DISCLAIMER

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Obtaining Approval of Non-Specified Foods’

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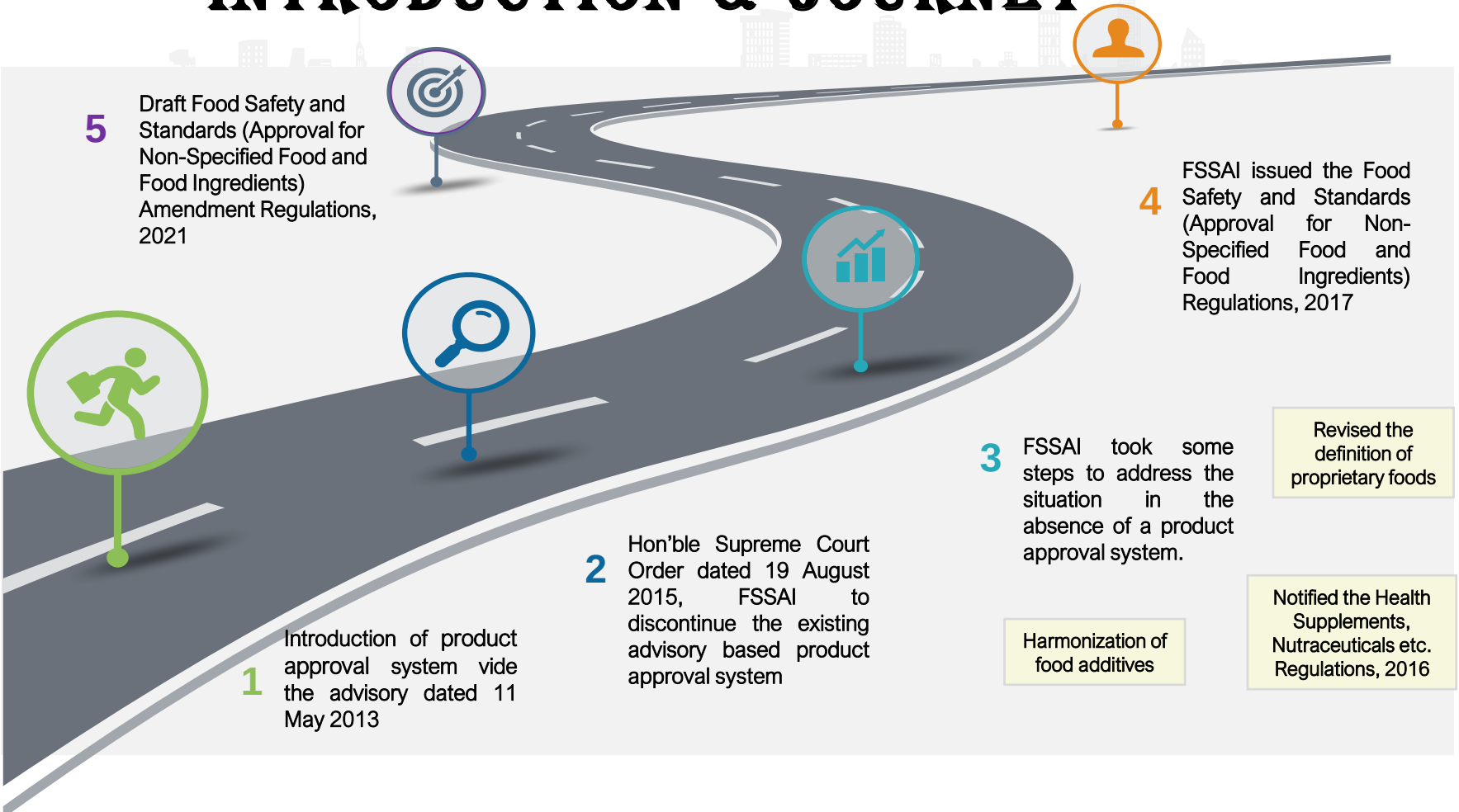
INTRODUCTION & JOURNEY



1 Introduction of product approval system vide the advisory dated 11 May 2013

2 Hon'ble Supreme Court Order dated 19 August 2015, FSSAI to discontinue the existing advisory based product approval system

3 FSSAI took some steps to address the situation in the absence of a product approval system.

- Revised the definition of proprietary foods
- Harmonization of food additives
- Notified the Health Supplements, Nutraceuticals etc. Regulations, 2016

4 FSSAI issued the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017

5 Draft Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Amendment Regulations, 2021

KEY POINTS

PRIOR APPROVAL

Prior approval of non-specified food and food ingredients is a necessary before taking licensing/ registration

