

Frequently Asked Questions (FAQs) on the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 (herein after referred as Nutraceutical Regulations) dated 06.10.2021

1. Are there any regulations in India specified for functional foods such as health supplements/nutraceuticals/probiotic /prebiotic foods?

Yes. The Food Safety and Standards Authority of India had notified the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 in the Gazette of India on 23.12.2016 and the same is available on FSSAI website www.fssai.gov.in. Link for the same is <https://www.fssai.gov.in/cms/food-safety-and-standards-regulations.php>. Any Food Business Operator (FBO) who wishes to manufacture, import, sell these products shall have to comply with these regulations.

2. What is the scope of these regulations?

These regulations will be applicable to foods covered under the following categories:

- i) Health Supplements
- ii) Nutraceuticals
- iii) Food for Special Dietary Use (FSDU)
- iv) Food for Special Medical Purpose (FSMP)
- v) Food with added Probiotic ingredients
- vi) Food with added Prebiotic ingredients
- vii) Specialty Foods containing Plant or Botanical Ingredients
- viii) Novel Food (Need prior approval as per FSS (Approval of non-specified food and food ingredients) Regulations, 2017).

3. Why category of 'Functional Foods' has not been created under these regulations?

The term 'Functional foods' means foods that provide benefits beyond basic nutrition and may play a role in reducing the risk of certain diseases and other health conditions, as described in these regulations. The likely categories where functionalities can be linked to either ingredients or the products so made, have been created under these regulations and fall under the basic definition of 'Functional Foods'.

4. What is the date of implementation of these regulations?

The Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 were Gazette notified on 23.12.2016. However, the FBOs were required to ensure compliance of their existing and new products with all the provisions of these regulations and subject to enforcement activities from 01.01.2018. Since some of the issues under the regulations were still under consideration of the Authority and the finalisation of the amendments was likely to take some time, various directions dated 29.12.2017, 29.06.2018, 24.08.2018, 31.12.2018 and 10.05.2019 have been issued for clarification w.r.t implementation of the various provisions of these regulations. The same is available on FSSAI website www.fssai.gov.in. Link for the same is <https://www.fssai.gov.in/advisories.php>

5. Do these regulations cover products/formulations for the different categories mentioned above?

These regulations cover ingredients and additives allowed to be used in different product categories specified under these regulations. FBO shall formulate the products based on the permitted ingredients, additives, and also in compliance to the other requirements specified under these regulations.

6. Which ingredients and additives can be used for preparation of foods covered under these regulations?

FBO's may use one or more ingredients and additives from various schedules specified in these regulations for respective category, as applicable. For example, in category nutraceutical at least one ingredient from those specified in Schedule VI would be required and ingredients specified in other schedules permitted in nutraceutical category may or may not be used.

In addition, these products may also contain ingredients, other than additives, which are either standardized or permitted for use in the preparation of other standardized foods as specified in the FSS (Food Products Standards and Food Additives) Regulations, 2011.

7. Do these regulations allow products in tablet/capsule/syrup formats?

The aim of these regulations is to promote maintenance of health primarily through food formats. However, as permitted under Section 22 FSS Act, 2006 tablet, capsule and syrup formats may also be used for presentation of certain products, as applicable.

8. Are there any extraction solvents specified for obtaining plant or botanical extracts?

As per the Section 22 FSS Act, 2006 a FBO may use water, ethyl alcohol or hydro alcoholic process for obtaining plant or botanical extracts used in the products covered under these regulations. Any new extraction method requires prior approval from the Authority.

9. Are there any restrictions for combining ingredients specified in these regulations?

There are no specific restrictions for combining ingredients. It is the responsibility of FBO to keep in mind the potential synergistic or antagonistic interactions amongst a combination of ingredients leading to impact on stability, bioavailability, safety, and efficacy. FBOs are required to provide data on the scientific rationale for formulating such combinations, based on the scientific literature in peer reviewed publications or data generated by FBO's/innovators or suppliers of such ingredients to the Authority as and when demanded.

10. Can products covered under these regulations claim to prevent or treat or cure any disease?

No. The products with these claims are more akin to drugs which do not fall under the ambit of FSSAI. Therefore, the labelling, presentation and advertisement of the products covered under these regulations shall not claim that the product has the property of preventing, treating or curing a human disease.

