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Compliance Timeline Provided for Ingredients under Functional Foods

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Exporter Guide
FAIRS Subject Report

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Report Highlights:

The Government of India's, Food Safety and Standards Authority of India (FSSAI) has provided compliance timelines on certain ingredients covered in their regulations relating to health supplements, nutraceuticals, food for special dietary use, food for special medical purpose, functional food and novel food.

General Information:

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On June 29, 2018, FSSAI notified compliance timelines that the food business operators (FBOs) need to comply with regulations covering health supplements, nutraceuticals, food for special dietary use, food for special medical purpose, functional food and novel food. The compliance timelines on the use of certain ingredients in food products are as follows:

1. New ingredients and additives approved by the Scientific Panel as per Annexure I of the previous direction issued by FSSAI on December 29, 2017 are now allowed to be continued and used in the existing formulations until such time the proposed amendment of the regulations are finalized and notified. The earlier notice had a timeline until June 30, 2018 (GAIN IN8007); however, FSSAI has directed the FBOs to comply with the provision relating to permissible limits of ingredients/additives as given in Annexure I of the earlier direction.

2. Certain ingredients previously not approved by the Scientific Panel due to lack of data were reviewed again based on additional data provided by FBOs. For easy reference, the timelines set by the panel on the use of certain ingredients are listed in Table 1. Readers may also refer to the full text of the current notification pasted along with Appendix I at the end of this report.

Table 1

Ingredients	**Timeline and Remarks by the Panel**
(i) S-acetyl glutathione (50-600 mg/day, Max) (ii) Alpha Cyclodextrin	FBOs are allowed to continue their use until the proposed amendment of the Nutraceutical Regulations are finalized and notified.
(iii) Succinic acid (iv)Inosine	FBOs to discontinue their use with immediate effect and no further manufacturing of products using these ingredients are allowed. However, any such products which are already manufactured/imported are allowed to be sold until September 30, 2018.
(v)Paraamino Benzoic Acid (PABA) (vi) Vanadium (vii) Prenolit (viii) Selenium dioxide	With immediate effect, FBOs will discontinue their use as well as further manufacturing of products using these ingredients. However, any such products, which are already manufactured/imported, should be withdrawn from the market immediately.
(ix) D-ribose	FBOs to discontinue the use of this ingredient with immediate effect and no further manufacturing of health supplements/nutraceuticals containing this ingredient for consumption by general population in unsupervised

	usage is allowed. For use of D-ribose in food for special medical purpose or food for special dietary use, prior approval will be required from the Food Authority. However, any such products which are already manufactured/imported are allowed to be sold until September 30, 2018
(x) Ipriflavone (xi) Polypodium leucotomos	FBOs to discontinue the use of this ingredient with immediate effect and no further manufacturing of products using these ingredients are allowed. However, any such products which are already manufactured/imported are allowed to be sold until September 30, 2018.
(xii) Artichoke (xiii) Kale Powder (xiv) Salvia hispanica (xv) Cashew fruit (xvi) Passion fruit (xvii) Kiwi fruit extract (xviii) Broccoli (xix) Enzymes (Pectinase & Xylanase)	FBOs to discontinue the use of these ingredient/enzymes as health supplements/nutraceuticals. However, FBOs may use them in the products as general ingredients, if allowed under the Food Safety and Standards Regulations, without claiming any health supplements/nutraceuticals benefits for the ingredients. Any such products which are already manufactured/imported are allowed to be sold until September 30, 2018.
(xx) Use of ingredients listed in Annexure I of the current notification	FBOs to discontinue the use of these ingredients with immediate effect due to lack of adequate data and no further manufacturing of products using these ingredients is allowed until these ingredients are assessed and approved by the Authority. FBOs are also required to furnish information data/in respect of these ingredients within one month from the date of the current direction for further assessment by the Food Authority.

3. FBOs can continue their business of existing formulations containing mere combinations of vitamins and minerals only up to one recommended dietary allowance (RDA) in dosage formats such as tablets, capsules and syrups for a period of six months from the date of the current direction or until further orders, whichever is earlier.
4. FBOs can continue utilizing for food use their existing formulations containing vitamins and minerals in Food for Special Dietary Use without referring to the energy value (kcal/kj) as specified under Schedule III, until such time the proposed amendment of the regulation is finalized and notified.