DECLARATION

FBOs must declare the top three ingredients that constitute 51 percent of the total product composition*

Its product approval not ingredient

STANDARDISED PRODUCT

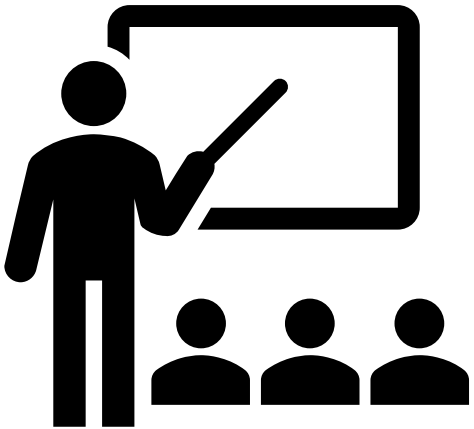
For standardized products, i.e., food products/ingredients for which standards are prescribed in the FSS Act, Rules and Regulations, which FBOs conform to, they do not require an approval.

REGULATIONS

In order to cover the other products/ ingredients (proprietary and novel) FSSAI has notified the various regulations.

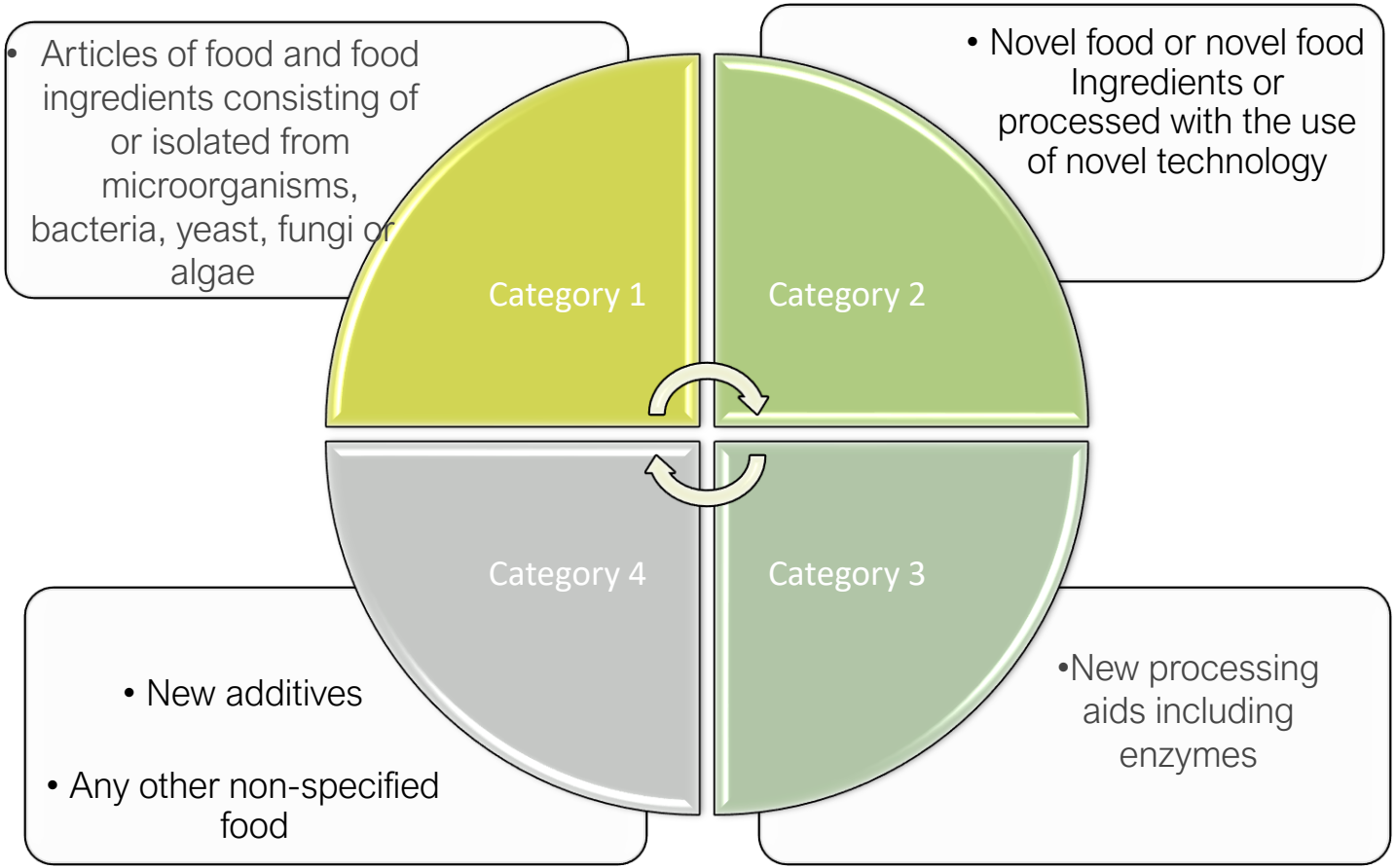
* ICRIER- Streamlining Food Safety Compliance Ecosystem in India Report 2019

