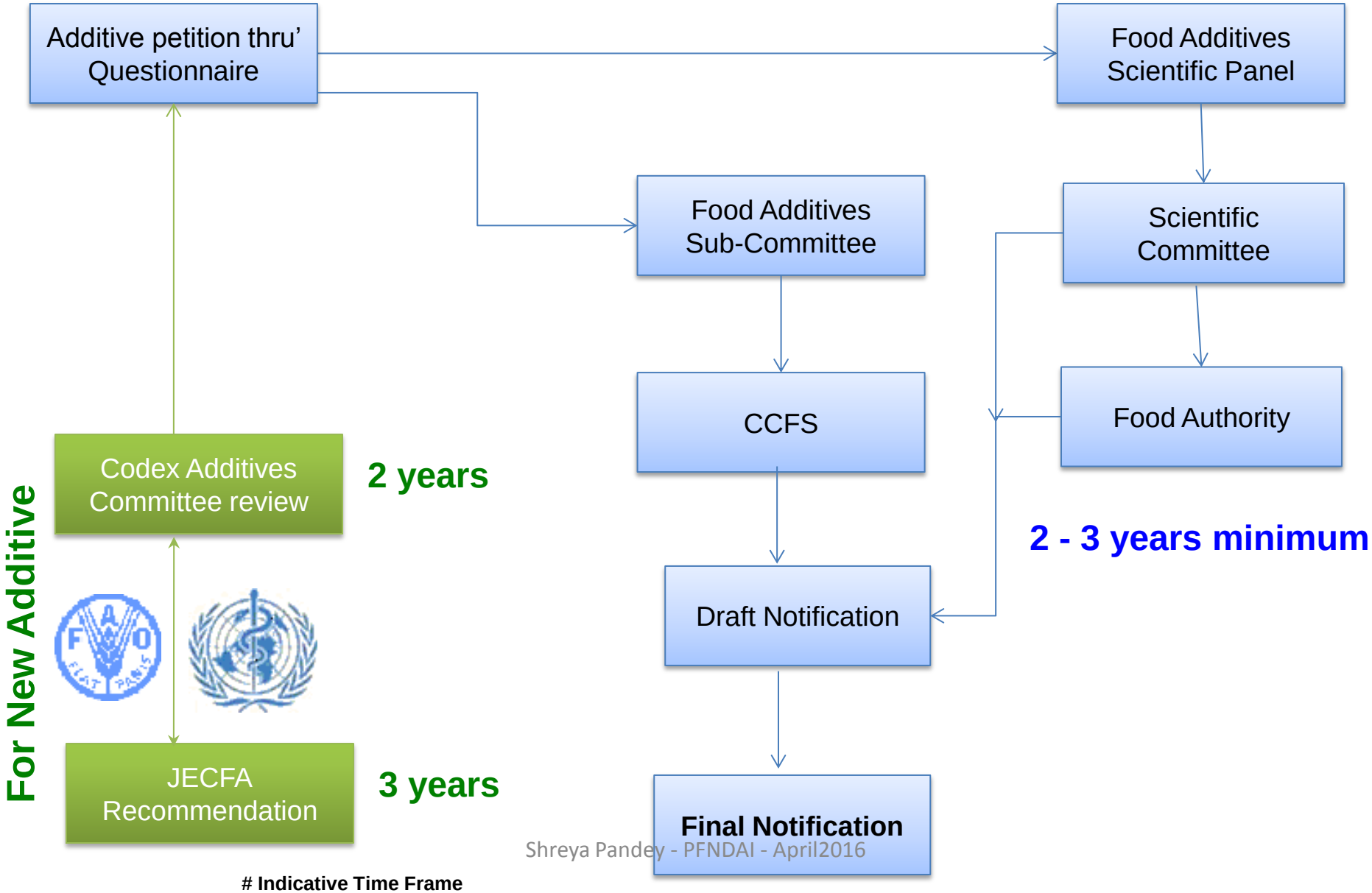
Additive Appendix Tables

- Per Table for those 330 standard items and some proprietary foods

India – Food Additives Approval Process



 # Indicative Time Frame

Current status

- Draft notifications dtd. Oct 2015
- Operationalization dtd. 23 Dec 2015
  - All provisions which were without comments
  - Few additives provisions left out for review in panel which had comments went into review in Scientific panel
  - Final ones are yet to come out
- Merged final notification yet to come out

Reading the document

- Definitions
- Appendix A - Food categorization system
- Functional classes, definitions and technological purpose
- Category wise approvals of additives
- All capitals cover multiple INS nos
- Notes
- GMP provisions
- Annex to GMP table category

Food Categorization System

01.0 Dairy products and analogues, excluding products of food category 02.0:

Includes all types of dairy products that are derived from the milk of any milking animal (e.g., cow, sheep, goat, buffalo). In this category, a "plain" product is one that is not flavoured, nor contains fruit, vegetables or other non-dairy ingredients, nor is mixed with other non-dairy ingredients, unless permitted by relevant standards. Analogues are products in which milk fat has been partially or wholly replaced by vegetable fats or oils.

