



\$~45

* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

%

Date of decision: 31.10.2025+ **W.P.(C) 16303/2025 and CM APPL.66695/2025****DR REDDYS LABORATORIES LIMITED & ORS**Petitioners

Through: Ms. Neelima Tripathi, Sr. Advocate along with Ms. Sanam Tripathi, Ms. Anjali Kaushik, Ms. Kriti Sharma, Mr. Harjeet Singh, Advocates and Mr. Gopal K. Gangawali, AR for petitioner (DRL).

versus

UNION OF INDIA & ANR.

.....Respondents

Through: Mr. Chetan Sharma, ASG along with Mr. Ashish K. Dixit, CGSC, Mr. Aamir Zafar Khan, Mr. Umar Hashmi, Mr. Amit Gupta, Mr. Shubham Sharma, Mr. Abdullah Shahid, Mr. Vikram Aditya Singh, Mr. Yash Wardhan Sharma, Mr. Naman, Ms. Iqra Sheikh, Mr. Harshit Chitransh, Mr. Aditya Shandily and Mr. Shivam Tiwari, Advocates.

CORAM:**HON'BLE MR. JUSTICE SACHIN DATTA****SACHIN DATTA, J. (ORAL)**

1. The present petition has been filed by the petitioner assailing the order bearing F.No.RCD-15001/6/2021-Regulator-FSSAI [E-1475] dated 14.10.2025 and the subsequent clarification / order bearing F. No. RCD-15001/6/2021-Regulatory-FSSAI [E-1475] dated 15.10.2025, both issued by the respondent no.2 (Food Safety and Standards Authority of India –



FSSAI) as also a communication bearing No. TS/Enforcement/FSSAI-SRO/25-26/01 dated 23.10.2025, issued by FSSAI. The order bearing F.No.RCD-15001/6/2021-Regulator-FSSAI [E-1475] dated 14.10.2025 reads as under :

F. No. RCD-15001/6/2021-Regulatory-FSSAI [E-1475]
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety and Standards Act, 2006)
Regulatory Compliance Division
FDA Bhavan, Kotla Road, New Delhi-110002

ORDER/ आदेश

दिनांक : 14 अक्टूबर, 2025

Subject: Withdrawal of Orders regarding 'Usage of the term "ORS" along with brand names'- reg.

विषय: 'ब्रांड नामों के साथ "ORS" शब्द के उपयोग' संबंधी आदेशों की वापसी के सम्बन्ध में।

Reference to:

- a. Order no. RCD-15001/6/2021-Regulatory-FSSAI [E-1475] dated 14th July, 2022
- b. Order no. RCD-15001/6/2021-Regulatory-FSSAI [E-1475] dated 2nd February 2024

This in respect to the orders cited above and all such orders issued in past regarding the 'Usage of the term "ORS" along with brand names.

2. In this regard, it has been decided that the aforementioned orders and any other order previously issued in this regard stands withdrawn with immediate effect.

This issues with the approval of the competent authority.

Digitally signed by
Sweety Behera
Date: 14-10-2025
16:44:28
(स्वीटी बेहेरा)
निदेशक

To

1. The Commissioners of Food Safety- All States/UTs
2. All Central Licensing Authorities, FSSAI

Copy for information to:

1. CP, FSSAI & Secretary, H&FW
2. CEO, FSSAI
3. All Regional Directors, FSSAI



Clarification / order bearing F. No. RCD-15001/6/2021-Regulatory-FSSAI [E-1475] dated 15.10.2025 is reproduced as under –

Annexure P - 2 45

F. No. RCD-15001/6/2021-Regulatory-FSSAI [E-1475]
Food Safety and Standards Authority of India
(A Statutory Authority established under the Food Safety and Standards Act, 2006)
Regulatory Compliance Division
FDA Bhavan, Kotla Road, New Delhi-110002

दिनांक: 15 अक्टूबर, 2025

विषय: ब्रांड नामों के साथ “ओआरएस” शब्द के उपयोग की अनुमति वापस लेने पर दिनांक 14.10.2025 के आदेश के संबंध में स्पष्टीकरण - तत्संबंधी।

Subject: Clarification regarding Order dated 14.10.2025 on withdrawal of permissions for use of the term “ORS” along with brand names – reg.

