

**Frequently Asked Questions (FAQs) on the Food Safety & Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional food and Novel food) Regulations, 2016**

**Q1: What is the date of compliance of these regulations?**

Food Business Operator shall comply with all the provisions of these regulations by January 1, 2018.

**Q2: What is the scope of these regulations?**

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

1. Health Supplements
2. Nutraceuticals
3. Food for Special Dietary Use (FSDU)
4. Food for Special Medical Purpose (FSMP)
5. Food with added Probiotic ingredients
6. Food with added Prebiotic ingredients
7. Specialty food containing plant or botanical ingredients with safe history of use
8. Novel Food

**Q3. Why category of Functional Foods has not been created under these regulations?**

The term 'Functional foods' means foods which provide benefits beyond basic nutrition and may play a role in reducing or minimizing 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'.

**Q4. How are foods under these regulations different from normal foods?**

As per explanation 1 and 2 given under sub-regulation (13) of regulation 3, food or ingredient as defined in Food Safety and Standards (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 forms shall not constitute a 'Health Supplement' or 'Nutraceutical', or 'Food for Special Dietary Use' or 'Food for Special Medical Purpose'. Also, mere food forms such as 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'.

**Q5: When a conventional food or food for mass consumption contains prebiotic fibres or probiotic organisms, does it automatically come under these regulations?**

No. Since conventional foods or foods for mass consumption can also have these ingredients, such a food shall not be considered as probiotic food or prebiotic food.

**Q6: Which ingredients can be used for preparation of foods covered under these regulations?**

FBO's may use one or more ingredients from various schedules specified in these regulations for respective category. However, the selection of ingredients, their levels, quality / purity criteria and other relevant provisions will need to be complied with while doing so. In some specific category namely Nutraceuticals at least one ingredient from those specified in schedule VI would be required while ingredients specified in other schedules permitted in the Nutraceuticals category may or may not be used. While combining ingredients specified in other schedules permitted in the nutraceuticals category the provisions of rationality, their levels, quality / purity criteria and other relevant provisions shall need to be complied.

**Q7. Are tablets, capsules, syrups of vitamins and minerals allowed as per these regulations?**

As per sub-regulation (21) of regulation 3, the mere combinations of vitamins and minerals formulated in tablets, capsules, syrups format are not covered under these regulations, unless, there is an inclusion of an element of food along with vitamins and minerals.

**Q8: Are there any restrictions for combining natural / plant materials / botanicals and their extracts with vitamins and minerals specified in these regulations?**

There are no specific restrictions for combining natural / plant materials / botanicals and their extracts with vitamins and minerals. It is the responsibility of FBO to keep in mind about potential interactions amongst a combination of ingredients leading to impact on stability, bioavailability, safety, efficacy and such combinations should be avoided which are potentially antagonistic to functional outcome of innovations. FBOs will need to provide data on scientific rationale for formulating such combinations, based on scientific literature in peer reviewed publications or data generated by FBO's / innovators or suppliers of such plant / botanical extracts to Food Authority at the time of application for license or when demanded by the Food Authority.

**Q9: Can any other ingredients be used in foods specified in these regulations?**

As per direction vide ZF. No. 1-5/Nutraceuticals/FSSAI-2003 dated 06<sup>th</sup> January, 2017 it may contain ingredients, other than additives, which are either standardized or permitted for use in the preparation of other standardized foods as specified in the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011.

**Q10: 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?**

Yes subject to the compliance of proprietary food as specified in regulation 2.12 of Food Safety and Standards (Food Product Standards and Food Additive) Regulations, 2011 without any claims relating to these regulations.

**Q11: Whether the list of food additives specified in Schedule VF are limited to food formats such as tablets, capsules and syrups?**

Yes. However, it can also be used in such formats as notified by the Food Authority from time to time.

**Q12. Whether definition of proprietary food applicable for the categories described in these Regulations?**

No. Proprietary food does not include Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional food and Novel food.

**Q13. Can genetically modified organisms or their products be used in products falling under these regulations?**

No.

**Q14. Can organic foods 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 the compliance of Food Safety and Standards (Organic Foods) Regulations, 2017.

