



THE ORS CASE – PROFIT OR PUBLIC HEALTH?

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BACKGROUND OF THE CASE

ORS, or Oral Rehydration Solution, is a medical product specifically designed to address dehydration in the body during illness due to its precise glucose-to-sodium ratio. A disruption in this ratio can do more harm than good. For instance, in the aforementioned case, excessive amounts of sugar (approximately 9-10 times the recommended amount by the WHO) in the product worsen dehydration by drawing water out of the cells.

In India, 'ORS' is a 'drug' under Section 3(b) of the Drugs and Cosmetics Act.¹ which is used for the treatment of acute diarrhoea and has a specific composition prescribed by the Drugs Controller General of India (DCGI). Responding to rising concerns about such misleading and detrimental marketing, in April 2022, FSSAI barred the use of the ORS label on fruit-flavoured beverages as 'misbranded'² and noted the possible 'serious health repercussions', particularly in children.³

In July, however, a new order was passed by the FSSAI that permitted the use of terms similar to 'ORS' for companies with valid trademarks. The FBOs were further directed to provide prominent disclaimers on the front of the pack indicating that the product did not comply with WHO standards. Companies without such a trademark were required to discontinue manufacturing.⁴

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¹ Drugs and Cosmetics Act 1940, s 3(b).

² The Food Safety and Standards Act 2006, s 3.

³ Food Safety and Standards Authority of India, 'Direction under Section 16(5) regarding misleading advertisement and marketing of ORS substitute Products-Reg' (8 April 2022) https://www.fssai.gov.in/upload/advisories/2022/04/6253ddfde2161Direction_advertisement_ORS_11_04_2022.pdf accessed 25 October 2025.

⁴ Food Safety and Standards Authority of India, 'Usage of the term "ORS" along with brand names' (14 July 2022) https://fssai.gov.in/upload/advisories/2022/07/62d533f8adb0fOrder_ORS_Name_18_07_2022.pdf accessed 25 October 2025.

The 2nd of February 2024 saw FSSAI issue an additional directive reiterating the disclaimer guidelines and mandating that FBOs make it clear that the said products use the term 'ORS' with a prefix/suffix only as a trademark/brand name and that it is not representative of its true nature.⁵

On October 14, 2025, FSSAI released an order withdrawing the July 2022 and February 2024 orders with immediate effect.⁶ Further, on 15th October 2025, FSSAI further clarified that use of the term "ORS" in the trademarked name or in the naming of any food product otherwise, whether fruit-based, non-carbonated, or ready-to-drink beverages, even when accompanied by a prefix or suffix, constitutes a violation of the provisions of the Food Safety and Standards Act, 2006 and the regulations made thereunder.⁷ The April 2022 order remained enforceable.

JNTL Consumer Health, a subsidiary of Johnson & Johnson, which markets 'ORSL', approached the Delhi High Court seeking a stay on the October 14 order, contending that the said withdrawal was enforced without prior notice. The company claimed that the orders exposed it to potential enforcement actions despite its compliance with FSSAI's previous directions. Thus, the Hon'ble Court on 17th October granted interim protection to JNTL Consumer Health by staying the FSSAI ban and permitting the company to sell its existing ₹155- ₹180 crore stock.

EXPLORING THE LEGAL ASPECTS

Firstly, the Rupa Singh⁸ judgement in 2021 by the Delhi High Court prompted the July 2022 order by FSSAI allowing companies with a trademark to continue to use the term 'ORS' on their labels with a disclaimer, despite concerns of it being potentially misleading. The rationale behind this was that certain registered companies had valid trademarks under the Trademarks

⁵ Food Safety and Standards Authority of India, 'Usage of the term "ORS" along with brand names' (2 February 2024)

https://fssai.gov.in/upload/advisories/2022/07/62d533f8adb0fOrder_ORS_Name_18_07_2022.pdf accessed 25 October 2025.

⁶ Food Safety and Standards Authority of India, 'Withdrawal of orders regarding usage of the term "ORS" along with brand names'(14 October 2025)

<https://www.fssai.gov.in/upload/advisories/2025/10/68ee3ba06bb7eWithdrawal%20of%20Orders%20regarding%20Usage%20of%20the%20term%20ORS%20along%20with%20brand%20names%20dt%2014.10.2025.pdf> accessed 27 October 2025.

⁷ Food Safety and Standards Authority of India, 'Clarification regarding Order dated 14.10.2025 on withdrawal permissions for use of the term "ORS" along with brand names' (14 October 2025)

https://fssai.gov.in/upload/advisories/2025/10/68ef8cea74223clarification_151025.pdf accessed 27 October 2025.

⁸ *Rupa Singh v. Ministry of Health and Family Welfare* (2021) SCC OnLine Del 4238.

Act, 1999, which they could rightfully display. Use of the term ‘ORS’ with a prefix or suffix is aligned with Section 17 of the Trademarks Act. However, the FSSAI direction sought a review of trademarks of such companies by the Controller General of Patents, Designs and Trademarks, and the final decision to allow use of the trademark was contingent on this review. This judgement made it a requirement for FSSAI to conduct stakeholder consultations before taking any adverse action on the issue.

On the other hand, there exist provisions in Indian food safety and consumer laws that prevent marketers from making misleading claims and jeopardising public interest. Sub-regulation 2.2.1(3) of the Food Safety and Standards (Packaging and Labelling) Regulations, 2011 prohibits *false, misleading or deceptive statements or is likely to create an erroneous impression regarding its character in any respect.*

Section 3 (zf) of the Food Safety and Standards Act, 2006 defines ‘misbranded foods’ to be articles *offered or promoted for sale with false, misleading or deceptive claims (on the label of the packaging as well)*. Section 23 of the same act prescribes that information about the product made available to consumers through ‘whatever medium’ (including labels as well) must not be misleading.

Clause 4(1) of the Food Safety and Standards (Advertising and Claims) Regulations, 2018 asserts that claims must be truthful, unambiguous, meaningful, *not misleading* and help consumers to comprehend the information provided. Sections 52 and 53 of the Food Safety and Standards Act (FSSA), 2006, establish penalties for misbranded food and misleading advertisements, respectively. Consumer Protection laws in India also contain provisions against misleading advertisements under Section 10⁹ (creation of the Central Consumer Protection Authority to address the same), Section 21¹⁰ (enforcement) and section 89¹¹ (penalties).

CONCLUSION

The interim stay by the Delhi High Court on the FSSAI order was deemed to be controversial on the stance that presumably appears to favour industry interests over public health. However, as one approaches the legal reasoning behind the same, a complex interplay between food

⁹ The Consumer Protection Act 2019, s10.

¹⁰ The Consumer Protection Act 2019, s 21.

¹¹ The Consumer Protection Act 2019, s 89.

safety and consumer protection laws and intellectual property rights can be encountered. It is only through critical analysis of provisions and possibilities that a fair outcome can be determined.