FREQUENTLY ASKED QUESTIONS (FAQS)

FSSAI-CHIFSS-IITR WORKSHOPS

ON

BASICS OF RISK ASSESSMENT OF ADDITIVES

RISK ASSESSMENT AND APPROVAL OF NOVEL FOODS AND INGREDIENTS

GENERAL QUESTIONS

1. What are food additives?

Food additive is any substance intentionally added to food for a technological purpose. This may be to improve shelf life, maintaining its nutritional qualities and sensorial attributes (taste, texture, appearance). Food additives are not normally consumed as a food by itself.

2. Why are food additives added to foods?

Food additives are used during food processing for various technological purposes like preservation, stablilizing an emulsion,adding colour, flavour etc.

3. Where do food ingredients come from?

Food ingredients come from the foods we eat.To inform consumers, food additives are declared on the label under the title “ingredients”.

4. Are food ingredients natural?

Majority of them are natural and some are synthetic.

5. How do I know what ingredients are in my food?

Under the title “ Ingredients” all ingredients in the food are declared and listed by their descending weight on the product label.

6. When were food additives first used in foods?

Reference for use of salt as preservative is found in as early as 2000BC, while use of food additives was widely recognised in early 19th Century

7. Can I use food additives in cooking at home?

Yes, for foods where additives are permitted at the quantities permitted by FSSAI.

8. Why are there chemicals in my food?

Certain chemicals (Food additives) havebecome an integralpart of the food, as they are used for various technological purposes in food processing.

9. Can I have sensitivity to a food ingredient or additive?

Yes, some of the ingredients like peanuts, eggs,milk etc can be allergic to sensitive

individualsand additives like sulphites to those with asthamatic condition. However where ever such ingredients arepresent in any food product, it will be indicated as advisory/caution on the food label.
10. Do organic foods contain food additives?
Yes, but only those which are permitted under the 'organic food' regulations of FSSAI.
FOOD SAFETY OF ADDITIVES
11. Are food additives harmful to my health?
No, as their safety is assessed before they are permitted to be used for specific use and use level. However, if a food additive is used beyond permissible levels, it may be unsafe to human health.
12. How are food additives determined safe?
Safety of food additives is assessed by the Joint Expert Committee on Food Additives (JECFA)- an expert ody of international scientists commissioned under FAO-WHO.There are well standardised methodologies, such as risk assessment in place to assess the safety of a food additive by using laboratory models.
13. I read that anadditive is unsafe. What should I do?
It is unlikely an unsafe additive is permitted, however if credible scientific evidence, is available, the FSSAI may be informed.
14. Are natural food additives better than artificial ones?
Scientifically there is no difference between natural and synthetic food additives from safety point of view
15. How did we come up with a value of 100, which are the safety parameters of 10*10?
Most of the safety studies on food additives are carried out on various animal models, but finally they are meant for human use. In order to convert the no observed adverse effect level (NOAEL) derived from animal toxicity studies to acceptable daily intake (ADI) for humans, an uncertainty factor of 100-fold (10x10) is usually included. This uncertainty factor is a composite parameter taking into consideration two separate 10-fold factors accounting for interspecies and interindividual variability in both toxicokinetics and toxicodynamics.
ALLOCATION TO CATEGORIES AND PERMISSIBLE LIMITS
16. Who are these people and bodies doing the work on identification ofand risk

assessment of food additives?
The safety of food additives is assessed by the Joint Expert Committee Food Additives (JECFA) – an expert body of international scientists commissioned under FAO-WHO.
17. How to decide the appropriate amount or limits of colours? Formula for that?
There is no formula to provide the appropriate amount of colour for any product. Permitted levels are maximum use levels which are decided based on the (Acceptable Daily Intake (ADI) specified for that particular colour. Actual use levels to colour a food product may be lower than permitted levels and vary depending upon regional preference. In the relevant FSSAI Compendlum or regulations for additives, the term "GMP" is defined against specific addtives. This means in a broad sense that the regulations doesnot specify any upper limit for the use of that additive, however, it does not give freedom to use 'any proportions'. As part of good manufacturing practice the quantity of an additive added to food should be limited to the lowest possible level necessary to accomplish its desired effectand with scientific rationale for use of the level selected.
18. Tartrazine INS 102 colour is not allowed in namkeens, but permitted in toffees, sweets and candies. What is the logic and reasoning behind this?
➢ Food additives are allowed to be used in a particular food product based on its technological purpose in that product. Not necessarily all food additives are technologically required in all food products. ➢ However, if a food additive is not currently permitted in a food product (e.g. namkeen), an application in the specified proforma,available on the FSSAI website, providing all the relevant information including its specific technological need for the product, safety data and its exposure assessment is to be made. ➢ The completed application, with necessary documents for approval of food additives and the food category/sub-category in which it is sought to be used, other than what is permitted in the regulation is to be submitted to FSSAI. ➢ If such appliation is made for Tartrazine in namkeens, if there is any missing information like effect of its heat stability on deep frying and by product formations or etc, then additional information will have to be provided for approval.
19. According to FSSAI, which additives can be used in Mithai and other dairy products to increase their shelf life, and which are the colours permitted in Mithai?
Refer to FSSAI regulation which is available online.

