

## **Frequently Asked Questions on Food Safety and Standards (Approval of non-specified food and food ingredients) Regulations, 2017**

**1. How does FSSAI address the concerns of FBOs regarding the food or food ingredients other than proprietary foods, which are not covered under Food Safety and Standards Regulations (FSSR)?**

FSSAI has notified Food Safety and Standards (Approval of non-specified food and food ingredients) Regulations, 2017 (hereinafter referred as NSF regulations) on 11.09.2017. These regulations lay down the rules and procedure for grant of prior approval of NSF and FI. Link for accessing the same is <https://www.fssai.gov.in/cms/food-safety-and-standards-regulations.php>

A notice dated 28<sup>th</sup> September, 2017 has been issued describing its implementation and fee structure. The same can be accessed at <https://www.fssai.gov.in/cms/non-specified-food.php>

**2. In case, my product does not confirm with product standards specified by FSSAI, but a combination of various standardized product, do I need to apply under NSF regulations?**

No, you need not have to apply under these regulations. Such types of products will fall under 'Proprietary Foods' and you need to comply with the provisions mentioned for the proprietary food category under FSSR.

**3. If my product confirms with specific product standards laid down under FSSR except one parameter, do I need to apply for approval as a NSF?**

It is advisable to comply with the quality standards of the product. In case of non-compliance with any parameter, you need to apply under NSF regulations with the clarity and supporting document for deviating from product standards specified under FSSR.

Or

It is advisable to comply with the standards specified under FSSR. In case, any changes is proposed, you can also submit a representation to the Authority (Standards division) with relevant supporting document for revising the particular parameters in the specific standard, which will be placed in the concerned Scientific Panel for deliberation.

**4. What does non-specified food or food ingredient means?**

Food products/ingredients that are neither standardized nor fall under proprietary food category as mentioned under Food Safety and Standards Regulations are called as NSF or FI.

**5. What food categories do these regulations cover?**

These Regulations broadly cover the following articles of food or food ingredients:

- Novel food or novel food Ingredients or processed with the use of novel technology
- New additives
- New processing aids including enzymes
- Articles of food and food ingredients consisting of or isolated from microorganisms, bacteria, yeast, fungi or algae.
- Any other non specified food

**6. Does food or food ingredients which are not listed under FSSR but available in other countries fall under the category of novel food?**

No. It will fall under any other non-specified food category and not the novel food.

**7. What is a novel food or food ingredient?**

Novel food or food ingredient is a food or food ingredient that may not have a history of human consumption; or may have any ingredient used in it which or the source from which it is derived, may not have a history of human consumption; or a food or ingredient obtained by new technology with innovative engineering process, where the process may give rise to significant change in the composition or structure or size of the food or food ingredients which may alter the nutritional value, metabolism or level of undesirable substances.

**8. What is a new additive?**

A new additive is the one, which is not listed or included in the FSSR for the Specific food category, this includes the additives assessed by JECFA for safety and is included in Codex and or available in other recognized regulatory bodies.



**9. Can application be made under these regulations to change the ADI of an Additive?**

No, the application may not be considered, as the ADI for an additive is fixed by the JECFA and the same is endorsed by the Codex. FSSR has no specific mention about ADI for additives and the one prescribed by Codex is applicable for all the additives listed under FSSR.

**10. Can the firm apply for an additive that is not included in the specific food category for example an additive is allowed in Food Category 6 but not allowed in Food Category 7?**

No, the additives specified in FSSR are harmonized with Codex, hence the request to include/use the same in a category where it is not permitted will not be considered. However, if the additive is included in Codex or revised recently in Codex GSFA then the firm can make an application quoting the same for consideration under Non- Specified foods Regulations or by making a representation to the Scientific Panel on Food Additives.

**11. Can the firm apply for revision of the limit of Additives specified for the food category?**

No, the same may not be considered, however if the Codex GSFA revised the limits and the same is not adopted by FSSR, then the firm can apply for revision of the same either through NSF approval or by making a representation to the Scientific Panel on Food Additives.

**12. What is a new processing aid?**

A new processing aid is the one, that is not listed in FSSR, but available in the Inventory of Codex or in any other well recognized regulatory bodies.

**13. Does FSSAI give approval for GM food under these regulations?**

No, currently products/ingredients from GM origin are not permitted under FSSR. FSSAI is in the process of finalizing regulations/guidelines for the safety assessment of such food. The application will be considered on the notification of such regulations/guidelines.

