

# Pharma & Healthcare Update

October 06, 2023

## REGULATORY UPDATE 2023: FOOD INDUSTRY IN INDIA

### INTRODUCTION

The first half of 2023 has seen a slew of activity from the regulatory authority for the food industry in India. According to news reports, the Food Safety and Standards Authority of India ("FSSAI") is considering implementing cautionary warnings about the amount of added salt, sugar and fat in the front label of packaged foods, alongside a star rating system. The revised practices are still in the pipeline and are yet to be released by the FSSAI. As with other industries, there has also been a strong focus on tackling misleading advertisements to protect the interests of the consumers.

Some of the key developments that have taken place in the first half of 2023 in the food sector are captured below.

### PROCESS OF RENEWING FOOD LICENSES HAS BEEN STREAMLINED FOR EASE OF DOING BUSINESS

The FSSAI – the central-level food regulator in India – vide order dated January 11, 2023<sup>1</sup> ("Renewal Order") has streamlined the process of renewing the license / registration granted to a food business operator ("FBO") to cater to the ease of doing business in India. Under the Food Safety and Standards (Licensing and Registration of Food Businesses) Regulations, 2011, the license / registration granted to a food business is required to be renewed on a periodic basis. At the time of making an application for renewal, the FBO was required to submit documents to the licensing authority which would be scrutinised by the licensing authority prior to granting the renewal. The timeline for such approval was long and the FBO were experiencing delays in such grant given the rise in the number of FBOs in the country.

The FSSAI has now done away with the requirement of scrutinization of documents by the regulatory authorities to reduce timelines and maximise efficiency for grant of renewal or registration. According to the Renewal Order, renewals will be granted instantly upon submitting the application provided that there are no changes to the existing details of the license / registration and the license / registration of the FBO has not been suspended or cancelled. Licenses will now have to be renewed annually, while registrations will continue to be valid for a period of 1-5 years based on the payment made by the FBO in the application.<sup>2</sup> The Renewal Order reiterates that the window for renewal of license / registration opens atleast 180 days prior to expiry date and enables FBOs to apply proactively for such renewal/ registration.

### FOOD REGULATOR CLARIFIES THAT PRODUCTS WITH VITAMINS/MINERALS GREATER THAN ONE RDA LEVEL WOULD NOT BE TREATED AS FOOD

The FSSAI has reiterated vide notice issued in May 2023<sup>3</sup> that vitamins with doses less than or equal to one Recommended Dietary Allowance ("RDA") are regulated under the Food Safety and Standards Act, 2006 ("FSS Act") and the Food Safety and Standards (Approval for Non-specified Food and Food Ingredients) Regulations, 2017. While vitamin preparations having prophylactic and therapeutic claims are to be regulated under the Drugs and Cosmetics Act, 1940 ("D&C Act").

Vitamin and mineral formulations may be considered either a food product or a drug, depending on their composition, and consequently are subject to different regulatory frameworks. The Drugs Technical Advisory Board ("DTAB") had examined the matter in 2020 and had recommended that vitamins with doses up to one RDA should be regulated as food, while those having prophylactic and therapeutic claims should be regulated under the D&C Act and rules thereunder. An Expert Committee on non-specified foods and food ingredients also adopted the same stance and recommended that vitamin and mineral formulations above one RDA should not be considered for approval under the FSS (Approval for Non-Specified Food and Food Ingredients) Regulations, 2017.

### CRACKDOWN ON MISLEADING ADVERTISEMENTS

The FSSAI has been actively cracking down on misleading advertisements involving food products. According to a press release<sup>4</sup>, the Advertising Monitoring Committee of the FSSAI had reported a large number of claims and advertisements made by FBOs in the country that were in violation of the Food Safety and Standards (Advertising and Claims) Regulations, 2018 ("FSS Advertising and Claims Regulations"). The FSS Advertising and Claims Regulations prohibit deceptive claims and advertisements to be made by FBOs. The FSS Advertising Monitoring Committee is responsible for periodically scrutinizing the advertisements and claims made by FBOs on various social media and e-commerce platforms regarding food products.

The FSS Advertising Monitoring Committee identified errant advertisers and has forwarded their details to the

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concerned licensing authorities for issuance of notices under the FSS Act to the FBOs for taking down misleading advertisements and for correcting misleading claims and to take further action.

On March 7, 2023, the FSSAI issued a circular<sup>5</sup> to the Commissioner of Food Safety in all states and union territories, the central licensing authorities and all regional directors of the FSSAI requesting them to carry out special enforcement drives to check for products falling under the FSS (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, and Prebiotic and Probiotic Food) Regulations, 2022 ("**Nutraceutical Regulations**") to check for compliance with both quality standards and Advertising and Claims Regulations in the consumer interest.

## FOOD PRODUCTS WITH "DECEPTIVE" NAMES TO CARRY DISCLAIMER ON FRONT OF PACK LABEL

The Advertising and Claims Regulations were amended by the FSSAI vide the Food Safety and Standards (Advertising and Claims) Second Amendment Regulations, 2022 ("**FSS Advertising Amendment Regulations**"). The FSS Advertising Amendment Regulations require that when the brand name, trademark or fancy name of a food product contains potentially misleading adjectives such as "*natural*", "*original*", "*fresh*", "*pure*", etc, the label must carry a disclaimer clarifying that it is only a brand name and does not represent the true nature of the food product.

