

# FSSAI Flavouring regulation

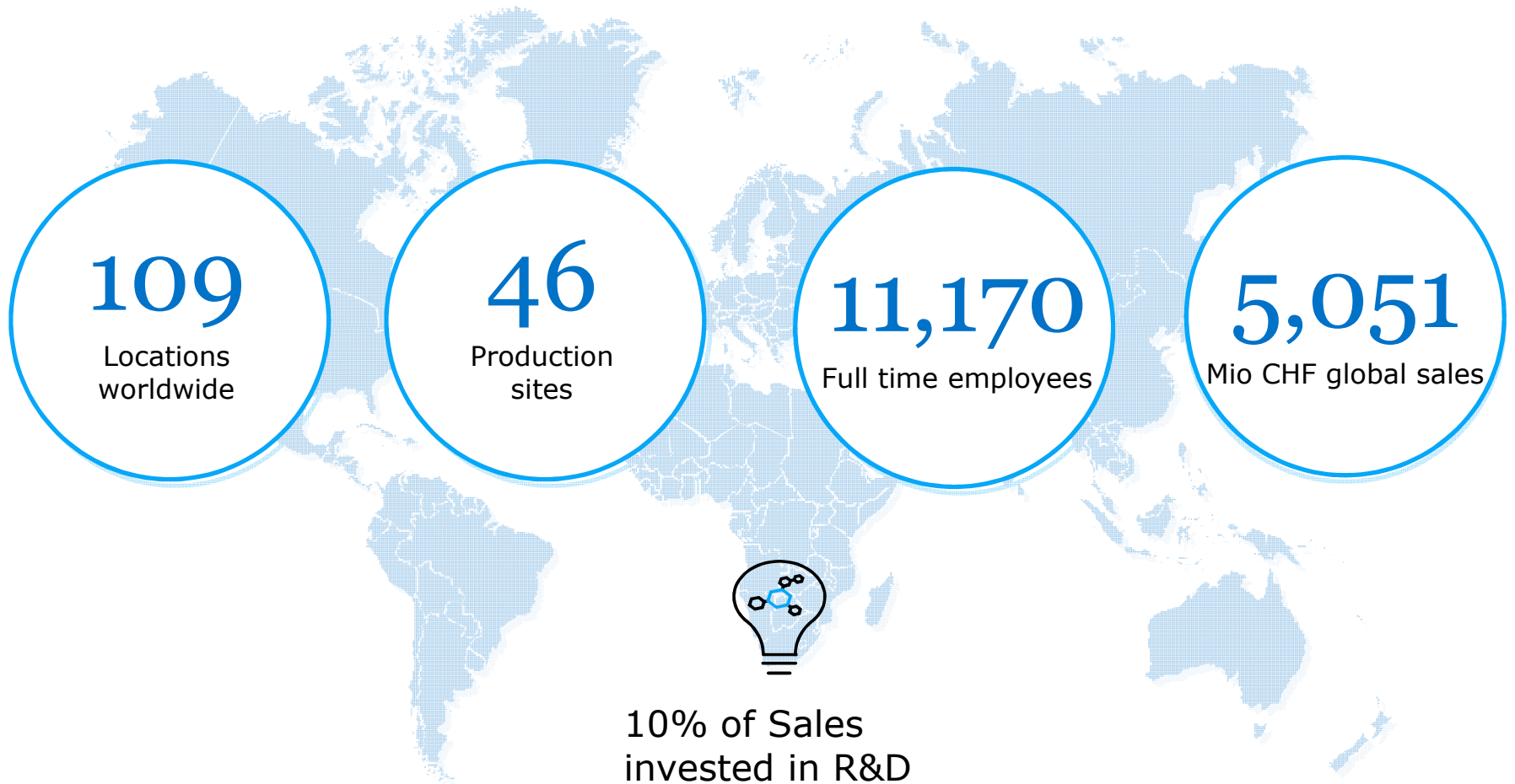


Givaudan



# Givaudan

Always by your side **a 250 year odyssey**



## What is a flavoring?

Each formula is the result of a complex creation process



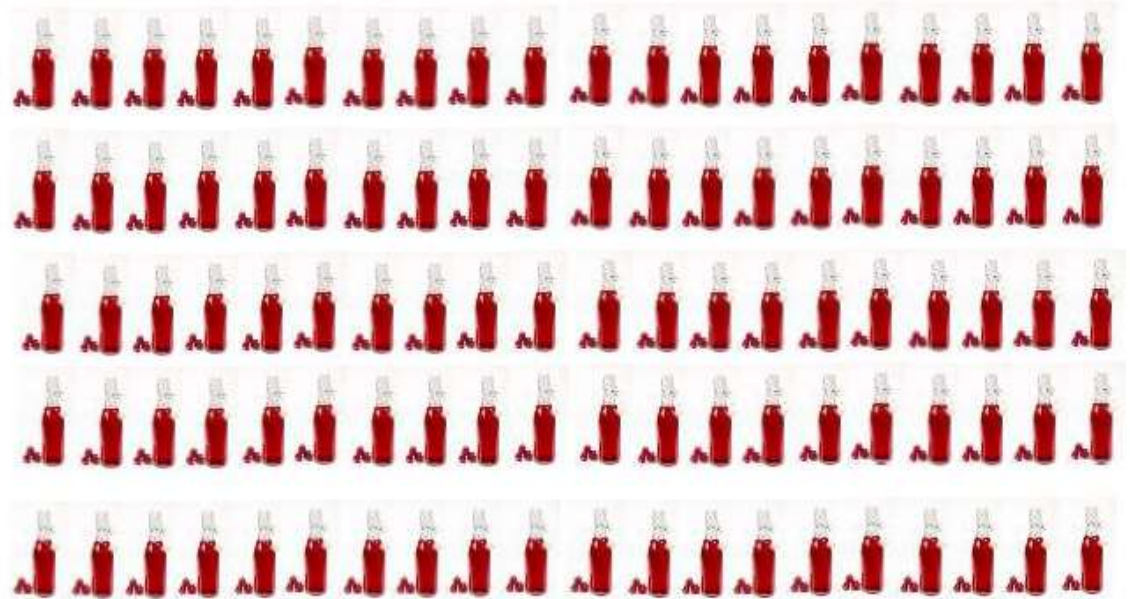
# What is a flavoring?

**Codex: Flavorings** (CAC/GL 66-2008 item 2.2) are products that are added to food to impart, modify, or enhance the flavour of food...

**FSSAI: Flavoring agents** include flavour substances, flavour extracts or flavour preparations, which are capable of imparting flavouring properties, namely taste or odour or both to food.



A bottle of 10  
gr of flavoring



100 bottles of 1 liter of beverage

# Flavorings Vs Food Additive

## FLAVORING SUBSTANCES

- Many occurs naturally in Food
- Being identified with their type – **Natural, NI or Art.**
- Used in complex mixture of flavoring components.
- Concentration varies with the type of Flavor
- Each flavoring substance used at low levels – Self limiting – results **in low exposure**

## FOOD ADDITIVES

- Only few derives from Natural Sources
- Being identified with **INS no.**
- Used in single or in combination
- Concentration – regularized by the Authority
- Usually not Self limiting

# FSSAI Flavouring Regulation-India

- **Flavours are standardized As per FSSAI Clause 3.3.1 FLAVOURING AGENTS AND RELATED SUBSTANCES:**

- **Types of Flavouring:**

## Natural Flavouring

- Are Flavour preparations and single substance, obtained exclusively by physical processes from vegetables.

## Nature Identical flavouring

- Substances chemically isolated from aromatic raw materials or synthetically; they are chemically identical to substances present in natural products.

## Artificial flavoring

- Substances which have not been identified in natural products.



# India Suitable Flavour Formula Composition

*permitted anti-oxidants, emulsifying and stabilising agents and food preservatives*

*Restricted use:  
Silicon Dioxide -  
2%*

**11Flavoring compound are forbidden to use in India ( Negative List)**

***Diethylene Glycol and Monoethyl ether  
Forbidden solvent.***

Flavour or flavouring shall be food grade not adulterated, misbranded, contaminated and safety evaluated under any of regulatory agencies like FEMA GRAS, CODEX JECFA, EFSA list .