**14. If the enzyme/ ingredient does not contain GMO, but if it is sourced from GMO will it be considered?**

No, currently it shall not be considered the same may be considered once relevant regulation/Guidelines on GM is available in FSSAI.

**15. If the manufacturer/importer wishes to formulate a product e.g. with 3 approved ingredients and 1 unapproved ingredient, does the firm need to apply for the approval of single unapproved ingredients or the product as a whole?**

The Manufacturer or Importer can choose to apply either for the approval of the single non-specified ingredient (or) for the product as a whole.

In case the FBO apply for the approval of single non-specified ingredient, it is recommended to mention the end use and apply as an intermediary product, and the Authority shall grant approval for that particular single non-specified ingredient. (or) If the FBO apply for the product as a whole, then the approval shall be granted for the product. The ingredient approved for use in the particular product cannot be allowed for use in other products .

**16. What is the mode of application and whom does the application need to be addressed?**

Currently the applications are being made manually. FSSAI is also working on online mode which will be made available once completed. The application shall be addressed to the CEO, FSSAI, FDA Bhawan, Kotla Road, New Delhi -110002 or Advisor (Standards), FSSAI, FDA Bhawan, Kotla Road, New Delhi -110002.

**17. What is the fee and mode of fee payment?**

A fee of Rs. 50,000/- only (Fifty thousand only) per application (per product or per ingredient) needs to be submitted via demand draft or cheque, payable to Senior Accounts Officer, FSSAI. Please ensure that the Demand Drafts, wherever submitted, are recent and are not left with a rather short period to become invalid. In case the DDs become invalid for any reasons, the applicant would be required to revalidate the same before the application is taken up for consideration.

**18. If approval is sought for two products with a slight change in the composition, can it be considered under a single application?**

No, it shall not be considered under a single application, the applicant shall make a two different application with requisite fee

**19. If approval is sought for two products with similar composition, but change in quantity, can it be considered under a single application?**

Yes, it may be considered under a single application



**20.If the applicant wishes to change the composition of the product/functional property of the product after filing the application, can it be considered under the same fee/application or they have to make a separate application with a fresh fee?**

The Authority may consider applicants request to change the composition of the product or the functional property of the product, within one-week time after submission of the application. However, if tangible action is initiated in the application the request regarding change in composition or the functional property shall not be considered by the Authority. In such cases, the applicant has to make a separate application with a requisite fee.

**21.If the composition of the product is not changed, but only the source of the ingredient used is changed, can it be considered under the same fee/application or they have to make a separate application with a fresh fee?**

It may be considered on a case to case basis under the same application / same fee.

**22.If the applicant wishes to change category in between such as from Health supplement to FSDU can it be considered under the same fee?**

It is advisable that the applicant shall make the application with a clear specification of the category to avoid the change in category after filing the application. Applicants shall go through the FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 (hereinafter referred as Nutraceutical regulations) for reference of the specific category.

**23. Is the fee submitted along with the application refundable?**

No. The fee once submitted is not refundable if tangible action is initiated.

**24.Can the firm withdraw the application made without asking for refund at any stage of the process of application?**

Yes, the firm may withdraw the application made without asking for refund at any stage of the process of application

**25.Can I request a refund if my application gets rejected?**

No.

**26.Is there any specific format and list of documents which need to be submitted for examination under these regulations?**

Yes. The documents shall be as per requirements of Form I provided under these regulations for consideration and further examination.

**27. Why Form I is divided into general information and additional specific information?**

All applicants are required to furnish the general information (20 parameters). In case of categories other than 'Any other non-specified food' applicants are required to submit additional information as applicable to the specific category along with the general information.

**28. Is it mandatory for all FBO's formulating products containing or isolated microorganisms to furnish information on Articles of food and food ingredients consisting of or isolated from microorganisms, bacteria, yeast, fungi or algae?**

Yes. In case of an application of food or food ingredients consisting or isolated from microorganisms, yeast, bacteria, fungi or algae, the FBO shall submit information as per clause 3 (d) of Form-I specified under NSF regulations along with other general information.