20. India is a member of CODEX, but If an additive/processing aid is approved by CODEX and not specified in FSSAI regulations, will it still require approval ?

Codex standards are reference standards for member countries. If an additive/processing aid is there in codex and not given under FSS Regulations, it will require approval for its use in India. A representation may made requesting inclusion of that provision under FSS Regulations or application may be made under product approval. Evaluation will be done by FSSAI keeping in view the Indian perspective.If

NOVEL FOODS

21. What is novel food?

A food which:

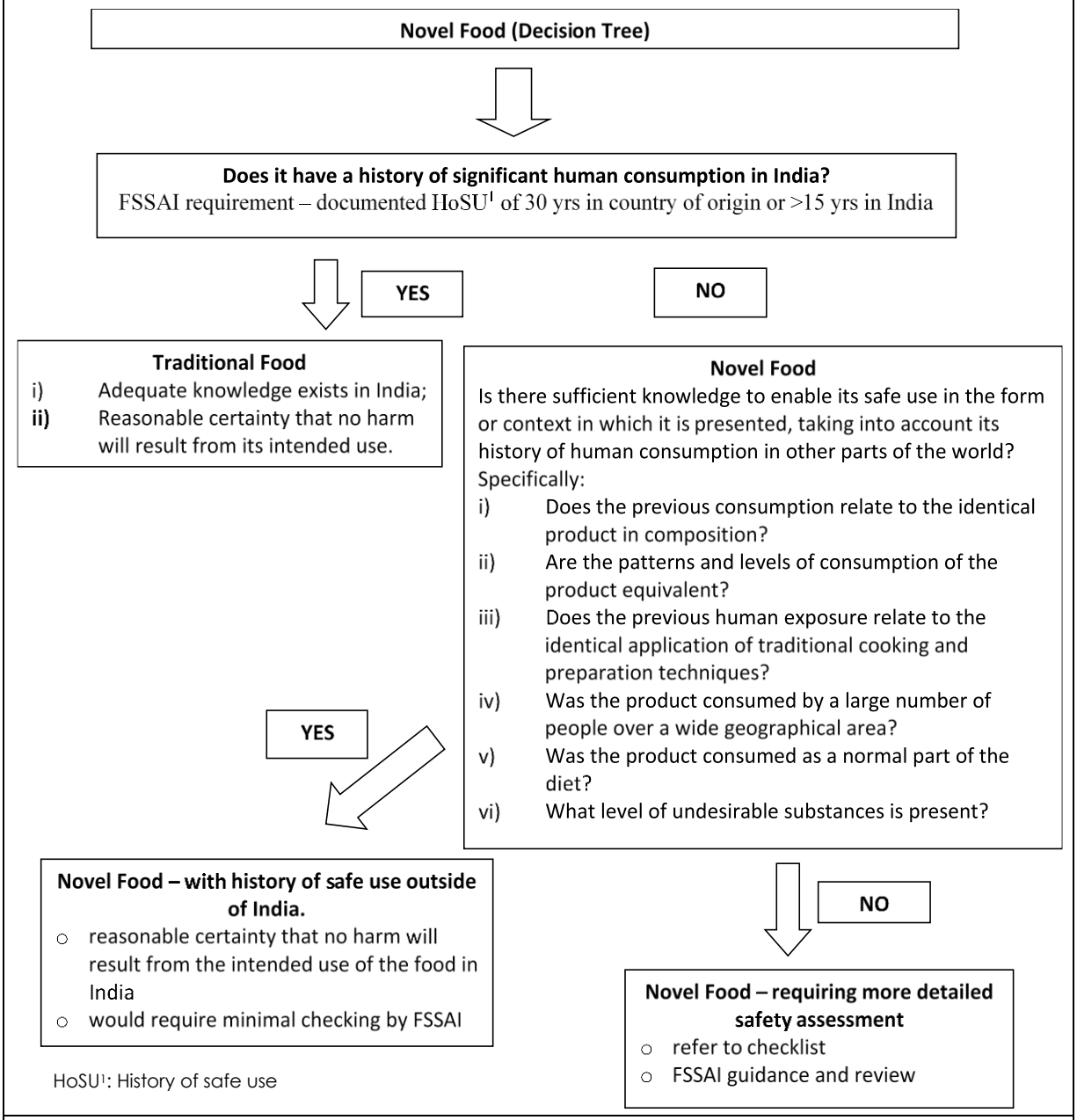
- May not have a history of consumption by humans, or may not have a history of consumption in the region/ country of interest; or
- May not have any history of consumption of any ingredient used in it or the source from which it is derived; or
- the food or ingredient is obtained by using new technology and/or innovative engineering process. This procedure may change the size, composition, or structure of the food or its ingredients – which may in turn change its nutritional value, metabolism, properties/ behaviour or level of undesirable substances.