11. How are the foods under these regulations different from normal foods?

Food or ingredient as specified in FSS (Food Products Standards and Food Additives) Regulations, 2011, and for which standards are provided, and the plants and botanicals listed in Schedule IV to these regulations offered in normal or naturally occurring food form shall not constitute a 'Health Supplement' or 'Nutraceutical', or 'Food for Special Dietary Use' or 'Food for Special Medical Purpose'.

Vegetables (eg. bhindi, karela etc.), cereals (eg. ragi, jowar, millets etc.), legumes (eg. Rajmah etc.), spices (pepper, jeera, turmeric etc.), fruits (amla, jamun, grapes etc.), and other plants or botanicals, minimally processed (cleaned, de-weeded, sorted, dried or powdered), in either as juice or cooked form, shall not constitute 'Health Supplement' or 'Nutraceutical' or 'Food for Special Dietary Use' or 'Food for Special Medical Purpose'.

12. Do these regulations cover foods for infants?

No. The regulations are not applicable to infants up to the age of 24 months. The standards for foods for infant nutrition are specified under 2.1.19 of the FSS (Food Products Standards and Food Additives) Regulation, 2011, and any other new product needs prior approval of the Authority. Further, 2.1.19 of FSS (Food Products Standards and Food Additives) Regulation, 2011 were revised and gazette notified as Food Safety and Standards (Foods for Infant Nutrition) Regulations, 2020 on 04.12.2020 which will be effective from 01.04.2022 for compliance.

13. When a conventional food or food for mass consumption contains nutrients, bioactives, prebiotics or probiotic organisms, does it automatically come under these regulations?

No. Since conventional foods or foods for mass consumption can also have these ingredients by its natural composition, such a food shall not be considered as supplements or nutraceuticals or probiotic or prebiotic food. Therefore, if an article of food which has not been particularly modified in any way but is suitable for use in a particular dietary regimen because of its natural composition, then such food may bear a statement on the label that 'this food is by its nature X' (where 'X' refers to the essential distinguishing characteristic as demonstrated by the generally accepted scientific data) to make consumer aware.

14. Are mere combination of vitamins and minerals in the tablet, capsule, syrup formats allowed as per these regulations?

FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) first amendment Regulations, 2021 Gazette notified on 06th September, 2021 mentions that 'The combination of vitamins and minerals, including use of single vitamin and mineral, in dosage formats such as tablets, capsules, syrups, at levels equal to a maximum of one Recommended Dietary Allowances or below shall be covered under these regulations'. The same shall come into force on the date of their publication in the Official Gazette and FBO shall comply with all the provisions of these regulations with effect from 1st April, 2022.

15. Whether the lists of food additives specified in Schedule VF are limited to food formats such as tablet, capsule and syrup only?

Yes. Currently, the Schedule VF additives (excipients) are specified for tablet, capsule and syrup formats only.

16. Can these products be licensed under proprietary food category?

No. Proprietary food standard as per 2.12 of FSS (Food Products Standards and Food Additives) Regulations, 2011 clearly excludes Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food.

17. Can genetically modified (GM) organisms or their products be used in the products falling under these regulations?

No. Currently, products/ingredients of GM origin are not permitted under FSSR. FSSAI is in the process of finalizing regulations/guidelines for the safety assessment of such food. The same may be considered once relevant regulation/guidelines are available in FSSAI.

18. Can organic ingredients or their products be used in products falling under these regulations?

Yes, organic foods or ingredients obtained or sourced from organic cultivation practices can be used in these foods subject to compliance with the Food Safety and Standards (Organic Foods) Regulations, 2017. Any claims regarding organic has to comply with the aforesaid regulations.

19. What is the permitted limit for nutrients such as vitamins, minerals and amino acids for health supplements/nutraceuticals/FSDU/FSMP under these regulations?