01.1 Milk and dairy-based drinks:

Includes all plain and flavoured fluid milk products based on skim, part-skim, low-fat and whole milk.

01.1.1 Milk and buttermilk (plain):

Includes plain fluid products only. Includes reconstituted plain milk that contains only dairy ingredients.

01.1.1.1 Milk (plain):

Fluid milk obtained from milking animals (e.g., cows, sheep, goats, buffalo). Milk is usually heat-treated by pasteurization, ultra-high temperature (UHT) treatment or sterilization.[13] Includes skim, part-skim, low-fat and whole milk.

01.1.1.2 Buttermilk (plain):

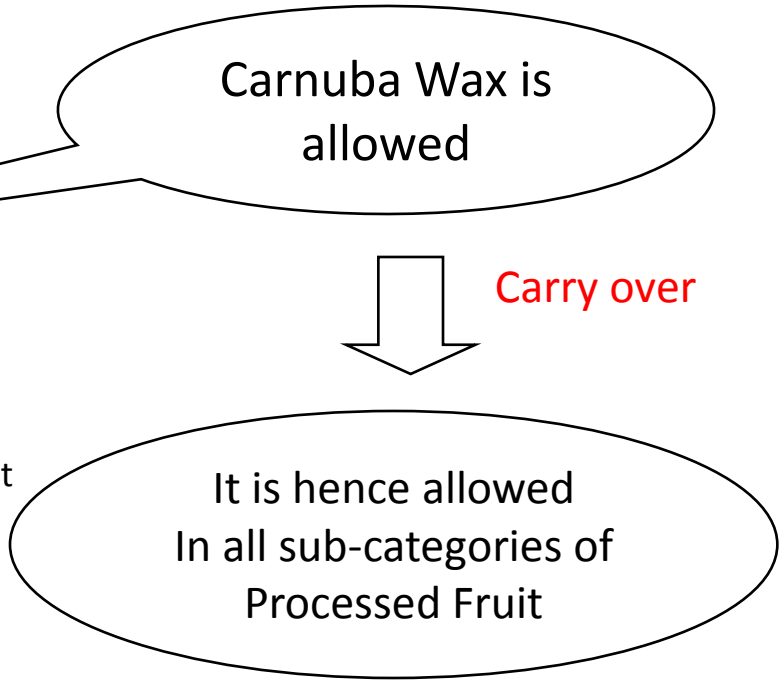
Buttermilk is the nearly milkfat-free fluid remaining from the butter-making process (i.e., the churning fermented or non-fermented milk and cream). Buttermilk is also produced by fermentation of fluid skim milk, either by spontaneous souring by the action of lactic acid-forming or aroma-forming bacteria, or by inoculation of heated milk with pure bacterial cultures (cultured buttermilk).[14] Buttermilk may be pasteurized or sterilized.

01.1.2 Dairy-based drinks, flavoured and/or fermented (e.g., chocolate milk, cooca, eggnog, drinking yoghurt, whey-based drinks):

Includes all ready-to-drink flavoured and aromatized milk-based fluid beverages and their mixes, excluding mixes for cocoa (cocoa-sugar mixtures, category 05.1.1). Examples include: hot chocolate, chocolate malt drinks, strawberry-flavoured yoghurt drink, lactic acid bacteria drinks, and *lassi* (liquid obtained by whipping curd from the lactic acid fermentation of milk, and mixing with sugar or synthetic sweetener) .

Additive allowance in a Food Category System – Example

- 04.0 Fruits and vegetables (including mushrooms and fungi, roots and tubers, pulses and legumes, and aloe vera), seaweeds, and nuts and seeds
  - 04.1 Fruit
    - 04.1.1 Fresh fruit
      - 04.1.1.1 Untreated fresh fruit
      - 04.1.1.2 Surface-treated fresh fruit
      - 04.1.1.3 Peeled or cut fresh fruit
    - 04.1.2 Processed fruit
      - 04.1.2.1 Frozen fruit
      - 04.1.2.2 Dried fruit
      - 04.1.2.3 Fruit in vinegar, oil, or brine
      - 04.1.2.4 Canned or bottled (pasteurized) fruit
      - 04.1.2.5 Jams, jellies, marmalades