**Q15. Whether overages of vitamins and minerals are permissible so as to ensure declared quantity on label till best before/expiry date?**

Yes. The regulations provide specific provision on limit of addition of overages under Schedule-I, Table C. However, higher percentage of overages can also be added if scientifically substantiated. FBO's should to provide such data to Food Authority at the time of application for license or when demanded by the Food Authority. FBOs will need to keep in mind the provisions of Schedule III while deciding the label claim and the overages. Label declarations should indicate addition of appropriate overages on the label wherever overages have been added.

**Q16: Is there any provision for tolerance limit for variation during sample analysis of finished product?**

Sub-regulation (11) of regulation 3 provides specific provisions on tolerance limits of (-) 10 per cent variations from the declared value of the nutrients or nutritional ingredients during analysis. The FBOs at the time of licensing should submit the sampling and test methods applied by them for characterization of their product. The Analyst(s) will keep these in mind while testing the samples.

**Q17. Why ingredients have been listed separately in Schedule VI, Part A and Part B of these regulations?**

Part A of Schedule VI provides 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 list of Nutraceuticals whose usage levels should be based on relevant scientific data. FBO's will need to provide such data to Food Authority at the time of application for license or when demanded by the Food Authority.

**Q18. 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. However, as per Direction under Section 16 (5) of Food Safety and Standards Act, 2006 dated 31<sup>st</sup> May 2017, use of heme iron is restricted as a source of iron in any form in any article of food.

**Q19. Do these regulations cover foods for children?**

Yes. However, as per clause (i) of sub-regulation (1) of regulation 6 health supplements may be used to supplement the normal diet of a person above the age of five years.

**Q20: Are Schedule III limits applicable to all categories of foods covered under these regulations?**

No. Schedule III is applicable to products covered under Food for Special Dietary Use and Foods for Special Medical Purpose.

**Q21. What are the packaging and labelling requirements for products covered under these regulations?**

In addition to the specific labelling requirements under these regulations, the products shall also comply with the Food Safety and Standards (Packaging and Labelling) Regulations, 2011.

**Q22. Does FBO need to submit any documents regarding purity criteria?**

The FBOs need to submit information on the purity criteria at the time of application for license or when demanded by the Foods Authority.

**Q23. What is the meaning of 'Fiber from other food sources' as mentioned at serial no. 82 of Schedule VI Part B?**

It means the fiber obtained from known well-established and safe food sources.

**Q24: Should the foods covered in these regulations contain vitamins, minerals and amino acids only in the forms as mentioned in schedule I and II?**

Yes. However, as per the note to the tables given under Schedule I and II suitable esters, salts and chelates with well documented evidence of their safety and efficacy may be used. FBO's will need to provide such data to Foods Authority at the time of application for license or when demanded by the Foods Authority.

**Q25: Is it mandatory to comply with the limits specified in Schedule IV of these regulations for all plants and botanicals?**

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 so be adjusted based on the extractive value of the extract to be within the minimum and maximum levels of the raw botanical specified in the Schedule IV.

**Q26: 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, parts of specified plants and botanicals can be used. For parts which are not listed FBO will have to apply to FSSAI for approval as per Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017.

**Q27: Whether prior approval of FSSAI is needed to make claims under these regulations?**

(i) The claims other than the ones listed under regulation 4 which are not drug claims; (ii) claims and where scientific evidence does not exist or if novel ingredient is to be introduced; and (iii) product led health claims, need prior approval of the Food Authority by submitting the relevant documents as mentioned under regulation 4 of these regulations.

However, nutrition and nutrient content claim can be made without any prior approval of FSSAI, in respect of foods that fall under the these regulations. Such content claims would

need to be based on supporting data related to that food and the content of nutrient or nutrition.

**Q28: Will the labelling requirements specified under regulation 10 & 11 (i.e Food with added probiotic and prebiotic ingredients) shall be applicable for all foods wherever the probiotic and prebiotic ingredients used?**

No. These labelling provisions are applicable only to those foods covered under regulation 10 and regulation 11 on food with added probiotic and prebiotic ingredients, respectively, of these regulations. Hence, this labelling requirement will not be applicable to other categories containing prebiotics or/and probiotics.

**Q29. Can products, individual ingredients and additives covered under these regulations be imported?**

Yes subject to the compliance of Food Safety and Standards (Imports) Regulations, 2017 requirements.

