

# Pharma & Healthcare Update

January 24, 2025

## REGULATORY WRAP 2024: FOOD INDUSTRY IN INDIA

The most significant regulatory developments in the food industry in 2024 are:

- The Food Safety and Standards Authority of India issued guidelines on the use of the term 'ORS' with brand names for products
- Regulatory landscape for nutraceuticals likely to be revamped
- Self-declaration requirement made applicable to advertisers/advertising agencies for food products to curb misleading advertisements
- Amendment proposed to the Legal Metrology (Packaged Commodities) Rules to standardize labeling requirements for pre-packaged goods for retail sale
- Framework for nutritional and supplemental food products re-operationalized

## INTRODUCTION

The past year has witnessed steady activity from the food regulatory authority in India. The Food Safety and Standards Authority of India ("FSSAI") continues to focus on consumer protection, food safety, and compliance with advertising standards.

Notable developments include the issuance of new guidelines regarding the use of the term 'ORS' by companies along with brand names and the proposed amendment to the labelling regulations to standardize labelling requirements for all pre-packaged commodities intended for retail sale. The FSSAI has also re-operationalized 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 pending the finalization and notification of the regulations while the Inter-Ministerial Committee assesses the manner of regulation of nutraceuticals and similar products under the existing regulatory framework in India. Additionally, the FSSAI is also actively taking steps to curb misleading advertisements in India by requiring food business operators ("FBOs") to submit the self-declaration certificate before publishing advertisements for food products in compliance with the Supreme Court directive.

These changes highlight the ongoing efforts to enhance transparency, safety, and fairness in the food sector. These key developments that have taken place in 2024 in the food sector are discussed below.

## FSSAI GUIDELINES ON THE USAGE OF THE TERM 'ORS' ALONG WITH BRAND NAMES

The FSSAI in early 2024 vide an order dated February 2, 2024 issued guidelines<sup>1</sup> regarding the use of the term 'ORS' along with brand names, following an order of the Controller General of Patents, Designs and Trademarks ("CGPDTM").

Previously, the FSSAI had allowed FBOs with valid trademarks for product names similar to 'ORS' to continue manufacturing products under their respective trademarked names until the CGPDTM decided on the matter. The CGPDTM subsequently clarified that the term "ORS along with other prefixes or suffixes" may be used by FBOs as a whole in accordance with Section 17 of the Trade Marks Act, 1999.<sup>2</sup>

In light of the above relaxation granted to FBOs for the use of the term 'ORS', the FSSAI has outlined the following conditions for FBOs manufacturing products with names containing 'ORS' or similar terms:

1. FBOs may use *"ORS along with other prefixes or suffixes"*;
2. A prominent disclaimer must be displayed on the Front-of-Pack of the product stating, *"The product is NOT a ORS formula as recommended by WHO"* or similar wording to avoid any confusion or misleading the consumers. The FSSAI has also prescribed the font and manner for display of such disclaimer;
3. The product must also include the disclaimer required by sub-regulation 4(7) of the Food Safety and Standards (Advertising and Claims) Regulations, 2018, which states, *"This is only a brand name or trademark, or fancy name and does not represent its true nature"*, as applicable.

The guidelines became effective from April 1, 2024 and all FBOs intending to use the term 'ORS' as part of their brand name are required to comply with these guidelines.

## ADVISORY ON CURBING MISLEADING ADVERTISEMENTS AND PROTECTING CONSUMER INTEREST

The FSSAI issued an advisory to the FBOs with an intent to curb misleading advertisements in the food industry. The advisory was issued by the FSSAI in furtherance of the order of the Supreme Court dated May 7, 2024. in the case of Indian Medical Association and Anr. vs. Union of India and Ors.<sup>3</sup>, which aims to curb misleading advertisements and protect consumer interests.

In furtherance of the order of the Supreme Court, the Ministry of Information and Broadcasting ("MIB") introduced the requirement for advertisers/advertising agency to submit a self-declaration on the Broadcast Seva Portal of the MIB before the advertisement is aired/printed/displayed.<sup>4</sup> The advertisers are required to certify that the advertisement proposed to be telecasted/published does not violate the advertising code prescribed under the Cable Television Networks Rules, 1994. The proof of uploading the self-certificate is also required to be made available by the advertiser to the broadcaster/publisher/printer/electronic media platform, etc. for record keeping purposes.

The FSSAI has proactively advised the FBOs to ensure compliance with the self-certification requirement prior to telecasting/publishing advertisements for their products. Advertisements in print/digital/internet are all subject to the self-certification requirement notified by the MIB.<sup>5</sup>

The intent of the MIB and the FSSAI in making compliance with the directives of the Supreme Court in safeguarding consumer interest is a step in the right direction. However, implementation of the directive in the fast-paced digital market remains to be seen.