This is in continuation to the order of even number dated 14.10.2025 with respect to the subject cited above. The said order has superseded and withdrawn the earlier Orders of FSSAI, namely Order No. RCD-15001/6/2021-Regulatory-FSSAI [E-1475] dated 14th July 2022 and Order No. RCD-15001/6/2021-Regulatory-FSSAI [E-1475] dated 2nd February 2024. Those Orders had permitted the use of the term “ORS” on food labels as part of the trademark with prefix or suffix in the product name, subject to the declaration/warning: “The product is NOT an ORS formula as recommended by WHO.”

2. It is hereby clarified that, upon further review, the 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.

3. Such practices are misleading to consumers by way of false, deceptive, ambiguous, and erroneous names/label declarations, and are in contravention of:

- Sections 23 & 24 of the Food Safety and Standards Act, 2006
- Sub-regulation 4(3) of the Food Safety and Standards (Labelling and Display) Regulations, 2020
- Sub-regulation 5(1) of the Food Safety and Standards (Labelling and Display) Regulations, 2020
- Sub-regulations 4(1) and 4(13) of the Food Safety and Standards (Advertising & Claims) Regulations, 2018

And thus misbranded & misleading, which is liable for punishment under Section 52 & 53 of the Food Safety and Standards Act, 2006.

4. Accordingly, the aforementioned **Orders dated 14.07.2022 and 02.02.2024 stand withdrawn with immediate effect.** It may be noted that the “Direction under section 16(5) regarding misleading advertisement and marketing of ORS substitute products dated 08.04.2022” shall remain in effect.



5. In view of the above, all Food Business Operators are directed to remove the word "ORS" from their food products, whether used as a standalone term or in combination with any prefix/suffix or as part of the trademark with prefix/suffix in the product name and to ensure strict compliance with the labelling and advertisement requirements prescribed under the Food Safety and Standards Act, 2006 and the regulations framed thereunder.

This issues with the approval of the Competent Authority.

Digitally signed by
Sweety Behera
Date: 15-10-2025
16:51:22

(स्वीटी बेहेरा)
निदेशक (विनियामक अनुपालन)

To

1. The Commissioners of Food Safety- All States/UTs
2. All Central Licensing Authorities, FSSAI

Copy for information to:

1. PPS to CP, FSSAI & Secretary, H&FW

Communication bearing No. TS/Enforcement/FSSAI-SRO/25-26/01 dated 23.10.2025 is reproduced as under –

Annexure P - 3

4 /



भारतीय खाद्य सुरक्षा एवं मानक प्राधिकरण, दक्षिणी क्षेत्रीय कार्यालय
Food Safety and Standards Authority of India, Southern Regional Office
प्रथम तल, बीएसएनएल सीएससी बिल्डिंग, बीएसएनएल टीई कंपाउंड में, सेंट टेरेसा अस्पताल के बगल में, एरगुड्डा, हैदराबाद, तेलंगाना - 500018
1st Floor, BSNL CSC Building in BSNL TE Compound, Beside St. Theresa Hospital, Erragadda, Hyderabad, Telangana - 500018

No.TS/Enforcement / FSSAI-SRO/25-26/01

Date: 23/10/2025

IMPROVEMENT NOTICE

To
M/s Dr Reddy's Laboratories Limited,
8-2-337.Road No:3, Banjara Hills,
Hyderabad, Telangana-500034

Sir,

Sub: Improvement notice against license no 10020047001849 as per Section 32 of Food Safety and Standards, Act.2006 – Non-compliance with the FSS Act and Rules and Regulations made thereunder– Reg.

Ref: (1) Section 32 1(a) of FSS Act.
(2) FSSAI Order No. RCD-15001/6/2021-Regulatory-FSSAI [E-1475] dated 15th October 2025.

As per the Food Safety and Standards Act 2006 and Regulations made there under, all the provisions of the Act and regulations must be always complied by the Food Business Operator. The above-mentioned premise was granted FSSAI-License number 10020047001849 and the license is active as on date.