F. No. Stds/Nutra(DCGI)/FSSAI - 2017 (Pt 1)
Food Safety and Standards Authority of India
(A Statutory Authority under the Ministry of Health and Family Welfare, Govt. of India)
FDA Bhawan, Kotla Road, New Delhi-110 002

Dated, the 29th June, 2018

Subject: **Implementation 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.**

In supersession of the direction dated 29.12.2017 (referred to hereinafter as 'earlier direction') regarding clarification on implementation of FSS (Health Supplements, Nutraceuticals, Foods for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016 (referred to hereinafter as 'Nutraceutical regulations'), the following timelines are laid down with respect to compliance to these regulations to ensure smoother transition for food businesses:

(i) New ingredients and additives recommended by the Scientific Panel for inclusion in Nutraceutical regulations and proposed to be included in the existing Schedules as per Annexure I of the earlier direction are allowed to continue to be used in the existing formulations* after 30th June, 2018 till such time the proposed amendment of the Nutraceutical regulations in this regard are finalized and notified. However, the Food Business Operators (FBOs) shall comply with the provision with respect to permissible limits of ingredients/additives as given at Annexure-I of the earlier direction.

(ii) The earlier direction dated 29.12.2017 contained list of 33 ingredients, which were not recommended by the Scientific Panel for inclusion in the Nutraceutical regulations due to lack of data. The Scientific Panel has again reviewed the use of these ingredients based on the additional data made available by the FBOs and the following decisions have been taken accordingly:

(a) FBOs are allowed to continue to use the ingredients namely 'S-acetyl glutathione (50 – 600 mg/day, Max)' and 'alpha cyclodextrin' (already covered under 'other fibre sources' as mentioned in Schedule VI, Part B of the Nutraceutical regulations) in the existing products covered under Nutraceutical Regulations, till such time the proposed amendment of the Nutraceutical regulations in this regard are finalized and notified.

(b) FBOs are directed to discontinue the use of ingredients namely 'Succinic acid' and 'Inosine' in the products covered under Nutraceutical Regulations with immediate effect as they are withdrawn by the applicant

*Criteria given in para 3 of the direction issued vide ZF. No. 1-5/Nutraceuticals/FSSAI-2003 dated 6th January, 2018.

and no further manufacturing of products using these ingredients is allowed. However, any such products containing these ingredients which are already manufactured/ imported are allowed to be sold till 30th September, 2018.

(c) FBOs are directed to discontinue the use of ingredients namely 'Para-amino benzoic acid (PABA)', 'Vanadium', 'Prenolit' and 'Selenium dioxide' in the products covered under Nutraceutical Regulations with immediate effect due to safety concerns and no further manufacturing of products using these ingredients are allowed. Any product containing these ingredients which are already manufactured/ imported shall be withdrawn from the market immediately.

(d) FBOs are directed to discontinue the use of ingredient namely 'D-ribose' in health supplements/nutraceuticals with immediate effect and no further manufacturing of health supplements/nutraceuticals containing this ingredient for consumption by general population in unsupervised usage is allowed. For use of D-ribose in Food for Special Medical Purpose or Food for Special Dietary Use, prior approval shall be obtained from Food Authority. However, any such products containing this ingredient which is already manufactured/ imported are allowed to be sold till 30th September, 2018.

(e) FBOs are directed to discontinue the use of ingredients namely 'Ipriflavone' and '*Polypodium leucotomos*' in the products covered under Nutraceutical Regulations with immediate effect since they exhibit properties of a drug and no further manufacturing of products using these ingredients is allowed. However, any such products containing these ingredients which are already manufactured/ imported are allowed to be sold till 30th September, 2018.

(f) FBOs are directed to discontinue the use of ingredients/enzymes namely 'Artichoke', 'Kale Powder', '*Salvia hispanica*', 'Cashew fruit', 'Passion fruit', 'Kiwi fruit extract', 'Broccoli', 'Enzymes (Pectinase and Xylanase)' as health supplements/ nutraceuticals. However, FBOs may use these ingredients/enzymes in the products as general ingredients, if permitted under Food Safety and Standards Regulations, without claiming any benefits as health supplements/ nutraceuticals for such ingredients. Further, any such products containing these ingredients which are already manufactured/ imported making any such claims are allowed to be sold till 30th September, 2018.

(g) FBOs are directed to discontinue the use of ingredients listed under **Appendix -I** of this direction in the products covered under Nutraceutical

Regulations with immediate effect due to lack of adequate data and no further manufacturing of products using these ingredients is allowed until these ingredients are assessed and approved by the Authority. Further, FBOs are directed to furnish information/data in respect of these ingredients within one month from the date of this direction for further assessment by the Food Authority.

Appendix-I

1. Raspberry ketone
2. Silica
3. *Angelica sinensis*
4. *Paullinia cupana*
5. Saw palmetto
6. Notoginseng
7. Chlorella Growth factor
8. Pine bark extracted from *Pinus radiata*
9. Pine bark extract from *Pinus pinaster*
10. Vitamin D3 (Veg)
11. Chaga extract (*Inonotus obliquus*)
12. *Oxalobacter formigenes*
13. Phytavail iron
14. Tea tree oil