**Q30. Do these regulations apply to pre-mixes?**

FBOs can manufacture pre-mixes for industrial use consisting of two or more ingredients listed in these regulations using additives permitted in FSSR. Such pre-mixes in addition to other relevant provisions shall be labelled with terms "For Industrial Use Only", and "Not for Direct Human Consumption". Pre-mix which complies with the relevant provisions of these regulations, and all other provisions of FSSR, may also be imported subject to fulfilling the requirements of Food Safety and Standards (Imports) Regulations, 2017.

**Q31: Is there any change in the import requirement of products covered under these regulations?**

No. Import requirements will remain the same as that of standardized foods. Import of products complying with these regulations shall be allowed in accordance with the Food Safety and Standards (Imports) Regulations, 2017.

**Q32: Can FBO apply for license under category 13 as broad category for food products under these regulations?**

No.

**Q33. Under which category these products would be licensed?**

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

**Q34: When will be the licenses under these regulations applicable to FBOs for renewal, conversions, modifications, corrections and issue the new license?**

With immediate effect, Regional and State Offices will issue licenses to FBOs for renewal, conversions, modifications, corrections and issue of new license, as applicable.

**Q35: Is there any change in the licensing requirement of such products?**

No. Licensing requirement will remain the same as that for standardized foods. License for products complying with these regulations shall be granted for the food category as requested by the FBO in the application form in accordance with the FSSR licensing regulation without any requirement of product approval except novel foods.

**Q36. What will happen to products licensed earlier but not listed in these regulations?**

As per direction vide ZF. No. 1-5/Nutraceuticals/FSSAI-2003 dated Jan 6, 2017 for ingredients or foods, other than additives, which were approved by FSSAI earlier, and which do not appear in any of the Schedules attached to these regulations, the license to produce such foods shall continue to be valid till 31<sup>st</sup> December, 2017. The FBO may approach the Food Authority with all relevant details for inclusion of such ingredients in the listed Schedules. However, such ingredients would not be allowed to be use after 31<sup>st</sup> December, 2017 unless they are included in these regulations or approved by Food Authority, as the case may be.

**Q37: what will happen to such ingredients or products which are novel or having 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, which have not been included in these regulations, as well as novel foods, FBO will have to apply to FSSAI for approval as per Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017.

**Q38. Do these regulations cover products/formulations for the different categories mentioned?**

These regulations cover ingredients and additives allowed to be used in different product categories specified under these regulations but not the products. FBO shall formulate the products based on the permitted ingredients, additives and also compliance to the other requirements specified under these regulations.

**Q39. What are the recommended levels of heavy metals for 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'.

**Q40. What is the permitted limit for vitamins, minerals and amino acids?**

The quantity of nutrients added to food shall not exceed the recommended daily allowance as specified by the Indian Council of Medical Research (except FSDU and FSMP category) and in case such standards are not specified, the standards laid down by international food standards body, namely, Codex Alimentarius Commission, shall apply.

**Q41. What is the meaning of viable number of organisms in food with added probiotic ingredients shall be  $\geq 10^8$  CFU/g ?**

Each of the probiotic microorganisms claimed in the product shall have  $\geq 10^8$  CFU/g. However, lower viable number may be specified with proven studies on health benefits with those numbers subject to the prior approval of the Food Authority.

**Q42. Can products covered under these regulations contain hormones or steroids or psychotropic ingredients?**

No, these regulations do not permit use of any hormones or steroids or psychotropic ingredients in the food specified under these regulations. In this regard, an order dated 09<sup>th</sup> May, 2017 has been issued for surveillance of use of performance enhancing drugs in health supplements.

**Q43. 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 draft the Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2015 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 Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2015 made available to the public on the 11<sup>th</sup> September, 2015.

The draft regulations issued on 11.09.2015 have been final gazette notified on 23.12.2016 with certain changes. However, the products which got covered under the draft notification on 11.09.2015 and not complying the extant regulations notified on 23.12.2016 would require product approval under the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017.

**Q44. 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 Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 notified on 23-12-2016.**

Product approval is not required in respect of the products for which applications seeking product approval were filed in the earlier PA regime but later on covered in 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 notified on 23-12-2016. However, products for which applications were 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 are required to submit application along with necessary documents, as per requirements of the Food Safety and Standards (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017 without additional fees.

**Q45. What is the date of operationalisation of Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016.**

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 came into force on the date of their publication i.e. 23-12-2016. However, the Food Business Operators 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 are still under consideration of the Authority and finalization of the amendments is likely to take some time, a direction dated 29.12.2017 was also issued for clarification w.r.t. implementation of various provisions of these Regulations.