Previously, the disclaimer was required to be made below the brand name on the pack label. However, following an amendment to the Advertising and Claims Regulations that was notified in December 2021<sup>6</sup>, the disclaimer must now be prominently displayed on the front of pack of the label.

The amendment came into force on December 13, 2022, with immediate effect and did not provide for a buffer period in which FBOs could change the artwork of the labels and exhaust existing inventory of their packaging materials for the products which made it impracticable to implement. Therefore, following repeated representations from FBOs, the FSSAI has granted till December 12, 2023 to comply with the new requirements.<sup>7</sup>

## NEW COMPLIANCES FOR IMPORT OF HIGH-RISK FOOD PRODUCTS

The FSSAI classifies certain categories of food such as dairy products, meat and meat products, fish and fish products, foods intended for nutritional use as high risk. Food businesses involved in these high-risk products are typically subject to more stringent requirements including compulsory food audits at regular intervals.

In October 2022, the FSSAI in furtherance of Food Safety and Standards (Import) First Amendment Regulations, 2021 introduced<sup>8</sup> a registration requirement of food manufacturing facilities that produce milk and milk products; egg powder; meat and meat products' foods for infant nutrition and infant foods and nutraceuticals, health supplements, foods for dietary uses, probiotic and prebiotic foods, and foods for special medical purposes ("**High Risk Imports**"). The requirement came into effect on February 1, 2023.

In an attempt to establish a robust import control system and ensure efficient monitoring and traceability of food products that are categorised as high risk, the FSSAI has now specified a list of ports<sup>9</sup> through which these food products may be imported into India. Effective March 1, 2023, High-Risk Imports may only be imported into India through the specified ports/channels.

Separately, in August 2022 the FSSAI had issued an order requiring that all consignments of milk and milk products; pork and pork products; and fish and fish products must be accompanied with a Health Certificate issued by the competent authority in the exporting country in the prescribed format. The deadline for implementation of the order had been extended to January 1, 2023, then March 1, 2023 and has now been extended till further order.<sup>10</sup>

## CONCLUSION

The developments from the first half of 2023 in the food industry indicate the FSSAI's intent to empower consumers to take informed decisions about what they consume. In addition to deliberating practices that would make labels more informative and readable for the common man, the authority has been cracking down on advertisements that are potentially misleading to consumers. It is likely that the second half of 2023 will also see efforts from the food regulator to improve and implement the food labelling practices in India.

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You can direct your queries or comments to the authors.

<sup>1</sup> Accessible at: <https://fssai.gov.in/upload/advisories/2023/01/63bfa4c0d8679FSSAI%20Order%20dated%2011-01-2023.pdf>

<sup>2</sup> Order accessible at: <https://fssai.gov.in/upload/advisories/2023/01/63bfa4c0d8679FSSAI%20Order%20dated%2011-01-2023.pdf>

<sup>3</sup> Accessible at: <https://fssai.gov.in/upload/advisories/2023/05/64672933c21b2RDA%20level%20notice.pdf>

<sup>4</sup> Accessible at: [https://fssai.gov.in/upload/press\\_release/2023/04/64436abae6d6fPRESS\\_NOTE\\_21042023.pdf](https://fssai.gov.in/upload/press_release/2023/04/64436abae6d6fPRESS_NOTE_21042023.pdf) and [https://fssai.gov.in/upload/press\\_release/2023/04/644cce8e880a5FSSAI\\_Press\\_Note\\_28042023.pdf](https://fssai.gov.in/upload/press_release/2023/04/644cce8e880a5FSSAI_Press_Note_28042023.pdf)

<sup>5</sup> Accessible at: <https://fssai.gov.in/upload/advisories/2023/03/64074f3f75dacenforcement%20drive-%20nutraceuticals.pdf>

<sup>6</sup> Accessible at: [https://www.fssai.gov.in/upload/notifications/2022/12/63998e33c2ad6Gazette\\_Notification\\_Amendment\\_14\\_12\\_2022.pdf](https://www.fssai.gov.in/upload/notifications/2022/12/63998e33c2ad6Gazette_Notification_Amendment_14_12_2022.pdf)

<sup>7</sup> Accessible at: [https://fssai.gov.in/upload/advisories/2023/07/64a669e74d46edirection\\_Ads\\_06072023.pdf](https://fssai.gov.in/upload/advisories/2023/07/64a669e74d46edirection_Ads_06072023.pdf)

<sup>8</sup> Accessible at: [https://fssai.gov.in/upload/advisories/2022/10/6343da0a0f78fOrder\\_Foreign\\_Food\\_10\\_10\\_2022.pdf](https://fssai.gov.in/upload/advisories/2022/10/6343da0a0f78fOrder_Foreign_Food_10_10_2022.pdf)

<sup>9</sup> Accessible at: [https://fssai.gov.in/upload/advisories/2023/02/63dd205dc1304Port\\_Restriction.pdf](https://fssai.gov.in/upload/advisories/2023/02/63dd205dc1304Port_Restriction.pdf)

<sup>10</sup> Accessible at: [https://fssai.gov.in/upload/advisories/2023/02/63f87d4359e13Extension\\_order.pdf](https://fssai.gov.in/upload/advisories/2023/02/63f87d4359e13Extension_order.pdf)

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