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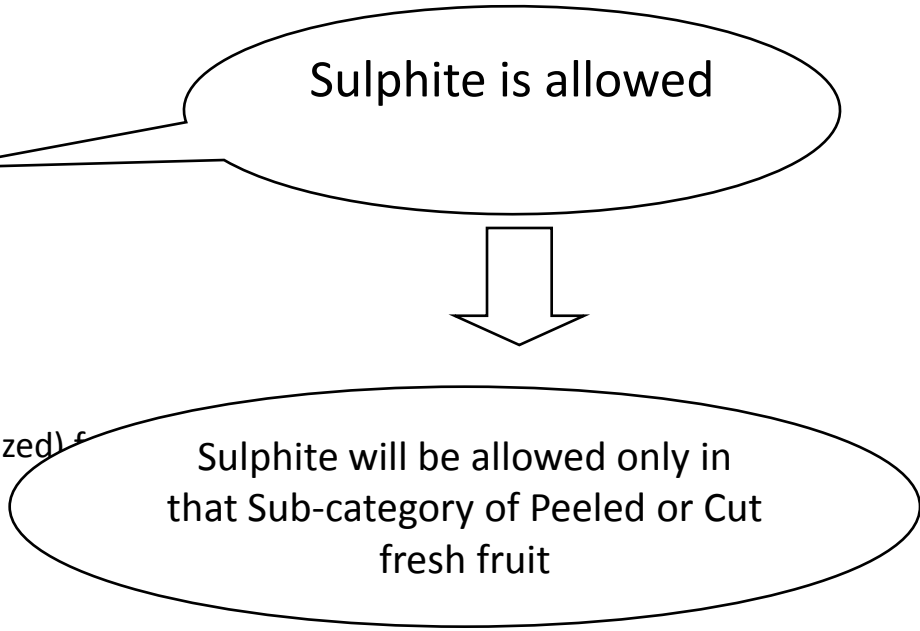

Future- Next Steps

1. Finalised merged document
2. Guideline on how to interpret and read the regulations- more seminars
3. Cross Reference IFC & FCS for few categories at variance
   - Cocoa products
   - Cereals
   - Frozen products
4. Entry of all FSSR standards into categories (like in IFC)
   - Including notification (draft, approved by authority) as come after years of review
5. All Current FSSR standards continue
   - Provisions being used from current regulations at levels >codex continue if no safety concern
   - Given time if there are safety concerns on account of ADI exceed
   - Colouring matter, Sweeteners , Preservatives etc.
   - Flavours provisions to be retained
6. Diet data for India so that ADI calculations can be local
7. Codex alignment continues as a yearly ongoing activity

15th Jan 2016 Proprietary foods

1. **Shor title and commencement.** -(1) These regulations may be called the Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations, 2016.

   (2) They shall come into force on the date of publication in the Official Gazette.

2. In the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, in regulations 2.12 relating to 'Proprietary Food', for the sub-regulations 2.12.1, the following shall be substituted, namely: -

"2.12.1: For the purpose of these regulations, -

(1) Proprietary food means an article of food that has not been standardized under these regulations, but does not include any novel food, food for special dietary use, functional food, nutraceutical, health supplement and such other articles of food which the Central Government may notify in this behalf.

(2) Proprietary food shall contain only those ingredients other than additives which are either standardised in these Regulations or permitted for use in the preparation of other standardised food under these Regulations.

(3) Proprietary food shall use only such additives as specified for the Category to which the food belongs and such category shall be clearly mentioned on the label along with its name, nature and composition.

(4) Proprietary food product shall comply with the food additives provisions as prescribed in Appendix A and the microbiological specifications as prescribed in Appendix B of these Regulations and all other Regulations made under this Act.

(5) The Food Business Operator shall be fully responsible for the safety of the proprietary food."

PAWAN AGARWAL, Chief Executive Officer

[ADVT-III/4/Extv./329]

23rd March 2016 - FAQs

5. Which additives can be used in proprietary foods?

The following Additives may be used in proprietary food:

i) Food additives permitted in chapter 3 and Appendix A of Food Safety and Standards (Food Product Standards and Food Additives) Regulations, 2011, for the particular food or food category (sub category) as amended from time to time.

ii) Food additives permitted in specific food or food category (sub category) that are made operational as per the "Notice for operationalization of standards of Food Additives for use in various Food Categories dated 23rd December 2015 issued by FSSAI".

FBOs who have received approval for any additive other than those mentioned above, under the erstwhile product approval process may continue to use them.

10. How will FBOs ensure compliance with the following provision in the notice - "such category shall be clearly mentioned on the label along with its name, nature and composition"?

i) "Category" – means category of the food as per the food category (sub category) system provided in the Food Safety and Standards (Food Product Standards and Food Additives) Regulation 2011, and permitted by the "Notice for operationalization of standards of Food Additives for use in various Food Categories dated 23rd December 2015 issued by FSSAI".

For labelling purpose, the FBO can use product name along with the category

ii) Name, Nature and composition are as provided in the Food Safety and Standard (Packaging and Labeling) Regulation 2011, as below:

a. "Name" – means the generic name of the product.

b. "Nature" means description of the food contained in the package.

c. "Composition" means list of ingredients in descending order.

Thanks