**4. Grounds:**

Your firm is involved in the manufacturing/marketing/distributing/selling/advertising the following product(s) which is in non complying to the directions issued by FSSAI vide its order dated 14.10.2025 & subsequent order dated 15.10.2025

Name of the product	FBO Details	Advertisement/Label Link	Objections on Advertisement/label for the Product
Dr Reddy's Rebalanz V ITORS™ - Electrolyte & Mineral-Rich ORS Drink	M/s Dr Reddy's Laboratories Limited, 8-2-337.Road No:3, Banjara Hills, Hyderabad, Telangana-500034. FSSAI Lic No: 10020047001849	https://www.bigbasket.com/pd/40224167/dr-reddys-rebalanz-vitors-electrolyte-mineral-rich-ors-drink-provides-energy-keeps-hydrated-apple-flavour-200-ml/	The use of the term "ORS" in the trademarked name or in the naming of any food product otherwise whether the 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

48

5. Violations: The product(s) listed in the above table are misleading to consumers by way of false deceptive, ambiguous, and erroneous names/label declarations, and are in contravention of:

- Sections 23 & 24 of the Food Safety and Standards Act, 2006
- Sub-regulation 4(3) of the Food Safety and Standards (Labelling and Display) Regulations, 2020
- Sub-regulation 5(1) of the Food Safety and Standards (Labelling and Display) Regulations, 202
- Sub-regulations 4(1) and 4(13) of the Food Safety and standards (Advertising & claims) Regulations, 2018

As per the above sections the product fall under misbranded & misleading, which is liable for punishment under Section 52 & 53 of the Food Safety and Standards Act, 2006.

6. Mandatory compliance and due date

In view of the above, your firm is hereby directed as follows:

- To discontinue manufacturing/selling/supplying/distributing/ advertising/ marketing the above listed products with immediate effect.
- To remove the term "ORS" in the trademarked name or in the naming of any food product whether fruit – based, non carbonated or RTS beverages even when accompanied by a prefix or suffix as it constitutes a violation of the FSS Act, 2006 and regulations made thereunder.
- To submit the amended copy of label of such products and its related advertisements thereof in compliance to the FSS Regulations.

Your firm is directed to rectify the contraventions within **14 days** of receipt of this notice, failing which suitable action as deemed fit under aforesaid FSS Acts, Rules and Regulations made thereunder will be initiated against your firm.

Regards,

(Balunaik Kethavath)

Designated Officer- Telangana,
FSSAI Southern Region,
Food Safety and Standards Authority of India.

Enclosure

Signature Not Verified

Digitally Signed
By: ABHISHEK THAKUR
Signing Date: 01.11.2025
19:32:21

W.P.(C) 16303/2025

Page 5 of 18



2. Thus, the FSSAI has sought to impose an embargo on the use of the word 'ORS', whether as a standalone term or in combination with any prefix/suffix, in the naming of any food product, *inter-alia*, any fruit-based or non-carbonated or ready-to-drink beverages.

3. It is the case of the petitioner that the impugned orders have been issued without any notice, hearing, or even consultation with the concerned stakeholders, including the petitioner. It is submitted that the impugned orders have a significant impact on the ongoing operations of the petitioner, as also their proprietary / trademark rights, and also infringes the fundamental rights of the petitioner.

4. It is submitted that, as on date, there are large quantities of the product lying in storage and within the supply chain, which had already been manufactured / distributed prior to the issuance of the impugned orders. It is submitted that the petitioner shall sustain huge monetary loss if the said finished goods are not allowed to be sold with their existing packaging. Further, according to the petitioner, the position of the finished goods inventory with the petitioner as on 15.10.2025 is as under:

Description	FG Stock (units)	FG Stock (value in Rs.)
Rebalanz VITORS Apple 200 ml	1,74,904	28,65,871
Rebalanz VITORS Orange 200 ml	2,33,784	36,23,652
Rebalanz VITORS 200 ml Mango	4,33,493	74,64,749
Total quantity of unsold finished goods of the Product and Total Realized Value	8,47,181	1,39,54,272

5. The petitioner has also placed heavy reliance on an order dated



17.10.2025, passed in **JNTL Consumer Health India Pvt. Ltd. Vs. Union of India & Anr.**, bearing W.P.(C) 16217/2025.