The quantity of nutrients such as proteins, vitamins, minerals, and amino acids added to health supplements and nutraceuticals shall not exceed the recommended daily allowance (RDA) as specified by the Indian Council of Medical Research (ICMR). In case RDAs are not specified by ICMR, the standards laid down by international food standards body, namely, Codex Alimentarius Commission shall apply. FSSAI has already placed the compiled information on RDA of various nutrients on its website on 16.07.2021 and 02.08.2021. Link for accessing the same is <https://www.fssai.gov.in/advisories.php>

Further, as per first amendment to nutraceutical regulations notified on 06th September, 2021 (to be effective for compliance from 1st April, 2022), FSDU and FSMP product (other than food specially prepared for weight reduction and intended as total replacement of complete diet) in food format (except tablet, capsule, syrup) with higher than RDA need prior approval of the Food Authority based on adequate scientific evidence.

20. Can FBO use vitamins and minerals more than RDA in health supplements/nutraceuticals based on the ICMR report placed on FSSAI website?

No. Regarding limit of vitamins and minerals in health supplements/ nutraceuticals, the FBO has to comply with the Nutraceutical Regulations only i.e not more than one RDA.

21. Whether terms like RDA, one RDA, and 100 per cent RDA mean the same?

Yes.

22. Are the limits specified under Schedule III applicable to all categories of foods covered under these regulations?

No. Schedule III specifies minimum and maximum nutrient limits linked to calorie of the products. As the minimum and maximum nutrient limits linked to calorie of the products, it is applicable for the FSDU and FSMP dietary formulations (with higher RDA) containing calories. Further, as per first amendment to nutraceutical regulations notified on 06th September, 2021 (to be effective for compliance from 1st April, 2022), FSDU and FSMP product with higher RDA need prior approval from the Food Authority and Schedule III has been made applicable to only food specially prepared for weight reduction and intended as total replacement of complete diet under FSMP category.

23. What is overage and is it allowed to add overages as per Nutraceutical regulations?

Overage means the amount of excess nutrient added above the quantity indicated on the label during manufacture as a means of maintaining at least the claimed amount of the ingredient(s) for the normal shelf life of the product to compensate for the expected manufacturing/storage loss and to allow for variation in assay performance.

Yes. The regulations provide the limits of addition of overages of various vitamins and minerals under Table C of Schedule-I. Wherever overages are added, the label of such product shall indicate 'appropriate overages added'. FBO's should provide such data when demanded by the Authority.

24. Are nutrient content claim provisions specified at provision 3(5) of these regulations applicable to ingredients also?

No. These provisions are applicable only for nutrients in case products fall under health supplements category. The permissible limits (both minimum and maximum) given for the ingredients on per day basis have to comply with the same.

25. Is there any provision for tolerance limit for variation during sample analysis of finished product?

These regulations provide a tolerance limit of minus 10 per cent variations from the declared value of the nutrients or nutritional ingredients during analysis.

26. Why ingredients have been listed separately in Part A and Part B of Schedule VI under these regulations?

Part A of Schedule VI provides a list of Nutraceuticals for which purity criteria and levels of usage per day (minimum and maximum) have been specified. Part B of Schedule VI provides a list of Nutraceuticals whose usage levels should be based on relevant scientific data. FBO's will need to provide such data to the Authority as when demanded.

27. Is there specific prohibition for ingredients obtained from animal source?

There are no prohibitions for use of ingredients derived from animal source as long as such ingredients are listed in these regulations as well as in Food Safety and Standards (Food Product Standards and Food Additive) Regulations, 2011. Such products should

make declaration of vegetarian or non-vegetarian as per the provisions of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011.

28. What are the labelling requirements for products covered under these regulations?

In addition to the general labelling requirements specified under the Food Safety and Standards (Packaging and Labelling) Regulations, 2011, the products falling under these regulations shall also need to comply with the mandatory specific labelling requirements provided under these regulations applicable to the concerned category.

29. Is it mandatory to declare nutritional values such as energy, carbohydrate, protein etc. for tablet, capsule, syrup formats also?

Yes. It is mandatory as per FSS (Packaging and Labelling) Regulations, 2011 and also applicable to products covered under nutraceutical regulations.

30. In case of tablet, capsule, syrup formats where quantity of active ingredient may be less than the additives, what is to be declared first in the ingredient list?