22. How can one prove that product has a history of use (what evidence or reference should one collect to prove historic use of product)?

- Various databases can be used to establish whether a particular product (food) has a 'history of safe use' as a food or food source. These include national food survey reports, global, regional and national surveys of plants with food uses. The data that is used to describe a 'history of safe use' should preferably be robust and reliable (e.g. peer reviewed scientific publications, governmental documents, Pharmacopeia's and scientific expert opinions) and be taken from referenced sources where possible.
- For example "history of safe consumption as food" for phytosterols and their esters are natural components of fruits and vegetables, with people typically consuming 100-300mg/day. The main sources of phytosterols in the diet are cooking oils and margarines; health margarines typically contain between 300-400mg/100g. Vegetarians typically consume more plant sterols.

23. How does the decision tree simplify the decision making for Risk Assessment process for Novel Foods? [simple step process given below)

Decision tree provides you step wise approach for highlighting the important points necessary for detailed safety assessment of Novel Foods. Decision tree helps the applicant to differentiate between the traditional food versus novel foods based on history of safe use.



HoSU[1]: History of safe use

24. How much time does it take for approval of novel foods?

- Timeline is determined by the risk profile of the ingredient or substance that is submitted for approval. The risk profile is determined by due consideration of the 4 steps of risk assessment namely; hazard identification, hazard characterization, exposure assessment and risk characterization.

- No such timeline is defined in the regulation for the approval of novel foods. The complete application with all relevant documents at the time of submission are placed before the expert committee (EC) for review and further decisions with in a time frame of approximately 3 to 4 months.
- However, if the application is incomplete the time limit of additional days for obtaining clarifications and/or receiving the missing information will further delay the process of placing the application before the EC.

25. Do we need to conduct clinical trials for all novel foods?

- Clinical trials are not always necessary for all novel foods, and will depend on the characterization of specific hazard(s) presented by the ingredient or substance and a determination of its safe level of consumption, including vulnerable groups of individuals. However, a rigorous risk assessment of novel food is necessary before authorisation to ensure consumer safety.
- Post launch monitoring can be done once the novel food is authorised to use on case to case basis if necessary. Post-launch monitoring provides a means to confirm that the actual intakes are within the anticipated range of intake and that there are no unexpected effects when a large population including diseased people and those of a diverse genetic make-up are exposed for potentially long periods of time.
- Clinical trials are decided by the scientific committee on case to case basisto establish the safety in Indian population, it should be done as per the guidelines stipulated in the ICMR for conduct of such clinical trials.

26. What about confidentiality in the novel food regulation?

- Under the Act, the Food Authority shall "not disclose or cause to be disclosed to third party's confidential information that it receives for which confidential treatment has been requested and has been acceded" except under certain conditions.
- All the documents submitted for Novel Food authorization remains with FSSAI. All the scientific committee members involved in the application evaluation bound to sign the non-disclosure agreement prior to assessing the information submitted to FSSAI for Novel Food authorization.

27. What are the conditions for authorisation of Novel Foods?

- A novel food must undergo rigorous scientific risk assessment prior to authorisation for ensuring its safety. A novel food will only be authorised if it does notpresent risk to consumer health.
- If a Novel Food is expected to replace a similar traditional food, it should not be nutritionally disadvantageous and should not be misleading to the consumer.

28. How to apply for novel food authorisation in India?

- Applicant should submit the application for novel food authorization as per the details given in 'Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017. Applicant should submit an application in FORM – I of these regulations along with necessary documents and fee to the Food Authority.
- In preparing the application, scientific data and information relevant to the food should be collated and presented bearing in mind the 4 steps of risk assessment (hazard identification, hazard characterization, exposure assessment and risk characterization).

  The Food Authority may either grant approval or reject the application, as per FORM-II, on the basis of the safety assessment of the novel food(https://fssai.gov.in/upload/uploadfiles/files/Gazette_Notification_NonSpecified Food_Ingredients_15_09_2017.pdf).

29. How can one know if novel food authorisation has already been granted to a product or ingredient?

The FSSAI website can assessed to check the list of authorised Novel Foods.

30. How to know whether a process used for making a Novel Foods is novel or not?

- A food that has been manufactured, prepared, preserved or packaged by a process that has not been previously applied to that food, and causes that food to undergo a major change (Outside of natural variation)" is considered as a novel process.
- If a process does not give rise to any significant changes in the composition or structure of the end-products which affect their nutritional value, metabolism or level of undesirable substances, the process is not considered a novel process.