***Coumarin and dihydrocoumarin  
Tonkabean ( Dipteryl adorat)  
 $\beta$ -Asarone and cinamyl anthracilate  
Estragole  
Ethyl Methyl Ketone  
Ethyl -3-phenylglycidate  
Eugenyl methyl ether  
Methyl  $\beta$  naphthyl Ketone  
P.propylanisole  
Saffrole and Isosaffrole  
Thujone and Isothujone &  $\beta$  Thujone***



# Flavouring (packaging & labelling)

## FSSAI regulation clause no.2.2.2.5.

### Disclosure of flavouring agent, in the ingredients list

- Disclosure of Flavouring ingredients not required on finish product label under the list of ingredients

### Addition of flavouring agents need to be mentioned on the finished product label

- **PRODUCT CONTAINS ADDED FLAVOUR** (Specify type of flavouring agent)

### In case both colour and flavour are used in the product

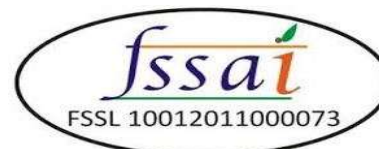
- **CONTAINS PERMITTED ADDED COLOUR(INS) AND ADDED FLAVOUR(S)**

### In case of artificial flavouring substances

- **CONTAINS ADDED ARTIFICIAL FLAVOUR (Chocolate)**

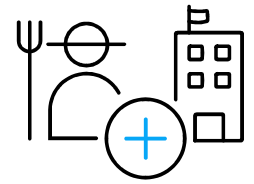
## Other labeling declarations:

- Name of the Product
- Ingredient list
- Legal status
- Net Weight
- Manufactured by/Consignee add.
- Batch No. / Lot No.
- Best Before / Date of Expiry
- FSSAI logo with Lic. No.
- Not For Retail Sale
- Veg Logo
- Allergen declarations





# Major limitations of FSSAI Flavoring clause 3.3.1



Flavoring regulation is under the Food additive regulation which has limited clarifications (No Separate flavouring Regulation)

Restriction on use of silicon dioxide 2% in flavours.

No reference list of globally accepted flavoring substances approved by FEMA GRAS, Codex JECFA, EFSA

Flavour regulation lacks information about thermal process flavorings, smoke flavorings & Flavor modifying properties (FMP) addition in flavorings.

Additives like anti-oxidants, emulsifying and stabilizing agents, preservatives, anticaking mention but not mention specific name of additive under these class

*Flavour Emulsion only allowed for Carbonated water.*



- ❑ Frequent reformulation – increasing cost
- ❑ Limiting Innovation
- ❑ Classification Issues (N/ NI /A) vs. global classification of N/A



# Expectation from Associations & Regulators

Sustained engagement and unified approach

## Sustained engagement



Sustained engagement : Flavor Manufacturers, Trade Bodies & FAFAI

Continued efforts to align with stakeholders like SMEs via FAFAI

Unified approach on framing Flavor Regulation under FSSAI

## Unified approach



Harmonized  
flavouring Regulation  
as Additives &  
Flavouring  
substances are  
different entities

Officially accepted  
globally approved  
reference list of  
flavorings substances  
from FEMA GRAS, Codex  
JECFA ,EFSA list.

Clear guidelines on  
flavoring terminology  
and, other than  
flavoring ingredients  
suitability

# IOFI-International Organization of Flavour Industry

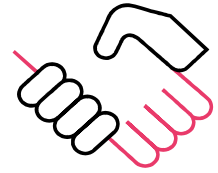
- IOFI has Observer Status” at the WHO/FAO Codex Alimentarius Commission and its subsidiary bodies.
- IOFI India Task Force- Givaudan Chair.
- It represents the interests of the global flavor industry and its partners by providing leadership in safety, scientific and regulatory matters
- Global harmonization of Indian Flavoring regulation.
- IOFI has developed Global Reference List of >4000 Flavoring substances which is a combination of all together:
  - *Flavourings evaluated by the Joint FAO/WHO Experts Committee on Food Additives (JECFA)*
  - *European Food Safety Authority (EFSA) or the Japanese Food Safety Commission (FSC).*
  - *Expert Panel of the Flavor and Extract Manufacturers Association of the United States (FEMA GRAS)*



## IOFI Company Members



# Flavour Advocacy track in India



**Development  
work of  
industry  
guidelines  
[2015~]**

**Meetings  
with FAFAI,  
FICCI, CII  
[Jan 2018]**

**Joint efforts  
by IOFI-  
FAFAI on  
GST (Goods  
& Services  
Tax) [2018]**

**FICCI-IOFI  
"Flavoring safety  
Awareness"  
Seminars  
[2018 & 2019]**



**FSSAI Codex  
harmonization  
started  
[2013]**



**Flavour Industry  
Workshop on  
Harmonization  
towards Codex  
[2016]**



**FSSAI Hearing  
( flavoring  
scientific  
panel)  
[Feb 2018]**



**Support development of  
flavoring regulation /  
Global reference list  
[2018~]**



# DRAFT - FOOD SAFETY AND STANDARDS (FLAVOURINGS) REGULATIONS, 2019

- ✓Structure/Definition: based on Codex Guidelines for the Use of Flavourings.
- ✓Details: Refer to current Indian regulations/provisions whenever applicable.
- ✓Complemented by IOFI recommendations.