6. Vide order dated 28.10.2025 passed in the present proceedings, it was, *inter-alia*, ordered as under:

“3.The present petition has been filed by the petitioners seeking the following prayers: -

“a) Issue a writ of certiorari or any other appropriate writ, order or direction setting aside/ quashing the order bearing F. No.RCD-15001/6/2021-Regulatory-FSSAI [E-1475] dated 14.10.2025 (Impugned Order-I) and the subsequent clarification / order bearing F. No.RCD-15001/6/2021-Regulatory-FSSAI [E-1475] dated 15.10.2025 (Impugned Order-II) both issued by Respondent No.2, and all consequential actions initiated against the Petitioners in pursuance thereto, including but not limited to the communication dated 23.10.2025 bearing no. TS/Enforcement/FSSAI-SRO/25 -26/01 issued by Respondent No.2 (Impugned Communication);

b) Issue a writ of Mandamus or any other appropriate writ, order or direction restraining the Respondents from taking any coercive steps against the Petitioners in pursuance of the impugned orders and the impugned communication and/or interfering with the manufacture, marketing, distribution, supply and/or sale of the product by/and/or on behalf of the Petitioners, during the pendency of this writ petition.

c) Issue a Writ of Mandamus or any other appropriate writ, order or direction directing the Respondents to convene a stakeholder consultation meeting involving all affected Food Business Operators (FBOs), industry bodies, consumer associations, and scientific experts and other stakeholders in spirit and in terms of the provisions of the FSS Act, ensuring public health protection and industry compliance;

d) Pass ad-interim order in terms of the above directions; and

e) Pass any other or further order(s) which may be just, fair and equitable.”

4. At the outset, learned senior counsel for the petitioners draws attention to, and relies upon an order dated 17.10.2025 passed by this Court in W.P.(C) 16217/2025. The same, *inter-alia*, reads as under:



“3. After some hearing, it is agreed that the petitioner would submit a representation against the impugned orders dated 14.10.2025 and clarification order dated 15.10.2025, annexed as Annexure-A (colly) to the present petition. Let the said representation be submitted within a period of one week from today.

4. It is further agreed that till the said representation is decided in accordance with law and after affording an opportunity of hearing to the petitioner, and duly taking into account the contentions raised in the present petition, the impugned order dated 14.10.2025 and 15.10.2025 shall not be given effect to, qua the petitioner.

5. Needless to say, in case the petitioner is aggrieved with the outcome of the aforesaid exercise, it shall be at liberty to avail appropriate remedies under law.

6. The petition is disposed of in the above terms.”

5. The exercise contemplated to be carried out in terms of the aforesaid consent order dated 17.10.2025, was inherently urgent in nature, and with a view to obviate any infirmity/omission in the impugned action/s taken by the respondent/s (FSSAI). It would result in a prejudicial situation if the offending product/s continue to be manufactured, while the aforesaid exercise get protracted.

6. At this stage, learned counsel for the respondent no.2/FSSAI, who appears on advance notice, submits that the exercise as contemplated in terms of the aforesaid consent order dated 17.10.2025 is underway, and a hearing has been scheduled today itself. Further, it is assured and undertaken that the said exercise shall be concluded before 31.10.2025. Let the outcome thereof be placed on record inasmuch as the same will also have a bearing on the present matter.

7. Learned senior counsel for the petitioner submits that the petitioner has ceased manufacturing of fresh stocks of its product (Relalanz Vitors). The said statement is taken on record. However, it is sought that appropriate order/s be passed to enable the petitioner to dispose of the already manufactured stock/s. The said aspect shall be considered on the next date of hearing.