**29. Is it necessary to submit all the information? What will happen if my application is incomplete?**

Yes, it is necessary to submit a complete application with all relevant supporting documents. In case, the applicant furnishes incomplete information, the division will seek clarification based on the preliminary scrutiny and the applicant will be informed to submit the requisite information within stipulated time period. This may delay the process of examination. Hence it is always advisable to submit complete information as per the Form I.

**30. What mode does FSSAI use to respond to the FBO on scrutiny of the application?**

The FBO will receive the clarifications sought by the Authority in both soft and hard copy. The contact details (email, contact address etc.) as provided in the application form will be used by the Authority for such communication.

**31. How should the FBO respond to the clarification sought by the authority?**

The FBO shall send the hard copy of the replies to the queries sought by the Authority which should be duly attested by the Authorized person. In addition, they shall also send the scanned copy of the same through email.



**32. What is the time duration given to the FBO to reply to the clarification?**

FBOs will be given 30 days' time period to submit the necessary clarification sought by the Authority from the date of issue of the clarification letter. Despite 30 days if the applicant furnishes incomplete information, the Authority may provide additional 15 days' time to submit the necessary clarification. In case the applicant has furnished all the major documents and failed to provide any minor information, then authority may seek the same by mail, giving maximum of 7 days to submit remaining information. So in actual, a maximum of 2 reminders (45 days duration) as specified shall be given to furnish the complete information, beyond this the application shall be considered for closure.

**33. If the FBO failed to submit the response on time, then what happens to the application?**

FBO can always write a letter to FSSAI stating the reasons of delaying of submission of requisite documents and mention the time needed to do so. In case, FBO fails to submit the desired documents/information within the extended timeline, a reminder will be sent to submit the same. In case, even after getting reminder, the information/documents are not provided by the applicant, FSSAI will send a closure notice before closing such application.

**34. Can FBO submit additional information other than those listed in the Form I?**

It is better to provide the additional information such as detailed composition (in case of product), information on the need and scientific rationale for combining the different ingredients and whether these combination has any synergistic or antagonistic effect along with supportive document (in case of product), proposed label of the product, End use declaration covering aspects like target group, dosage, duration of usage., claim to be made on the product and supporting document namely systematic review, human studies etc., detailed method of analysis and technical specification. It is highly recommended and useful to speed up the process and to arrive at a decision.

**35. Do I have to submit the label along with the application form?**

Although it is not a mandatory requirement as per NSF regulation at present, FBO need to submit the label as per FSSR along with the application. In case of premix, prototype label for the intermediary product needs to be submitted.

**36. Is the firm required to submit technical specification and method of analysis, and why?**

Although it is not a mandatory requirement as per NSF regulation at present, it is recommended that if the firm is making an innovative product, or manufacturing or importing a novel botanical/herb, for which technical specification and method of analysis is not available and the firm has developed a new method of testing and

technical specification , the same need to be shared with the Authority along with the application. The Authority will share the same with the referral labs & licensing authorities as a reference test method and specification for testing the products once it is placed in the market.

**37.What kind of additional information/documents need to be submitted with regards to Technical specifications?**

It shall be firm’s in-house product/ingredient specifications on its letter head covering the following information:

S.No.	Tests	Specifications*	Test Method#

\*Provide the acceptable tolerance limits giving lower and upper values as applicable.

#Give reference to any official method prescribed, for example AOAC / BIS / FAO/ IP / BP etc. If it is not an official method provide a reference to a document or provide the method in detail in this document after the tabulated data of specifications. Such methods should describe in sufficient details for any qualified and trained analyst to perform the testing. FBOs should retain validation of the method data with them for submission when requested.

	Prepared By	Approved By	Authorised by
Name			
Designation			
Signature & date			

**38.Is a test for marker compound mandatory?**

It is recommended to provide the same in the certificate of analysis especially for botanicals, herbs and nutraceuticals.

**39.Do I have to mention the end-use of the product, if I am applying for the approval of an ingredient or pre-mix?**

Yes, if the FBO have the information on the end use then it is appropriate to share the same, in case if they are planning to give the premix to other third party manufacturers and if they don't have information on the end use, in such instance the FBO shall share the necessary information stated in the Form II to the end use formulators.



**40. Do I need to provide the serving size of the product?**

Yes, it is advisable to provide the serving size of the product (number of servings per day)

**41. Can the firm make a claim to be used on the label of the product?**

Yes, the firm can submit details of claim to be made on the product/ingredient label along with NSF applications. The firm shall also submit sufficient scientific substantiation to support the claim which will be reviewed by the Authority before approving or rejecting the same.

