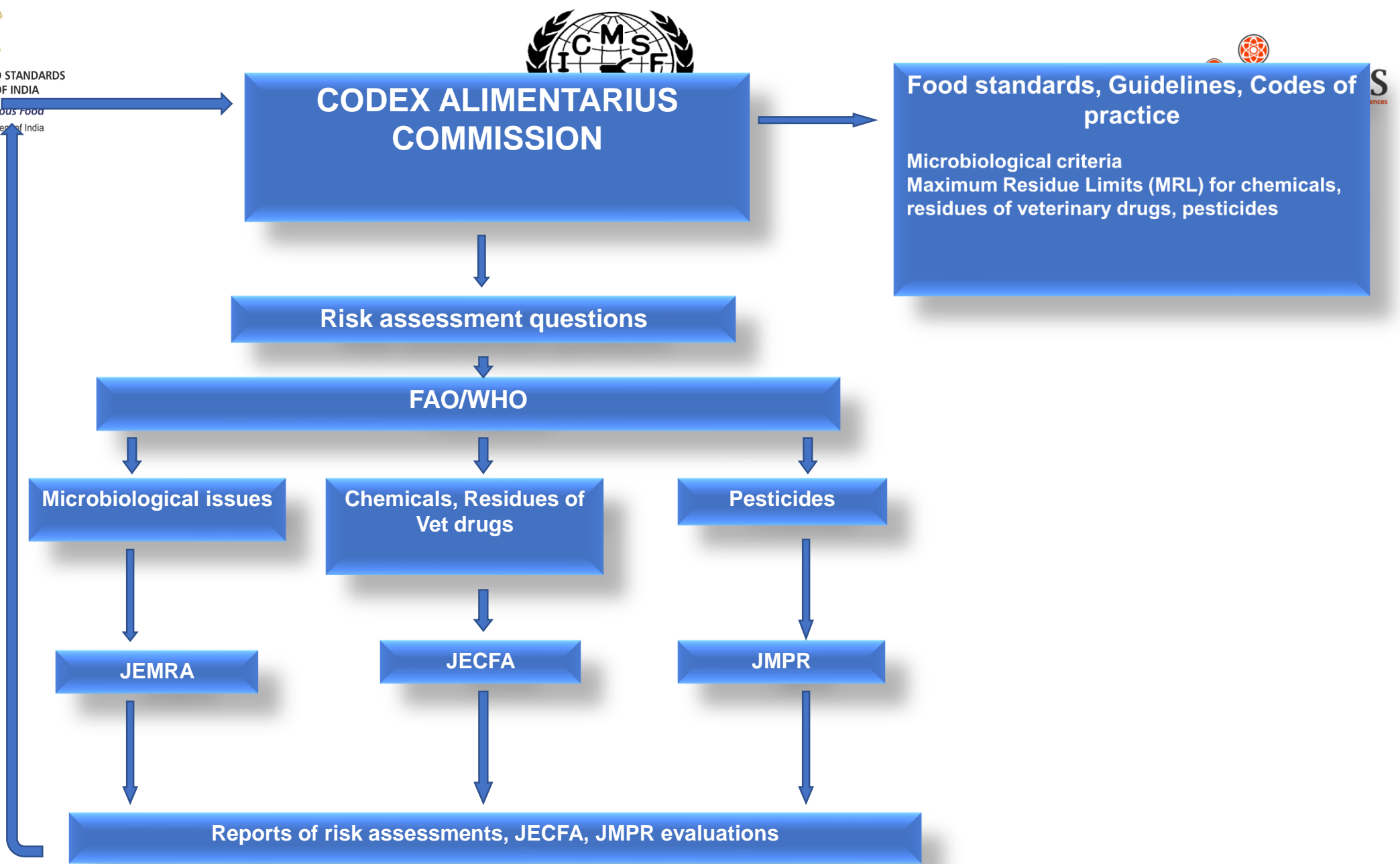


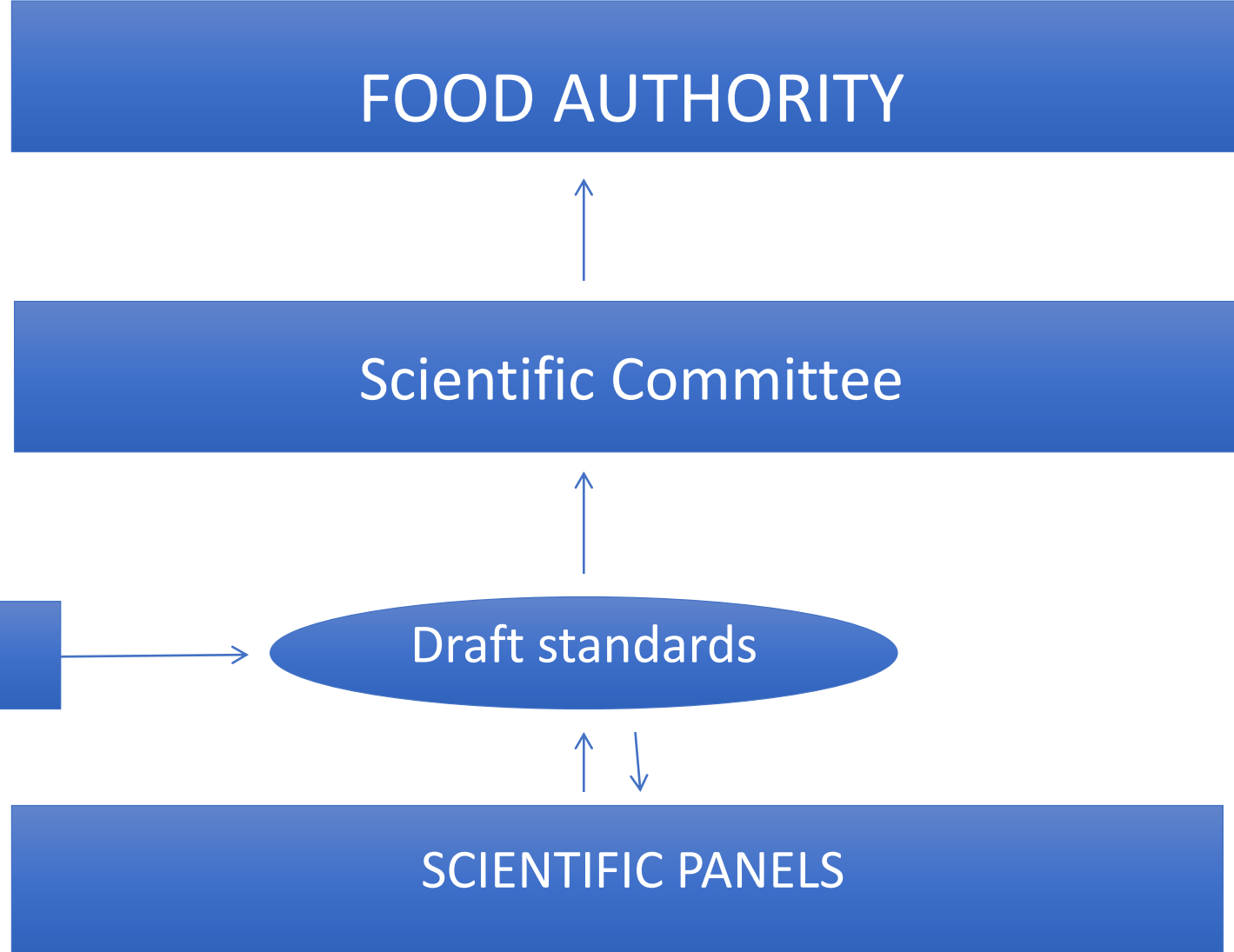
INITIATIVES OF THE FSSAI SCIENTIFIC PANEL ON BIOLOGICAL HAZARDS

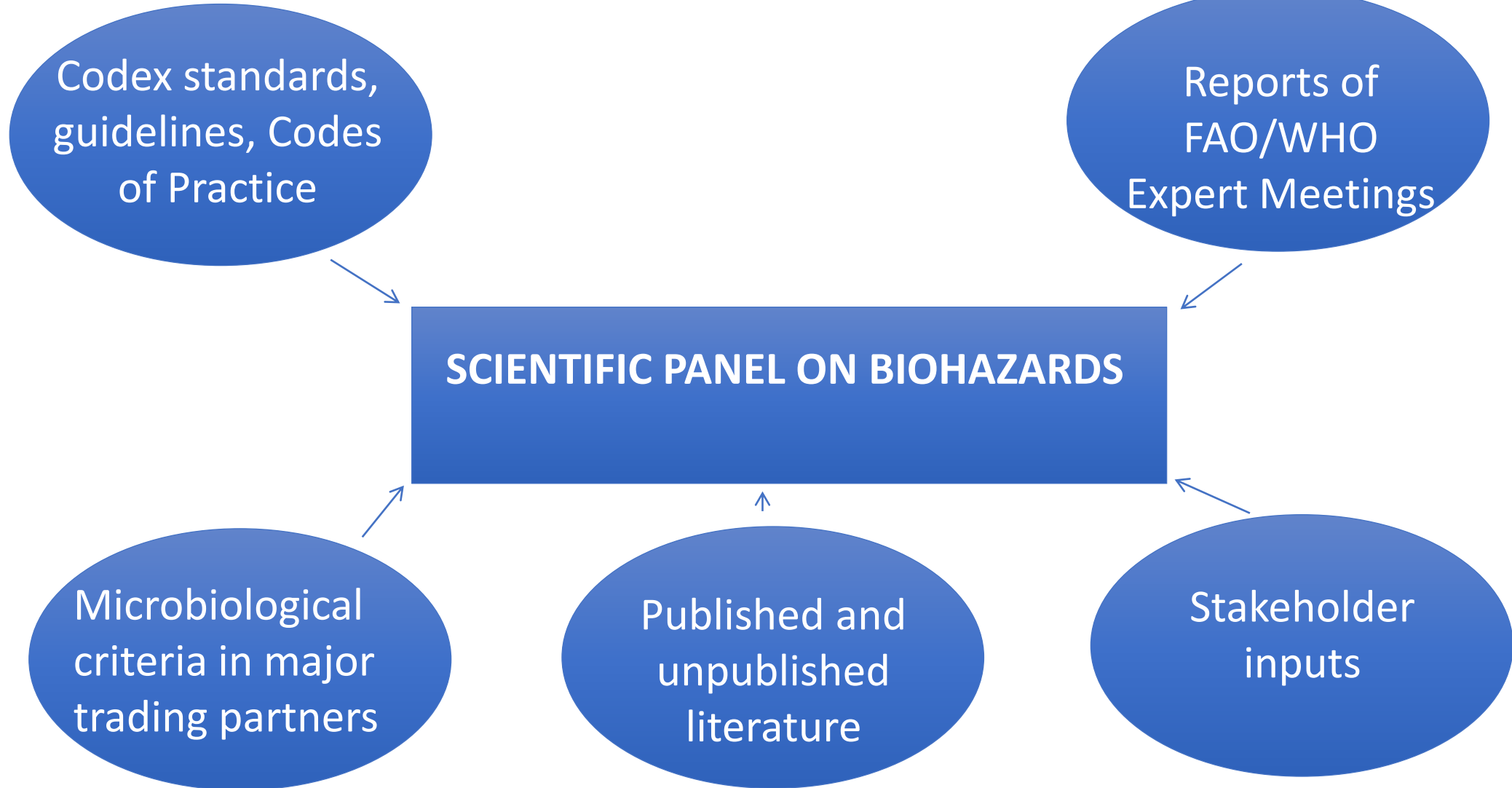
Delivered By:

Iddya Karunasagar

Chair, FSSAI Scientific Panel on Biological Hazards









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Ministry of Health and Family Welfare, Government of India



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Statistical Aspects of Microbiological Criteria Related to Foods

A RISK MANAGERS GUIDE





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PRINCIPLES AND GUIDELINES FOR THE ESTABLISHMENT AND APPLICATION OF MICROBIOLOGICAL CRITERIA RELATED TO FOODS

CAC/GL 21 - 1997

Revised and renamed 2013

Microbiological Criteria (Codex)

- A microbiological criterion is a risk management matrix, which indicates
 - the acceptability of food
 - Or
 - the performance of either a process or food safety control system
- Following the outcome of sampling and testing for the microorganisms, their toxins/metabolites or markers associated with their pathogenicity or other traits at specified point in the food chain.

Principles for establishment of microbiological criterion (Codex)

- Should be appropriate to protect the health of the consumer and to ensure fair practices in trade.
- Should be practical, feasible and applied only when necessary.
- The purpose of applying criterion should be clearly articulated.