8. List on 31.10.2025, in the category of **“Supplementary Matters.”**

7. Today, learned ASG appearing for the FSSAI has placed on record a



detailed order dated 30.10.2025, passed by the FSSAI in compliance with the directions contained in the order dated 17.10.2025 in W.P.(C) 16217/2025. The order dated 30.10.2025 copiously examines various facets of the matter in the light of similar grievance advanced by the petitioner in W.P.(C) 16217/2025 and finds as under:

“a) the term “ORS” (Oral Rehydration Salts) is a non-proprietary, generic name for a WHO-prescribed therapeutic formulation recognized under the Drugs and Cosmetics Rules, 1945, and is in the public domain. Its use in any food product label or brand name even as part of a composite mark creates confusion between a Drug/ therapeutic product (Licenced under CDSCO) and a food product (Licenced under FSSAI);

b) it is wrongly understood by the Petitioner that the orders have no scientific basis. WHO-prescribed ORS is a life-saving therapeutic formulation for the management of diarrhoeal dehydration. Its precise composition (sodium chloride 2.6 g, potassium chloride 1.5 g, sodium citrate 2.9 gm glucose 13.5 g per litre) with osmolarity of 245 mOsm/L, is critical to its clinical efficacy. Whereas, beverages marketed under brand names such as ORSL, etc., are water-based, flavoured, or fruit based non-therapeutic drinks containing high sugar levels and imbalanced electrolytes in comparison to WHO recommended ORS formula;

c) except for Sr. no.1 of the table at point (c) of para IV of this order, which is drug licenced by CDSCO under the Drugs and Cosmetics Rules, 1945, the other ORSL products are food item that do not meet the WHO formulation.

d) complaints have been received that such products have been mistakenly consumed by patients, particularly children, in place of WHO recommended ORS, resulting in adverse health outcomes. The ingestion of a high-sugar electrolyte drink, can worsen dehydration rather than alleviate it, by drawing water out of body cells through osmotic imbalance. The risk is further aggravated among children, diabetic patients, and elderly persons, who represent the most vulnerable categories of consumers. Accordingly, the said product poses a direct and



immediate risk to human health as it induces consumers to believe that the product is intended for medical or rehydration use. Such use of the term “ORS” constitutes misbranding and misleading representation under Sections 23 and 24 of the FSS Act, read with the FSS (Labelling and Display) Regulations, 2020 and FSS (Advertising and Claims) Regulations, 2018;

e) the prior approvals granted vide orders dated 14.07.2022 and 02.02.2024 did not create any vested or perpetual rights, the orders were expressly conditional and subject to regulatory review. In view of subsequent review regarding consumer deception on the basis of complaints received, the FSSAI, in exercise of its continuous and regulatory oversight, deemed it necessary to review and supersede those approvals in public interest. Accordingly, the said orders stand replaced by the orders dated 14.10.2025 and 15.10.2025, issued under Sections 16 and 18 of the Act;

f) the contention of the Petitioner that disclaimers were included on labels to avoid confusion, cannot be considered. There are a number of complaints that disclaimers are ineffective when (i) the brand name containing “ORS” visually dominates the label; (ii) the product labelling prominently displays the terms “ORS” and uses colour schemes, fonts, and representations identical or similar to medically approved oral rehydration solutions; and (iii) consumers, particularly laypersons, do not read or comprehend such disclaimers at the time of purchase;

g) the principal display panel or the fond of pack, it's the term/brand name – “ORSL[®]” which appears & presented to the consumer while making decision to purchase and not the work in Devnagri script ‘औरसल’, which is there on side of the pack and not distinctively on the principal display panel/front of pack. Disclaimers cannot neutralize the inherent deceptiveness arising from the use of a therapeutic term in a food product label;

h) the impugned product under the brand name “ORSL” claims to be used as an adjuvant in non-diarrhoeal conditions, for faster recovery during non-diarrhoeal illness/conditions viz., nausea & vomiting, fever & general weakness, heat exhaustion, fever & muscle pain/cramps, tropical fevers



like dengue, chikungunya & typhoid, viral illnesses, infections like URTI, to support faster recovery from dehydration during pregnancy (due to increased water demand, Renal & respiratory system losses, & increased sweating), for hydration of Diabetic individuals with acute non-diarrheal illnesses etc., to aid faster recovery from “silent dehydration” resulting from fluid, electrolyte, and energy (FEE) loss. Such a claim is not admissible in terms of Section 22 (1)(b)(iii) of the Act’