**42. Do I have to submit a separate application for claims approval along with the application of Non- Specified food ingredient/ product approval application?**

No, there is no need to apply separately for claims approval in case of NSF and FI. However, the applicant shall clearly state the claim(s) to be made on the label with sufficient scientific literature to support the same while applying for approval of such product.

**43. How much time does the Authority take to decide on approval /rejection of application?**

No such specific timeline is defined. The complete applications with all relevant documents at the time of submission are placed before the Expert Committee(EC) for review and further decisions within a time period of approximately 3 to 4 months. However, if the application at the time of submission is incomplete the time limit of additional days for obtaining clarifications (as specified for question No 32) and the missing information will further delay the process of placing the application before the EC.

**44. Is the email and address of the authorized person mandatory to be mentioned in the form?**

Yes, all communications will be made vide the email and letters will be addressed to the address of the authorized person.

**45. Can there be two different names; one as applicant's name and other as authorized person's?**

Yes, but the firm shall provide the contact details of the authorized person to share all necessary information.

**46. Is there any difference between authorized office address and registered office address?**

Yes, the registered office for the firm can be different from the manufacturing unit. The firm shall provide both and clearly mention where the communication to be sent to.

**47. Can exporters from outside India without having any office in India apply for approval under these regulations for the foreign address?**

Exporter having registered office address outside India can only apply for approval under NSF regulations through an importer having registered office in India. In such case a valid copy of agreement between the manufacturer (outside India) and importer shall be submitted along with the application.

**48. What kind of information is required under the nature of business?**

Information such as whether the FBO is manufacturer, Importer, marketer, is to be provided.

**49. What kind of information is expected under justification of the name?**

In case the product has a brand name the justification behind the same needs to be provided.

**50. Does the firm have to mention the detailed composition of the product?**

Yes, it is recommended to provide the detailed composition of the product with quantities along with the list of ingredients & additives.

**51. Is it necessary to mention the source of the Ingredient/product?**

Yes, the Source of food ingredient(s) whether it is from animal, chemical, botanical or micro-biological can be clearly mentioned in the application. In case of animal, botanical or micro-biological source, the genus and species of the organism shall be mentioned.

**52. Do the firms have to provide GMO/Non-GMO certification/declaration?**

Yes. The Authority may seek declaration from the firm about GMO/Non-GMO for certain products/ingredients on case to case basis.

**53. What kind of information is expected under the proposed category?**

The FBO shall provide details of licensing category of the product/ingredient based on the intended use as per the Food categorization system given under Food Licensing



Registration System (FLRS). For example, in case of intermediate products/ingredients then the same shall be sub categories of 99 (i.e Substance added to food and its sub categories like functional ingredients etc.), as applicable. If it is a final product such as health supplement then 13.6.

**54. What is to be mentioned under functional use?**

The FBO shall mention proposed health/nutritional benefit claimed for the applied product. In case the product is a mixture of various ingredients, the combined benefit of the applied product shall be mentioned instead of the benefits of individual ingredient used for preparing the product.

**55. What is to be mentioned for intended use of the product?**

The FBO shall mention specific end use of the applied product including target group, usage level, duration of use, any contraindications or advisories etc.

**56. What details need to be covered under Certificate of Analysis (CoA) parameter?**

One complete CoA covering all physical parameters, chemical parameters like nutritional details, active component, heavy metals, residues and microbiological parameters, pesticide residues, naturally occurring toxicants (if any) relevant to the product along with the validated test method and other test methods, if any with references wherever applicable need to be provided.

**57. Are there any specific requirements for the food testing labs from where I can get CoA?**

Yes. The CoA shall be from third party National Accredited Board of Laboratories (NABL) or International Laboratories Accreditation Cooperation (ILAC) recognized laboratory. Such certification details shall be submitted as part of application.

**58. Will it be considered if I submit CoA of in-house lab having NABL or ILAC certification?**

As per NSF regulations it is mandatory to submit CoA from third-party NABL or ILAC recognized laboratory. Therefore, CoA of in-house lab having NABL or ILAC accreditation will not be considered.