THE FOOD SAFETY AND STANDARDS (APPROVAL FOR NON-SPECIFIED FOOD AND FOOD INGREDIENTS) REGULATIONS, 2017

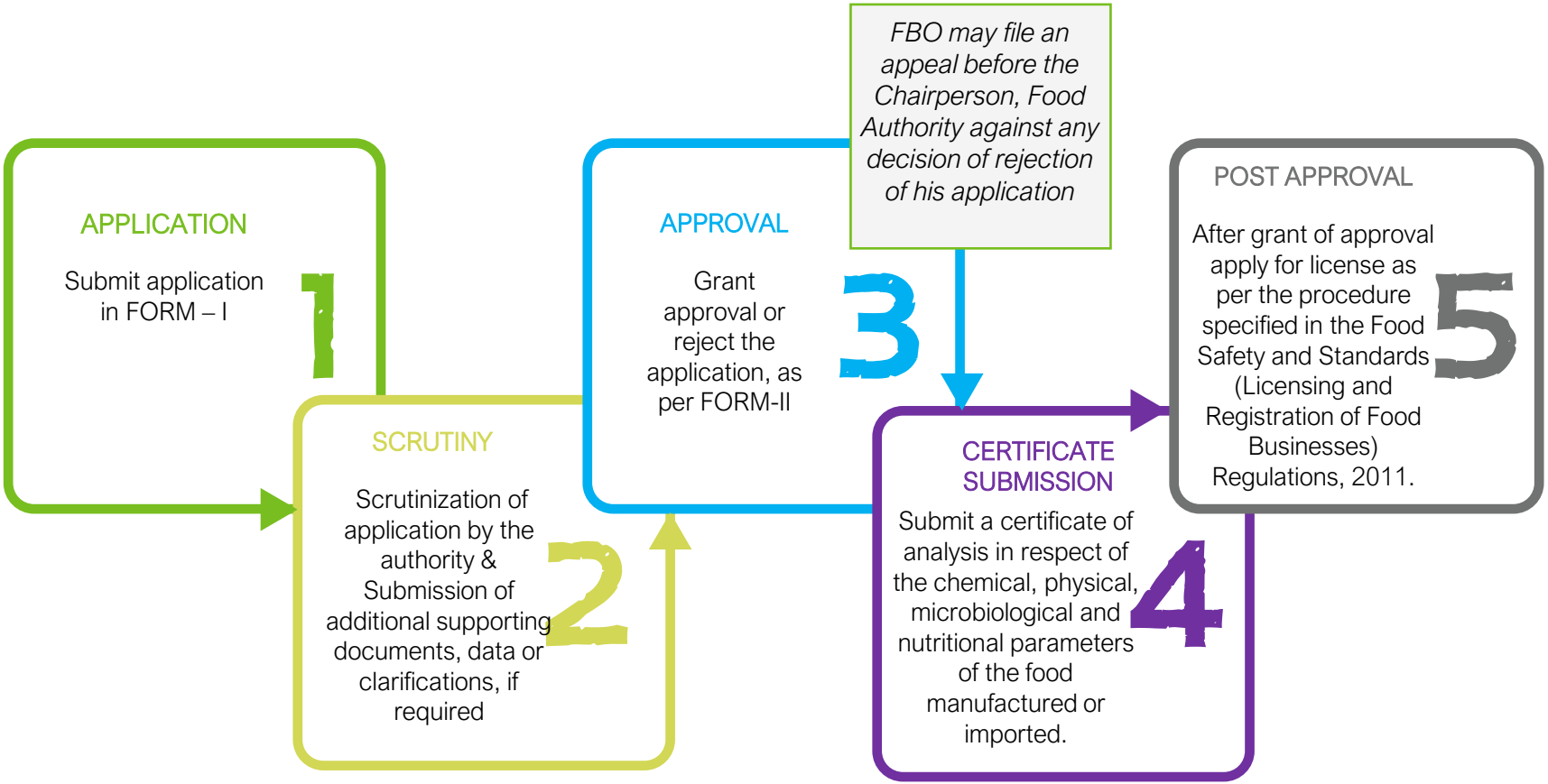


"Non-specified food" means any food other than proprietary food or food ingredients, including additives, processing aids and enzymes for which standards have not been specified in any regulation made under the Act.