i) the marking material (product profile of the ORSL) submitted to the authority during the personal hearing, contains a note that the material is for “Registered Medical Professionals only”. This implies that these ORSL products are also marketed to the medical practitioners suggesting its use to combat silent dehydration during non-diarrhoeal illness/conditions (i.e. fever, general weakness, muscle pain/cramps, tropical fevers like dengue, chikungunya & typhoid, viral illness, infections like URTI etc);

j) given the consumer confusion and potential health risk, withdrawal of permissions for the use of the term “ORS” in food product names is a necessary, proportionate, and preventive measure consistent with the statutory mandate of FSSAI. That disclaimers have been ineffective in preventing consumer deception. The orders dated 14.10.2025 and 15.10.2025 are regulatory directions under Section 18 of the FSS Act, applicable across the food industry. They do not determine individual liability or impose penalties and should not be linked to adjudicatory orders under Section 68;

k) the Trade Marks Act, 1999, sets rules for registering, protecting, and enforcing trademarks. A trademark helps identify one company’s goods or services from other. Under the Trade Marks Act the organizations only have the right to stop others from using their marks without permission. The Trade Marks Act, 1999 nowhere gives permission to the organizations to use the trademarks for creating deception amongst the consumers. The jurisdiction of the CGPDTM is confined to trademark registration and protection under the Trade Marks Act, 1999. It does not extend to determining compliance with food safety laws. As per Section 89 of the FSS Act, 2006, the provisions of the FSS Act have overriding effect over any other law in matters relating to food. In the matter of Ram Nath v. State of



UP (2024), the Hon'ble SC while interpreting Section 89 of the FSS Act has held that

“ In this context, we must consider the effect of Section 89 of the FSSA. Section 89 reads thus:

“89. Overriding effect of this Act over all other food related laws. – The provisions of this Act shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time being in force or in any instrument having effect of virtue of any law other than this Act.”

The title of the section indeed indicates that the intention is to give an overriding effect to the FSSA over all ‘foodrelated laws’. However, in the main Section, there is no such restriction confined to ‘food-related laws’, and it is provided that provisions of the FSSA shall have effect notwithstanding anything inconsistent therewith contained in any other law for the time being in force. So, the Section indicates that an overriding effect is given to the provisions of the FSSA over any other law. The settled law is that if the main Section is unambiguous, the aid of the title of the Section or its marginal note cannot be taken to interpret the same. Only if it is ambiguous, the title of the section or the marginal note can be looked into to understand the intention of the legislature. Therefore, the main Section clearly gives overriding effect to the provisions of the FSSA over any other law in so far as the law applies to the aspects of food in the field covered by the FSSA.....”

l) even a validly registered trademark cannot be used in a manner that misleads consumers or contravenes food safety provisions. Therefore, even if a trademark is validly registered, its use on food products must comply with the provisions of the FSS Act and Regulations. Section 9(2) and Section 13(b) of the Trade Marks Act, 1999 themselves prohibit registration of marks that are deceptive or derived from International Non-Proprietary Names (INNs). “ORS” is such a non-proprietary name;

m) the letter dated 05.06.2023 from the Controller General of Patents, Designs and Trademarks (CGPDTM), and the Hon'ble Telangana High Court's rulings on composite marks, do not decide the issue of food



safety. The matter falls solely under the jurisdiction of FSSAI as the competent statutory authority under the FSS Act;

n) the Petitioner's contention that "ORSL" is a coined term is not sustainable. The prominent element "ORSL" is phonetically and visually similar to "ORS", creating a direct association with the WHO therapeutic product. Commercial goodwill or prior use cannot justify continuation of a misleading practice;

o) FSS (Labelling & Display) Regulations, 2020, mandates that every package of food shall carry name of the food which indicate the true nature of the food contained in the package, on the Front of Pack and it should not be deceptive in nature;

p) it is the duty of FSSAI as a regulator to ensure protection of consumer's interests, including fair practices and protect the consumer from misleading claims/designs etc. The orders have been issued to ensure compliance of the provisions contained in Section 16, 18, 23, 24 of the Act and Regulation 4(3); 5(1) of the FSS (LABELLING AND DISPLAY) REGULATIONS, 2020, Regulation 4 (1) of the FSS (Advertising and Claims) Regulations, 2018;