**59. Whether a detailed manufacturing process needs to be submitted as part of the application?**

In case of non-specified food, only a brief of the manufacturing process preferably in flow chart explaining all critical steps is considered sufficient. However, a detailed

process with step by step explanation is needed in novel food or food ingredient applications or ingredient/product made out of novel technology.

**60. What is a Copy of agreement? Is it necessary to submit the same?**

A Copy of agreement is an agreement made between applicant and manufacturer, and other entities involved in the food business of the proposed product namely marketer, importer and re-packer. In case, if the manufacturer himself is the marketer, then there is no need to submit the same. However, submission of copy of agreement is mandatory in case of following conditions:

- a) when applicant is an importer and manufacturer is from outside India;
- b) when applicant is a marketer or a re-packer and manufacturer is different

**61. What kind of documents need to be submitted under regulatory status?**

Information related to approval of the ingredient/product in other countries along with evidence such as regulatory status from a well-recognized regulatory body is required to be submitted. The pictures of label of the products will not be considered as an evidence.

**62. What kind of documents need to be submitted as supportive documents for safety and efficacy studies?**

The applicant shall submit only the relevant documents in a precise manner from authentic source and complete published articles from peer reviewed journals. Reports shall include safety studies both preclinical and clinical data.

**63. Are toxicological studies/tests and Allergenicity studies mandatory?**

Yes, it is mandatory for Novel ingredients/Products. However, the FBO shall submit the same for, new ingredients, botanicals, herbs, ingredients/products from animal origin

**64. What documents need to be submitted for history of consumption of the Product/ingredients?**

Yes, as stated in the NSF Regulation the Geographical area of use (with established history of safe use in at least two countries, with well-established regulatory status), the Quantity of consumption & the duration of consumption (in years)



**65.If no safety and efficacy data available in the Indian population, then what to do?**

Unlike drugs, food is consumed by the common man with no supervision in most instances. Thus, it is important to provide safety data of use of the product in human population. To approve the product as 'food' in India, the history of safe use for 15 years in India and 30 years in the country of origin is a requirement as per the Nutraceutical regulations and in addition the safety data from Indian population if available is preferred. However, if the safety data from Indian population is not available, the applicant can submit relevant safety studies available on south east Asian population for consideration. In case of novel foods and new ingredients where the safety data from Indian population will not be available, the FBO shall have to conduct the clinical trial in consonance with the guidelines stipulated in the ICMR including ethical clearance, and where the product is to be imported the FBO shall import the ingredient/product for the purpose of R & D as stated in the FSS (Import) Regulations,2017 to conduct the clinical trials to generate the safety data for approval of the product / ingredient

**66.Does the FBO need to provide a declaration that the Product or ingredient will not have an adverse effect on the vulnerable population?**

The FBO shall provide a declaration on the Product or ingredient that it will not have an adverse effect on the vulnerable population (infants, pregnant & lactating mothers and elderly population) especially if the product is intended to be used by the population of all age group and specified physiological conditions.

**67.Are the recommendations of the Expert Committee treated final for approval or rejection of the application?**

The recommendations of the EC will be approved by the Competent Authority, the approval of the Competent Authority shall be treated final to issue the Form II (Approvals & Rejections)

**68.Can approval be granted in the name of the brand or brand name?**

No, approval will not be granted in the brand name of the product, it will only be granted to the functional consequences of the ingredients/products.

**69.Whether the approval or rejection is granted to a specific firm or it can be applicable to any FBO?**

Approval or rejection are for the specific firm who applied under NSF regulations based on their documents submitted.

**70.If approval is granted for a firm, can another manufacturer/importer manufacture/import the same, without applying for NSF approval?**

No, it is not applicable till the time the ingredient(s) are included in the regulations. Hence another manufacturer /importer has to apply separately to the authority wherein they can provide the reference of the approval already granted to the ingredient/product.

**71.Is the importer required to obtain prior approval before importing the consignment of products falling under NSF regulations?**

Yes, it is mandatory for the Importer to get prior approval of the NSF ingredient/product before importing the same.

**72.Will the Authority have the power to withdraw the approval granted?**

Yes, the Food Authority may, for reasons to be recorded in writing, suspend or revoke any approval granted to any food business operator.

**73.Whether the firm has to apply/get a license/registration prior to applying under NSF regulations or vice-versa?**

Approval under NSF regulations is a pre requisite requirement for applying for license/registration under Food Licensing and Registration System (FLRS) for any non-specified foods.

