

# Pharma & Healthcare Update

July 01, 2022

## MID-YEAR REGULATORY UPDATE 2022: FOOD INDUSTRY IN INDIA

### INTRODUCTION

The food sector is one of the largest and diverse industries in India. In the recent past, the food industry has been gearing up to keep up with shift in consumer preferences towards health foods and sustainability. The first half of 2022 has witnessed a lot of activity in this sector in terms of regulation as well. To keep up with the ever-evolving industry, the apex food regulator in India has brought under regulation the growing vegan food manufacturing industry and revamped the nutraceutical regulation.

Some of the key developments that have taken place in the first half of 2022 in the food sector are captured below.

### NEW FRAMEWORK FOR NUTRITIONAL AND SUPPLEMENTAL FOOD PRODUCTS IN INDIA

Food Safety and Standards Authority of India ("FSSAI")- India's apex food regulator- issued a direction on March 29, 2022 ("Nutra Regulations Interim Direction") to operationalize certain provisions of the proposed Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, and Food for Special Medical Purpose, Prebiotic and Probiotic Food) Regulations, 2022 ("Nutra Regulations") from April 1, 2022.<sup>1</sup>

The Nutra Regulations are intended to supersede the Food Safety and Standards (Health, Supplements, Nutraceuticals, and Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016. The draft Nutra Regulations are in the process of publication. Till such time the Nutra Regulations come into force, the Nutra Regulations Interim Direction will be effective. The Nutra Regulations Interim Direction specifically applies to products which (i) are articles of food specially processed or formulated for specific nutritional or dietary purposes which are clearly distinguishable from foods intended for normal consumption by their special composition; (ii) are health supplements, nutraceuticals, food for special dietary use, food for special medicinal purpose, prebiotic food and probiotic food; (iii) are not referred to as food or ingredients under Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011; (iv) are not regulated as 'drugs' under the Drugs and Cosmetics Act, 1940; (v) do not contain steroids or a narcotic drug or a psychotropic substance; (vi) do not claim to cure, prevent or mitigate any specific disease, disorder or condition and; (vii) are not mere food forms such as vegetables, cereals, spices, fruits and other plants or botanicals, minimally processed.

The Nutra Regulations Interim Direction contains schedules applicable to different categories and provides compliance requirements with respect to ingredients, list of additives and purity criteria, tolerance limits, labelling, claims and approval process.

The Nutra Regulations Interim Direction has been issued under Section 16(5) of the Food Safety and Standards Act, 2006 which enables the FSSAI to issue binding directions on matters relating to food safety and standards.

### FSSAI REGULATIONS FOR AYURVEDA AAHARA PRODUCTS

The FSSAI in collaboration with the Ministry of AYUSH under the Ministry of Health and Family Welfare has formulated the Food Safety and Standards (Ayurveda Aahara) Regulations, 2022 Rules ("Ayurveda Aahara Regulations")<sup>2</sup> under the Food Safety and Standards Act, 2006 ("FSSA") to lay down the safety and quality standards for food products prepared in accordance with the recipes or ingredients specified under the Schedule to the Ayurveda Aahara Regulations.

According to the Ayurveda Aahara Regulations, manufacturing and marketing of Ayurveda Aahara products will now adhere to strict regulations and will be available in market only after obtaining license/approval from FSSAI. Health claims and disease risk reduction claims for the different categories of Ayurveda Aahara and their approval process will be in accordance with the requirements specified under the Ayurveda Aahara Regulations. The requirement of printing 'Ayurveda Aahara' in the immediate proximity of the name/brand name of the product with the special logo has been introduced to enable easier identification of such products.

The labelling of 'Ayurveda Aahara' shall specify the intended purpose, the target consumer group, recommended duration of use and other specific requirements. However, Ayurveda Aahara will not include Ayurvedic drugs or proprietary Ayurvedic medicines and medicinal products, cosmetics, narcotic or psychotropic substances and herbs.

Ayurveda Aahara needs prior approval, the same shall be in accordance with the Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017. FSSAI shall constitute an Expert Committee under the Ministry of AYUSH consisting of relevant experts including representatives of FSSAI for providing recommendation on approval of claims and products and the committee shall also empower to address concerns regarding registration or licensing or certification or laboratory accreditation or testing or quality issues

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NEW FRAMEWORK FOR VEGAN FOOD PRODUCTS IN INDIA

The FSSAI has notified the Food Safety and Standards (Vegan Foods) Regulations, 2022 on June 10, 2022 ("Vegan Food Regulations").<sup>3</sup> The Vegan Food Regulations define what constitutes vegan foods and provides for the compliances to be undertaken by persons who manufacture, pack, sell, offer for sale, market or otherwise distribute or import any food as vegan food. The FBOs are required to submit an application to the concerned licensing authority with all necessary details to obtain the license for manufacturing, processing, selling or distributing vegan foods. FBOs are also required to obtain a certificate issued by the recognised authorities of the exporting countries prior to import of vegan foods.

Vegan food products should not involve animal testing for any purpose and the packaging material used for the vegan foods is required to be in compliance with the packaging regulations. The labelling and display requirements provide that such vegan foods should be stored and displayed in a manner which distinguishes them from non-vegan foods. Every package of vegan foods after being approved by the food authority is required to vary the logo of as stipulated under the Vegan Food Regulations for vegan foods. The FBOs are required to ensure Good Manufacturing Practices are followed at all stages of production, processing and distribution to avoid any unintended contact of vegan foods with non-vegan substances. The FSSAI also requires the FBOs to maintain vegan integrity of foods or ingredients by enabling traceability up to the manufacturer level.

CONCLUSION

The developments in the food industry in the first half of 2022 is evidence that the regulator is taking a positive approach in recognising and regulating the changing trends in the food sector with Ayurveda Aahara products being recognised as food products and the regulation of the manufacture of vegan food products to ensure the quality and standards of the commodity is maintained in the country. We are yet to see the implementation and adoption of the regulations by the industry.

– Varsha Rajesh, Tanya Kukade, Darren Punnen & Dr.Milind Antani

You can direct your queries or comments to the authors

<sup>1</sup> Accessible at: [https://fssai.gov.in/upload/advisories/2022/03/6243ef28079ceDirection\\_Nutra\\_30\\_03\\_2022.pdf](https://fssai.gov.in/upload/advisories/2022/03/6243ef28079ceDirection_Nutra_30_03_2022.pdf) (Last accessed on June 28, 2022).

<sup>2</sup> Accessible at: <https://egazette.nic.in/WriteReadData/2022/235642.pdf> (Last accessed on June 28, 2022).

<sup>3</sup> Food Safety and Standards (Vegan Foods) Regulations, 2022, accessible at: <https://egazette.nic.in/WriteReadData/2022/236584.pdf> (Last accessed on June 28, 2022).

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