As per the FSS (Packaging and Labelling) Regulations, 2011, product label shall contain list of ingredients (in descending order of their composition) followed by declaration regarding food additives (class titles shall be used together with the specific names or recognized international numerical identifications). Accordingly, it is recommended to list the active ingredients first followed by the additives on the label.

31. Is it mandatory that label shall mention information related to precautions to be taken while consuming or contraindications, and the product-drug interactions?

As per the specific labelling requirements mentioned under these regulations every product falling under these regulations shall carry information w.r.t a warning or precautions to be taken while consuming, known side effects, if any, contraindications, and published product-drug interactions, as applicable.

It is necessary since the majority of the products falling under these regulations except certain FSDU and FSMP are consumed by general population in an unsupervised manner. Specifying such information on label will help consumer to make an informed choice.

32. Is it necessary to declare energy value on the label of amino acid based products?

Energy is a mandatory parameter in nutrition information table as per the FSS (Packaging and Labelling) Regulation, 2011 and labels need to comply with it. Generally, in the absence of any other macronutrients like carbohydrate and fat, it is known that amino acids are used by the body as the energy source. Each gram of amino acids provides 4 calories of energy. Since amino acids can contribute to the energy intake, the same may be used to calculate the energy for the products containing amino acids.

33. Is it allowed to add other forms of ingredients listed under these regulations than those mentioned?

Currently, as per the note given under Schedule I (list of vitamins and minerals) and II (list of amino acids and the nutrients) suitable esters, salts and chelates with well documented evidence of their safety and efficacy may be used. FBOs will need to provide such data to the Authority as and when demanded. Further, as per first amendment to

nutraceutical regulations notified on 06th September, 2021 (to be effective for compliance from 1st April, 2022), the note has been amended to add 'Derivatives' in addition to esters, salts and chelates. However, whenever FBO use esters, salts, chelates and derivatives as applicable shall notify in writing to Food Authority and also required to submit additional safety data/information when requested by the Food Authority for such cases.

34. Is it mandatory to comply with the limits specified in Schedule IV of these regulations for all plants and botanicals?

Yes. Schedule IV provides a list of plant/botanicals and their parts used along with minimum and maximum levels of usage in g or ml per day. However, if an FBO is using an extract of these botanicals the quantity of extract shall be so adjusted based on the extractive value of the extract to be obtainable from the minimum and maximum levels of the raw botanical specified in the Schedule IV.

35. Should the foods covered in these regulations contain only those parts of plants and botanicals as mentioned in Schedule IV?

Yes. As per Schedule IV, only parts of specified plants and botanicals can be used. For parts which are not listed FBO will have to apply to FSSAI for approval.

36. Whether prior approval of FSSAI is needed to make claims under these regulations?

The claims other than the ones listed under regulation 4 which are not drug claims; claims where scientific evidence does not exist or if novel ingredient is to be introduced; need prior approval from the Authority which shall be based on adequate scientific evidence as per FSS (Advertising and Claims) Regulations, 2018. However, nutrition and nutrient content and their function claims based on available scientific data can be made without prior approval. The details of documentation are specified under regulation 4 and such details need to be submitted to Authority for review when called for. In case of product led health claims, the FBO shall mandatorily notify the Authority before putting the same in the market, by submitting relevant documents along with a copy of the label for examination by the Authority. The Authority after scrutiny may recommend alter or modify or stop such claim.

37. Will the labelling requirements specified under regulation 10 and 11 (i.e Food with added Probiotic and Prebiotic ingredients) be applicable to all foods where probiotic and prebiotic ingredients are used?

No. These labelling provisions are applicable only to 'foods with added probiotic and prebiotic ingredients' categories, as applicable.

38. How can pre-mixes be used under these regulations?

FBOs can manufacture pre-mixes for industrial use consisting of two or more ingredients listed under these regulations using additives permitted in these regulations. However, such pre-mixes may bear the statements such as "Not for retail sale" or "For Industrial Use Only" to clearly differentiate these products from end products.

39. Can products covered under these regulations contain hormones or steroids or psychotropic ingredients?

No. Hormones, steroids, and psychotropic substances are not permitted in the food specified under these regulations.