Adopting a positive list by reference to the following international lists :

- I. Flavourings evaluated by the Joint FAO/WHO Experts Committee on Food Additives (JECFA)*
- II. Flavourings materials that are deemed to be Safe or approved as published by the independent Expert Panel of the Flavor and Extract Manufacturers Association (FEMA)*
- III. Materials that have been evaluated by authoritative bodies such as the European Food Safety Authority (EFSA)*

# FEMA GRAS



- Flavor and Extract Manufacturers Association of the U.S.
- FEMA was established in 1909 & working under FDA for flavour safety.
- The Expert Panel of FEMA is the primary body for the safety evaluation of food flavouring for the flavour industry and the public through its "generally recognized as safe" (GRAS) assessment of flavouring substances .
- Promotes Global Harmonization of Flavourings & flavor safety in all global markets.



FEMA GRAS.mp4

# Meeting with FSSAI Scientific Panel (Flavorings & Food Additives)





## *F2F meeting discussion:*

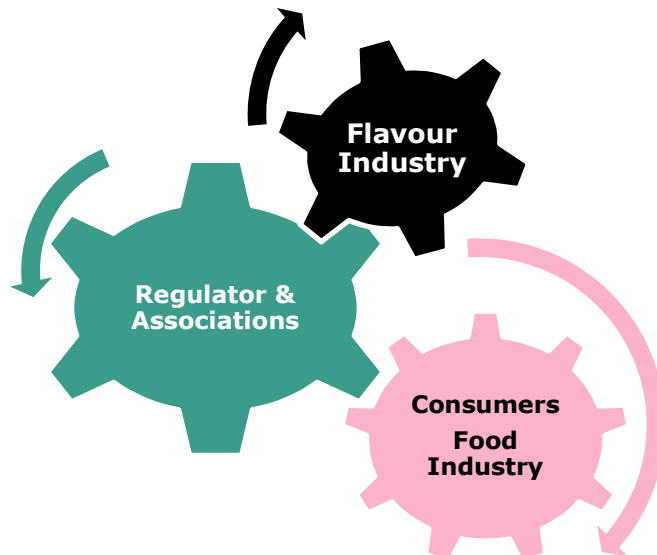
- Existing FSSAI regulation Rule 3.3.1/ negative list/limitations
- Global list of flavoring which approved from FEMA GRAS/US FDA, Codex JECFA & EU
- Codex –Guidelines for the use of Flavorings CAC/GL 66-2008



# Expectation from Associations & Regulators



<p><b>FSSAI unlikely agree to "Approval by Reference to International list from FEMA GRAS/US FDA, Codex JECFA &amp; EU"</b></p> <p><b>- Perceived as loss of control</b></p>  <p>Food Safety and Standards Authority of India भारतीय खाद्य सुरक्षा एवं मानक प्राधिकरण</p> <p>India</p>	<ul style="list-style-type: none"> <li>• Flavour houses along with Associations to lead the discussion with Regulator to push for "Approval by Reference to FEMA GRAS/US FDA, Codex JECFA &amp; EU Flavoring list."</li> </ul> 	<ul style="list-style-type: none"> <li>➤ <b>Best Option</b> : Regulation on Flavouring Substances basis "Approval by Reference to FEMA GRAS/US FDA, Codex JECFA &amp; EU Flavoring list"</li> <li>➤ <b>Back Up Option</b>: Regulation on Flavouring Substances basis "Approval by Reference" for existing molecules &amp; "Approval by Submission" for new substances (Approval time frame 3-6 month)</li> </ul>
---	--	--






# Thank You



सुरक्षित आहार, स्वास्थ्य का आधार



FOOD SAFETY AND STANDARDS AUTHORITY OF INDIA  
(Ministry of Health and Family Welfare)  
FDA Bhawan, Kotla Road, New Delhi-110002  
PORTAL: [fssai.gov.in](http://fssai.gov.in) FSSAI HELPLINE: 1800-11-2100

 [www.facebook.com/fssai](https://www.facebook.com/fssai)