**74.Does the firm apply for State/Central License on grant of approval under NSF Regulation?**

The FBO shall apply for Central Licensing for Non- Specified food ingredients/Products.

**77.Do I have to comply with one Recommended Dietary Allowance (RDA) for the product formulation applied under NSF regulations?**

Yes, as stated in the FSS Act, 2006 all the product formulation shall comply with the one RDA of ICMR. In case of Food for Special Dietary Use (FSDU) and Food for Special medical Purpose (FSMP) the relevant provisions mentioned in the Nutraceutical regulations can be followed.



**78. Can I use the TUL of vitamins or minerals for formulation of NSF?**

No, Tolerance upper limit is uploaded in the website only for reference, all the product formulation shall comply with the one RDA of ICMR. In case of FSDU and FSMP the relevant provisions mentioned in the nutraceutical Regulation can be followed.

**79. When will the application be considered as closed by the Authority?**

The application will be **considered for closure** by the Authority in the following instances:

- i. When the applicant fails to submit the necessary information for the clarifications sought by Authority on repeated reminders as detailed in Q. No. 32.
- ii. If the applicant wishes to withdraw the application

In above cases, the application will be considered for closure by the Authority.

**80. On what grounds, the products applied under NSF regulations gets rejected by the authority?**

The ingredients/products may be rejected by the Authority, if

- i. the safety and efficacy of the ingredient/product is compromised;
- ii. it is akin to a drug;
- iii. sufficient data/studies are not available to substantiate the safety & efficacy of the product/ingredient.

**81. If application got rejected, does regulation allows the FBO to file an appeal?**

Yes. Appeal can be made to Chairperson, FSSAI within 30 days from the date of rejection. The appeal shall be supported with scientific evidence as supporting documents against the reasons of rejection.

**82. Can the product once rejected be approved again by making an appeal?**

If the product is rejected based on the safety and the efficacy data and the applicant fails to produce any further data to substantiate the safety and efficacy of the product, it cannot be approved even after making the appeal. However, the product that has been rejected based on the insufficient safety data, or any other relevant reasons and the applicant produces the additional data to substantiate the safety and efficacy of the product the application can be reconsidered for review after the appeal

**83. What are the documents to be submitted along with the appeal once the product is rejected?**

The applicant shall submit relevant documents to challenge the grounds of rejection, and to provide item wise rebuttal to the reasons for rejections along with sufficient and authentic scientific literature.

**84. Can I change my intended use while submitting my appeal for the rejected products?**

No. The intended use also shall be as per the original application. In case of any change in intended use while submitting appeal after the product has been rejected, shall not consider under appeal.

In case of new intended use of once rejected product the FBO shall submit a fresh application with all relevant information . .

**85. Who is the appellate authority for NSF approval?**

Chairperson, FSSAI is the appellate authority for NSF approvals

**86. When will the firm get a personal hearing from the Chairperson, FSSAI?**

If the application gets rejected after first review by EC, the applicant shall file an appeal to the Chairperson, FSSAI. The appeal once received will be placed before the Expert Committee on NSF for further deliberation. If the Committee reiterates its earlier decision of not recommending the product/ingredient for approval, then the Authority will request the applicant to clearly state whether they require a personal hearing before the Chairperson, FSSAI, within 15 days of the issuance of the letter

**87. What is the appellate order denoting?**

The Appellate order issued by the Appellate Authority is the final decision on the application and the applicant is expected to comply on the same.

**88. If the FBO aggrieved by the decision of Chairperson, then how to proceed further?**

Food business operator, who is aggrieved by the decision of the Chairperson, Food Authority may file a review petition to be placed for consideration in the meeting of the Food Authority.

**89. Are the details of approved/rejection will be made available on FSSAI website?**

Yes, the same will be uploaded on the FSSAI website for information. The same can be accessed at <https://www.fssai.gov.in/cms/non-specified-food.php>



**90. In case, I find any error in the Form-II (Approval letter) issued by FSSAI, can I approach the Authority for modification in Form-II?**

Yes. You can mention the modification to be done in your representation and attach the Form-II (Approval letter) issued to you. Revised Form-II will be issued and the earlier Form-II issued will stand withdrawn. In case, the Authority does not agree with the modifications suggested by you, a letter will be issued from the Authority's with a reason that why the same was not considered.