40. What are health supplements and which products qualify under this category?

Health supplements are intended to supplement the normal diet of a person above the age of five years with concentrated sources of one or more nutrients with known or established nutritional or beneficial physiological effect. The kind of products falling under this category includes products such as protein supplements intended for general population, vitamin and mineral formulations with plant or botanical extracts etc.

43. What are Nutraceuticals and which products qualify under the same?

Nutraceuticals include naturally occurring ingredients that are extracted, isolated and purified from food or non-food sources and upon consumption in measured amounts, provide a physiological benefit and help maintain good health. The kind of products falling under this category includes the products made out of ingredients specified under Schedule VI of the regulations.

44. What is FSDU and which products qualify under FSDU?

Foods for Special Dietary Uses (FSDU) are foods specially processed or formulated to satisfy particular dietary requirements which may exist or arise because of certain specific health conditions like low weight, obesity, diabetes, high blood pressure, pregnant and lactating women, aging population and celiac disease etc.

FSDU shall not include normal food which is merely enriched or modified with nutrients and meant for mass consumption, intended for improvement of general health for day to day use and do not claim to be targeted to consumers with specific disease conditions and also not include the article of food intended to replace complete diet which is covered under food for special medical purpose below.

The kind of products falling under FSDU includes the products such as meal replacement products intended for slimming/weight management/weight control products (conditions laid down under the said category of Nutraceutical regulations), sport supplements, specifically designed dietary formulation for pregnant and lactating women, geriatric population, celiac disease etc.

45. Is it mandatory to take FSDU products under medical advice?

Not necessary for all products, but some FSDU products have to be taken under medical supervision. As per Nutraceutical regulations, in case of products falling under FSDU category, the FBO is responsible for declaring whether the product is to be taken under medical advice or not. The same shall be clearly specified on the label of the product.

46. Under which category gym supplements and products for sport persons will fall?

These products will fall under the category of FSDU and shall only be used under medical advice or dietetic supervision. A Guidance note on 'Food for Special Dietary use for Sportsperson' was also issued by FSSAI which can be accessed at <https://www.fssai.gov.in/cms/guidance-notes.php>

47. Is there any guideline available for prohibited substances in food for sport persons?

Prohibited substances declared by World Anti-Doping Agency (WADA) shall not be added in any of the articles of food specified for sport persons. FBO must ensure to check the list of prohibited substances which is published annually by World Anti-Doping Agency and is effective from January 1st every year. The same can be accessed at <https://www.wada-ama.org/en/content/what-is-prohibited>

48. What is FSMP and which products qualify under FSMP?

Foods for Special Medical Purpose (FSMP) are foods specially processed or formulated for exclusive or partial feeding of persons with a limited, impaired or disturbed capacity to take, digest, absorb, metabolize or excrete ordinary foodstuffs or certain nutrients contained therein or metabolites or other medically determined nutrient requirements, whose dietary management cannot be achieved only by modification of the normal diet, by food for specific nutritional use, or a combination of them. These products are to be taken under medical advice only. The kind of products falling under FSMP includes special dietary formulas for persons suffering from metabolic disorders including food protein allergy, fatty acid metabolism, gastrointestinal disorders, kidney disease etc.

49. What is the difference between FSMP and drug?

Unlike drug which is used to prevent or treat disease, FSMP is a food formulation given to patients and not a medicine. FSMP is intended to provide nutritional support to persons who suffer from a specific disease, disorder or medical condition as detailed above. Unlike other functional foods these products focus on the nutrition support, rather than health function.

50. Is it mandatory to take FSMP products under medical advice?

Yes. Because the consumers of FSMP are persons suffering from specific diagnosed disease, disorder or medical condition, who as a result of such disease, disorder or medical condition need to consume FSMP. Therefore, their use must take place under supervision of a medical doctor or clinical dietician. As per Nutraceutical regulations FSMP products need to be mandatorily labelled as 'FOOD FOR SPECIAL MEDICAL PURPOSE' printed in the immediate proximity of the name or brand name of the product as well as carry a mandatory warning "RECOMMENDED TO BE USED UNDER MEDICAL ADVICE ONLY".