q) it is wrong understanding of the Petitioner that FSSAI cannot modify its orders. Section 92 is for the purpose of framing regulations and has no application in the present matter. The impugned orders only emphasize upon the true compliance of the FSS Act 2006 in letter and spirit;

r) the Food Authority under the Act maintains vigilant regulatory oversight and continuously reviews and addresses complaints, representations and cases emerging from the field. This ensures that regulatory measures remain responsive to public health needs and aligned with the objectives of the FSS Act. Accordingly, the orders dated **14.10.2025 and 15.10.2025** have been lawfully under various provisions of the FSS Act, 2006, Rules and Regulations made under it;

s) marketing and labelling fruit based beverages etc. under FSSAI licence and naming such product with terms which contain ORS is not only misleading for ordinary consumers but may also be harmful to patients who may consume such products under the impression created by the term ORS; and



t) registration or prior use of a composite mark containing “ORS”, with or without prefix/suffix, does not confer an unfettered right to use the mark in contravention of other statutory prohibitions. Registration of a trademark cannot be used to circumvent health, safety, or consumer protection statutes.”

8. In the light of the above, the following conclusions have been arrived at in the aforesaid order dated 30.10.2025:

“a) the use of “ORS” or any phonetically/visually similar expression in food product names, trademarks, or labels is misleading and deceptive within the meaning of Sections 23 and 24 of the FSS Act and violates the FSS (Labelling and Display) Regulations, 2020 and the FSS (Advertising and Claims) Regulations, 2018;

b) FSSAI’s actions are consistent across food business operators and are based on public health risk, and legal mandates, not on the identity or market power of any particular manufacturer or brand. Statutory obligations under the FSS Act and Regulations cannot be subordinated to private commercial losses – particularly where the regulatory object is to advert consumer deception and safeguard health;

c) the Authority reiterates that the impugned orders are not directed at any single entity but are general regulatory directions aimed at protecting consumers especially children from misleading representations in the food market; and

d) withdrawal of permissions for use of the terms “ORS” in food products is a necessary measure to uphold the integrity of public health and consumer safety, in line with the precautionary principle and the objectives of the FSS Act.”

9. It is evident that the impugned orders / measures taken by the FSSAI are impelled by serious public health considerations. The same is in pursuance of, and to effectuate the statutory mandate of the FSSAI.

10. The impugned orders dated 14.10.2025 and 15.10.2025 are regulatory measures applicable across the food industry. In these proceedings, this



Court does not find it apposite to sit in appeal over a measure taken by the FSSAI on public health considerations.

11. In **Vincent Panikurlangara v. Union Of India And Others**, (1987) 2 SCC 165, the Apex Court, while dealing with the issue concerning the withdrawal of certain fixed-dose combination drugs and licenses of manufacturers engaged in manufacturing 30 drugs which had been licensed by the Drug Control Authorities, observed as under:

“15. Having regard to the magnitude, complexity and technical nature of the enquiry involved in the matter and keeping in view the far-reaching implications of the total ban of certain medicines for which the petitioner has prayed, we must at the outset clearly indicate that a judicial proceeding of the nature initiated is not an appropriate one for determination of such matters. There is perhaps force in the contention of the petitioner that the Hathi Committee too was not one which could be considered as an authoritative body competent to reach definite conclusions. No adverse opinion can, therefore, be framed against the Central Government for not acting upon its recommendations.”

12. A coordinate Bench of this Court in **Sanjay Khanna v. Director General Foreign Trade & Another**, 2006 SCC OnLine Del 215, by placing reliance on **Vincent Panikurlangara v. Union Of India And Others** (supra) has observed as under –

11. Reference may also be usefully invited to the Judgment of the Supreme Court in Vincent Panikullangara v. Union of India and Ors., (1987) 2 SCC 165 as to the approach to be adopted by the court while dealing with technical issues where the question of public health was involved. The court in Vincent Panikullangara v. Union of India and Ors. (supra) was considering question of withdrawal of fixed dose combinations of drugs and withdrawal of licences there for. The issues falling for consideration were technical and specialised matters relating to therapeutic value, justification and harmful side effects of drugs as also correctness of the action taken by the Drugs Control Authorities on the basis of advice. The court observed “In view of the magnitude, complexity and technical nature of the enquiry involved in the matter as also the far reaching implications of the total ban of certain medicines



for which the petitioner has prayed, a judicial proceeding of the nature initiated is not an appropriate one for determination of such matters.”