**91. If my application is rejected earlier and subsequently after appeal, the same is approved, whether the rejection letter (Form-II) issued by FSSAI will still be valid by the Central/State Food Authority?**

No, the Rejection letter (Form-II) issued earlier will be withdrawn by FSSAI and the same will be mentioned in your final Approval letter (Form-II), which will also be shared with central/state licensing and importing Authorities.

**92. After approval is granted, is it necessary to submit CoA of the approved product/ingredient once again?**

As per NSF regulation, it is mandatory to submit the CoA of the approved product/ingredient to the Authority within one year of placing the product in the market.

**93. My Form-II (Approval letter) issued for the application mentions submission of post-market surveillance data for the product as conditions of approval. In case, I fail to submit within the timeline or the product shows any adverse effect, will the approval be cancelled by the Authority?**

The firm needs to submit the post-market surveillance data for the approved product within the timeline specified in the Form-II (Approval letter). In case the firm fails to submit the data within the timeline, the Authority will take necessary decisions regarding the product. Besides, if any report shows that the product has an adverse effect or is not safe for human consumption, the Authority can cancel the approval given earlier and the license granted. The FBO shall recall the product from the market immediately with intimation to the Authority.

**94. Is post-market surveillance required for all the products that are approved under NSF regulation?**

The Authority may ask the applicant to conduct the post-market surveillance of the product/ingredient approved under NSF regulations, if required on a case to case basis. The firm shall submit the same for review by the Authority within 1 year of placing the product in the market.

**In case, an FBO changes their product composition after the approval, whether they need to submit a new application with requisite fees or can continue with the old application.** The applicant shall comply with the composition such as ingredients and additives along with their quantities as provided with the original application. In case, any change is made in composition of the product (addition or deletion of ingredients, additives or to increase or decrease the quantities of the ingredients and additives) FBO shall submit a new application.

**95. In case, there is a change/revision in the artwork of the product label, whether a FBO need to take approval for the same from FSSAI?**

FSSAI do not approve the product label under the NSF regulations. However, if any health claims/nutrients claims are being made on the label except that are permitted under FSSR, the FBO shall apply for claims approval as per the procedure mentioned under FSS (Advertising and Claims) Regulations, 2018.

**96. In case, any FBO find their approved product as not safe for human consumption at any point of time, how to approach the Authority?**

The FBO, in any circumstance has a reason to believe that the approved product is not safe for human consumption, the FBO shall immediately suspend the manufacture, import, sale, or distribution of such article of food and take steps to recall the same under intimation to Food Authority in accordance with the provisions of the Food Safety and Standards (Food Recall) Regulations, 2017.

**97. If the intermediary product is approved under the NSF regulations and firm wish to provide such ingredient to other company or use it in final product at their own company, do the firm or the other company has to apply for approval of that final product again?**

The applicant or the other company shall not require a separate approval if the approved is an intermediary product and shall be used in the quantities as specified in Form II for formulation along with other ingredients standardized and allowed under FSSR for the specific category.

**98. Can the firm use the ingredients listed under Nutraceutical regulations in the product for which an approval is sought?**

Yes, the firm can use the ingredient with the specified quantities listed under Nutraceutical regulations. In case, there is any deviation from the quantity or source of that ingredient, then the firm have to apply for approval.

**99. Will the EC provide audience to the applicant on request?**



EC may provide audience to the applicant on a case to case basis, as and when required.

**100. Is clinical trial mandatory for all the products or ingredients for its introduction in the Indian market?**

Clinical trial is not mandatory for all the ingredients /products applied under the NSF Regulation. However, novel products, new ingredients including plant or botanicals, herbs, ingredients/products from animal origin may require a clinical trial on Indian / South Asian Population, for its introduction in the Indian market on a case to case basis

**101. Are there any guidelines defined by the Food Authority to conduct clinical trials in food on Indian Population?**

Currently there are no guidelines available with the Authority to conduct clinical trials in the Indian population. In the absence such specified guidelines for food by the Authority, the FBO's shall conduct the clinical trial in consonance with the guidelines stipulated by the ICMR including ethical clearance.

**102. Will the Authority maintain the confidentiality of the information shared by the applicant?**

The firm shall inform the Authority regarding the information is to be kept confidential while submitting the application and FSSAI is obliged to maintain the confidentiality of the information under the Section16 (6) of the FSS Act, 2006.