51. Is it mandatory to take approval of the Authority for all FSMP products falling under nutraceutical regulations?

As per Nutraceutical regulations it is mandatory that every package of FSMP product shall carry the statement "For the dietary management of _____" (with the blank to be filled in with the specific disease, disorder or medical condition for which the product is intended, and for which it has been shown to be effective) supported by appropriate scientific, and clinical or epidemiological data, and subject to its approval by the Authority.

52. Is it mandatory to declare quantity of nutrients in terms of percentages of the RDA for FSMP products?

Nutraceutical regulations under its labelling requirements of FSMP mention that 'the quantity of nutrients expressed in terms of percentages of the recommended daily allowances, where it is appropriate'. Unlike other categories of functional foods, mentioning per cent RDA for the nutrients present in case of FSMP is not mandatory as

FSMP products are intended for specific medical conditions/disorders, which leads to specific medically-determined nutrient requirements and are to be taken under medical supervision only. However, if the FBO deems it appropriate, the same may be mentioned on the label.

53. What are different categories of FSMP?

FSMP may be classified in to following three categories, namely:-

(a) 'nutritionally complete food with a standard nutrient formulation', which when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended. e.g. enteral formulas for gastroenterological conditions;

(b) 'nutritionally complete food with a nutrient-adopted formulation specific for a disease, disorder or medical condition', which when used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom they are intended; e.g. MCT (Medium Chain Triglycerides) containing formulas for mal absorption conditions; and

(c) 'nutritionally incomplete food with a standard formulation or a nutrient-adopted formulation specific for a disease, disorder or medical condition', which is not suitable to be used as the sole source of nourishment e.g. a protein substitute for metabolic conditions.

The foods referred to in points (a) and (b) above may also be used as a partial replacement or as a supplement to the patient's diet.

54. What is the product format of FSMP?

FSMP products are for dietary management rather than treatment, intended to provide nutritional support to a person who suffers from a specific disease, disorder or medical condition. The product should be administered through oral or enteral route (tube feeding). Therefore, it is a common practice to have these products in food formats including powder or liquid.

55. Can FBO advertise FSMP products in general public?

No. As per nutraceutical regulations it is not allowed to advertise FSMP for use by general public.

56. What is Probiotic food and which products qualify under Probiotic food?

Probiotic foods are foods with live micro-organisms which when ingested in adequate amount provide benefit to human health. Products formulated using micro-organisms listed under Schedule VII of these regulations can be considered as probiotics. As per nutraceutical regulations claimed desired microorganisms in the product shall be $\geq 10^8$ CFU/g (revised as $\geq 10^8$ CFU in the recommended serving size per day, as per first amendment to nutraceutical regulations notified on 06th September, 2021. However, lower viable number may be specified with proven studies on health benefits with those numbers subject to the prior approval of the Authority.

57. What is Prebiotic food and which products qualify under Prebiotic food?

Prebiotic foods are foods that contain prebiotic ingredients, which are non-viable food components, and confer health benefits to the consumer by modulation of gut microflora. Products formulated using ingredients listed under Schedule VIII of these regulations can be considered as prebiotics.

58. Which products qualify under Specialty food containing plant/botanical ingredients?

The products based on only plants or botanicals or their extracts specified in Schedule IV qualify under this category.

59. What is novel food and can novel food manufacturer or importer take license directly from the Authority?

Novel foods are foods that do not have a history of human consumption or has any other ingredient used in it which or the source from which it is derived, does not have a history of human consumption, or a food or ingredient obtained by new technologies with innovative engineering processes, 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.

Novel food manufacturer or importer needs prior approval as per NSF regulations before taking licence.

60. How to use ingredients or products which have a history of safe consumption in India and/or abroad, but not included under these regulations?

For ingredients which are in use for a number of years with history of safe consumption in India and/or abroad, and which have not been included in these regulations also require approval from FSSAI as per NSF regulations.

61. Can products, individual ingredients, additives, and premixes to be imported be covered under these regulations?

Yes, subject to fulfilling of the requirements of FSS (Imports) Regulations, 2017 and Nutraceutical regulations.

62. Are import requirement of these products different?

Import of products complying with these regulations is in accordance with the FSS (Imports) Regulations, 2017.

63. Do exporters of these products also need to comply with these regulations?

No, such FBOs need to comply with the exporting countries regulations subject to the condition that they are not distributing the products domestically.