12. In view of the foregoing discussion, the rationale and the justification for the prohibition and the recent events in which virus has surfaced in India, the need to prevent ingress and further spread of HPAI virus into the country cannot be undermined. The approach of utmost caution as adopted by the respondents on an issue which could endanger public health gravely cannot be faulted with. Petitioner is thus not entitled to the reliefs sought. Respondents may permit the petitioner to reshipe the goods and upon the petitioner not exercising the option, respondents are free to carry out destruction of the same.

13. Furthermore, in ***E. Merck (India) Ltd. and another v. Union of India and Anr***, MANU/DE0054/2001, a Division Bench of this Court has observed as under –

28. By now it is also well settled that the matters which are to be decided by experts, are to be left for them to decide and once such expert bodies take decisions in technical and scientific matters, it is not for the Court to interfere with the evaluation made by these expert bodies. In fact the argument which is advanced by the petitioners on the basis of the reports of DTAB and the arguments raised before Supreme Court and was considered by the Supreme Court in the case of Systopic Laboratories (Pvt.) Ltd. v. Dr. Prem Gupta (Supra) and other connected petitions reported in the said judgment. That was a case where validity of the notification issued by the Government of India prohibiting completely the manufacture and sale of fixed dose combination of corticosteroids with any other drug for internal use was challenged. In the said notification it was stated that Central Government was satisfied that long term use of steroids in fixed dose combinations for treatment of asthma is likely to involve risk to human beings and such formulations do not have therapeutic justification and further that it was necessary and expedient in public interest to prohibit the manufacture and sale of the said drugs. On behalf of the petitioners, scientific data in the form of published papers in the various medical journals had been filed to show that fixed dose combination of a corticosteroid and an antihistamine is highly beneficial for the treatment of asthma. Relying upon such studies, it was sought to be argued that the decision of the Central Government in prohibiting the manufacture and sale of the drug in question was not proper. While rejecting the contention of the petitioners, the Court observed as under:



“Having considered the submissions made by the learned counsel for the petitioners and the learned Additional Solicitor General in this regard, we must express our inability to make an assessment about the relative merits of the various studies and reports which have been placed before us. Such an evaluation is required to be done by the Central Government while exercising its powers under Section 26-A of the Act on the basis of expert advice and the Act makes provision for obtaining such advice through the Board and the Drugs Consultative Committee (DCC)”.

14. In the circumstances, this Court is not inclined to interdict with the impugned orders, in light of the aforesaid order dated 30.10.2025 passed by the FSSAI. This is particularly in light of the deleterious effect and adverse health outcomes (as noticed in the aforementioned order dated 30.10.2025, issued by FSSAI) in the event of consumption of the offending products by those who are in medical need of an ORS (Oral Rehydration Salts) formulation.

15. It is noticed that on the previous date of hearing, learned senior counsel for the petitioner made a statement that the petitioner has ceased manufacturing fresh stocks of its products. Today, it is stated that the petitioner is willing to re-label / re-brand its existing inventory / stock of the concerned food products. It is further submitted that the stock which is already in the supply chain be allowed to be sold to prevent irreparable and huge loss to the petitioner. This Court is not inclined to pass any directions in this regard in these proceedings except to direct the regulatory body (FSSAI) to consider this aspect of the matter on a representation being made by the petitioner in this regard. Accordingly, the present petition is dismissed, while granting liberty to make such a representation to the FSSAI, which shall be duly considered and disposed of by FSSAI by way of a reasoned order, after affording an opportunity of hearing to the petitioner,



within a period of one week of receipt thereof.

OCTOBER 31, 2025/cl

SACHIN DATTA, J