- Establishment of the criterion should be based on scientific information and analysis and follow a structured and transparent approach.
- Should be established based on knowledge of the microorganisms and their occurrence and behaviour along the food chain.

Principles for establishment of microbiological criterion (Codex)

- The intended and the actual use of the end product by the consumers should be considered.
- The stringency of the criterion should be appropriate for the purpose.
- Periodic review of the criterion should be conducted, as appropriate to ensure that the criteria continue to be relevant for the stated purpose under current conditions and practices.

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- Preparation of a BASE PAPER on biological hazards associated with a commodity.
- **Title:**
- **Background about the commodity:** (production practices, volume of production of different formats of products, consumption volumes)
- **Hazard - product combination of concern:** Microbiological hazards associated with the commodity and products thereof, occurrence of the hazard in different segments of supply chain, prioritization for risk management)

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- **Description of public health problem:** public health significance of the hazards, data on outbreaks associated with the hazards in India, characteristics of the pathogen (virulence characters, thermal resistance, survival and multiplication), characteristics of disease, susceptible population, consumption practices, epidemiology.
- **Commodity production, processing, distribution, consumption:** Characteristics of the commodity/product that are involved and that may impact on risk management; description of the farm to table continuum including factors which may impact the microbiological safety of the commodity (i.e., primary production, processing, transport, storage, consumer handling practices);

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- **Commodity production, processing, distribution, consumption (contd):** what is currently known about the risk, how it arises with respect to the commodity's production, processing, transport and consumer handling practices, and who it affects; Summary of the extent and effectiveness of current risk management practices including food safety production/processing control measures.
- **Other risk profile elements:** Potential public health and economic consequences of establishing microbiological criteria, experience of risk management in other countries, regions.
- **Data gaps:**
- **Summary and recommendations:**

FSSAI Scientific Panel on Biological hazards initiative

- Considering data on levels of microorganisms that can be achieved under conditions of implementation of Good Hygienic Practices and HACCP based process.
- Scientific data and feedback from industry.
- Test methods: validated methods mostly ISO methods or equivalent.