64. Can FBOs apply for license under category 13 as a broad category for food products under these regulations?

No, as category 13 also covers standards for infant formula, follow up formulae etc. which are not part of these regulations, the license needs to be given in the specific sub-category.

65. Under which sub-category these products can be licensed?

The final formulations/products falling under these regulations can be licensed under the following sub-categories, as applicable:

- 13.3: Food for Special Medical Purpose
- 13.4: Dietetic formulae for slimming purposes and weight reduction
- 13.5: Food for Special Dietary Use (excluding category 13.4)
- 13.6: Health Supplements, Nutraceuticals, Probiotic and Prebiotic, Specialty food containing plant or botanical ingredients with safe history of usage.

66. Under which category the ingredients/premixes would be licensed?

The ingredients or premixes can be licensed under the following sub-categories under category 99, as applicable:

- 99: Substances added to food
 - 99.1 Food Additives
 - 99.2 Enzymes and their preparations
 - 99.3 Flavouring and their preparations
 - 99.4 Processing Aids
 - 99.5 Nutrients and their preparations
 - 99.6 Microorganisms and Microbial Preparations
 - 99.7 Functional Ingredients

67. Is there any change in the licensing requirement of products falling under these regulations?

License for products complying with these regulations shall be granted in accordance with the FSS (Licensing and Registration of Food Businesses) Regulation, 2011 except for novel foods which need prior approval as per NSF regulations.

68. What will happen to products licensed earlier but not covered under these regulations?

FBOs were required to ensure compliance of their existing and new products with all the provisions under these regulations by 01.01.2018. Any products/ingredients not covered under these regulations are not allowed from January 1, 2018 unless they are included in these regulations or approved by the Authority under NSF regulations, as the case may be.

69. Whether the product approval is required in respect of the products for which applications seeking product approval were filed as per the earlier PA regime in FSSAI but later on covered in the draft nutraceutical regulations notified on 11.09.2015.

The earlier process of Product Approvals was quashed pursuant to Hon'ble Supreme Court's Order dated 19.08.2015 and the same was conveyed by FSSAI Order issued vide F.No.P-15025/SCJ/2015-PA/FSSAI dated 26.08.2015. Subsequently, FSSAI vide Order No.1(2)2011/States/FSSAI(Vol.I) dated 30.03.2016 clarified that all those applications seeking product approval pending for decision as on 19.08.2015 became defunct and no product approval is required, if such products explicitly got covered under the draft nutraceutical regulations, 2015 made available to the public on September 11, 2015.

The draft regulations issued on 11.09.2015 were gazette notified on 23.12.2016 with certain changes. However, the products which got covered under the draft notification on 11.09.2015 but not complying to the extant regulations gazette notified on 23.12.2016, would require approval under NSF regulations.

70. Whether the product approval is required in respect of the products for which applications seeking product approval were filed as per the earlier PA regime and are pending but later on covered in the nutraceutical regulations.

Product approval is not required in respect of the products for which applications seeking product approval were filed in the earlier regime but later on covered in the Nutraceutical regulations gazette notified on 23.12.2016. However, the applications filed for product approval as per the earlier PA regime and are pending in light of directions of the Hon'ble court dated 19.08.2015, and which do not comply the extant regulations were given a chance to re-submit application along with necessary documents as per requirements of the NSF regulations without additional fees for further examination of their application. Since the given timeline was over, the applications where details were not received, have been closed.

71. Has FSSAI specified any FSMS guidelines applicable for manufacturing of ingredients/products covered under these regulations?

The manufacturing of ingredients/products covered under these regulations shall be established in accordance with the schedule 4 of Food Safety and Standards (Licensing and Registration of Food Businesses) Regulation, 2011. FSSAI has also placed 'FSMS Guidance document for Health Supplements and Nutraceuticals' on its website. The same can be accessed at <https://www.fssai.gov.in/cms/guidance-document.php>

72. Are there any general quality requirements and standards for products in tablet, capsule and syrup formats for compliance?

Yes. FBOs shall fulfil the general quality requirements and standards as specified in Indian Pharmacopoeia, British Pharmacopoeia or United States Pharmacopoeia.