THE FOOD SAFETY AND STANDARDS (APPROVAL FOR NON-SPECIFIED FOOD AND FOOD INGREDIENTS) REGULATIONS, 2017



PROCEDURE


APPLICATION
Submit application in FORM – I
1
SCRUTINY
Scrutinization of application by the authority & Submission of additional supporting documents, data or clarifications, if required
2
APPROVAL
Grant approval or reject the application, as per FORM-II
3
FBO may file an appeal before the Chairperson, Food Authority against any decision of rejection of his application
CERTIFICATE SUBMISSION
Submit a certificate of analysis in respect of the chemical, physical, microbiological and nutritional parameters of the food manufactured or imported.
4
POST APPROVAL
After grant of approval apply for license as per the procedure specified in the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011.
5

CHALLANGES

LACK OF INFRASTRUCTURE

Such as food testing laboratories and specialized testing equipment .

Shortage of qualified manpower

DOCUMENTATION

License renewal and ingredient approval are cumbersome and involve submission of all documents already submitted.

NO SPECIFIED TIMELINE

The FSSAI has not specified any timeline for the steps involved in approval of non-specified foods

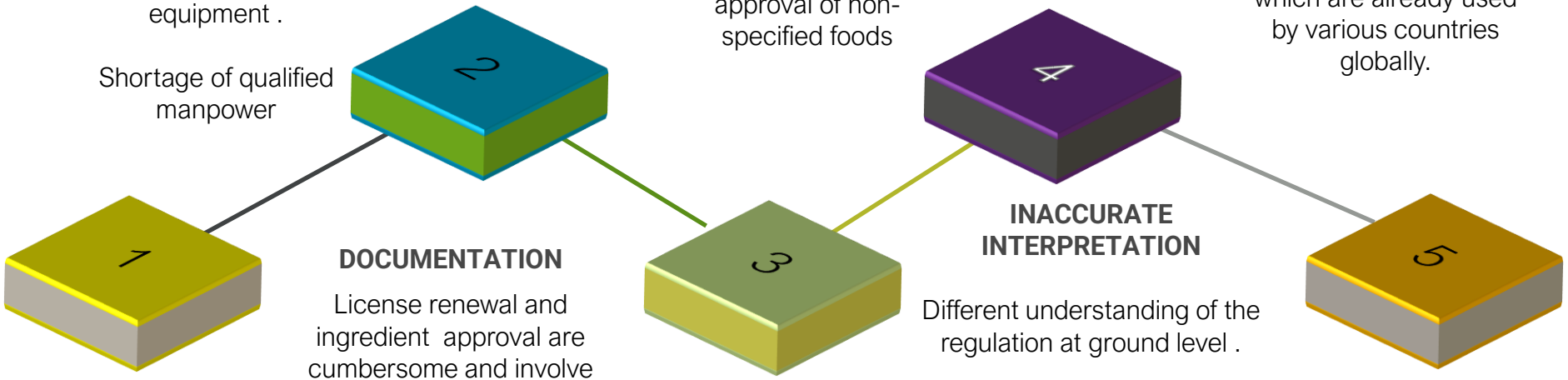
INACCURATE INTERPRETATION

Different understanding of the regulation at ground level .

Judging Nutra ingredients viz a viz conventional food

AVERTABLE REQUIREMENT

Unnecessary condition to submit supporting data for ingredients which are already used by various countries globally.



CHALLENGES:

INSTANCES

CAFFEINE

INGREDIENT

Caffeine is used in nutraceutical product as ingredient

VERTICAL REGUALTION LIMIT

Used as per the Additives Regulation i.e caffeinated beverages standard 300 mg/L

NOT RECONISED FOR NUTRA

Food Safety officers interprets that there is no allowance for caffeine in Nutra. Therefore, product becomes non-compliant

FSSAI APPROACH

Documents submitted to FSSAI and after detailed review
Scientific panel decided that Nutra products can use upto 3 mg/kg and 300mg/ day from all sources

PERSISTANT AMBIGUITY

Keeping in mind the average weight of Indian as 60kg, it actually comes down to 180mg (approx.) which is even lower than already prescribed limits for carbonated beverages

GUARANA

DISAPPROVAL

FSSAI prohibited use of Guarana under Nutra, which is safe ingredient and used globally 40-50 yrs

CLARITY

FBO approached FSSAI for clarity & submitted the adequate data w.r.t safety etc.

DECISION

FSSAI clarified that ingredient having food origin can be used for Caffeinated beverage, however need to maintain the purity criteria established for caffeine.