MANUAL ON METHOD OF MICROBIOLOGICAL TESTING

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GOOD FOOD LABORATORY PRACTICES (GFLPs)



GOOD FOOD LABORATORY PRACTICES



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GOVERNMENT OF INDIA
NEW DELHI
2018

FSSAI Microbiological criteria

- **Process hygiene criteria** – total plate count, *Staphylococcus* count, coliform count, *Escherichia coli*.
- Sampling plan and test methods
- **Food Safety criteria**: Pathogens of relevance
- Sampling plan and test methods
- n = number of sample units comprising the sample
- c = maximum number of units having microbiological counts above m for 2-class sampling plan and between m and M for 3 class sampling plan



FSSAI sampling plan

- m = Microbiological limit that separates unsatisfactory from satisfactory in 2 – class sampling plan or acceptable from satisfactory in a 3 – class sampling plan
- M = Microbiological limit that separates unsatisfactory from satisfactory in 3 – class sampling plan
- Two class sampling plan: Satisfactory if all the values observed are $\leq m$. Unsatisfactory if more than c units have values $> m$ or if any one or more units exceed m .

FSSAI sampling plan

- Three class sampling plan: Satisfactory if all the values observed are $\leq m$.
- Acceptable if a maximum of c units are between m and M and rest of the values are $\leq m$.
- Unsatisfactory if more than c units have values $> m$ or if any unit exceeds M .

FSSAI sampling plan - example

- Cut or minimally processed fruits and vegetables (non-thermally processed)
- Process hygiene criteria:
 - Aerobic plate count: $n = 5$; $c = 2$; $m = 1 \times 10^6/\text{g}$; $M = 1 \times 10^7/\text{g}$
 - Enterobacteriaceae: $n = 5$; $c = 2$; $m = 1 \times 10^2/\text{g}$; $M = 1 \times 10^4/\text{g}$
 - *Staphylococcus aureus*: $n = 5$; $c = 1$; $m = 1 \times 10^2/\text{g}$; $M = 1 \times 10^3/\text{g}$
- Food safety criteria:
 - *Salmonella*: $n = 5$; $c = 0$; absent in 25g
 - *Listeria monocytogenes*: $n = 5$; $c = 0$; absent in 25g

FSSAI Microbiological criteria

- **Process hygiene criteria** – indicate acceptable functioning of the production process.
- These are not to be used as requirements for releasing the product into the market.
- These are indicative values above which, corrective action is required in order to maintain the hygiene of the process in compliance with food law.
- These shall be applicable at the end of the manufacturing process.

FSSAI Microbiological criteria

- FBO can decide sampling and testing frequency to ensure compliance with microbiological requirements.
- **Process hygiene criteria** – in case of failure, FBO shall:
 - Check and improve process hygiene by implementing guidelines in schedule 4 of FSS (Licensing and Registration of Food Business) Regulation.
 - Ensure that all food safety criteria are met with.



FOOD SAFETY AND HYGIENE REQUIREMENTS

To provide assurance of food safety, Food businesses must implement an effective Food Safety Management System (FSMS) based on Hazard Analysis and Critical Control Point (HACCP) and suitable pre-requisite programmes by actively controlling hazards throughout the food chain starting from food production till final consumption.

As per the condition of license under FSS (Licensing & Registration of Food Businesses) Regulations 2011, every food business operator (FBO) applying for licensing must have a documented FSMS plan and comply with schedule 4 of this regulation. 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 as under:

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

[Click here for Schedule 4 of FSS \(Licensing & Registration of Food Businesses\) Regulations 2011](#)

FSSAI Microbiological criteria

- Regulator: Sampling to be done aseptically at manufacturing unit or retail as applicable.
- Sampling to be done by a person trained in microbiology
- Samples to be stored at frozen temperature (-18°C) or under refrigerated conditions (2-5°C) as applicable except in the case of products recommended to be stored at room temperature by the manufacturer
- Analysis to be initiated within 24hrs of sampling.

FSSAI Scientific Panel on Biological hazards initiatives

- Review and adapt to Indian conditions of production and processing:
- Codex Code of Hygienic Practice for egg and egg products
- Codex Code of Hygienic Practice for packaging and transport of fresh fruits and vegetables
- Codex Code of Hygienic Practice for meat
- Codex Code of Hygienic Practice for milk and milk products



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THANK YOU