73. What purity criteria need to be adopted by the FBOs for use of the ingredients listed under these regulations?

Till the purity criteria for the ingredients determined and notified by the Authority, the FBO shall adopt the purity criteria generally accepted by pharmacopoeias, namely, Indian Pharmacopoeia, Ayurvedic Pharmacopoeia of India, relevant Bureau of Indian Standards Specifications, Quality Standards of Indian Medicinal Plants, Indian Council of Medical Research, British Pharmacopoeia, United States Pharmacopoeia, Food Chemical Codex,

Joint Food and Agriculture Organization or World Health Organisation Expert Committee on Food Additives or CODEX Alimentarius.

74. Is it mandatory to submit documents regarding purity criteria to the Authority?

Yes. As per Nutraceutical regulations it is mandatory that the FBO shall intimate the purity criteria adopted for ingredients to the Authority including any change when adopted.

75. Are methods of analysis available for products covered under these regulations?

Since these products are prepared with mix of various ingredients, it is impractical to validate analysis methods for all the products by the Authority. The FBO shall keep complete details of sampling and validated test methods applied by them for characterization of their product and/or ingredients and such details need to be submitted to Authority for review when called for.

76. What are the limits of heavy metals permitted in products covered under these regulations?

The products shall conform to the Food Safety and Standards (Contaminants, Toxins and Residues) Regulations, 2011 under the 'foods not specified' category.

77. What are the microbiological limits permitted in products covered under these regulations?

These standards are currently being developed. The products in market must conform to the best practices in industry. However, the products will be tested for the basic indicator micro-organisms with respect to food safety.

78. Can dosage formats like sprays be allowed under these regulations?

No. Any new or novel formats (except food formats as specified) need prior approval of the Authority.

79. Is it allowed to use ingredients prepared using nano technology under these regulations?

Any product of a novel technology as explained above including nano-technology need prior approval of the Authority.

80. Is it mandatory to comply with both minimum and maximum permissible level specified per day?

Yes, since it has been specified keeping in mind both efficacy and safety.

81. Is it mandatory to maintain a product master file, and if so, what is the requirement for that?

As per regulation 5 of the nutraceuticals regulations 'General principles for query or challenge', it is mandatory to maintain such file. The same need to be submitted to the Authority as and when requested. For further details the regulation may be referred.

82. Whether only history of consumption in Indian population or country of origin is required to include plant or botanical or nutraceutical ingredient in these regulations?

The Authority may include a plant or botanical or nutraceutical ingredient in these regulations only after undertaking proper scientific evaluation of all the aspects. Hence, such requests shall be accompanied with complete details on its safety and efficacy along with the documented history of usage of at least fifteen years in India, or thirty years in the country of origin under NSF regulations.

83. Is there any positive or negative list of claims allowed to be made on the products covered under these regulations?

No such list of claims is available. However, FBO may refer to FSS (Advertising and Claims) Regulations, 2018 for information on allowed claims.

84. Under Schedule VI of these regulations many actives/ ingredients have been listed without mentioning their source. What are the sources that are allowed for such ingredients?

The actives/ ingredients listed under Schedule VI may be extracted from permitted /listed sources under Food Safety and Standards Regulations only. A new or novel source requires approval from the Authority.

85. Whether nutritional ingredients specified in these regulations are allowed to be used in other food categories specified in the Food Safety and Standards (Food Product Standards and Food Additive) Regulations, 2011?

The nutritional ingredients specified under these regulations may be allowed to use in other standardized foods subject to compliance to the safe limit specified per day and other warnings and contra indications without making any claims pertaining to products covered under Nutraceutical regulations.

86. Do Water-based flavoured drinks, including 'sport' 'energy', or 'electrolyte' drinks fall under the newly notified FSDU category 'Food for sportspersons'?

No. These products do not fall under the newly notified FSDU category 'Food for sportspersons'. However, such products would fall under food product category 14.1.4 (Water-based flavoured drinks, including "sport," "energy," or "electrolyte" drinks and articulated drinks) and shall comply with the concerned vertical standards notified under Beverages category of FSS (Food Products Standards and Food Additives) Regulations, 2011.