FACT

Caffeine is less in GUARANA, therefore, product failed in purity criteria available. Note: there is no purity criteria set by FSSAI

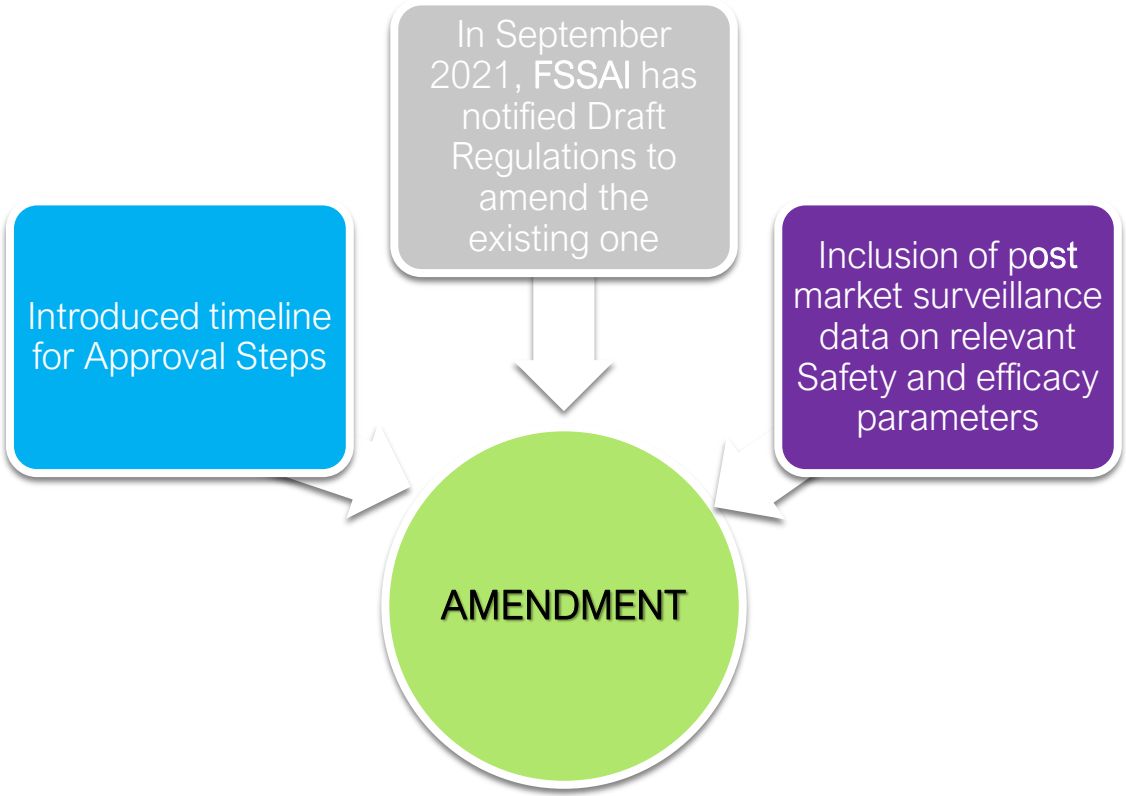
ACCEPTANCE

Adopt globally acceptable safe use as reference for approval of new ingredients.

EXCLUSIVITY/ PROPRIETARY

APPLICATION	One FBO apply for approval of new ingredient after detail background exercise including R& D	01
APPROVAL	FSSAI reviews and approves the ingredient basis substantiation submitted by the FBO	02
USAGE	An exclusive right to use to be given to the applicant FBO for a specific time period before making it general	03

DRAFT: FOOD SAFETY AND STANDARDS (APPROVAL FOR NON-SPECIFIED FOOD AND FOOD INGREDIENTS) AMENDMENT REGULATIONS, 2021,



POSSIBLE CHALLENGES

INCOMPLETE TIMEFRAME

Proposed draft **doesn't not specify time for the authority** to respond after submission of additional information by FBO

UNREASONABLE REQUIREMENT

Unnecessary condition to submit **post market surveillance data on relevant Safety and efficacy parameters** for ingredients which are already established as safe globally.

RESOLUTION

DECISION TREE

Decision Tree for systematic & scientific approval

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TIMELINE

Define proper timeline for each stage till completion of the procedure to avoid any unnecessary delay

SAFE USAGE HISTORY

History of safe use & efficacy data established by other countries/ established regulatory framework as supporting data for ingredient approval

SCOPE

State clear scope and requisite for specific ingredients.

COMPETENT RESOURCE

Technical resources to be competent to handle complex scientific data

THANK YOU