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<div>REGULATORY MECHANISM FOR NUTRACEUTICALS LIKELY TO BE REVAMPED</div> <div>Nutraceuticals and health supplement products have gained momentum in the past few years in India. While the health supplements and similar products in India were regulated by the drug regulator earlier, in 2008, the FSSAI was established and a significant shift happened in the regulation of such products. Under the existing regulations, vitamins and mineral products meant to have certain physiological benefits to humans are regulated in two ways – one as a drug and the other as a food product for which the food regulator has notified specific regulations.</div> <div>Nutraceutical products are required to contain ingredients in compliance with the Nutra Regulations with quantity of nutrients added not exceeding the recommended limits / daily allowances (“<b>RDA</b>”) prescribed by Indian Council of Medical Research to be regulated as food products. While products containing vitamins and minerals with dose/dosage formats as defined under Schedule V of Drugs Rules, 1945 (“<b>Drugs Rules</b>”) (which specifies the prophylactic and therapeutic doses of such ingredients) are regulated as drugs.</div> <div>In furtherance of the debate surrounding the regulation of such products, the Ministry of Health and Family Welfare formed the Inter-Ministerial Committee to review the regulatory purview of Nutraceuticals. The committee has recommended that vitamins, minerals and amino acids added in food (as defined in the FSS Act 2006) where such products make only nutritional and health claims may be retained under the purview of FSSAI. However, the formulations having such ingredients with dose and/or dosage formats and permitted excipients or products making disease risk reduction related claims as defined in Drugs Rules shall be shifted under the purview of the drug regulator. The committee also suggested a separate provision on Good Manufacturing Practices (“<b>GMP</b>”) for health supplements and nutraceuticals to be specified in the applicable food regulations. The FSSAI may also consider examining the advertisement for Nutraceutical products and establish a dedicated cell for its monitoring. The recommendations have been made by the committee to address regulatory challenges, avoid overlap in regulation and to promote consumer safety. The adoption and implementation of the suggestions provided by the committee remain to be seen.</div> <div>FRAMEWORK FOR NUTRITIONAL AND SUPPLEMENTAL FOOD PRODUCTS RE-OPERATIONALIZED</div> <div>The FSSAI issued a direction on August 30, 2024 (“<b>Nutra Regulations Interim Direction</b>”) to re-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 (“<b>Nutra Regulations</b>”) from July 1, 2024.<sup>6</sup></div> <div>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.</div> <div>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 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.</div> <div>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 for such products.</div> <div>The Nutra Regulations Interim Direction has been issued under Section 16(5) of the Food Safety and Standards Act, 2006 (“<b>FSS Act</b>”) which enables the FSSAI to issue binding directions on matters relating to food safety and standards.</div> <div>PROPOSED AMENDMENT TO LEGAL METROLOGY RULES TO MANDATE LABELING ON ALL PRE-PACKAGED COMMODITIES FOR RETAIL SALE</div> <div>The Department of Consumer Affairs, Government of India, has proposed an amendment<sup>7</sup> to the Legal Metrology (Packaged Commodities) Rules, 2011 (“<b>LM Rules</b>”), aiming to mandate the labelling requirements to all pre-packaged commodities intended for retail sale.</div> <div>At present, the LM Rules expressly exclude its applicability to packages of commodities of more than 25 kilograms, cement, fertilizer and agricultural farm produce in bags above 50 kilograms and packaged commodities meant for industrial consumers or institutional consumers. The proposed amendment seeks to clarify the obligations of manufacturers, packers, and importers of packaged goods, ensuring that such commodities meet uniform labeling standards regardless of their quantity, with the continued exception for goods intended for industrial or institutional consumers.</div> <div>The revised rules would require all packaged commodities, sold in retail settings, to display essential details including the name and address of the manufacturer/packer/importer, country of origin, common name of the commodity, net quantity, month and year of manufacture, Maximum Retail Price, unit sale price, and best-before/use-by dates where applicable. These provisions aim to provide consumers with complete and transparent information, promoting informed purchasing decisions.</div> <div>The proposal aims to standardize labeling across products, benefitting both consumers and businesses by ensuring fairness and consistency in the marketplace, especially as the retail environment continues to expand across offline and online platforms.</div> <div>CONCLUSION</div> <div>The regulatory developments in the food sector in 2024 reflect the government’s commitment to enhancing food safety, consumer rights, and fair business practices. As the food industry evolves, adherence to these regulations and guidelines by FBOs will assist in enhancing the trust of the consumers in the food industry in the country. It is crucial for businesses to ensure compliance and avoid legal repercussions. FBOs must stay informed and implement these changes to foster transparency, trust, and consumer protection in the ever evolving and expanding food industry in the country.</div>	<div>SIAC 2025 Rules: Key changes &amp; Implications</div> <div>February 18, 2025</div>

<sup>1</sup>Accessible at: [https://fssai.gov.in/upload/advisories/2024/02/65c0d35e786e4Order%20dated%2002nd%20Feb%202024\\_Use%20of%20term%20ORS.pdf](https://fssai.gov.in/upload/advisories/2024/02/65c0d35e786e4Order%20dated%2002nd%20Feb%202024_Use%20of%20term%20ORS.pdf)

<sup>2</sup>Section 17 of the Trade Marks Act, 1999 provides that when a trade mark consists of several matters, the registration of the mark confers the proprietor with the exclusive right to use of the trade mark as a whole.

<sup>3</sup>WPC No. 645 of 2022

<sup>4</sup>The Broadcast Seva Portal of the MIB has become active w.e.f. from June 4, 2024.

<sup>5</sup>Accessible at: <https://fssai.gov.in/upload/advisories/2024/11/6731f1565cdf0Advisory%20-Supreme%20court.pdf>

<sup>6</sup>Accessible at: <https://fssai.gov.in/upload/advisories/2024/08/66d1af4da0deeRe->

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